FDA Final Hiring and Retention Assessment

Final Report

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LIST OF EXHIBITS

ACRONYMS

ACRONYM	MEANING
AARP	American Association of Retired Persons
AO	Administrative Officer
AOIS	Administrative Officer Information System
APS	Alternative Pay Structure
ATLAS	Applicant Tracking Lifecycle Analysis Solution
BIIS	Business Intelligence Information System
BsUFA	Biosimilar User Fee Act
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CoP	Community of Practice
DE	Delegated Examining
DEU	Delegated Examining Unit
DHA	Direct Hire Authority
DMS	Division of Management Services
DPS	Division of Program Services
EEOC	Equal Employment Opportunity Commission
EHCM	Enterprise Human Capital Management
EOD	Entrance on Duty
ERM	Enterprise Risk Management
EVP	Employee Value Proposition
FDA	Food and Drug Administration
FDARA	FDA Reauthorization Act
FEVS	Federal Employee Viewpoint Survey
FTE	Full-time Equivalent
FY	Fiscal Year
GP	General Physician
GS	General Schedule
HC	Human Capital
HCBP	Human Capital Business Partner
HHS	Department of Health and Human Services
HR	Human Resources
HRIS	Human Resources Information System
HRIT	Human Resources Information Technology
JOA	Job Opportunity Announcement
KPI	Key Performance Indicator
KSA	Knowledge, Skills, and Abilities
MCO	Mission Critical Occupation
MP	Merit Promotion
MSPB	Merit Systems Protection Board
OC	Office of the Commissioner
OHCM	Office of Human Capital Management
OHR	Office of Human Resources
OM	Office of Management
OO	Office of Operations
OPM	Office of Personnel Management
OTS	Office of Talent Solutions
PD	Position Description
PDUFA	Prescription Drug User Fee Act
PM	Program Manager
PMAP	Performance Management Appraisal Program
POC	Point of Contact
RPA	Robotic Process Automation

ACRONYM	MEANING
SLA	Service Level Agreement
SME	Subject Matter Expert
SMO	Senior Management Officer
SOP	Standard Operating Procedure
SSOB	Scientific Staffing Outreach Branch
SSWG	Scientific Staffing Working Group
STEM	Science, Technology, Engineering, and Mathematics
STRS	Scientific Talent Recruitment Staff
TSO	Talent Strategy Officer
VA	Vacancy Announcement
VRP	Voluntary Recruiter Program
WIP	Work-in-Progress

1. EXECUTIVE SUMMARY

1.1 Background

The Food and Drug Administration (FDA) is authorized to collect user fees from sponsors and applicants to help expedite the development, review, and approval processes of human drugs and biologics. Related to this authority, the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II commitment letters assert that FDA must perform continuous assessments—by an independent contractor with the appropriate expertise—of its hiring processes as well as its hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in hiring human drug and biologics review program staff (i.e., all staff within the Center for Drug Evaluation and Research [CDER] and the Center for Biologics Evaluation and Research [CBER]).[1] Accordingly, this report summarizes the findings, conclusions, and recommendations of the third in a series of three such assessments, the Final Hiring and Retention Assessment (hereafter, referred to as the Final Assessment). This independent assessment focuses specifically on FDA's Human Resources (HR) organization (comprised of the Office of Talent Solutions [OTS] and the Office of Human Capital Management [OHCM])—as well as additional CDER and CBER Office of Management and program staff performing HR work—and their delivery of recruiting, hiring, and retention services for CDER and CBER.

Context for FDA's Recruiting, Hiring, and Retention Services for CDER and CBER

Hiring, and the interrelated talent management functions of recruiting and retention, are among FDA's most important organizational challenges. The confluence of numerous external and internal factors (including, but not limited to, FDA's role and reputation as the premier pharmaceutical and medical device regulator; a highly competitive labor market; prescriptive federal hiring regulations; federal ethics regulations; policy requirements established by the Department of Health and Human Services [HHS]; FDA's own hiring practices and workflows; the capabilities and proficiencies of FDA staff performing HR work) can have substantial positive and negative impacts on the Agency's ability to attract, hire, and retain talented human drug and biologics review program staff.[2]

Specifically, FDA has continued to face competition for high-value talent from other public health organizations at the federal, state, and local levels; the private sector; and academia. To succeed in attracting, assessing, and hiring top candidates with the proper qualifications, competencies, experiences, and often hard-to-find specialized expertise, FDA must complete the end-to-end hiring process quickly and effectively, make compelling initial job offers to candidates, and provide a positive applicant experience. Compounding the challenge, FDA operates under a complex set of hiring and pay authorities from multiple federal statutes and regulations, such as Title 5 (including Merit Promotion [MP], Delegated Examining [DE], Direct Hire Authority [DHA], and Schedule A excepted service hiring), 21st Century Cures Act (Title 21 or Cures), Title 38, and Title 42 hiring flexibilities. Combined, these authorities offer considerable flexibility in hiring and pay setting, but they also lead to complication and lack of standardization in the hiring function. In addition, because most of these authorities are delegated to the "Executive Agency" level (i.e., to HHS rather than to FDA), additional layers of guidance, restrictions, and delay that are sometimes present may inadvertently limit effectiveness for FDA.

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[1] Sources: FDA Reauthorization Act of 2017 (FDARA), FDA.gov; PDUFA VI Commitment Letter FY2018 to FY2022, FDA.gov; BsUFA II Commitment Letter, FDA.gov.

[2] FDA is technically an operating division of the Department of Health and Human Services (HHS); however, staff colloquially refer to FDA as an Agency when denoting the FDA organization, writ large. The use of that term should not be confused with the term "Agency" as it is used in federal statutes and regulations where the term explicitly refers to an executive agency as defined in Section 105 of Title 5, United States Code; a legislative branch agency; a judicial agency; and the U.S. Postal Service and Postal Rate Commission. For FDA, the executive agency is HHS.

During the relatively short period since the June 2020 publication of the Interim Hiring and Retention Assessment (hereafter, referred to as the Interim Assessment) report, FDA has worked to address many recommendations and implement improvement activities to enhance its recruiting and hiring functions. For example, OTS increased collaboration with CDER and CBER to plan and track talent acquisition efforts for each fiscal year, which also sets the stage for FDA to further streamline recruiting efforts to minimize variation and duplicative efforts in the future. To increase hiring efficiency and effectiveness, OTS implemented classification reform and optimization (including clearing the classification backlog, which was a major pain point in the Interim Assessment timeframe), established the FDA Delegated Examining Unit (DEU), reorganized Center-focused hiring teams, and increased usage and maturity of its expanded DHA and Title 21 procedures. In addition, OHCM worked with the FDA Enterprise Risk Management (ERM) Program develop a Retention Risk Assessment that examined the current state of retention and explored potential drivers of attrition at FDA. OHCM also established a collaborative succession planning working group that includes CDER, CBER, and other FDA Centers. The Final Assessment revealed signs of progress—some measurable, others anecdotal—indicating that HR improvement initiatives and efforts are starting to have the desired impact. Additional opportunities exist; however, ongoing challenges illuminate several urgently needed improvements. This is particularly the case for the following areas: HR Information Technology (HRIT), including integration, user adoption, and customer experience; organization and management of FDA's HR workforce; HR workload management and processes; and strategic coordination to establish an HR service model that focuses on the needs of customers and integrates the HR processes that support the full talent lifecycle.

While FDA has made substantial progress in process enhancements and service delivery to CDER and CBER, HR work is still burdened by cumbersome, often manual, HR processes and a disparate, non-integrated collection of HRIT and software applications, all contributing to ongoing challenges with data collection, curation, and management that impact data quality, validity, and availability. In Fiscal Year (FY) 2022, the Agency plans to broaden its deployment of the Applicant Tracking Lifecycle Analysis Solution (ATLAS) system that is designed to mitigate several of the challenges with applicant workflow management and transparency.[3] In addition, CDER and CBER have developed Center-specific auxiliary systems to help track and manage their local administrative activities that feed into the HR processes. However, these solutions do not resolve the underlying challenge of having to rely on multiple non-integrated systems to execute recruiting and hiring processes, nor can these solutions fully remediate the resulting issues of process inefficiencies, data deficiencies, and limited transparency.

In addition, FDA employs a complex network of HR service providers comprised of the Agency's HR organization in OTS and OHCM and additional Center-specific staff performing HR work in CDER and CBER. Each of these groups operate under separate leadership, performance standards, and workload management processes. These challenges, coupled with the lack of an integrated HR infrastructure and operating model, make it difficult for FDA to enact integrated, coordinated approaches to HR strategies, policies, performance management, professional development, and achievement of process outcomes.

Lastly, the challenges of retaining mission-critical skills and planning for succession in leadership and other key positions also loom large for FDA. The Agency is working to implement succession planning to manage the impact of having large numbers of senior leaders eligible for retirement. In addition, while attrition among CDER and CBER staff remains relatively low, losses can be detrimental to the Centers' mission-critical work. Losses also initiate the time-consuming process of hiring the unique talent FDA needs. To avoid mission disruption and maintain FDA's world-class workforce once new employees join the Agency, CDER and CBER must quickly institutionalize and mature strategic retention and succession planning efforts to prepare for future waves of attrition.

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[3] ATLAS Update and Way Forward, June 2021, OTS.

Impact of COVID-19

At the time of the Interim Assessment report's publication in June 2020, the global COVID-19 pandemic had already begun to dramatically alter FDA operations.[4] As a national authority in public health, FDA focused on meeting this unprecedented public health emergency with an "all-hands-on-deck" approach to fill urgent, high-priority positions and to handle an intense surge in workload. While scientific, regulatory, and technical staffs across Centers tackled mission-critical work such as advancing the development of vaccines and treatments for the virus, the Agency's operational and administrative staff worked behind the scenes to transform major aspects of HR service delivery.[5] For example, the shift to a maximum-telework policy for FDA staff, the transition to all-virtual recruiting and hiring processes, and the implementation of temporary COVID-related hiring authorities fundamentally altered FDA's recruiting, hiring, and retention functions. While these new programs and innovations were largely unplanned and provisional, they also served as a test environment to demonstrate how FDA could operate using completely new ways of working.

COVID-19's HR-related impacts extend beyond FDA.[6] For example, the pandemic profoundly altered the perceptions and expectations of job seekers about the nature of work (such as when and where knowledge work is performed), what aspects of work are most important (e.g., social connectedness and wellbeing), and what job seekers value in an employer. The pandemic also temporarily reduced the willingness of employees across industries to seek other jobs. However, by June 2021, this trend had reversed, and at the time of this report, the United States is experiencing perhaps the most dynamic and competitive labor market of this century. Similarly, 2021 has seen the fastest wage and salary growth in the United States since the dotcom bubble of the late 1990s, though over a wider swath of occupations. While it is outside the scope of this report to fully explore these broader trends and the impacts they are likely to have on FDA in the coming months and years, these trends and impacts provide context for examining CDER and CBER workforce patterns and for informing FDA's plans to implement improvements in its recruiting, hiring, and retention services. For example, some of the plans, strategies, and timelines that FDA developed in conjunction with the prior assessment reports may not address these still-emerging external realities.

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[4] Reference: FDA Interim Hiring and Retention Assessment_Final Report for Publication_5.20.20, OTS.
[5] Source: A Perspective on FDA's COVID-19 Response, https://www.fda.gov/news-events/fda-voices/perspective-fdas-covid-19-response
[6] Summarized from multiple sources, including: Making the Great Attrition the Great Attraction, McKinsey, September 2021; Why Wages are Growing Rapidly, The Conference Board, 2021; The Reimagined Workplace a Year Later: Human Capital Responses to the COVID-19 Pandemic, The Conference Board, 2021.

1.2   Overview of the Assessment

As the last of three assessments over the past five and a half years, this Final Assessment provides a comprehensive review and draws conclusions about FDA's progress over time. Exhibit 1 presents the assessment design. Booz Allen organized the results of the Final Assessment into five categories that are consistent with the Interim Assessment:

- Strategy

- Culture, Collaboration, and Communication

- Recruiting and Hiring Processes

- Data Management and Systems

- HR Staff Capability and Capacity.

The assessment team conducted trend analyses to compare changes since the Interim Assessment, and incorporated data from the Initial Assessment timeframe when possible, to yield a more comprehensive view of the impact and sustainability of results.[7, 8]

Exhibit 1: Assessment Design

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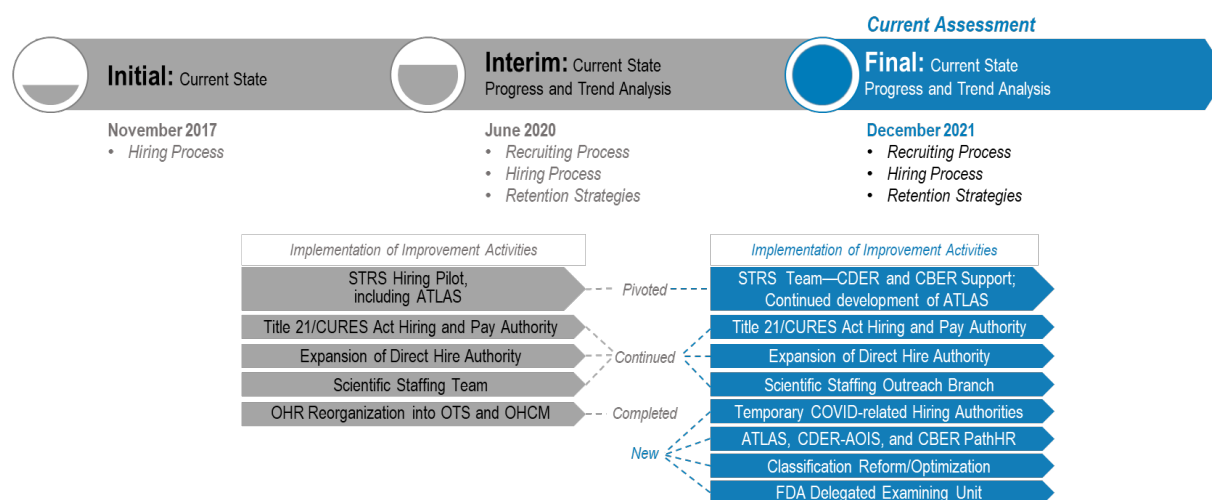
[7] The Initial Assessment established a baseline for hiring at FDA. FDA expanded the scope of the Interim and Final Assessments to include recruiting and retention, thus limiting comparability with the Initial Assessment. Nevertheless, where feasible and relevant, the assessment includes data trends that date back to the Initial Assessment timeframe.

[8] Booz Allen worked with FDA to define the time parameters of the Final Assessment as FY20 through the third quarter of FY21 (i.e., October 1, 2019 to June 30, 2021), which directly followed the end of the Interim Assessment's data collection phase. Accordingly, data presented in the report are as of FY20-FY21 Q3, unless otherwise noted.

The assessment team collected data from multiple sources (see Exhibit 2) to garner complete, accurate, and useful data while minimizing the burden on FDA employees providing the data.

Exhibit 2: Data Collection by the Numbers[9]

3 Center and HR Workforce Surveys	**50+** FDA Data Files	**24** HR Stakeholder Focus Groups	**135+** FDA Documents	**22** Leadership Interviews	**2** Data Calls
• CDER/CBER Staff Survey: 32% Response Rate • HR Staff Survey: 48% Response Rate • HR Manager Survey: 59% Response Rate		• Includes HR stakeholders in OTS, OHCM, CDER and CBER • 131 Participants • 1,186 Comments		• Includes leaders in OC/OO, CDER, and CBER • 30 Participants • 576 Comments	• HR Workload Data Call with HR Managers in OTS, OHCM, CDER, and CBER • HR Servicing Ratio Benchmarking Request from external agencies

Considerations and Limitations

The assessment team incorporated as much rigor as possible into the design of the present study to support stakeholder confidence in the defensibility and actionability of its conclusions and recommendations. As with other organizational research, however, certain data collection and analysis factors can impact results. In this study, the following factors, at a minimum, have impacted the assessment:

- The limited availability (and maintenance) of reliable data and information limited the assessment team's ability to make accurate or unconditional determinations of process efficiency and effectiveness as well as to assess staff capability, workload distribution, and resource requirements.

- The team conducted interviews and focus groups, two useful methods for generating rich information given questions' open-ended format and the facilitator's ability to probe on responses. Recognizing that themes can be biased by group composition (e.g., participants self-selecting to participate, the dynamics that occur in group settings), the assessment team attempted to minimize these biases by inviting a broad range of participants, encouraging all participants to speak in the sessions, and reporting the more dominant perspectives in the thematic analyses.

- Surveys, interviews, and focus groups provide thematic and qualitative perceptions of FDA staff, but such perceptions may not accurately or unconditionally reflect objective reality. For example, in interviews, managers may opine that they need more staff when in fact managers or Offices may need to improve efficiencies, optimize processes, clarify priorities, or make other changes to improve operations. This report attempts to accurately convey the themes collected in surveys and heard in interviews and focus groups without attempting to judge the objective accuracy of participants' beliefs. Instead, using the multi-method approach, the assessment team combined perceptual results with objective results to corroborate or identify differences in perspectives, taking all results into account when developing findings and conclusions.

In addition, the report at times discusses the need for FDA to take a more enterprise-wide view, such as by employing a more strategic focus or by promoting inter-Center consistency. While the focus of this study is CDER and CBER review program staff, some recommendations would have the most benefit to CDER and CBER (and indeed all FDA Centers) if they were executed at the enterprise-wide level. (e.g., HRIT system enhancement, integrated HR servicing model).

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[9] Data collection numbers are somewhat higher for the Final Assessment than for the Interim Assessment. For the Interim Assessment, data collection included 3 surveys, 26 data files, 15 focus groups, 120 organization documents, and 29 interviews.

Stakeholders for the Assessment

The assessment included perspectives from staff who provide the HR services that this document examines, as well as the CDER and CBER staff who receive the HR services. Representatives of these groups shared their feedback in surveys, focus groups, and interviews conducted for the assessment. Exhibit 3 presents an overview of the OTS, OHCM, CDER, and CBER staff who are typically involved in providing and receiving HR services.

Exhibit 3: Assessment Stakeholders: FDA HR Service Providers and Recipients
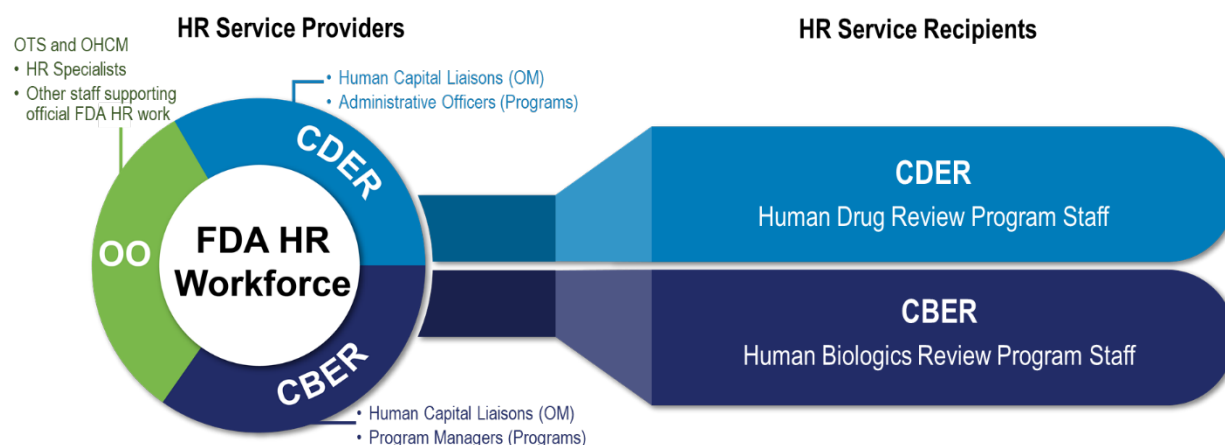
The HR service providers include several groups of staff who perform HR work at FDA, as detailed below. The Agency's official HR organization is comprised of OTS and OHCM staff within FDA's Office of Operations (OO). In addition, depending on their organizational alignment and role, staff within the Centers often perform HR work that is different yet complementary to OTS and OHCM support, including support for recruiting, hiring, and retention functions. Center staff are not responsible for processing official HR actions.

- **OO (OTS and OHCM).** Includes HR Specialists in the 0200 Occupational Series (the officially recognized HR staff per the Office of Personnel Management [OPM]) and staff in other positions related to HR work.
- **CDER.** Includes Human Capital Liaisons in CDER's Office of Management (OM), and Administrative Officers (AOs) in CDER's Program Offices.
- **CBER.** Includes Human Capital Liaisons in CBER's Office of Management (OM), and Program Managers (PMs) in CBER's Program Offices.

As part of this assessment, the evaluation team collected data from the whole cadre of staff performing HR work to gather information from the perspective of "HR Staff." Where applicable, descriptions of these results distinguish between the groups of HR service providers (i.e., "OTS and OHCM staff" or "CDER and CBER staff performing HR work"). Other times, the report references "HR Staff results from surveys and focus groups," indicating they include responses from all HR service providers: OTS and OHCM staff and staff in CDER and CBER who perform HR work. In addition, the term "HR workforce" is used to reference combined survey results of HR staff and managers of HR staff. Also, the term "HR workforce" refers to the unified planning and management of HR service providers, including those working in OTS, OHCM, CDER, and CBER.

The HR service recipients, also referred to as "customers" in this report, encompass all of CDER and CBER staff: the specific roles that provided input for the assessment include Center leadership, Office leadership, hiring managers, new hires, and human drug and biologics review program staff (i.e., all CDER and CBER staff).

1.3 Summary of Progress

FDA has made considerable strides in its recruiting, hiring, and retention functions since the November 2017 publication of the Initial Assessment report. Primary improvements that took place during the Interim Assessment timeframe include the implementation of the Scientific Talent Recruitment Staff (STRS) Hiring Pilot, the Office of Human Resources reorganization that established OTS and OHCM, and FDA actions to begin formalizing processes for some of its special hiring and pay authorities. After the publication of the Interim Assessment report in June 2020, FDA has taken further steps to address challenges from both a strategic and a tactical perspective; FDA has done so while serving as a national leader in the COVID-19 response and pivoting to perform most of its operations virtually.

As a high-level summary, the assessment team has identified ***three cross-cutting takeaways*** that broadly apply to FDA's overall HR effectiveness and undergird the results for each assessment category. Specifically:

- ***HR Service Model:*** FDA must develop, instill, and sustain a clear and consistent understanding of its HR service model that balances a strategic business partner role with a customer-focused mindset. This issue is foundational to every category, has been raised in all three assessments, and continues to be a challenge for the Agency.

- ***Talent Experience Lifecycle:*** FDA's service model should incorporate an end-to-end talent experience lifecycle that considers the perspective of individual employees (pre-application through separation). A key aspect to this concept is integrating HR functions and Center management activities, which together have a major influence on the employee experience, talent outcomes, and mission success.

- ***Data Integration:*** FDA needs to make an enterprise-level investment in the integrated information technologies, systems, and tools required to operationalize an end-to-end talent experience model. Only when data and workflows are integrated across the talent experience lifecycle can FDA achieve effective talent outcomes.

Exhibit 4 provides a summary of the overall progress and impact observed for each assessment category, to include the extent to which FDA has addressed Interim Assessment recommendations and made overall progress toward a long-term, sustainable solution. To provide a visual display of current progress and simplify cross-referencing among assessment categories, the assessment team developed a progress rating scale with three levels: ***Minimal, Moderate, and Substantial***. The progress ratings are defined by evidence of accomplishments in each category and the impact (or potential future impact) of those accomplishments. Based on assessment results, all five of the Assessment Categories are rated as ***Moderate***. FDA has made measurable progress in each of these areas, with varying degrees of additional effort needed to realize long-term transformational change. See Section 2, Findings and Conclusions, for more detail about FDA's progress and assessment results for each category.

Exhibit 4: Summary of Progress for each Assessment Category

> **Based on assessment results, all five Assessment Categories are rated as Moderate. FDA has made measurable progress in each of these areas, with varying degrees of additional effort needed to realize long-term transformational change.**

PROGRESS RATING SCALE
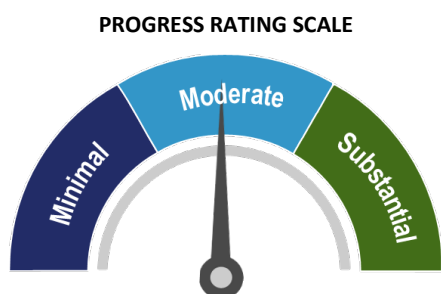
Substantial: In this category, there is extensive evidence of progress toward the goal of improving FDA recruiting, hiring, and retention support for CDER and CBER. Efforts have had or are likely to have long-term impact.

Moderate: In this category, there is solid evidence of progress toward the goal of improving FDA recruiting, hiring, and retention support for CDER and CBER. Efforts have had or are likely to have near-term impact.

Minimal: In this category, there is little or no evidence of progress toward the goal of improving FDA recruiting, hiring, and retention support for CDER and CBER. Efforts have had or are likely to have limited impact.

PROGRESS RATINGS AND SUMMARIES FOR EACH ASSESSMENT CATEGORY

Strategy

Rating: Moderate

- FDA established several strategic plans and measurable objectives, like FY hiring targets and Service Level Agreements (SLAs) with Key Performance Indicators (KPIs) for CDER and CBER.
- Together, these plans and objectives establish a framework for linking strategy with operations, actively managing HR performance, and increasing HR accountability.
- Further progress in strategic integration across the talent lifecycle (e.g., recruiting, hiring, and retention) and across HR organizations will help drive the volume and velocity of changes FDA needs to build and sustain a world-class human drug and biologics review staff workforce.

Culture, Collaboration, and Communication

Rating: Moderate

- OTS has aligned staff to specific customer groups and made notable progress on collaborating more frequently and effectively with CDER and CBER to plan and monitor hiring actions and providing more communication and documentation about hiring processes.
- However, staff performing HR work across FDA must adopt a shared customer-focused mindset coupled with clear roles, KPIs, and accountability mechanisms to understand and meet CDER and CBER needs.
- FDA must actively address and manage cultural issues such as the challenges of collaboration across groups to achieve true and lasting success in shifting to a strategic HR service delivery model focused on customers' requirements.
- In addition, these fundamental improvements are not possible without parallel enhancements of essential enablers, such as technology, tools, processes, and day-to-day practices.

Recruiting and Hiring Processes

Rating: Moderate

- FDA attracts qualified applicants but needs a more strategic approach to recruiting that is integrated with the hiring process.
- FDA made substantial improvements, including clearing the classification backlog, increasing use of shared certificates, using a variety of hiring and pay authorities to meet hiring needs, and improving communications to help expedite recruiting and hiring.
- Process challenges persist, including stakeholder expectations about the hiring process (e.g., qualification and selection) and continued frustrations about lengthy time to hire.
- Improving process integration and efficiency requires enterprise investment and commitment of leaders across organizations to institutionalize a shared HR service model.

Data Management and Systems

Rating: Moderate

- FDA has begun to lay a foundation for improved data management by developing an inventory of HRIT systems to better understand the multiple systems and tools used and by creating a roadmap for ongoing system development and integration.
- FDA also continued to develop ATLAS to integrate additional hiring processes, add function-specific applications, and increase workflow transparency, but FDA is still relying on cumbersome manual data management processes until ATLAS is fully functional.
- As planned, ATLAS will not integrate the talent experience lifecycle (including recruiting and hiring) nor capture Center work prior to submitting to OTS, leading CDER and CBER to develop their own administrative management systems.

HR Staff Capability and Capacity

Rating: Moderate

- OTS and OHCM increased staff capacity to keep pace with growth of FDA end-strength, and CDER and CBER continued to invest heavily in dedicated resources (i.e., funding and staff) to support HR work.
- OTS developed its competency framework and conducted training and development; capability of staff performing HR work has measurably improved.
- OTS and OHCM are tracking and monitoring workload and performance against KPIs; customer satisfaction with HR services has measurably improved but is still quite low.
- FDA lacks systematic, integrated, and automated workflows for tracking, managing, and monitoring the HR workload, the effectiveness of its workforce, or how work is assigned, which hampers FDA's ability to plan and manage strategic improvements.

1.4 Crosswalk of Conclusions and Recommendations

The body of this report details the assessment's 20 findings (based on collected data), nine conclusions (based on syntheses of the findings), and 10 recommendations (based on syntheses of the conclusions), organized into five major categories (accessible via the following links for easy reference by the reader):

1. Cross-Cutting (incorporates Findings and Conclusions across all five categories; Recommendations)
2. Strategy (Findings and Conclusions; Recommendations)
3. Culture, Collaboration, and Communication (Findings and Conclusions; Recommendations)
4. Recruiting and Hiring Processes (Findings and Conclusions; Recommendations)
5. Data Management and Systems (Findings and Conclusions; Recommendations)
6. HR Staff Capability and Capacity (Findings and Conclusions; Recommendations)

This section presents a high-level crosswalk of the study's conclusions and recommendations, including a Cross-cutting category that demonstrates the interconnectedness of the assessment categories. Some conclusions lead to one or more recommendation(s) from the Interim Assessment that have not been fully addressed; in these instances, the associated recommendation statement references the connection with an Interim recommendation. To clarify the references, Final Assessment recommendations are labeled with an "RF" (e.g., RF-1), and Interim Assessment recommendations are labeled with an "R" (e.g., R-1).

Cross-cutting

CONCLUSION	RECOMMENDATIONS
Incorporates conclusions across all five categories	**RF-1.** Engage leaders and stakeholders across HR organizations and CDER and CBER to collaboratively plan, develop, and institutionalize FDA's shift to a strategic service delivery model designed to meet customer requirements (e.g., human capital business partner model). *(Incorporates R-10)* **RF-2.** Establish an enterprise-level HRIT system (e.g., through expanding ATLAS or using a single interface for multiple systems) that integrates the entire talent lifecycle; cultivate user adoption and leverage integrated data to support process automation and advanced analytics. *(Incorporates R-4)*

Strategy

CONCLUSION	RECOMMENDATIONS
C1-1. FDA has made progress in formalizing its strategic plans and measurable performance goals; more specificity and coordination would facilitate the success and impact of their execution. **C1-2.** The workforce conditions established for recruiting, hiring, and retaining CDER and CBER staff during the pandemic response provide a helpful lens for anticipating and managing workforce patterns in the future. **C1-3.** Taking a more proactive, strategic approach to managing attrition would help FDA retain the highest-priority, mission critical skills in CDER and CBER.	**See also Cross-cutting Recommendations RF-1 and RF-2** **RF-3.** Refine retention strategies to enable improved coordination and integration across the Agency, establish targets for effective use of strategies, and more proactively address succession needs.

Culture, Collaboration, and Communication

CONCLUSION	RECOMMENDATIONS
C2-1. Building on progress with procedural and operational collaboration, FDA needs a clearly defined service delivery model to address customer requirements and integrate efforts of all staff performing HR work.	**See also Cross-cutting Recommendation RF-1** **RF-4.** Continue developing a stakeholder engagement strategy to encourage two-way communication that will increase awareness and efficient adoption of recruiting and hiring process improvements. *(Repeats R-11)*

Recruiting and Hiring Processes

CONCLUSION	RECOMMENDATIONS
C3-1. FDA attracts qualified candidates to apply and has advanced its strategic recruiting efforts; better data tracking and linkage with the hiring process will increase recruiting effectiveness. **C3-2.** Process improvements and targeted use of multiple hiring authorities helped OTS effectively support urgent hiring needs for CDER and CBER; further maturity in process coordination, guidance, and data tracking is essential for benefits to be sustainable and impactful.	**See also Cross-cutting Recommendations RF-1 and RF-2** **RF-5.** Establish new service delivery metrics (e.g., collaboration, time to hire) based on the throughput and other hiring metrics achieved during the pandemic, while seeking to realize additional efficiencies. **RF-6.** Examine the disconnect between the large number of qualified candidate referrals provided by OTS and the low number of CDER and CBER selections from these referrals.

Data Management and Systems

CONCLUSION	RECOMMENDATIONS
C4-1. ATLAS will help improve hiring process workflow and transparency; however, FDA does not currently utilize the full range of available system capabilities to integrate HR processes and data management across the talent lifecycle.	**See also Cross-cutting Recommendation RF-2** **RF-7**. Continue to infuse more uniformity and structure into data management and reporting practices for recruiting, hiring, and retention data. *(Incorporates R-4)*

HR Staff Capability and Capacity

CONCLUSION	RECOMMENDATIONS
C5-1. FDA HR servicing ratio has remained consistent, as OTS and OHCM staff have increased in parallel with FDA's workforce size; meanwhile, CDER and CBER continue to invest heavily in their own dedicated resources (i.e., funding and staff) to support HR work. **C5-2.** OTS initiatives to build capabilities of its staff have led to measurable improvements; coordinating and leveraging these efforts in other organizations would equip all staff who support HR work to provide the consistent, customer-focused performance needed in the future.	**See also Cross-cutting Recommendation RF-1** **RF-8.** Continue to refine workload management processes for assessing and distributing work across the HR workforce, with consideration for adopting an Agile workflow management technique, such as Kanban. *(Incorporates R-8)* **RF-9.** Continue to hold managers of staff performing HR work—across OTS, OHCM, CDER, and CBER—accountable for actively managing staff performance by establishing standardized performance assessment goals. *(Incorporates R-9)* **RF-10.** Create and implement an updated, unified HR competency model for all FDA staff performing HR work, aligned to the customer-focused performance expectations and expanding use of technology. *(Incorporates R-10)*

2. FINDINGS AND CONCLUSIONS

This section presents the Final Assessment's results—derived from multiple data sources—organized into five sub-sections with detailed information for each assessment category:

- Strategy
- Culture, Collaboration, and Communication
- Recruiting and Hiring Processes
- Data Management and Systems
- HR Staff Capability and Capacity

Each sub-section contains a summary of progress since the Interim Assessment (or since the Initial Assessment, where possible). The summary also includes a checklist of accomplishments and development opportunities that, if completed, would represent optimized and sustainable progress for each category. In addition, each sub-section presents conclusions—and the findings that support them—most pertinent to the ongoing refinement of FDA recruiting, hiring, and retention support for CDER and CBER.

2.1 Strategy

As summarized in Exhibit 5 FDA has made noticeable strides in establishing strategic plans and measurable objectives, like FY hiring targets and Service Level Agreements (SLAs) with Key Performance Indicators (KPIs) for CDER and CBER. Together, these plans and objectives establish a framework for linking strategy with operations, actively managing HR performance, and increasing HR accountability. However, for the most part, these documents are not integrated across HR functions or across the organizations with a stake in recruiting, hiring, and retention for CDER and CBER. Without integration, even the best stand-alone strategic plan cannot drive the volume and velocity of changes FDA needs to build and sustain a world-class human drug and biologics review staff workforce.

Exhibit 5: Key Takeaways for Strategy

MAJOR ACCOMPLISHMENTS

☑ Established SLAs; monitored and reported on KPIs
☑ Implemented a strategic focus on hiring
☑ Created and monitored FY-specific talent acquisition plans and fulfilled urgent hiring requirements
☑ Developed several detailed strategic plans

DEVELOPMENT OPPORTUNITIES

☐ Integrate strategies with implementation guidance, empowering HR staff to work collaboratively
☐ Develop an integrated strategy that spans the talent experience lifecycle, including recruiting and hiring
☐ Actively manage attrition and strategic use of retention incentives

The strategic plans and other initiatives offer valuable roadmaps for continued recruiting, hiring, and retention service improvement. For example, there are current versions of an OTS Strategic Plan, an FDA Diversity and Inclusion Strategic Plan, Center-specific Talent Acquisition Plans (developed in coordination with OTS), a CBER Human Capital Hiring and Recruiting Strategy, a CBER Retention Strategy, and an Agency-level Retention Risk Analysis jointly developed by OHCM and the ERM team. In addition, OHCM is developing a strategic plan and coordinating a Succession Planning Working Group in which Center representatives collaborate to develop guidelines to help facilitate and standardize succession planning across the Centers. FDA has invested considerable time and effort into developing these plans and initiatives, which represent important milestones on a longer journey; the findings and conclusions in this section provide additional detail about plans' content and impact.

An integrated, holistic, systems-based strategy for talent management, as depicted in Exhibit 6, will help FDA proactively plan for and manage the entire lifecycle of CDER and CBER talent, including, but not limited to recruiting, hiring, and retention. This broader view of talent management recognizes that the Centers, not HR, drive several of the factors that impact an employee (e.g., supervisory relationship, job-specific onboarding). Amidst the pressures to improve these functions, it is important to move toward creating strategic solutions that fit within the context of a larger "systems-based approach"

Exhibit 6: Integrated Talent Lifecycle

Integrated Planning

Attract | Hire | Develop | Retain

Recruiting & Workforce Management
Onboarding
Direct Supervisor/Office Leadership
Career Progression
Way of Working
Employee Value Proposition
Process and Systems Transformation
Governance & Accountability

designed to maximize the collective value of each employee's contribution to FDA and maintain a proactive integration of HR functions. Hiring, for example, is not an end unto itself. As a critical piece of the talent management lifecycle, hiring solutions work best when integrated with the following HR activities: workforce planning, recruiting, continually developing and reskilling staff, deploying staff within (and across) FDA,

managing employee performance, planning for succession management, coordinating knowledge management, and tailoring retention initiatives. More effective recruiting of qualified, interested candidates could also enhance hiring improvements, and vice versa. Likewise, a strong, integrated, and well-managed recruiting and hiring pipeline can feed an engaging employee experience that motivates staff to develop essential and emerging skills, contributing to CDER and CBER missions, and to their own careers at FDA. In this way, integrated talent management can help FDA create a sustainable and balanced talent ecosystem.

The remainder of this section presents three conclusions and the associated findings related to Strategy.

> **CONCLUSION**
>
> C1-1. FDA has made progress in formalizing its strategic plans and measurable performance goals; more specificity and coordination would facilitate the success and impact of their execution.

Development of a variety of strategic documents, including a strategic plan for OTS, CDER and CBER Talent Acquisition Plans, and strategic plans for key human capital functions (such as diversity and inclusion, recruiting, hiring, and retention), signals FDA's progress in beginning to integrate and optimize its service delivery model. These plans constitute a necessary first step to help FDA shift from a reactive state to a state of more deliberate and proactive planning. However, without effective implementation, integration, and coordination, even the best plans and strategies will have limited impact. FDA has laid the groundwork for aligning strategy with operations through establishing HR performance metrics and monitoring procedures. These are necessary components to drive accountability for accomplishment of the goals and objectives outlined in strategic plans. To build on this foundation, stronger integration and operational linkages across these plans and functions are needed, combined with actionable guidance, to further advance successful implementation of these strategies. For example, the OO OTS Strategic Plan (FYs 2021-2023) contains Success Definitions such as "OTS leadership provides Centers/Offices with best practice information to improve hiring." That goal could be expanded upon to include more specific implementation guidance for those best practices (e.g., terms, conditions, magnitude, and timing of a hiring flexibility) to help determine the actual degree of hiring improvement.

F1.1   FDA has established HR performance metrics that allow for objective progress monitoring and data to support decision-making.

OTS and OHCM have established detailed SLAs with defined targets for KPIs across several specific services.[10] Similarly, OTS has increased its collaboration with each Center, including CDER and CBER, to develop Talent Acquisition Plans with FY-specific hiring targets.[11] As further detailed in the Recruiting and Hiring Processes Sub-section 2.3, OTS and the Centers regularly track progress against the targets and coordinate on both in-progress and upcoming hiring actions. These defined and measurable targets have established an important mechanism to help tie strategies to specific outcomes that can be monitored, reported, and managed over time. To achieve long-term results, FDA progress against those measures needs to be used to shape ongoing process improvements and increased accountability.

In interviews, leaders acknowledged that strategic planning for recruiting, hiring, and retention has become more evident and better connected. For example, strategic plans list hiring and retention as priorities; collaborative working groups are actively meeting to work on hiring and retention-related objectives; and planning documents related to budget, risk management, talent acquisition, and diversity and inclusion incorporate key factors related to recruiting, hiring, and/or retention (see Supplement Exhibit S-1).

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[10] Sources: FY20 SLA_OHCM-Signed, OHCM; OTS Service Level Agreement, OTS.
[11] Sources: CDER FY21 Talent Acquisition Plan, OTS; CBER Talent Plan (FY19 Q3 and FY20 Q1), CBER.

F1.2 Current strategic plans prioritize talent and hiring, but they lack the integration, operational linkages, and actionable guidance needed to implement, resource, and standardize efforts.

Talent acquisition and hiring are core components of several FDA strategic plans, including the OTS Strategic Plan, FDA Diversity and Inclusion Strategic Plan, and the CBER Human Capital (HC) Hiring and Recruiting Strategy.[12, 13, 14] However, these plans lack the clear and actionable guidance that managers, HR Specialists, and other service providers need to work consistently and confidently toward achieving the stated goals. For example, the Diversity and Inclusion Strategic Plan details actions for coordinating Agency-wide outreach and recruiting strategies but does not fully account for the fact that that recruiting responsibilities are often delegated down to the hiring manager level in the Centers, and there are no centralized tools and tracking systems to facilitate such coordination. In addition, the OTS Strategic Plan includes well-developed objectives, but many are based on transactional or top-down services rather than collaborative procedures that clarify specific roles and decision-rights and focus on meeting customer-defined requirements. The very fact that so many separate organization-specific and function-specific strategies exist demonstrates that any single plan's reach and impact are limited without the support of an integrated enterprise-level strategy.

Interview themes reveal that stakeholders recognize the potential value of a more integrated suite of strategic plans that provide guidance for practical and cooperative implementation. Leaders interviewed noted that an integrated strategy and the associated enterprise-level coordination would help inform decisions and the alignment of operational actions and resources to HR priorities and would enable access to more timely and comprehensive information that could support more sophisticated analytics. Interview participants also said that better strategic integration would help improve process quality, as integration would enable more thoughtful planning and coordination (e.g., stronger partnerships between managers and HR; more effective candidate screening; more clarity on the hiring process for candidates; a recruiting pipeline designed for specialized positions; and a data-driven decision model for complex considerations like classification, compensation, and diversity and inclusion (see Supplement Exhibit S-2).

CONCLUSION

C1-2. The workforce conditions established for recruiting, hiring, and retaining CDER and CBER staff during the pandemic response provide a helpful lens for anticipating and managing workforce patterns in the future.

The COVID-19 pandemic impacted FDA's workforce in many ways. HR and operational functions needed to quickly pivot procedures and guidelines to help the workforce balance their professional commitments with health, safety, and other personal needs. The pandemic response also highlighted factors that impact employee engagement, such as a renewed appreciation for FDA's critical public health mission and an increased workload for CDER and CBER. Paying attention to associated changes in workforce patterns and HR performance offers insight into potential lasting improvements that would affect how FDA sources, builds, manages, and sustains a world-class workforce in CDER and CBER.

F1.3 CDER and CBER's intense experience with the COVID-19 pandemic (including increased workload, and renewed focus on the critical public health mission) influenced recruiting, hiring, and retention efforts for CDER and CBER.

In surveys, over half of CDER/CBER staff and managers of HR staff reported that the pandemic had a moderate or high impact on recruiting, hiring, and retention. In contrast, less than half of HR staff reported that the COVID-19 pandemic had a moderate or high impact, and over one-third expressed that the pandemic had *no* impact on recruiting, hiring, and retention. (see Exhibit 7).

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[12] Source: FDA OO OTS Strategic Plan FY21-23, OTS.
[13] Source: FDAU Diversity and Inclusion Strategic Plan 2018-2021, OTS.
[14] Source: CBER Human Capital Hiring and Recruiting Strategy, CBER OM.

Exhibit 7: Survey Results on the Extent of COVID-19 Impact on Recruiting, Hiring, and Retention

Recruiting	CBER/CDER Staff	15%	27%	28%	30%
	HR Manager	21%	18%	32%	29%
	HR Staff	39%	19%	19%	23%
Hiring	CBER/CDER Staff	14%	26%	29%	31%
	HR Manager	21%	21%	26%	32%
	HR Staff	33%	24%	6%	36%
Retention	CBER/CDER Staff	21%	29%	23%	27%
	HR Manager	14%	25%	31%	31%
	HR Staff	35%	26%	23%	16%

Legend: High Impact, Moderate Impact, Little Impact, No Impact

X-axis: Percent of Responses (0% to 100%)
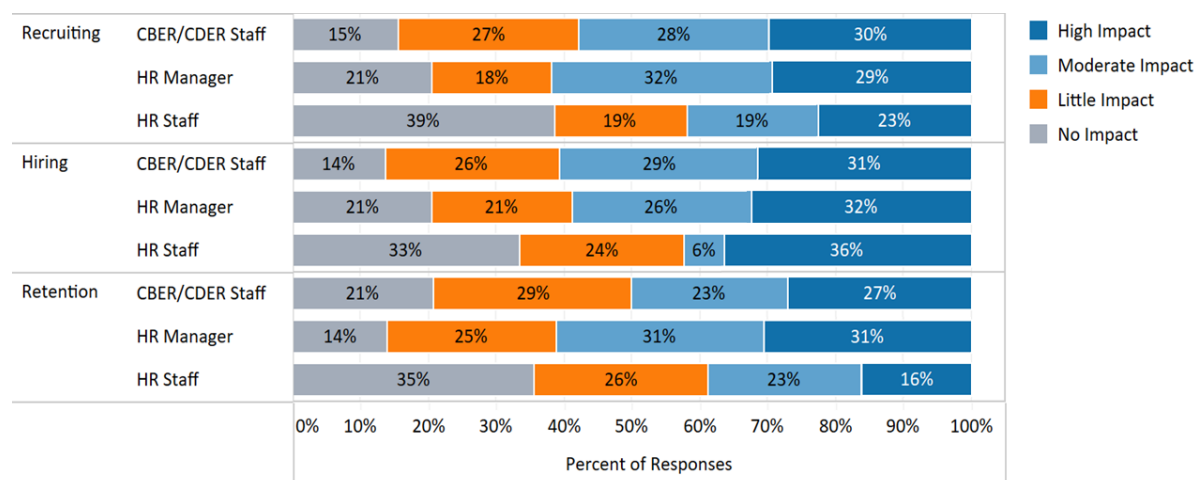
Respondents: CDER/CBER staff (responses vary by item; n=433-443); HR managers (responses vary by item; n=34-36); HR staff (responses vary by item; n=31-33). Survey Item: "Based on your experiences, to what extent has COVID-19 impacted the following HR functions: Recruiting, Hiring, Retention," with a response scale of No Impact, Little Impact, Moderate Impact, High Impact, and Don't Know. "Don't Know" responses were excluded from the analysis. This question is in the Final Survey only.

Exhibit 8 shows the results from surveys, interviews, and focus groups about whether COVID-19's impact on recruiting, hiring, and retention has been positive, negative, or both. Heat charts at the bottom of the exhibit present survey results showing that more CDER and CBER hiring managers said COVID-19 had a negative impact than did the HR staff or the managers of HR staff. Darker shaded colors under each column indicate a higher percentage of responses for the nature of impact (i.e., negative, both positive and negative, or positive) for recruiting, hiring, and retention.

Exhibit 8: Survey, Interview, and Focus Group Feedback on COVID-19 Impact on Recruiting, Hiring, and Retention

NEGATIVE IMPACT	BOTH POSITIVE AND NEGATIVE IMPACT	POSITIVE IMPACT
• Increased workload in CDER and CBER • Risk of burnout of current employees	• Value of maximum telework policy • Potential for higher turnover when maximum telework policy ends	• Stronger draw to the stability and flexibility of government work • Surge of pride and commitment to FDA's public health mission • Adoption of virtual recruiting • Use of COVID-related retention incentives

Survey Results

Respondents*	Recruiting	Hiring	Retention	Recruiting	Hiring	Retention	Recruiting	Hiring	Retention
HMs	43%	47%	37%	41%	39%	37%	17%	14%	26%
HR Managers	15%	15%	13%	55%	55%	53%	30%	30%	33%
HR Staff	7%	7%	13%	54%	52%	52%	39%	41%	35%

*Survey Respondents include: CDER and CBER Hiring Managers (HMs), Managers of HR staff (HR Managers), and HR Staff.

Respondents: CDER/CBER Hiring Managers (responses vary by item; n=501-503); HR managers (responses vary by item; n=40-41); HR staff (n=39). Survey Item: "Based on your experiences, has COVID-19 primarily had a positive or negative impact on the following HR functions: Recruiting, Hiring, Retention" with a response scale of Negative Impact, Positive Impact, Both Positive and Negative Impact, and Don't Know. "Don't Know" responses were excluded from the analysis. This question is in the Final Survey only. See Supplement Exhibit S-3 for more information on the themes from interviews, focus groups, and open-ended responses to the survey question "Please share more information about your perspective on the impact of COVID-19 on recruiting, hiring, or retention of CDER/CBER staff."

In addition, clear themes emerged from the open-ended survey item, interviews, and focus groups, as presented as bulleted summary statements in the exhibit. These results show that CDER and CBER staff felt that they bore the brunt of the negative impacts of higher workload and burnout, which may help explain their more negative survey response patterns summarized above. Interestingly, all survey audiences seemed to experience direct benefits from the positive impacts of the pandemic, which functioned to help FDA attract and hire talent for CDER and CBER, build a sense of common purpose, and potentially increase retention for CDER and CBER staff. These results also establish that the workforce highly values the provisional flexibilities offered during the pandemic response.

> ### CONCLUSION
> **C1-3. Taking a more proactive, strategic approach to managing attrition would help FDA retain the highest-priority, mission critical skills in CDER and CBER.**

FDA's turnover rates are low in comparison to its industry counterparts.[15] Still, the lack of established transition plans can hamper continuity efforts and onboarding of employees responsible for the workload. Pockets of higher attrition in key leadership ranks, specialized occupations, or any given Office in CDER or CBER also have the potential to disrupt mission-critical work. Given the need to anticipate patterns and plan for attrition, it is crucial to incorporate knowledge transfer, succession planning, and goals for healthy attrition into a proactive and integrated talent management strategy. To begin to address these challenges, CDER, CBER, and other FDA Centers are involved with a succession planning working group that helps provide consistency and support for succession planning activities.

F1.4   Attrition remains relatively low for CDER and CBER; reasons employees choose to leave FDA and where they go after leaving FDA appear similarly stable and predictable.

CDER and CBER maintain relatively low and stable attrition rates that are consistent with attrition rates reported in prior assessments, with CDER averaging 6 percent and CBER averaging 8 percent from FY18 to FY20. Still, CDER and CBER attrition rates are higher than FDA's average rate of less than 5 percent in FY20. Both Centers experienced attrition spikes in specific Offices and occupations (e.g., CDER Regulatory Counsel; CBER Medical Officers), posing a challenge for accomplishing certain missions and for maintaining workforce stability and consistency.[16]

Despite this generally low attrition, the challenges of retaining mission-critical skills and planning for leadership succession loom large for FDA. Over 22 percent of leaders in CDER and nearly 50 percent in CBER are eligible to retire or are close to reaching retirement eligibility, and FDA averages over 350 retirements per year.[17, 18] Unmanaged attrition can be detrimental to the Centers' mission work, and each loss or potential loss begins the time-consuming process of competing with other internal or external organizations to hire the unique talent that CDER and CBER need. For these reasons, maintaining healthy retention remains an important objective for FDA. CDER, CBER, and other FDA Centers are beginning to coordinate succession planning activities; however, it is imperative that FDA base these efforts on a thorough understanding of the factors that cause employees to remain at or leave the Agency. FDA also must quickly institutionalize and mature these efforts to prepare for waves of attrition that will continue to occur.

In the Final Assessment survey data, current CDER and CBER staff reported that higher compensation, career advancement, and retirement were the top three reasons they might *potentially* leave their current position

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[15] The Pharma and Biotech sector has an average annual turnover rate of 10 percent, according to https://www.skilohr.com/blog/2021/why-is-pharma-and-biotech-the-most-employee-engaged-industry/, Skilo, 2021.
[16] Sources: CDER FY20 Workforce Analysis Profile, CDER OM; CBER Workforce Analysis Profile FY20, CBER OM; FDA-wide Workforce Analysis Profile FY20, OTS.
[17] Sources: CDER FY20 Workforce Analysis Profile; CBER FY20 Workforce Analysis Profile. Percentages include average retirement eligibility from FY18-FY20, combined for Senior Executive Service and General Schedule (GS) 15 level staff.
[18] Source: Report on FDA Retirement Trends; FedScope Separations Trends Cube Visualizations accessed September 2021.

or their Center, but staff are primarily considering other positions within FDA or the federal government (see Supplement Exhibit S-4). CDER and CBER staff who actually did leave the Agency echoed these sentiments in exit surveys, with the most common reasons for leaving being a more competitive salary, career development, and promotion. Exit survey responses also show that most staff departing CDER and CBER take positions in another federal Agency or the pharmaceutical industry.[19]

F1.5 FDA is beginning to take an enterprise perspective on retention, and further coordination is necessary to drive consistent, discerning, and targeted usage of retention incentives.

OHCM and ERM collaboratively developed an Agency-level Retention Risk Analysis that explains how retention is tied to other human capital considerations, such as recruiting, onboarding, and embedding (e.g., engagement, making workplace connections). The analysis also established an estimated cost of turnover, examined the impact of backfilling positions on the overall hiring workload, and presented an analysis of turnover by factors, such as race/ethnicity and reasons for leaving. The analysis provided recommendations for FDA action, including a review of the interdependencies between retention and other human capital practices and a more sophisticated analysis to forecast the external factors that drive competition with the private sector.[20] However, this analysis alone is not sufficient to spur consistent action across FDA organizations to adopt and institutionalize the recommendations (e.g., leadership accountability for progress, data-driven profiles of retention scenarios aligned to the incentives found to be most effective) or to promote consistent and effective application.

Focus group participants indicated that both financial incentives (e.g., retention incentives, student loan repayments) and non-financial benefits (e.g., telework, flexible hours) are effective in supporting retention (see Supplement Exhibit S-5). In addition, according to the OO Annual Report, OTS processed hundreds of retention incentives in 2020.[21] However, it is unclear how FDA decides which employees will be offered an incentive or how it calculates the return on investment of such incentives. It also is not evident whether FDA has formal procedures in place for discerning which retention incentives to use or for applying them consistently and effectively (e.g., payment terms, continued service terms). OTS is currently developing a standard operating procedure (SOP) for Recruitment, Relocation and Retention (3Rs) Incentives, but FDA documents available at the point of data collection for this assessment (e.g., the CBER Succession Plan, the OHCM Activity Catalog) do not contain specific guidance for the effective and consistent use of retention incentives.[22, 23]

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[19] Source: Exit Survey FY20Q1 – FY21Q3, SurveyMonkey. Note Exit Survey results must always be taken with a grain of salt. Many transitioning employees consider reasons such as leaving for higher compensation to be an acceptable answer to provide, independent of whether the employee actually will receive higher pay. In addition, the three most common reasons cited for leaving correspond to the first three options listed in the exit survey so some of those responses may indicate primacy bias based on the construct of the survey.
[20] Source: Retention Risk Analysis, OHCM.
[21] Source: OO Annual Report, OTS.
[22] Source: CBER Human Capital Succession Plan, CBER OM.
[23] Source: FY20 OHCM Activity Catalog v.03, OHCM.

2.2 Culture, Collaboration, and Communication

The <u>Initial</u> Assessment Report identified challenges related to the lack of a constructive, team-oriented culture (and accompanying mindsets and behaviors), noting that inadequate collaboration and communication prevent FDA from successfully executing hiring, recruiting, and retention functions. The <u>Interim</u> Assessment identified similar issues, prompting recommendations, such as additional and clearer communication, augmented stakeholder engagement, and the shift to a customer-focused culture.

FDA has made notable progress on three of the five recommendations provided in the Interim Assessment Report. For example, OTS has aligned staff to specific customer groups and instituted regular meetings with CDER and CBER to collaborate on talent acquisition needs and provide updates on hiring actions. In addition, OTS and OHCM have created and disseminated tactical communication products to increase awareness and share information to support more efficient and consistent service delivery.

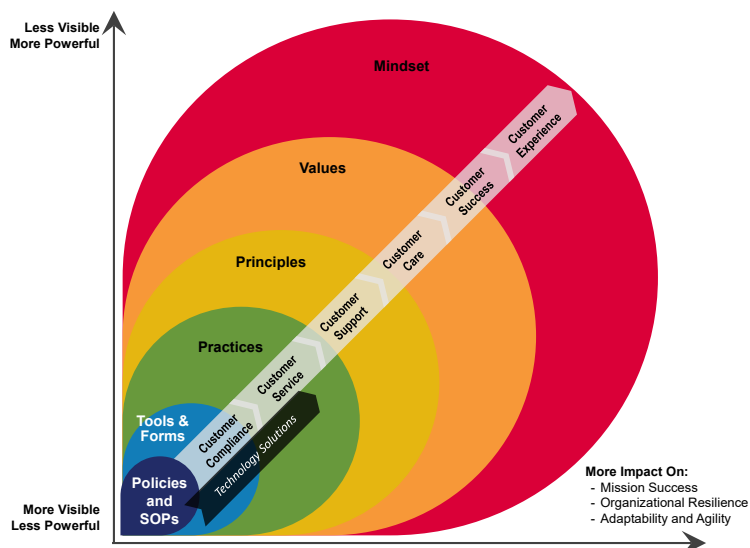**Exhibit 9: Key Takeaways for Culture, Collaboration, and Communication**

MAJOR ACCOMPLISHMENTS

☑ Developed updated SOPs and process guidance
☑ Better aligned OTS staff to specific customer groups
☑ Held regular collaboration meetings and provided status update meetings, trackers, and reports

DEVELOPMENT OPPORTUNITIES

☐ Instill a customer-focused culture to unify HR operations across FDA; clarify and expand decision rights
☐ Identify the customer-focused delivery model that FDA desires to provide
☐ Engage with stakeholders to improve awareness and usage of SOPs and policy guidance

To reinforce these improvements and strengthen the ability to effectively deliver integrated hiring, recruiting, and retention solutions, FDA also needs a clearly defined and commonly accepted HR service delivery model that is grounded in a customer-focused mindset and coupled with clear roles, KPIs, and accountability. As illustrated in Exhibit 10, communications-based improvements such as SOPs and tools are often the most visible and easiest items to tackle to address immediate challenges. However, these improvements tend to be the least powerful in terms of advancing deeper types of change, such as instilling a commitment to quality or a customer-focused mindset among staff. Instead, to achieve this more fundamental transformation, FDA needs to address and manage cultural issues head-on and implement parallel enhancements of essential enablers, such as technology, tools, processes, and day-to-day practices. Equally important, collaboration among OTS, OHCM, CDER, and CBER is critical to the successful adoption of a customer-focused mindset.

Exhibit 10: Conceptual Framework of Cultural Elements that Support a Customer-focused Mindset

FDA's accomplishments to date show important progress upon which to build a more impactful and deliberate service model. FDA has addressed the more urgent 'broken bones' aspects of the recruiting, hiring, and retention processes, and there is evidence of recovery. Now FDA must engage in the sustained 'physical therapy' of tackling the more challenging, less visible cultural issues at hand. This includes changing habits

and building 'new muscles' to transition from a set of reactive practices geared toward transactional compliance to a suite of collaborative, proactive behaviors strategically designed with the customer in mind. Longer-term 'recovery' requires that all staff performing HR work adopt a shared mindset supportive of constructive interactions and collaborative problem-solving focused on customer needs. FDA also must continue to refine performance measures and accountability mechanisms for staff who perform HR work to understand and meet business needs, and these actions must be driven by a customer-focused mindset.

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CONCLUSION

C2-1.   Building on progress with procedural and operational collaboration, FDA needs a clearly defined service delivery model to address customer requirements and integrate efforts of all staff performing HR work.

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Positive feedback across multiple sources indicates notable improvements in communication and collaboration among stakeholders involved in HR functions, particularly regarding the hiring process. In addition to more frequent and more constructive interactions, there has also been an increase in the volume of process documentation and information available. These changes support increased awareness and understanding of process requirements that, in turn, tend to increase accuracy and consistency throughout the process. Positive feedback from CDER and CBER stakeholders has measurably increased since the Interim Assessment, although the overall percentage of positive responses remains low. This upward trend may indicate that the improvement efforts are on the right track and customer sentiment is starting to shift. However, the continued low percent of satisfied customers is a signal that more efforts are needed to help FDA further improve its HR services to CDER and CBER.

F2.1   OTS has improved customer-focused communication and operations; positive feedback from CDER and CBER has increased, but the overall percentage of satisfied customers remains low.

Since the Interim Assessment, there has been a positive change in stakeholders' perceptions around communications and collaboration. The Interim Assessment showed that most stakeholder feedback was critical of HR services from all staff performing HR work (i.e., within OTS, OHCM, CDER, and CBER). In the Final Assessment, interview participants reported a noticeable improvement in HR services due to OTS's efforts to increase communication with CDER and CBER and to provide targeted solutions to support the Centers' needs. For example, OTS and OHCM have conducted information sessions, including working group meetings, customer councils, and consultative HR discussions (see Supplement Exhibit S-6).

In addition, OTS' organizational structure shows that it aligned staff within certain HR functions to specific customer groups (including CDER and CBER).[24] OTS also has enhanced its operational management by clarifying processes and establishing SLAs that include metrics and KPIs.[25] These developments increase OTS staff's understanding of CDER and CBER and accountability for results. The enhanced documentation also provides clearer HR points of contact for CDER and CBER. On the other hand, while OTS tailored these efforts to better respond to the immediate needs of CDER and CBER, these changes introduced additional variability in HR service delivery across Centers. On that point, CDER and CBER participants in interviews and focus groups expressed issues with unclear HR procedures, inconsistent guidance from staff performing HR work (aligned to OTS, CDER, and CBER), and confusion about OTS points of contact due to HR staff turnover (see Supplement Exhibit S-7).

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[24] OTS Organizational Chart, OTS.
[25] OTS Service Level Agreement, OTS.

Survey results are consistent with the interview and focus group feedback, with nearly one-third of CDER and CBER hiring managers reporting that OTS and OHCM support has increased their satisfaction with the recruiting and hiring process. As shown in Exhibit 11, positive responses from hiring managers more than doubled from 14 percent (Interim) to 32 percent (Final). And, as in the Interim Assessment, HR staff and managers of HR staff—regardless of their organizational alignment—tended to have a far more favorable view of the HR support provided by OTS and OHCM, compared to the hiring managers who are the recipients of that support. More than 75 percent of HR staff and managers of HR staff reported their satisfaction with recruiting and hiring has increased due to OTS and OHCM support. These results highlight not only evidence of increasing satisfaction among hiring managers but also the distinct difference in perspectives that still exists between the customers (CDER and CBER) and their service providers (OTS and OHCM).
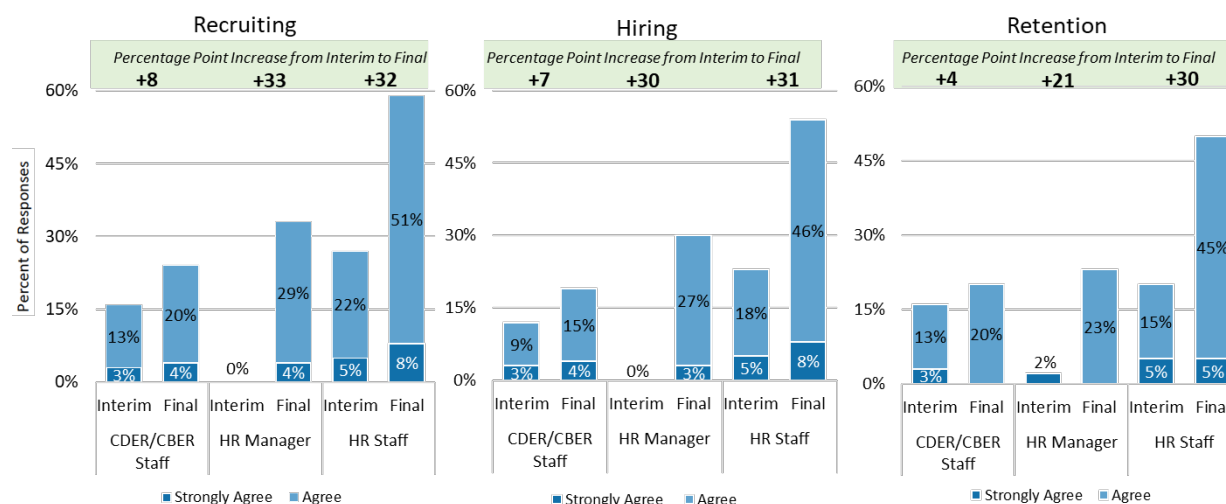
Exhibit 11: Increased Satisfaction with Recruiting and Hiring due to OTS and OHCM Support
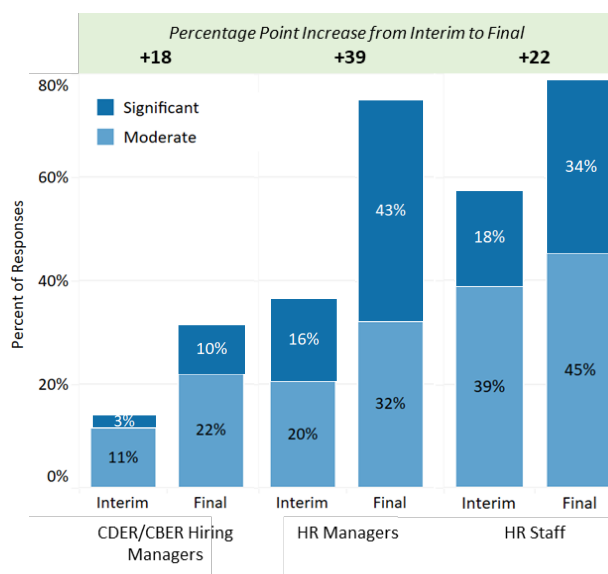
Respondents: HR Staff (Final: n=73, Interim: n=91); HR Managers (Final n=32, Interim: n=48); Center (CDER and CBER Hiring Managers only; Final: n=449, Interim: n=354). Response scale: None, Little, Moderate, Significant, and Don't know. "Don't Know" responses were excluded from the analysis. Chart shows "Significant" and "Moderate" responses only. See Supplement Exhibit S-8 for all response data.

- *Final Assessment Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Support provided by the Agency's HR Organization (OTS/OHCM) to the Centers has improved your overall satisfaction with FDA's recruiting and hiring processes."*
- *Interim Assessment Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to support provided by the Agency's HR organization (formerly the Office of Human Resources [OHR]) to the Centers, in terms of your overall satisfaction."*

Similarly, as shown in Exhibit 12, survey data from the Interim to Final Assessment reveal an increase in the percent of respondents who believe hiring, recruiting, and retention meet the Agency's needs, especially among HR staff and managers of HR staff. These results also show the contrast in perspectives between HR service recipients (i.e., CDER and CBER staff) and HR service providers (i.e., HR staff). Specifically, the majority of CDER and CBER staff and managers of HR staff do not agree that these processes meet FDA's needs, yet the majority of HR staff agree that FDA's needs are being met.

Exhibit 12: Increased Agreement that Hiring, Recruiting, and Retention Meet FDA's Needs

Respondents: CDER and CBER staff (Final: n=2315, Interim: n=1805); HR managers (Final: n=35, Interim: n=52); HR Staff (Final: n=77, Interim: n=120). Survey item: "Survey items: "Overall, I believe the FDA's current recruiting process for human drug and biologics review program staff meets the needs of the Agency"; "Overall, I believe the FDA's current hiring process for human drug and biologics review program staff meets the needs of the Agency"; and "Overall, I believe the FDA's current retention strategies for human drug and biologics review program staff meets the needs of the Agency," with a response scale of Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree. Chart reflects" Strongly Agree" and "Agree" responses only. For full response data see Supplement Exhibit S-9.

F2.2   FDA has updated and enhanced documents and guidance for several HR process steps, but the HR workforce and CDER and CBER hiring managers say they need more.

Consistent with recommendations in the Interim Assessment, FDA developed or refined documentation and guidelines that help facilitate collaboration, such as HR processes, SOPs, and roles and responsibilities. During the Final Assessment timeframe, FDA completed 19 new or updated SOPs, bulletins, advisories, and guidance memos, and was in the process of updating 58 more, covering process steps of classification, interview and selection, job analysis, onboarding, and recruiting, among many other topics.

In addition, OTS developed more than a dozen resources to help standardize and improve understanding of the classification process (further discussed in Finding F3.3). Resources include training modules and a classification checklist to support utilization of eClass, an online application to support FDA classification. OTS has also developed new resources to support the standardization and quality of Title 21/Cures packages, including biweekly meetings with Centers, weekly email update, training sessions, and lunch and learn sessions.[26]

Despite OTS's active development of process guidance, interview, focus group, and survey respondents consistently said that they need HR process-related resources. It is possible that the respondents are not familiar with the additional guidance that OTS has provided, or the new guidance may not meet respondents' needs (e.g., difficult to use in practice, not easily accessible, not written in a user-friendly format).

Specifically, interview and focus group participants said that they would like up-to-date and easily accessible process documentation and guidance, clear and consistent information about the different FDA hiring authorities and how to use them, more clearly defined roles and responsibilities for all staff who work on HR processes, and tracking systems that support both transparency and compliance (see Supplement Exhibit S-10). Survey findings echo those sentiments. For example, as shown in Exhibit 13, CDER and CBER hiring managers expressed that the top three resources they need to be more efficient and effective were more

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[26] Source: FDA Cures Communications and Engagement Update, OTS.

engagement with OTS and OHCM, documented process guidance, and checklists and job aids for the hiring process. The need for documented process guidance and checklists and job aids for the hiring process were also the top two resources that HR staff and managers of HR staff reported.

Exhibit 13: Stakeholder Needs for Additional Resources to Make HR Processes More Successful
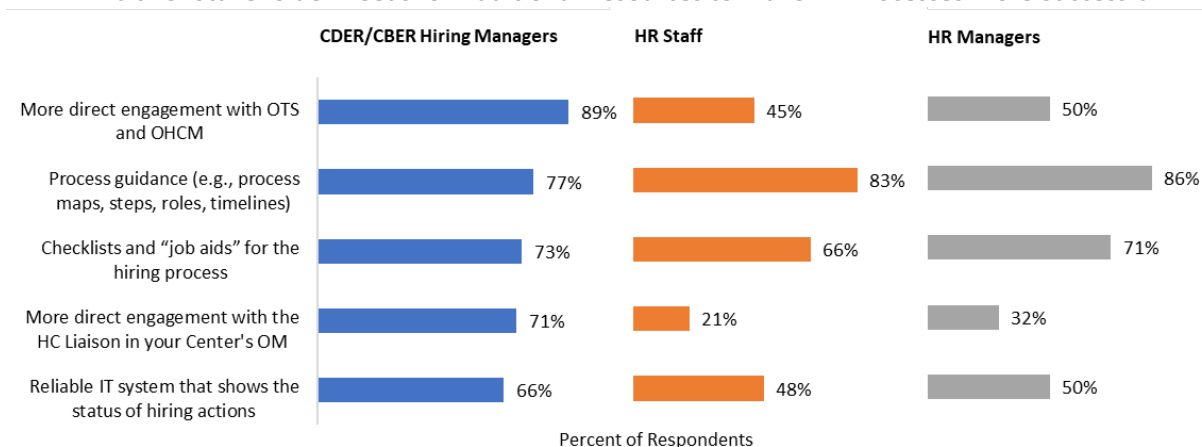
Respondents: CDER/CBER hiring managers (n=241); HR managers (n=29); HR staff (n=28). "I do not need additional resources" and "Other" responses were excluded from the analysis. This item type is Select All That Apply, so the chart presents percent of respondents who selected each item. This chart shows the top five choices for CDER and CBER hiring managers and the corresponding percent of respondents from HR managers and HR staff for those choices. See Supplement Exhibit S-11 for all response data.

- *CDER/CBER Staff Survey item: "What additional resources do you need to be more efficient and effective in the hiring process? Please select all that apply."*
- *HR Staff Survey item: "What additional resources would help you be more successful when performing work related to the recruiting and hiring processes and/or retention initiatives? Please select all that apply."*
- *HR Manager Survey item: "What additional resources would help your HR staff be more successful when working on recruiting and hiring processes and/or retention initiatives? Please select all that apply."*

F2.3   HR collaboration and handoffs are improving, and further clarity of roles and coordination across HR functions will help FDA develop an integrated approach to HR services across the talent lifecycle.

As discussed in both the Initial and Interim Assessments, the FDA HR service providers (including staff working in OTS, OHCM, CDER, and CBER) and the CDER and CBER hiring managers continue to contend with underlying cultural issues that hamper efforts to work together as a unified team to improve the customer experience. Interview and focus group participants described challenges with communication and coordination hamper FDA's ability to integrate and optimize service delivery across the talent lifecycle. For example, more frequent communication between the recruiting and hiring functions could help recruiters be more proactive in anticipating upcoming hiring needs and planning to tap into the appropriate talent pools when vacancy announcements (VAs) are open. Also, OTS staff found it difficult to effectively exchange information and convey consistent guidance with multiple points of contact (POCs) in CDER in CBER who have siloed roles and use internal review procedures that vary among different CDER and CBER Offices (see Supplement Exhibit S-7).

Efforts to increase role clarity and collaboration between the full cadre of staff in OTS, OHCM, CDER and CBER who perform HR work (as discussed in Finding F2.1) are helping to alleviate these challenges. Interview and focus group participants indicated that the opportunity for more frequent, informal touchpoints with assigned POCs enable staff to further improve coordination across HR functions and organizations. Interview and focus group participants also said that having established POCs and working with people who have decision-making authority help to maximize the effectiveness of these meetings (see Supplement Exhibit S-6).

As demonstrated in the heat map in Exhibit 14, the percent of HR staff who agree or strongly agree that there are effective process handoffs between OTS, Center OMs, Center Offices, and hiring managers has increased considerably since the Interim Assessment. Specifically, HR staff agreement that handoffs are effective for recruiting increased by 44 percentage points. Similarly, HR staff agreement that handoffs are effective for the Job Analysis, Classification, and Interview and Selection process steps all increased by over 20 percentage points. In contrast, the percent of managers of HR staff who agree that handoffs are effective did not change much since the Interim Assessment, and their responses are mixed. Manager agreement that handoffs are effective for the recruiting step decreased by 13 percentage points (which was the *highest* increase of agreement for HR staff), and their agreement that handoffs are effective for the interview and selection process step increased by 11 percentage points. It is not clear why managers and staff expressed such different perspectives of the effectiveness of handoffs for recruiting.

Exhibit 14: Trends in HR Workforce Agreement that Handoffs are Effective for Recruiting and Hiring Process Steps

CHANGE IN AGREEMENT THAT HANDOFFS ARE EFFECTIVE FOR EACH PROCESS STEP INCREASE OR DECREASE BETWEEN INTERIM AND FINAL SURVEY RESULTS			
PROCESS STEP		**HR MANAGERS**	**HR STAFF**
Job Analysis		+0	+21
Classification		-2	+22
Recruiting		-13	+44
Interview and Selection		+11	+26
Onboarding		+1	+11
Percent Strongly Agree or Agree (range)	**Interim**	12-30%	20-47%
	Final	10-35%	42-78%

Respondents for the Final Assessment survey: HR Managers (n=32-34) and HR Staff (n=31). Survey item: "There are effective handoffs between OTS, Center Office of Management (OM), Center Offices, and hiring managers for the following process steps," with a response scale of Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree, and N/A. "N/A" responses were excluded from the Interim and Final analysis. Data shown reflects "Strongly Agree" and "Agree" responses only.

Ultimately, the initiatives to increase coordination, as currently planned, cannot adequately address the broader cultural influences that continue to underlie challenges, such as disconnected perspectives, process inefficiencies, and siloed operations across staff performing HR work in different organizations. Therefore, these initiatives tend to have limited impact beyond their respective organizations and are unable to drive cultural change or to embed a shared customer-focused mindset for integrated HR quality and effectiveness across the talent lifecycle. In fact, even the OHR reorganization, a major improvement activity completed prior to the Interim Assessment, focused mainly on OTS and OHCM staff and did not proactively formalize coordination with staff in CDER and CBER who perform HR work.

Furthermore, the current improvement efforts do not address the full talent lifecycle (e.g., recruiting, application, hiring, and post-hire support). For example, the FDA website content about special hiring authorities was last updated in 2018, and it does not mention the Agency's most competitive pay and hiring authorities (e.g., Title 21).[27] In addition, process and technology changes to date have focused primarily on enhancing the experience of hiring managers and the staff performing HR work, but efforts could be expanded to consider improving the candidate experience of learning about FDA, finding FDA jobs, and applying for positions.[28] An enterprise-level commitment to a unified HR servicing model, including clearly defined roles and responsibilities, performance goals and expectations, and an integrated tracking system, would reinforce the delivery of high-quality, integrated HR services across the talent lifecycle and drive mission performance.

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[27] https://www.fda.gov/about-fda/jobs-and-training-fda/hiring-programs; https://www.fda.gov/about-fda/jobs-and-training-fda/special-hiring-authorities; accessed 9/23/2021.
[28] Source: FDA HRIT Business Case, OHCM.

2.3 Recruiting and Hiring Processes

As summarized in Exhibit 15 FDA has made strides in improving its recruiting and hiring processes and in addressing several of the Interim Assessment recommendations. As a noteworthy success, OTS cleared the classification backlog and implemented new processes for classification and the FDA DEU. OTS also has engaged in extensive communications with Centers about opportunities to effectively use the Title 21 hiring and pay authority. Other notable changes, such as pivoting the STRS team hiring efforts to include greater use of hiring flexibilities (i.e., Title 21, DHA) and shared certificates, have helped to expedite recruiting and hiring. It is important to consider whether recent operational and performance enhancement wins are based on surge efforts as well as whether these improvements can be institutionalized in a sustainable way to be a foundation for continual enhancements.

Exhibit 15: Key Takeaways for Recruiting and Hiring Processes

MAJOR ACCOMPLISHMENTS

☑ Applied lessons learned from the STRS Pilot to customize HR support to CDER and CBER

☑ Expanded the effective use of specialized hiring and pay authorities

☑ Reformed the Classification process, cleared the backlog, and stood up FDA's DEU

DEVELOPMENT OPPORTUNITIES

☐ Leverage predictive analytics to anticipate and inform hiring and recruiting efforts

☐ Track talent cohort metrics from applications through attrition

☐ Optimize recruiting resources and channels based on ROI and quality

OTS has also continued to build talent pools and coordinate with CDER and CBER on recruiting efforts; however, recruiting and hiring data are not integrated, which limits FDA's ability to assess and refine recruiting effectiveness. Other process challenges include different stakeholder expectations about carrying out the hiring process (e.g., qualification and selection) and continued frustrations about lengthy time to hire. Addressing the longstanding issues of process integration and efficiency requires enterprise investment and commitment of leaders across multiple organizations to build and operate from a central HR service model.

> CONCLUSION
>
> C3-1. FDA attracts qualified candidates to apply and has advanced its strategic recruiting efforts; better data tracking and linkage with the hiring process will increase recruiting effectiveness.

As was the case at the time of the Interim Assessment, FDA is able to attract a large talent pool for the human drug and biologics review program and create a reasonably positive experience for most (albeit not all) of their new hires. FDA has since made progress with building a recruiting pipeline and providing opportunities to coordinate with Centers on recruiting activities. To build on this framework, FDA needs a more holistic system linking recruiting with hiring (and eventually post-onboarding) to establish standardized data tracking and performance measures, streamline recruiting efforts, and minimize duplicative efforts.

F3.1   OTS and Center-based staff have made progress in planning and organizing recruiting activities using both non-traditional and tried-and-true recruiting sources to identify candidates.

Since the Interim Assessment, FDA has made strides to incorporate a more strategic approach to recruitment. For example, FDA's Scientific Staffing Outreach Branch (SSOB)—known as the Scientific Staffing Team in the Interim Assessment—pivoted quickly to use virtual recruiting practices at the start of the COVID-19 pandemic and supported COVID-19 related hiring priorities for CDER and CBER (e.g., CDER's focus on Title 21, CBER's hiring surge leveraging DHA).

As presented in Exhibit 16, SSOB also continued its efforts to build external strategic partnerships to help increase FDA's talent pipeline for the scientific talent sought by CDER and CBER (e.g., Society of Toxicology,

Drug Information Association, American Chemical Society) and to support the Agency's goals to diversify its workforce (e.g., Historically Black Colleges and Universities, Society for the Advancement of Hispanics/Chicanos and Native Americans in Science, Maryland STEM Girls, AARP). Since its inception in 2018, SSOB has managed to build 149 external strategic partnerships including 90 academic partnerships, 24 government partnerships, 19 with associations, 10 with organizations, and 6 with other miscellaneous partners.

Exhibit 16: SSOB External Strategic Partnerships Growth from FY18 to FY21 Q3

	FY18	FY19	FY20	FY21 Q3
Academic	26	53	71	90
Government	16	21	22	24
Association	9	14	19	19
Organization	0	2	6	10
Other	3	6	6	6
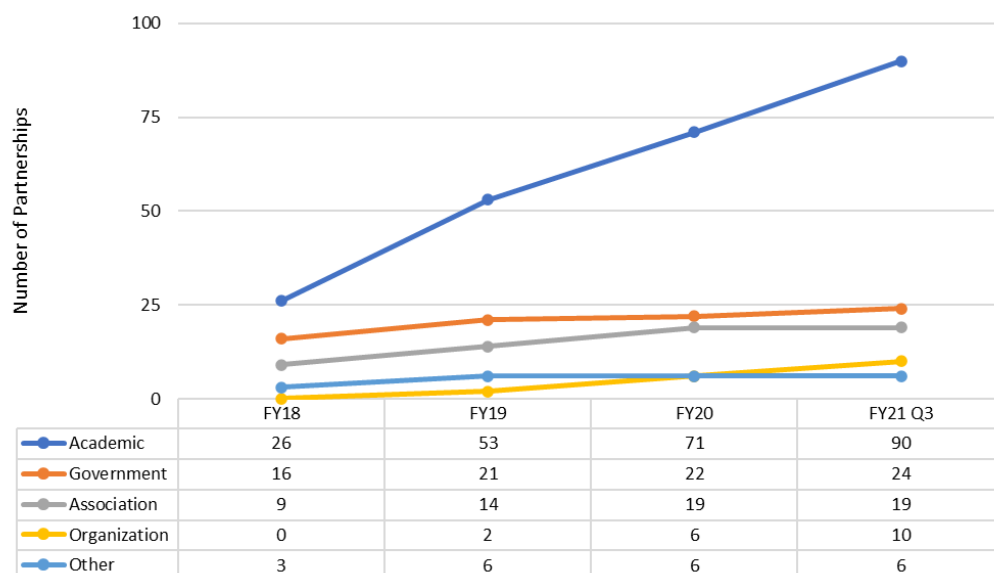
Source: SSOB Strategic Partnerships, OTS. Results show the cumulative numbers of strategic partnerships from FY18 to FY21 Q3.

Leveraging these connections, SSOB also established a schedule of conferences and events and invited Centers to sign up to participate.[29] As evidence that this coordination has improved, Center representatives participated in 25 out of the 32 SSOB planned events tracked in FY20 to FY21.[30] Similarly, SSOB works with the Scientific Staffing Working Group (SSWG), which was established in 2017 and includes representatives from all Centers, to help coordinate recruiting efforts and promote a "One FDA Voice" approach, rather than focusing on individual Centers. Recent accomplishments include creating a SSWG SharePoint site to house a toolbox, materials, and a calendar for FDA outreach and recruitment events. SSOB also continued to promote the FDA recruitment brand with an online presence on FDA's website, LinkedIn, and Twitter. Metrics for followers and website traffic has increased across platforms, but it is unclear how frequently this online engagement leads to applications or hires for CDER and CBER.[31]

As an example of Center-specific accomplishments, CDER planned and enacted efforts to enhance recruitment and outreach efforts of diverse candidates during FY20 and FY21. These efforts include continuing to build and strengthen strategic partnerships and leading virtual recruitment fairs to attract people with disabilities and people of color, developing five Diversity and Inclusion trainings, and establishing a CDER Recruiter Community of Practice (CoP) to serve as the focal point of recruitment and outreach activities.[32, 33] As of the Final Assessment time period, CDER's Division of Management Services (DMS) was

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[29] Source: FY21 Conference Calendar.pptx, OTS.

[30] Source: 2020 and 2021 Conferences and Academic Visits.xlsx, OTS.

[31] Source: SSOB Social Media Report 2019-2021, OTS.

[32] Sources (3): FINAL FEORP FY20 CDER Strategic Activities 1. related to Hispanic Employment, 2. related to the employment of people with Disabilities; 3. Progress Tracker, CDER OM.

[33] Source: CDER Recruitment and Outreach, CDER OM.

preparing to launch Recruitment and Outreach SharePoint Online, create job aids, and train its Recruiter CoP. Similarly, CBER implemented its FY20 Hiring and Recruiting Strategy with the intention to create efficiencies in the hiring process to shorten the time to fill, find, and attract diverse candidates.[34]

Interview participants acknowledged that more effective collaboration between OTS and the Centers has been helpful for recruiting efforts in general but noted that that better coordination and communication would help make further improvements and help diversify the talent pool (see Supplement Exhibit S-6 and Supplement Exhibit S-12). In surveys, hiring managers and HR staff consistently indicated that the most productive recruiting sources are FDA referrals, USAJOBS, and word of mouth. Similarly, interview and focus group participants noted that the most effective candidate outreach methods include word of mouth, conference attendance and professional networks (especially if FDA staff make a one-on-one connection with potential recruits), and advertisements in academic media. A smaller number of respondents in surveys, interviews, and focus groups noted that outreach methods not traditionally used by FDA, such as social media (e.g., LinkedIn, Facebook, and Twitter) and job posting websites (e.g., Monster.com), were useful but were not used very often at FDA (see Supplement Exhibit S-13).

Without tracking the outcomes of recruiting and outreach efforts (e.g., a relationship management system, tracking how applicants heard about the job) and comparing those results with hiring and longer-term retention data, conventional wisdom about the effectiveness of different recruiting sources will continue to be based solely on anecdotal evidence or perceptions vice data.

F3.2 The recruiting process is not well defined and lacks the standardization and coordination necessary to track key data and monitor the effectiveness of recruiting for CDER and CBER.

Despite SSOB's efforts to build the recruiting pipeline more strategically, FDA's overall recruiting process is not sufficiently standardized to truly measure the effectiveness and efficiency of recruiting. Staff in OTS, CDER, and CBER conduct and manually track various recruitment and outreach activities; however, none of these organizations has established key performance measures or trackers for key outcomes (such as applicants and hires by recruiting/advertising source) in a way that allows FDA to optimize recruiting resources and activities. For example, neither CDER, CBER, nor SSOB have established the KPIs needed to monitor the effectiveness of recruitment efforts. In addition, there is no consistent workload data to proactively plan for the time and resources needed for recruitment and outreach. In short, these limitations in recruiting data tracking (such as integration with the hiring process and data systems) continue to stifle the potential impact of strategic recruiting efforts. Similarly, interview participants noted that the recruiting process needs to be more refined and targeted (see Supplement Exhibit S-12). These results suggest an opportunity for FDA to standardize the recruiting process; clarify roles and responsibilities of OTS and the Centers; and drive more consistent and efficient integration, coordination, procedures, and data tracking.

CONCLUSION

C3-2. Process improvements and targeted use of multiple hiring authorities helped OTS effectively support urgent hiring needs for CDER and CBER; further maturity in process coordination, guidance, and data tracking is essential for benefits to be sustainable and impactful.

FDA's response to the COVID-19 pandemic showed the Agency's ability to pivot HR functions quickly amidst a challenging operating environment. Efforts to improve and modernize aspects of the hiring process and the broad use of Direct Hire and other expedited appointments enabled OTS and CDER and CBER staff to support urgent pandemic-related hiring needs. These gains in hiring efficiency and productivity when the Agency needed it most likely boosted CDER and CBER confidence in HR (see Finding F5.5, for example), though the Centers still expressed a strong sentiment that the hiring process takes too long. In addition, the apparent

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[34] Source: CBER Human Capital Hiring and Recruiting Strategy, CBER OM.

disconnect between OTS and hiring manager expectations for candidate qualifications is a potential source of inefficiency and wasted effort (e.g., hiring managers making few selections from referred candidates).

At this juncture, FDA has an opportunity to institutionalize the processes and systems that made the hiring successes possible and address the continuing efficiency challenges. By doing so, FDA can establish "next-level" performance for its HR functions so that this period becomes a steppingstone rather than an unsustainable short-term surge by dedicated HR professionals. Further maturity in documentation, guidance, and data tracking are essential for these changes to make substantial, lasting improvements over time.

F3.3   OTS reformed the classification process and cleared the backlog, which improved overall hiring process efficiency; OTS also stood up FDA's delegated examining unit.

Over the past several years, classification emerged as a major area of concern as the program accrued a large backlog and contributed to hiring process inefficiencies.[35] To respond to these challenges, OTS implemented a classification reform and optimization initiative. In FY19, OTS established a Classification Division, which has delegated classification authority for FDA. In FY20, OTS partnered with OPM's Human Resources Solutions to assess the current state of FDA's position classification program.

As a formidable accomplishment, the OTS Classification Division cleared the backlog of outdated classification requests by establishing guidelines for archiving draft position descriptions (PDs) older than 90 days. The division also reformed the procedures for providing services to the Centers, including greater use of standardized PDs and eClass as a repository of up-to-date classified PDs.[36] The division is composed of two branches staffed by 14 federal classifiers and five contractors that share responsibility for providing classification support to FDA Centers. HR liaisons located in CDER and CBER also support the classification program by helping CDER and CBER hiring managers compile classification request packages and sending them to the Classification Branches for final review and approval. HR Liaisons also serve as a conduit for classifiers to obtain information when questions arise during the review of a classification request.[37]

OTS also committed to classification KPIs in the SLA and has been monitoring progress. Results show that the Classification Division is meeting its KPI targets for less than half of CDER and CBER PDs. The target for FY19 and FY20 was to complete classification within 22 business days for 75 percent of the PDs. In FY21 the target was adjusted to completing classification within 20 business days for 80 percent of the PDs.[38] As depicted in Exhibit 17, the division has classified over 1,300 PDs for

Exhibit 17: OTS Classification of CDER and CBER Position Descriptions from FY20 to FY21 Q3

Average Time to Classify PDs (in Business Days)

Number of PDs Classified	822	150
Percent meeting KPI *FY20 target is 75%*	48%	49%

Number of PDs Classified	534	109
Percent meeting KPI *FY21 target is 80%*	45%	36%

CDER and over 250 PDs for CBER (this includes PDs drafted for positions with multiple grade levels). OTS has substantially reduced the average time for classification from the 22-300 days reported in the Initial

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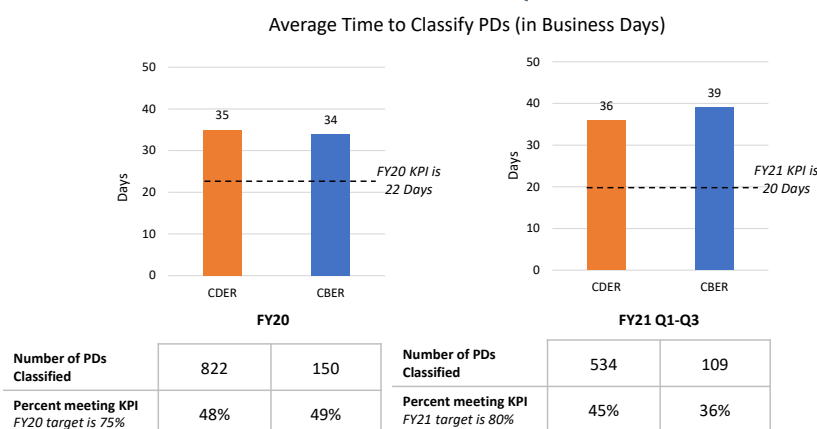
[35] Source: Classification Program Assessment Report 10/13/20, OTS.
[36] Sources (2): 1. Final Hiring and Retention Assessment Informational Interviews with SMEs; 2. OTS March 2021 Classification Update, OTS.
[37] Source: Classification Program Assessment Report 10/13/20, OTS.
[38] Sources: Classification Reform PDs KPIs FY20, eClass; Classification Reform PDs KPIs FY21, eClass.

Assessment. However, classification packages for CDER and CBER are not consistently processed within the 20-business day (4-week) target.

Nevertheless, the classification reform is starting to have a positive impact on customer satisfaction. In survey results, 18 percent of CDER and CBER staff responded that classification reform has improved their overall satisfaction with the hiring process to a moderate or significant extent. Because classification reform is a new initiative, there are no comparable Interim survey results. Final Assessment results still indicate a decidedly positive shift in tone from the Interim Assessment, when CDER and CBER interview and focus group feedback on the classification process was almost universally negative.[39] In contrast, when asked about classification reform during the Final Assessment, interviewees across OTS, CDER, and CBER note that, while some challenges still exist, there have been improvements in classification. Elements of classification reform that have been beneficial include standardized PDs and closer coordination between classifiers, CDER and CBER HR liaisons, and CDER and CBER hiring managers (see Supplement Exhibit S-14).

F3.4 The Agency effectively used a broad range of tools at its disposal, including special hiring authorities, pay authorities, and shared certificates.

As shown in Exhibit 18, CDER and CBER used a range of hiring and pay authorities to hire staff from FY20 to FY21 Q3. The fact that OTS, CDER, and CBER made use of a variety of hiring processes shows the complexity of HR work taking place and indicates that they are identifying different situations in which the different hiring processes are effective (e.g., certain types of positions or targeted professional groups). For example, the CDER FY21 Talent Acquisition Plan lists 434 positions to be filled, along with the FY Quarter target for the new hire to enter on duty, the User Fee designation, and hiring authority (specified from a list of eight different options) for each position.[40]
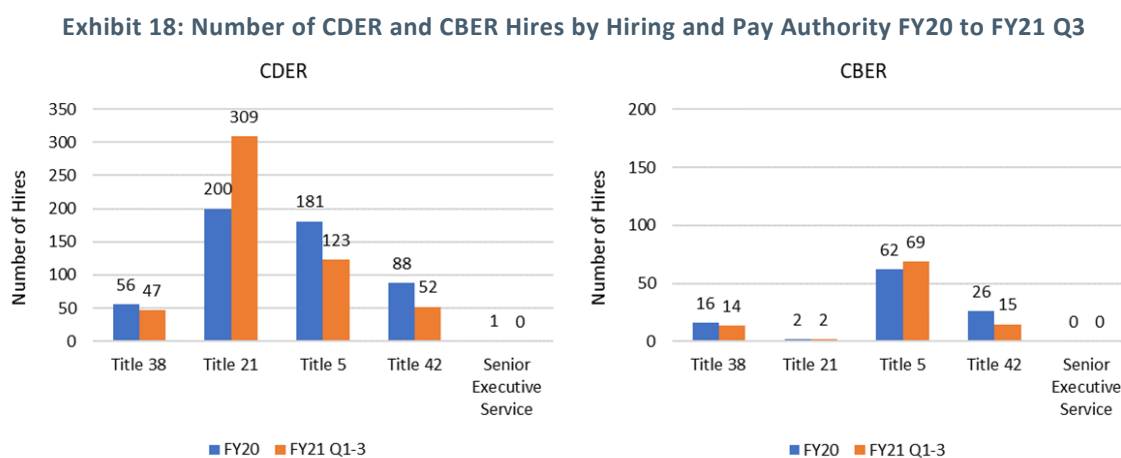
Exhibit 18: Number of CDER and CBER Hires by Hiring and Pay Authority FY20 to FY21 Q3

Sources: Cures Conversions FY18 – FY21 Q3, Business Intelligence Information System (BIIS); Post Hire Personnel Data FY20–FY21 Q3, Business Intelligence Information System (BIIS). Title 38 includes Direct Hire; Title 5 includes Direct Hire, Pathways, and Schedule A; Title 42 includes Title 42(g) and Title 42(f). Title 21 includes external and internal hires and excludes internal conversions (defined below, based on the Cures Working Group definitions):

- External Hires (including Government and Non-Government Recruits and Reemployed Annuitants) –candidates from another federal agency, candidates being hired into the federal government for the first time, federal service retirees returning to federal service as a Cures appointment
- Internal Hires–FDA federal employee moving to a Cures appointment in a new position
- Internal conversions–Non-Cures federal employees moving to a Cures appointment in the same position of record).

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[39] Classification Reform/Optimization is a new improvement activity for the Final Assessment timeframe, so there are no Interim Assessment survey responses to reference for a trend analysis.
[40] Source: FY21 Talent Acquisition Plan – OTS submission 12 1 20 (for CDER), OTS.

The STRS Team has incorporated time-saving approaches as part of its Global Recruitment process. For example, using shared recruitment efforts across Offices means there are fewer VAs (along with a reduction in the work it takes to prepare them) per Office. The Global Recruitment process also uses shared certificates, which permit interview selections to be made from a certificate of eligible candidates from another requisition of the same position type. The use of shared certificates saves time by bypassing the first three stages of the hiring process: Talent Launch, Talent Sourcing, and Talent Evaluation.

Exhibit 19: Efficiency Gains with Shared Certificates (in Business Days) FY20 to FY21 Q3

Hiring is **~18** DAYS FASTER using Shared Certificates

Stand Alone Certificates	Shared Certificates
Average Time to Hire	Average Time to Hire
86 DAYS	**68** DAYS

Global Recruitment results indicate time savings are achievable using shared certificates as shown in Exhibit 19. Specifically, the use of shared certificates saved an average of 18 business days in end-to-end time to hire (from Hiring Package Initiation to Entrance on Duty), compared to stand alone certificates.[41]

In addition, FDA has made increasing use of the Title 21 hiring and pay flexibilities, with over 600 Title 21 employees in CDER and CBER combined.[42] Since the Title 21 program's inception through FY21 Q3, CDER has hired or converted a total of 608 appointments, with its usage steadily rising each year. CDER has opted to embrace Title 21 for most of its hiring and conversion needs, which accounts for the large number of appointments since FY20. On the other hand, CBER is using Title 21 less frequently, with a total of 41 appointments since FY18. As presented in Exhibit 20, CDER and CBER are able to use Title 21 in three different ways: 1) convert FDA existing employees to the Title 21 pay plan without changing their position of record to allow for greater pay flexibility (known as conversions); 2) hire existing FDA employees into a new position (known as internal hires); and 3) hire employees from outside FDA (known as external hires). CDER has made greater use of Title 21 for internal hires (319 employees; 52 percent), compared to external hires (209 employees; 34 percent) and conversions (80 employees; 13 percent). On the other hand, the distribution of CBER's Title 21 employees is moderately higher for conversions (18 employees; 44 percent) than external hires (13 employees; 32 percent) and internal hires (10 employees; 24 percent).

Exhibit 20: Use of Title 21 in CDER and CBER from FY18 to FY21 Q3
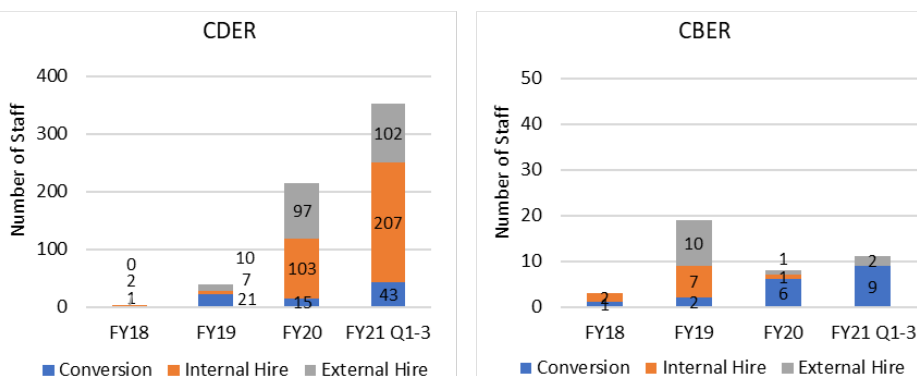
Sources: Cures Conversions FY18 – FY21 Q3, Business Intelligence Information System (BIIS); Post Hire Personnel Data FY20 – FY21 Q3, Business Intelligence Information System (BIIS).
*Title 21 categories are based on the Cures Working Group definitions:*

- *External Hires (including Government and Non-Government Recruits and Reemployed Annuitants) –candidates from another federal agency, candidates being hired into the federal government for the first time, federal service retirees returning to federal service as a Cures appointment*
- *Internal Hires–FDA federal employee moving to a Cures appointment in a new position*
- *Internal conversions–Non-Cures federal employees moving to a Cures appointment in the same position of record).*

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[41] Source: STRS Hiring CBER Global Recruitment FY20 - FY21 Q3, STRS Hiring Global Recruitment FY20, Manual Reporting (OTS).
[42] Source: Cures Workforce FY20 – FY21 Q2, EHCM.

FDA has also made use of DHA, as shown in Exhibit 21. FDA received expanded DHA in FY20, to include additional occupational series eligible for DHA, to support the response to the vaping and COVID-19 public health emergencies. The COVID-19 temporary authority is set to expire on December 31, 2021, and the vaping temporary authority was set to expire on October 16, 2021, although FDA has requested an extension.
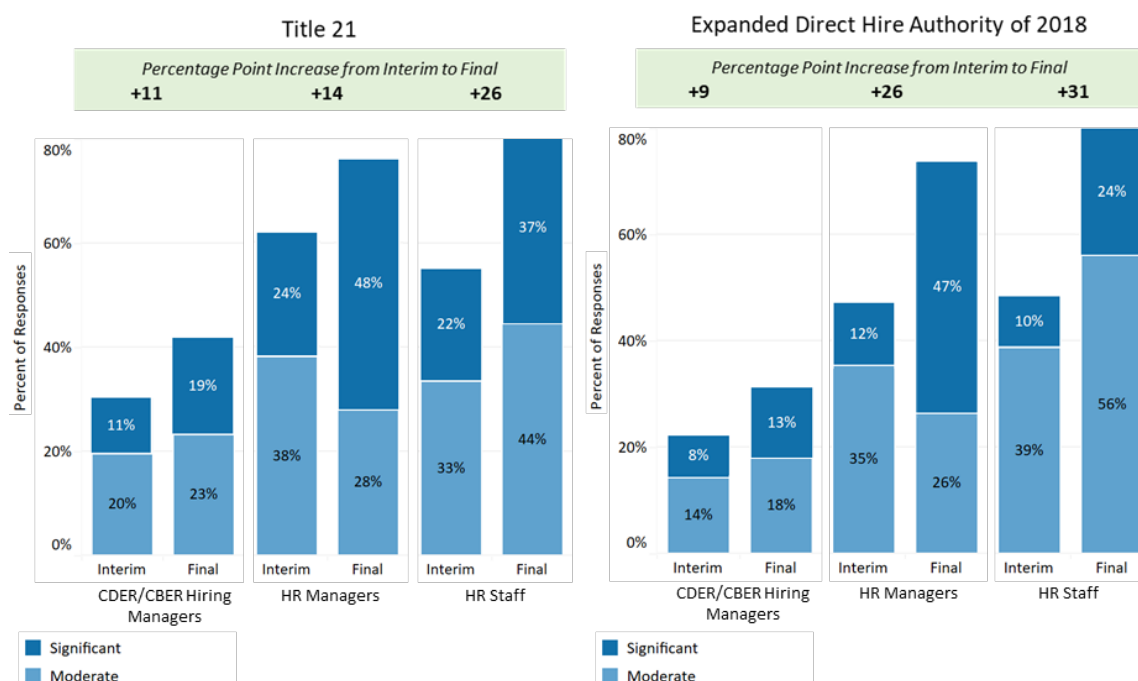
Exhibit 21: Trends in Number of Hires in CDER and CBER Using Direct Hire Authority from FY18 to FY21 Q3
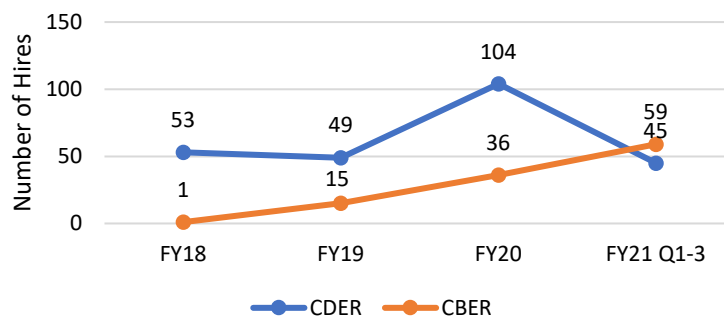
Sources: FDA Interim Hiring and Retention Assessment, Booz Allen; Post Hire Personnel Data FY20 – FY21 Q3, Business Intelligence Information System (BIIS).

In light of FDA's success in using a range of hiring and pay authorities to fill CDER and CBER vacancies, it is informative to examine any change in perceptions about how well the hiring, recruiting, and retention functions meet the Agency's needs. Results show a positive trend across the board for all survey audiences: CDER and CBER hiring managers, managers of HR staff, and HR staff (see Exhibit 22). While there remains a considerable percentage of respondents who do not agree, especially among CDER and CBER hiring managers, the increase in positive results suggests that HR improvement efforts are beginning to have a measurable impact on customers. Similarly, interview and focus group participants highlighted Title 21 and DHA as among the most effective aspects of hiring. Specifically, stakeholders appreciate the faster hiring timeframes, pay flexibility, and the ability to have direct contact with candidates (see Supplement Exhibit S-15).

Exhibit 22: Increased Satisfaction with Recruiting and Hiring due to Title 21 and Direct Hire

Title 21 Respondents: HR Staff (Final: n=73, Interim: n=90); HR Managers (Final: n=33, Interim: n=47); Center (CDER and CBER Hiring Managers only; Final: n=446, Interim: n=337). Direct Hire Respondents: HR Staff (Final: n=74, Interim: n=91); HR Managers (Final n=33, Interim: n=46); Center (CDER and CBER Hiring Managers only; Final: n=436, Interim: n=339).

- *Final Assessment Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Use of special hiring authorities through Title 21 (21st Century Cures Act)/Expanded Direct Hire Authority of 2018 (inclusion of additional scientific occupational series) has improved your overall satisfaction with FDA's recruiting and hiring processes."*
- *Interim Assessment Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to Access to special hiring authorities through the 21st Century Cures Act/Expanded Direct Hire Authority options (e.g., inclusion of additional scientific occupational series) in terms of your overall satisfaction."*
- *Response scale: None, Little, Moderate, Significant, Don't Know. "Don't Know" responses were excluded from the analysis. Data shown reflects "Moderate" and "Significant" responses only. For all response data see [Supplement Exhibit S-16](#).*

F3.5   Procedural complexities, frustration about lengthy hiring times, and difference in perspective on applicant qualification are ongoing challenges to hiring process efficiency.

One major component of the Interim Assessment was its evaluation of the impact of the STRS hiring pilot, which FDA designed to be a streamlined, more efficient version of the Title 5 hiring process. Based on a shift in CDER and CBER needs, the STRS team has since redirected its focus away from the STRS hiring pilot to working with a wider range of hiring and pay authorities beyond Title 5 (e.g., Title 21, Title 42[g]). Also, using an approach called Global Recruitment, the STRS team can process appointments under Title 5, including Direct Hire, Schedule A, MP, and Delegated Examining appointments, while incorporating practices found to be effective in the hiring pilot, such as shared certificates and strategic talent launch meetings. The STRS team worked extensively with CBER using Global Recruitment to support a series of hiring surges. The STRS team also supported CDER in its focus on using Title 21 for most of its hiring needs.

Because the Global Recruitment processes differ from the STRS pilot processes, is it not possible to compare process efficiency data from the Interim Assessment with data from the Final Assessment (e.g., time for each hiring process step). Instead, the Final Assessment focuses on the current state of hiring timeframes for which data are available combined with available trend data (e.g., number of staff hired) to support conclusions.

FDA is also continuing development of the ATLAS system to correspond with the redirected focus of the STRS team. OTS is designing the ATLAS system to automate hiring workflow tracking for all FDA hiring authorities. OTS is currently pilot testing ATLAS in CDER and CBER; however, all features are not yet fully deployed, and ATLAS cannot be used to generate data reports. The ATLAS reporting feature is currently set to be deployed by March 2022. Therefore, OTS staff must manually record the timing of hiring process steps in a centralized SharePoint repository for a consolidated view of the process. Exhibit 23 presents the timeframes for each step of the hiring and pay authorities that are currently being used by the STRS team in support of CDER and CBER hiring. These results reflect the new processes for Global Recruitment, Title 21, and Title 42(g).

Exhibit 23: Average Time for Hiring Process Steps by Hiring Authority from FY20 to FY21 Q3 (in Business Days)

	Talent Launch	Talent Sourcing	Talent Evaluation	Interview & Selection	Tentative Offer	Final Offer and Onboarding	Overall Average Time to Hire
Title 5 – Merit Promotion	12 days	5 days	11 days	35 days	4 days	15 days	77 days
Title 5 – Delegated Examining	8 days	8 days	6 days	25 days	3 days	11 days	61 days
Direct Hire	3 days	6 days	15 days	24 days	3 days	12 days	64 days
Direct Hire (COVID-19)	2 days	7 days	17 days	42 days	0 days	14 days	67 days
Schedule A	5 days	5 days	11 days	68 days	6 days	29 days	143 days
Title 21	-	-	7 days	-	4 days	32 days	47 days
Title 42(g)	-	-	-	-	-	-	29 days

Sources: Global Recruitment Data (for all hiring authority types except Title 42(g) and Title 21, n=234); Title 42(g) data (n=64); Title 21 Data (n=485). Note: Data available for each hiring authority are not comprehensive as processes vary and data for some steps remain untracked. Data shown reflects 59 percent (783 out of 1333) of FY20–FY21 Q3 CDER and CBER hiring actions. Overall average time to hire has the most data available, including all actions with at least the start and end dates provided; this is not a sum of the average days for each process step. Process maps were not available to compare the timing of process steps against KPIs or other established targets.

Available data from hiring actions processed under the STRS team's Global Recruitment, Title 21, and Title 42(g) processes show that the average overall time to hire varies by hiring authority (see Exhibit 24). The fastest hiring authorities, on average, were Title 42(g) and Title 21. Title 42(g), which is designed to allow streamlined appointments to mission-critical positions, was the most efficient process with an average of 29 business days (6 weeks).[43] Title 21 took an average of 47 business days (10 weeks), which may illustrate its efficiency and reflect FDA's increased focus on formalizing and prioritizing its use.

On the other end of the spectrum, Schedule A took considerably longer (an average of 143 business days [29 weeks]). Schedule A enables federal agencies to make noncompetitive appointments of qualified applicants with

Exhibit 24: Average Time to Hire by Hiring Authority from FY20 to FY21 Q3 (in Business Days)
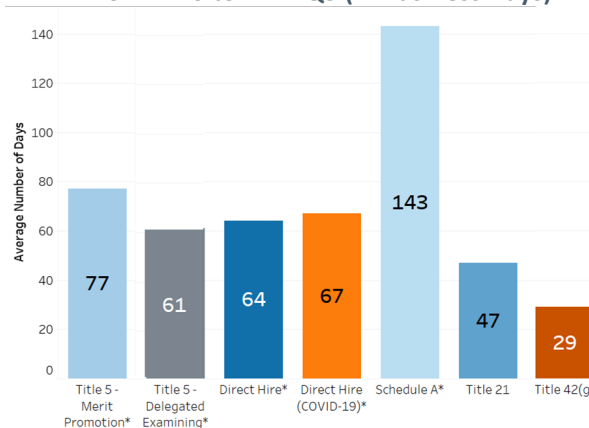
*Sources: *Global Recruitment Data (Used for all hiring authority types except Title 42(g) and Title 21, n=234); Cures Data (n-=485); Title 42 (g) Data (n=64). Does not include all actions due to incomplete data availability/manually tracked data.*

disabilities "without going through the often-lengthy traditional hiring process."[44] OPM authorized expanded

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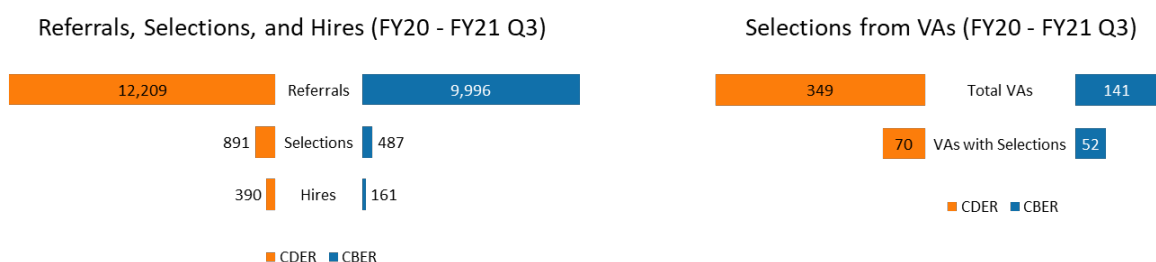[43] Source: Human Capital: HHS and EPA Can Improve Practices Under Special Hiring Authorities; GAO-12-692.
[44] Schedule A Authority, https://www.usgs.gov/about/organization/science-support/human-capital/schedule-a-authority, accessed 09/24/2021.

use of Schedule A to support COVID-19-related hiring needs.[45] The other hiring authorities, including Title 5 and DHA, clustered in the middle, with timeframes ranging from 61 to 77 business days (12 to 15 weeks).

However, perceptual data largely contrasts to the quantitative time to hire results reported in Exhibit 23 and Exhibit 24. On one hand, interviews and focus group respondents noted that they appreciate the more efficient timeframes with Title 21 and Direct Hire, as well as the flexibility to offer higher salaries with Title 21 and Title 38 (see Supplement Exhibit S-15). On the other hand, new hire survey respondents emphasized that there are substantial challenges: they believe hiring still takes too long overall, there are inconsistencies in communication, and processes are not standardized or well documented (see Supplement Exhibit S-17). As displayed in Supplement Exhibit S-18, 68 percent of CDER and CBER new hire survey respondents report that it took more than 12 weeks to receive an initial job offer from the time of application, resume, or curriculum vitae (CV) submission. Also, over half of CDER and CBER new hires disagreed or strongly disagreed (21 and 35 percent, respectively) that the hiring process took a reasonable amount of time to complete.

Reviewing certificate logs from FY20 to FY21 Q3 further illustrates the need for stronger alignment between process expectations between OTS, CDER, and CBER. The certificate logs track the number of selections and hires that result from each VA for delegated examining (including DHA) and MP appointments. The certificate logs also track the number of candidates that OTS determines to be qualified; these are the candidate referrals listed on certificates that are sent to the hiring managers to consider for selection (i.e., an initial job offer). The certificate logs show that OTS staff conducted qualification reviews for applicants and referred thousands of candidates they determined to be qualified. However, hiring managers selected only a small fraction of the referred candidates: 7 percent for CDER and 5 percent for CBER. A similar pattern exists for the total number of VAs posted compared to the number of VAs leading to selections: 20 percent for CDER and 37 percent for CBER (see Exhibit 25).

Exhibit 25: FDA Certificate Log—Number of Qualified and Selected Applications[46]

Referrals, Selections, and Hires (FY20 - FY21 Q3)

	CDER	CBER
Referrals	12,209	9,996
Selections	891	487
Hires	390	161

Selections from VAs (FY20 - FY21 Q3)

	CDER	CBER
Total VAs	349	141
VAs with Selections	70	52

These data suggest that there is a disconnect or difference in expectations between the qualification standards used by OTS staff (to generate qualified referrals) and the quality sought by CDER and CBER hiring managers (reflected by the low number of selections made from referrals). In addition, the fact that relatively few VAs produced selections also suggests that managers often find that the full vacancy process does not produce viable candidates. It is important to note there are other factors and considerations that may shed further light on these results. For example, FDA's use of shared certificates (which are open for 240 days) and continuously advertised VAs result in high referral counts, even though there are only a limited number of open positions for which to select candidates. Nevertheless, the high numbers of unselected referrals and VAs with no selections reflect a considerable expenditure of time, talent, and energy on the part of all the staff involved in these hiring actions for whom there was no return on the investment. Such work without return adds to the HR workload, prevents staff from focusing on other priorities, and adds inefficiency to the hiring process. For these reasons, it is worth further investigating the dynamic of large numbers of referred candidates and low numbers of selections.

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[45] OPM, CORONAVIRUS DISEASE 2019 (COVID-19), https://www.opm.gov/policy-data-oversight/covid-19/opm-memorandum-coronavirus-schedule-a-hiring-authority/, accessed 09/24/2021.
[46] Source: Pre Hire Data FY19 – FY21, USA Staffing and IBM Cognos.

2.4   Data Management and Systems

FDA has planned and funded several upcoming functionality enhancements for ATLAS and other HRIT systems to help address data tracking and reporting challenges raised since the Initial and Interim Assessment. As summarized in Exhibit 26, OHCM developed an inventory of HRIT systems and a roadmap for ongoing system development and integration. As another example, OTS continued to develop ATLAS to support additional hiring processes, increase workflow transparency, and integrate relevant data from USAStaffing and eClass. In upcoming enhancements, ATLAS will have the capacity to pull in data from a suite of applications recently debuted enterprise-wide (e.g., eClass; eMedCred medical credentialing; "One HR" employee portal, data warehouse, HelpDesk, and HR policy content). ATLAS may also be able to incorporate data

Exhibit 26: Key Takeaways for Data Management and Systems

MAJOR ACCOMPLISHMENTS
☑ Developed ATLAS to include more of the hiring processes used by FDA
☑ Inventoried HRIS technologies and built HRIS roadmap

DEVELOPMENT OPPORTUNITIES
☐ Instill a culture of transformative HR to match the potential of new tools
☐ Integrate and automate workflows that span the talent experience lifecycle
☐ Integrate collection, curation, analysis, and sharing of data
☐ Provide customer-focused user interfaces and experiences

from supplementary Center-specific administrative management systems developed by CDER and CBER in the future. As of the time of Final Assessment data collection, the ATLAS data reporting capability was not yet functional, so FDA continued to rely on manual, stand-alone methods for tracking data. The limited ability to generate centralized reports, coupled with inefficient data management practices, made it cumbersome and time-consuming for FDA to run and reconcile data reports and respond to data calls.

The bigger challenge FDA faces is to establish an HRIT infrastructure that spans the full talent lifecycle (e.g., talent sourcing, hiring, employee experience, offboarding). Even after deployment of the ATLAS enhancements and system integration improvements referenced above, there will still be substantial gaps in system integration and the availability of relevant data across the talent lifecycle—particularly with talent sourcing and offboarding. Current efforts to manage these gaps tend to be disparate organization-specific efforts contained within the separate OTS, OHCM, CDER, and CBER spheres of influence; therefore, the impact of these initiatives is limited to the parts of the process and staff that are managed by these organizations. An Agency-level directive, adequate funding, and collaborative participation from all stakeholder groups is necessary to enact an integrated, end-to-end enterprise solution for the talent lifecycle. An integrated enterprise solution would enable a consistent view of the status of the recruiting and hiring workload; progress against recruiting and hiring goals; transparency across stakeholders; and integration of relevant, official data from HR systems that support the full talent experience lifecycle. This kind of enterprise solution also supports advanced technologies to drive sophisticated IT support and performance metrics, including the ability to compete more effectively with private sector hiring, which is one of the Agency's most significant pain points.

> CONCLUSION
>
> C4-1.   ATLAS will help improve hiring process workflow and transparency; however, FDA does not currently utilize the full range of available system capabilities to integrate HR processes and data management across the talent lifecycle.

The extent to which FDA will be able to successfully manage upcoming and continuing workforce changes such as competing for world-class biomedical talent and managing upcoming waves of attrition depends on having access to fully-functional HRIT systems and consistent data management tools. As currently planned and funded, FDA's HRIT systems (including ATLAS, USAStaffing, EHCM, ePortal, and several eSolutions tools), are not able to optimally capture, manage, and integrate key data from several crucial aspects of the talent

lifecycle, including workforce planning, position management, talent sourcing, interviews, and offboarding. Therefore, FDA staff performing HR functions must resort to using disparate stand-alone systems and manual tracking processes. Although these alternatives are needed for staff to complete day-to-day work, the processes are ultimately exacerbating the HRIT issues of non-integration and data inconsistencies. For the purposes of this report, the concept of data integration relates to the availability of source data across systems that support the full talent lifecycle—ideally official systems of record—and the reliability, integrity, and report capabilities of these data to drive business decisions. Addressing this fundamental challenge of HRIT data integration requires collective enterprise-level strategy and investment to facilitate timely access to high-quality and integrated data and enable future achievements, such as forecasting, automation, and digital transformation. OHCM has developed an HRIT roadmap to begin to address these limitations and progress is being made as e-Solutions are implemented enterprise wide. Portions of the roadmap are still pending formal approval, investment, and sponsorship to realize the potential of end-to-end HRIT data integration.

F4.1 FDA has invested in some new and soon-to-be deployed enhancements in ATLAS and a suite of HRIT applications that will help improve HR process workflow and data integration.

OHCM maintains an HRIT unit that manages many of the HR systems of record and has been conducting activities to improve data management and systems issues. For example, OHCM conducted an inventory of HRIT systems used for recruiting, hiring, and retention and developed an HRIT Roadmap that reflects plans for building and delivering an enterprise solution within a single IT platform. While some aspects of the HRIT Roadmap are pending investment (discussed further in Finding F4.2), FDA has shown a commitment to continuing development of ATLAS and modernizing the HRIT infrastructure to support comprehensive and continuous assessment of the hiring and retention processes.[47] FDA launched its STRS Hiring Pilot in 2017 and began piloting the ATLAS system in 2018 as part of FDA's reimagined hiring process to modernize technology, increase transparency, streamline the hiring process for Title 5, and reduce the overall time to hire. At that time, the Agency was planning for an FDA-wide deployment of ATLAS by FY21.[48]

However, a year-long break in the ATLAS contract (from September 2019 to September 2020) delayed enhancements and its broader deployment. When the contract resumed in October 2020, the STRS team strategically pivoted to developing ATLAS to support a wider range of hiring authorities, rather than focusing solely on Title 5. Because of the shifted deployment schedule and broader focus, ATLAS's reporting functionality—a critical aspect of anticipated transparency, consistency, and quality control improvements—was not yet implemented at the time of the Final Assessment.[49] In addition, plans to integrate data from multiple systems (e.g., USA Staffing, EHCM) were not yet fully implemented, and the HRIT infrastructure did not support all the hiring processes used for the special hiring and pay authorities. As a result, some manual data tracking was currently unavoidable when completing HR work during the Final Assessment timeframe. For example, the current STRS work for Title 21, Title 42, and Global Recruitment continued to be captured in SharePoint which, like all manual data tracking processes, are inevitably hampered by data management and quality concerns.[50]

FDA is currently continuing to develop the ATLAS system to support these processes through a phased roll-out, with plans for FDA-wide deployment by March 2022. Highlights of the planned FDA-wide ATLAS implementation include the following:

- **Workflow processing for all FDA hiring authorities.** Title 21 Physicians, Title 21 Executives, Title 21 Non-Physicians/Non-executive, DE (single and multiple candidates), Title 42(f) and Title 42(g), Title 5 MP, Title 5 Direct Hire, Title 5 Non-Competitive, Senior Executive Service, Title 38, Named Actions, and functionality for shared certificates and workload management

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[47] Source: FDA HRIT Business Case, OHCM.
[48] Source: FDA Interim Assessment Management Response, OTS.
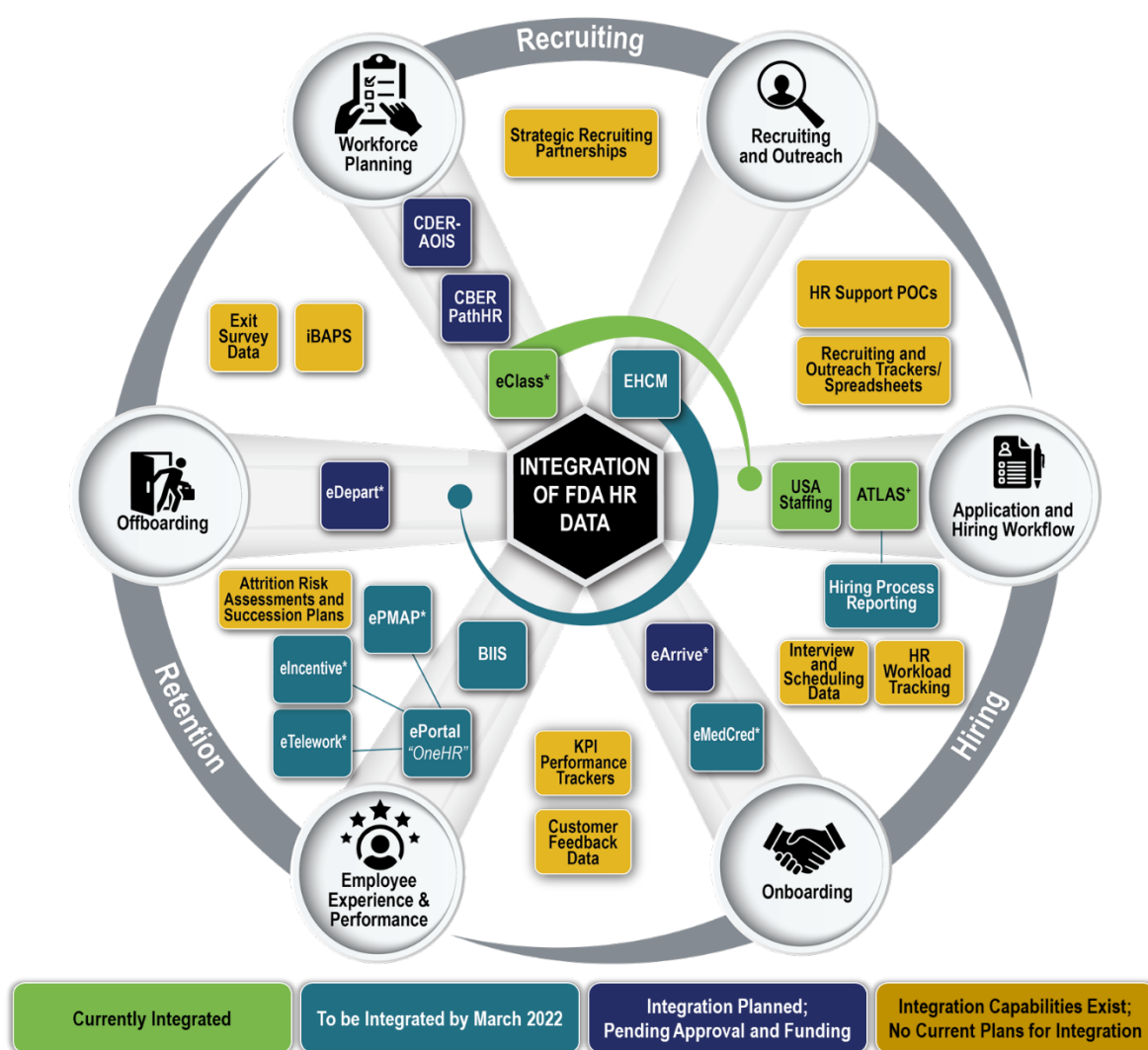[49] Source: ATLAS Hiring Pilot to Enterprise Solution Enhancements and Schedule 10.01.2021, OTS.
[50] Source: ATLAS Update and Way-Forward, OTS.

- **Increased transparency and user-friendly interface.** Workflows with digitized checklists, Outlook notifications, and approver dashboards and signatures for accountability and auditability
- **Integration with external HR applications.** EHCM, eClass, and USA Staffing
- **Availability to pull relevant source data through an eSolutions suite of applications.** eClass (classification), ePortal ("OneHR" employee portal, data warehouse, HelpDesk, and HR policy content), eMedCred (medical credentialing), ePMAP (performance management), eTelework (teleworking), eIncentive (incentives and awards)

By March 2022, the integration of ATLAS with many of the applications used to support HR processes should be complete.[51] However, several stand-alone systems and associated workarounds continue to constrain true end-to-end integration, transparency, and data reporting. Exhibit 27 provides a conceptual view of FDA HRIT systems and applications and plans for data integration. Color coding depicts whether the systems are currently integrated, will be integrated by March 2022, have plans for integration that are pending approval and funding, or have capabilities to integrate but no current plans for integration.[52]

Exhibit 27: Conceptual View of FDA HR Data Integration

Data are integrated through an eSolutions suite of applications
Currently using Excel and SharePoint to manually track until ATLAS Reporting is fully functional

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[51] Source: ATLAS Hiring Pilot to Enterprise Solution Enhancements and Schedule 10.01.2021, OTS.
[52] Source: FHRA Improvement Activity Contextual Information Interview, OHCM.

F4.2 FDA's HRIT enhancements neither fully address data limitations nor eliminate the need for multiple IT systems and manual processes to perform HR work across the talent lifecycle.

In its HRIT Business Case, FDA acknowledges that the lack of a comprehensive infrastructure for HR data, duplicative systems, and insufficiently tracked data hinder its ability to fully understand the challenges and root causes of HR issues and to deliver consistent, high-quality service. Integrating applications and data availability across all HR processes—rather than duplicating systems within organizational business units (i.e., Centers)—will help FDA enhance the quality and transparency of its HR services.[53, 54]

To date, FDA has invested in substantial system improvements that will integrate some of the disparate HR systems, as discussed in Finding F2.1, but that is only a partial solution. The HRIT enhancements that are currently planned and funded (including ATLAS integration with USAStaffing, EHCM, ePortal, and several eSolutions tools), are not able to optimally capture, manage, and integrate key data from several crucial aspects of the talent lifecycle, including workforce planning, position management, talent sourcing, interviews, and offboarding. Therefore, FDA staff performing HR work must resort to using disparate stand-alone systems and manual tracking processes (e.g., HR workload, distribution of work, competencies and performance staff performing HR work). In addition, some data that are tracked within an automated system are also tracked separately in other systems (e.g., position management, status of hiring actions, Cures hiring data). The presence of a dispersed infrastructure, varied data management processes, and disparate tools creates difficulty in maintaining consistent, reliable HR data in a system of record. While these data issues clearly persist, it is noteworthy that FDA was able to generate more usable system data reports for the Final Assessment, compared to the Interim Assessment.

To address ongoing workflow and data management gaps, both CDER and CBER have subsequently begun developing their own HR tracking systems to be used by their staff. CDER has developed an Administrative Officer Information System (AOIS) to standardize and automate workflows, provide transparency to process execution, track process timeliness, and provide system communication.[55] Similarly, CBER recently began developing PathHR, a system intended to track CBER's full range of HR work (e.g., HR and budget activities, recruitment, and HR actions) and to ultimately serve as CBER's long-term solution to enhance its HR business capability overall.[56] In the meantime, CBER has been using HR Management as a short-term solution; however, due to current instability with this system, CBER manually enters and tracks recruitments, employee records, positions, and personnel actions.[57]

It is important to note that while there are intentions to integrate relevant data from these Center-specific systems with ATLAS, until those intentions are brought to bear, ATLAS will not have the capability to track and manage Center activity prior to submitting the action to OTS. This limitation is especially consequential for Title 21 actions, for which the Center conducts a large portion of the work before submitting them to OTS. Therefore, CDER and CBER are creating additional alternate systems and workarounds, using either formal or informal processes. For example, CDER leadership made the strategic decision to implement CDER-AOIS to invest in the technology necessary to advance administrative operations (including managing personnel actions) as an essential component of the Center's business operations.[58] CDER-AOIS manages not only personnel actions but also other administrative operations to maintain CDER's relevant workforce data in one internal system of record separate from the Agency's system of record. The Centers' investment in these systems highlights stakeholders' need for end-to-end data and workflow integration that is not attainable in the systems' current state.

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[53] Source: FDA HRIT Business Case, OHCM.

[54] Source: FHRA Improvement Activity Contextual Information Interview, OHCM.

[55] Source: CDER-AOIS User Survey Results Final, CDER OM.

[56] Source: CBER Business Process and Tools Analysis and Improvement (BPTI) Project Quarterly Review and Update, CBER OM.

[57] Source: CBER PathHR Application Overview, CBER OM.

[58] Source: FHRA Improvement Activity Contextual Information Interview, CDER.

Feedback from interviews and focus groups related to FDA systems expressed the need for improved HRIT integration. Some stakeholders believe current HR systems are sufficient to recruit, hire, and retain employees, but system upgrades and integration are needed for increased transparency and data integrity. Others noted that HR systems do not have the ability to track all relevant data. Interview and focus group participants also noted that the needed fundamental improvements require an Agency-wide strategy and investment (e.g., buying or building an enterprise system) to define processes and maintain adequate dedicated resources, training, and budget (see Supplement Exhibit S-19). Similarly, as presented in Section F2.2, survey results show that having a "reliable IT system that shows the status of hiring actions" emerged as one of top five resources CDER and CBER hiring managers and managers of HR staff need for success, and it is in the top six for HR staff (see Exhibit 13 and Supplement Exhibit S-11).

2.5   HR Staff Capability and Capacity

Exhibit 28 summarizes the main accomplishments and development opportunities under HR Staff Capability and Capacity. Since the Interim Assessment, the size of FDA's HR organization (OTS and OHCM staff) has increased to keep pace with growth of FDA's workforce size. OTS and OHCM have also taken steps to improve staff capability, and now have access to more data to track workload. Yet, CDER and CBER's relatively large investments in their own internal staff performing HR work indicate that existing OTS and OHCM staff capability and capacity are not meeting Center needs. Most importantly, FDA lacks a commonly accepted service delivery model (e.g., human capital business partner [HCBP] model) that clearly defines a strategic role for OTS and OHCM and establishes logical, non-duplicative integration with staff performing HR work in CDER and CBER. For example, using an HCBP model, OTS

Exhibit 28: Key Takeaways for HR Staff Capability and Capacity

MAJOR ACCOMPLISHMENTS

☑ Expanded competency models and implemented a variety of training and development resources

☑ Established service-focused workload drivers and KPIs

☑ Increased the HR staff in proportion to growth in overall FDA workforce

DEVELOPMENT OPPORTUNITIES

☐ Implement Agile workload management practices

☐ Leverage integrated and automated workflows to maximize HR efforts

☐ Establish a strategic HR service delivery model designed to meet customer needs, and align HR workforce and workload management accordingly

and OHCM would work with other Agency leaders to address FDA's HR-related challenges, including more clearly differentiating between the duties of HR staff in OTS and the duties of Center staff who support HR work and by eliminating duplicative roles. Under this same model, OTS and OHCM would work in a consultative relationship with CDER and CBER (and other FDA Centers) to provide customer-focused HR solutions and share accountability for organizational results.[59] Unless FDA establishes such a unified service model to account for the full HR workforce—staff in OTS and OHCM and Center-based staff who also perform HR work—the Agency will be limited in its ability to proactively manage FDA's HR capability and capacity and to fully assess the competencies critical for HR effectiveness.

As noted in the Interim Assessment report, it is also critical for FDA to develop a clear understanding and an actionable plan to manage the dynamics of HR workforce capacity (e.g., workload management, workflows and automation, customer alignment) and capability (e.g., competencies, proficiencies, priorities, and focus). To realize its full potential for proactive HR workforce and workload management, FDA requires an HRIT infrastructure with systematic, integrated, and automated workflows for tracking, managing, and monitoring the HR workload, the effectiveness of the HR workforce, and how work is assigned (further discussed in Sub-section 2.4). This plan for HR workforce and workload management will enable FDA to determine and maintain the appropriate HR workforce numbers (including OTS and OHCM staff and staff in CDER and CBER who perform HR work) and to know if those staff possess the right skills and capabilities to successfully complete their workload.

Since the Interim Assessment, FDA has begun tracking workload data more precisely, which is important for establishing a baseline to inform future decision-making about capacity requirements. However, on the supply side, FDA continues to lack a systematic way to track and manage the HR workforce (i.e., the full cadre of staff performing HR work across OTS, OHCM, CDER, and CBER), how work is assigned to these staff, and the capabilities they need to carry out the work. For example, compiling the CDER and CBER staff performing HR work is a manual effort because they are not consistently identifiable as having HR responsibilities in a system of record. Increasing the ability to better account for both the HR workload and workforce can be used to support predictive modeling of workload and more sophisticated methods of assigning and performing work. Also, the ability to track HR workforce and workload across FDA would help the Agency

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[59] Source: The State of the Federal HR Workforce: Changes and Challenges, May 2020, MSPB (https://www.mspb.gov/studies/researchbriefs/State_of_the_Federal_HR_Workforce_Changes_and_Challenges_1724758.pdf)

pinpoint and calibrate the appropriate HR workforce size relative to the workload and adjust to changes in workload demand (e.g., work surges, seasonal variation), and identify the capabilities needed for the HR workforce to effectively carry out the work.

CONCLUSION

C5-1. FDA HR servicing ratio has remained consistent, as OTS and OHCM staff have increased in parallel with FDA's workforce size; meanwhile, CDER and CBER continue to invest heavily in their own dedicated resources (i.e., funding and staff) to support HR work.

One way to measure HR capacity is to examine the number of staff available to support recruiting, hiring, and retention functions. FDA has successfully increased the number of OTS and OHCM staff since the Interim Assessment, including the number of individuals working as HR Specialists in the 0201 and 0203 occupational series. The growth of FDA's HR Specialist workforce matched the growth of FDA's workforce at large. The commensurate growth of service providers to total workforce serviced is also a useful indicator when assessing the appropriateness of the size of FDA's HR workforce.

Looking at the HR support available to CDER and CBER specifically, the cadre of staff performing HR work includes a proportion of OTS and OHCM staff as well as a considerable number of staff in CDER and CBER, including HR liaisons, AOs, and PMs. CDER and CBER staff work as a supplemental force for HR support, rather than as an integral element of FDA's HR service delivery model. Therefore, CDER and CBER staff involvement in HR work, though valuable in representing the technical needs of the Centers, likely adds inefficiency, inconsistency, and higher costs to the process overall. In addition, having CDER and CBER staff perform roles that overlap with the Agency's official HR function limits the potential benefits of OTS and OHCM's role as HR business partners.

F5.1 FDA's HR servicing ratio has not changed since the Interim Assessment and is comparable to that of other HHS Agencies; improved workforce and workload metrics will enable FDA to proactively plan and manage its HR workforce size in the future.

There are a total of 476 staff within OTS and OHCM. This number includes onboard government staff, vacancies, and contractors (see Exhibit 29). These professionals perform a variety of HR functions related to recruiting, hiring, retention, and other work on behalf of current FDA employees (e.g., training and development, employee and labor relations, work-life programs, awards, HRIT).

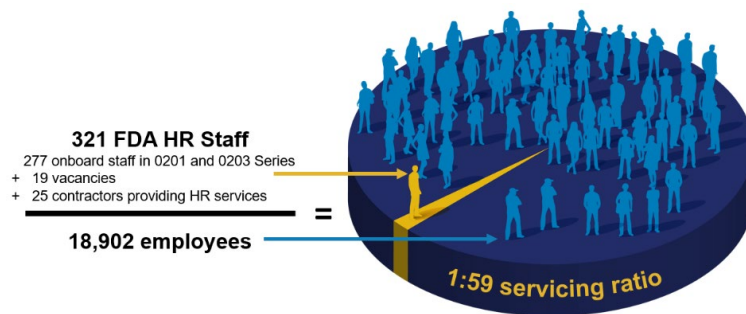#### Exhibit 29: HR Staff in OTS and OHCM as of FY21 Q3

STAFF	OTS	OHCM	TOTAL
Total Staff	**268**	**208**	**476**
• **Onboard Government Staff (201 and 203 series)**	205	72	277
• **Onboard Government Staff (other series)**	31	41	72
• **Vacancies**	15	4	19
• **Contractors**	17	91[60]	108

Sources: FDA Workforce Snapshot FY20Q1 – FY21 Q3 (Onboard Government Staff); HR Workload Data Call (Vacant FTE, Contractor FTE)

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[60] Numbers represent OHCM contractors working in FDA's childcare center and fitness center, who do not perform any type of staff augmentation work for OHCM. They also represent contractor FTE who support FDA in some capacity but may not be working full-time on FDA work.

HR Specialists (i.e., staff in the 0201 and 0203 occupational series and contractors performing equivalent HR work) comprise a subset of the OTS and OHCM workforce. HR Specialists provide official HR support and action processing for the Agency, and they are all aligned to OTS and OHCM. A standard and comparable metric for the HR servicing ratio is to account for the HR Specialist workforce available to support the total FDA workforce. Establishing this clear definition of the HR servicing ratio enables FDA to conduct trend analyses and gauge how the size of their HR Specialist workforce compares to those of other federal agencies.

Exhibit 30: FDA HR Servicing Ratio (OTS/OHCM staff only)

321 FDA HR Staff
277 onboard staff in 0201 and 0203 Series
+ 19 vacancies
+ 25 contractors providing HR services
_____
**18,902 employees**   =

1:59 servicing ratio

As of FY21 Q3, 321 HR Specialist Full-time Equivalents (FTEs), including vacancies and contractors, support 18,902 FDA employees, yielding a 1:59 HR servicing ratio (see Exhibit 30).[61] In other words, for each HR Specialist FTE, there are approximately 59 FDA FTE customers to serve. FDA's current HR servicing ratio is essentially the same as the 1:60 ratio from the Interim Assessment. This stability is impressive given the considerable changes in FDA workforce size. Since the Interim Assessment, both the FDA workforce and the number of OTS and OHCM staff in the 0201 and 0203 series increased by 9 percent.[62]

FDA's HR servicing ratio falls between those of two other benchmarked HHS agencies: a smaller agency (approximately 6,000 FTE) with a ratio of 1:71 and a larger agency (approximately 11,000 FTE) with a ratio of 1:52 (not including HR contractors). Comparison of HR servicing ratios provides only a general indication of capacity, as organizations may deliberately choose to have a higher or lower servicing ratio for strategic reasons. For example, an agency may have a lower servicing ratio (i.e., more HR Specialists) to address backlogs, provide a greater number of services, or provide a more customized service. Conversely, an agency may have a higher HR servicing ratio (i.e., fewer HR Specialists) due to a greater use of automated processes or workflows.

While FDA has maintained a consistent and comparable HR servicing ratio, there is insufficient evidence to determine if this is the "right" HR servicing ratio for FDA. Several considerations related to identifying an appropriate ratio are currently in transition, such as initiatives to improve process efficiency and enhancements of supporting technologies. Feedback from stakeholders corroborates this notion. Interview and focus group participants note that they do not have sufficient resources such as HRIT systems, job aids, and funding to effectively manage their work (see Supplement Exhibit S-10). Survey results similarly found that 56 percent of managers of HR staff do not believe HR staff have access to sufficient resources (e.g., HR IT systems, budget, job aids) to manage their work (see Exhibit 31).

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[61] Refers to the number of regular, non-overtime hours worked by employees per year. For example, an employee who works 40 hours per week counts as 1 FTE, and an employee who works 24-hours a week is counted as 0.6 FTE.
[62] Source: FedScope (Sep 2020 data cube), https://www.fedscope.opm.gov.

Exhibit 31: HR Manager Survey Responses on HR Staff Capacity
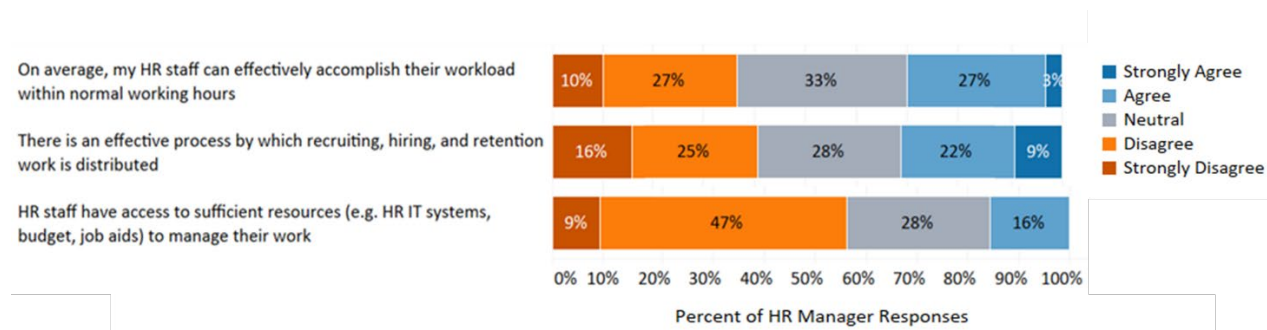
Respondents: HR managers (n=34). Survey Item: "Please indicate your agreement with the following statement," with a response scale of Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree, and N/A. "N/A" responses were excluded from the analysis.

Despite the perceived need for more staff and other resources, several workforce management changes could help create a system that operates effectively with existing resources. These changes include more data-driven allocation of resources, use of automation, streamlining of processes, clarification of priorities, and logical alignment of work. These methods to balance and distribute the workload will allow current staff to support recruiting, hiring, and retention work and may mitigate the need for additional resources or staff. For example, with further automation and streamlining, FDA could reduce the number of staff required to perform certain HR functions, or FDA could shift work from transactional support roles to more strategic functions and to roles that focus more heavily on customers' needs. In addition, determining the appropriate size of the HR workforce depends on whether FDA plans to continue its current rate of hiring in the future. Formulation of a clear strategy for delivering integrated talent management services and more robust workforce planning can help FDA more proactively plan and manage its HR capacity needs moving forward.

F5.2 A substantial number of CDER and CBER staff provide HR support in addition to the HR Specialist workforce, and their roles are not clearly defined and distinguished from OTS and OHCM staff.

OTS and OHCM serve as the Agency's official HR organization. Essentially, OTS is responsible for recruiting and hiring staff, and OHCM works to support and retain the onboard workforce. In addition, CDER and CBER have dedicated additional support staff to perform HR work; these additional staff are aligned to OMs and Program Offices in their respective Centers. Clearly defining the nature and volume of work that these different groups of staff performing HR work support and how these groups work together is essential to fully understanding both the opportunities to enhance quality and efficiency and the risk of unhelpful duplication and disorganization.

Because of the FDA-wide HR servicing ratio's specificity (i.e., counting only the HR Specialists), it does not account for staff performing HR work in CDER and CBER or the range of support provided by OTS and OHCM staff in occupational series other than 0201 and 0203. Results from an HR workload data call provided the number of CDER and CBER FTEs who perform HR work. In addition, data from HR workload trackers and relative size of the Centers formed the basis to estimate the number of OTS and OHCM FTE dedicated to supporting CDER and CBER.

Exhibit 32: Estimated FTE HR Support to CDER and CBER by Organization

| ORGANIZATION	FTE[63]
OTS	83
OHCM	39
CDER	43
CBER	63
Total	228

[63] OTS and OHCM FTE is an estimated proportion of staff time devoted to CDER and CBER work (approximately 35 percent, based on relative size of the CDER and CBER workforce, with some adjustments based on type of work and Center-specific workload data). CDER and CBER FTE is based on the HR workload data call.

As presented in Exhibit 32, results from those analyses showed that approximately 228 FTEs, located across OTS, OHCM, CDER, and CBER, provide a variety of HR support for recruiting, hiring, and retaining human drug and biologics review program staff. A little more than half of this HR support (122 FTEs) are in OTS and OHCM, and 106 FTEs are aligned to CDER and CBER OMs and Program Offices. CDER and CBER FTEs provide HR administrative and operational support to their Centers. This constitutes a considerable investment by CDER and CBER, as the total salaries for 106 FTEs represent an expenditure of approximately $13.5 million annually.[64] Establishing a reliable way to identify the staff in CDER and CBER who perform HR work and track their workload will help FDA accurately monitor and manage the size of the workforce providing HR support to CDER and CBER.

Although the Agency does not currently track HR workload at the functional level, managers of staff who perform HR work responded to an HR workload data call to provide estimates of how much time their teams spend on different kinds of work. Managers of OTS and OHCM staff distributed work time across a more detailed list of HR activities, because these organizations manage their performance of a wide range of specialized functions. Managers of staff in CDER and CBER distributed the work time for their staff against a broader set of HR-related work categories. These data call results show that, in the breakdown of time spent supporting HR work for CDER and/or CBER, managers estimate that OTS staff dedicate 63 percent of their work time and OHCM staff spend 37 percent of their work time to supporting HR work for the two Centers. The comparatively low percent for OHCM staff likely results from the fact that they provide general support to the entire Agency, rather than dedicated support to specific Centers. For the Center staff identified as performing HR work, CDER staff spend 75 percent of their time on HR work and CBER staff spend 70 percent of their time on HR work for their respective Centers (see Exhibit 33). Work classified as "other HR work" includes functions, such as HRIT, workplace flexibility programs (e.g., telework), and awards. Work classified as "other non-HR work" includes administrative duties, such as budgeting, facilities management, contracting support, records management, and travel management.

Exhibit 33: Time Spent on HR work in OTS/OHCM, CDER, and CBER
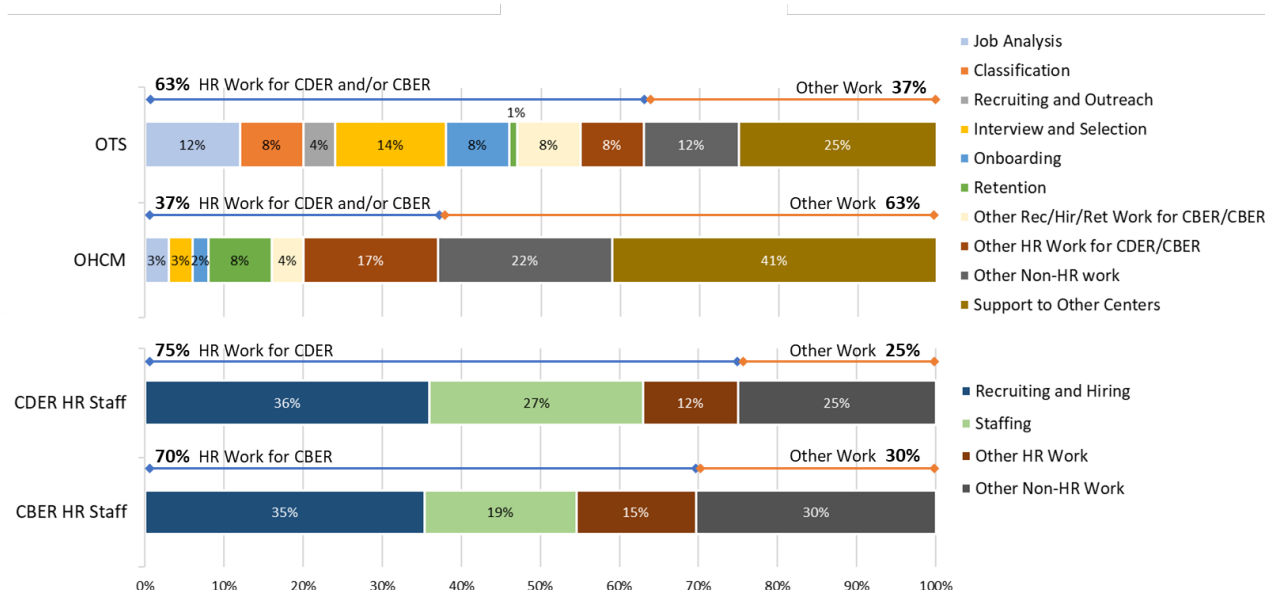
F5.3 OTS and OHCM have improved workload tracking and performance accountability and have set the stage for more sophisticated workload management and distribution in the future.

As the Agency matures its workforce and workload management tools and processes, it will be better positioned to make data-driven decisions about the size of HR workforce needed and how to best allocate the work. As part of the responsibility to measure performance against KPI targets for the SLAs, OTS and OHCM have improved consistency in workload tracking.[65] For example, the OTS Workload Driver Report documents workload related to Center-specific activities, such as prior FY hires, current FY staffing targets, job opportunity announcements (JOAs), and certificate utilization rate.[66] In addition, OHCM created an Activity Catalog that defines and aligns services, activities, and associated cost drivers. Comparing the total number of actions and the number of FTEs in the OTS staffing branch can provide a baseline productivity measure to inform future decision making around HR capacity, so long as adjustments are made to account for expected productivity gains (e.g., due to increased automation or process efficiencies). OTS has set a strategic objective for the future to create dashboards to track overall progress against KPIs to build FDA's capability for making data-driven decisions.[67] To achieve the objective's full potential, FDA requires more detailed and integrated measurements tied with leadership decisions (e.g., HR service model, baseline workload capacity). These more sophisticated metrics would allow the Agency to begin to proactively manage and distribute workload based on a servicing model and establish targets for the size and mix of its HR workforce.

In addition, both CDER and CBER have instituted separate time reporting systems that could be leveraged in the future to account for the HR workforce. Both systems currently include a code for HR work, which employees use to track time spent performing HR functional work as well as broader, less technical, HR work, such as hiring manager duties and personnel management. People may also spend time doing HR work in other reportable categories, such as training, communications, internal improvements, and general administration activities. Out of 1,740 CDER and CBER employees who charged time to HR during FY20 to FY21 Q3, only about one in 10 (10 percent for CDER and 12 percent for CBER) indicate that HR is a large portion of their job, and the majority (83 percent for CDER and 67 percent for CBER) of these employees charged 10 percent or less of their time supporting HR work for CDER and CBER.[68, 69]

CONCLUSION

C5-2. OTS initiatives to build capabilities of its staff have led to measurable improvements; coordinating and leveraging these efforts in other organizations would equip all staff who support HR work to provide the consistent, customer-focused performance needed in the future.

The Interim Assessment revealed that a lack of an integrated performance and development structure, which is exacerbated by FDA's distributed HR workforce, impacts OTS's ability to provide consistent quality delivery of HR services. Since then, OTS invested in further developing its competency frameworks and professional development opportunities for OTS staff. Based on feedback from multiple sources, the capabilities of OTS staff have measurably improved. Looking more broadly across the HR community, FDA continues to lack a unified set of competency requirements (including proficiency ratings and development opportunities), which inhibits FDA from instilling a consistent approach to managing the capabilities of its full HR workforce.

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[65] Sources: FY20 SLA_OHCM-Signed, OHCM; OTS Service Level Agreement, OTS.
[66] Sources: FY20 OHCM Activity Catalog v.03, OHCM; FY21 OTS Staffing Workload Driver Report, OTS.
[67] Source: FDA OO OTS Strategic Plan FY21-23, OTS.
[68] Source: CDER Time Reporting Data, ITR.
[69] Source: CBER Time Reporting Data, CATTS.C

F5.4 OTS has implemented a variety of competency-based training and development resources; further integrating and coordinating efforts across all staff performing HR work will help with onboarding new hires and maintaining performance quality and standardization.

OTS continues to implement activities intended to improve staff capability. One of these activities is the OTS Team Development Assessment.[70] The assessment was intended to help bring awareness to the team's strengths and developmental needs. Team building and facilitation sessions were offered to OTS staff to "increase connectedness in the virtual environment and allow teams to focus beyond day-to-day urgencies" and measure satisfaction with the experience. In addition, OTS will develop and administer a team development satisfaction survey to collect information that identifies OTS's team needs.

OTS has also implemented leadership coaching for each leader throughout the Office.[71] The program includes a 360-degree assessment, pairing with a Leadership Coach, and an assessment to evaluate participants' satisfaction with the coaching. In the 360-degree assessment, leaders select multiple people from varying levels (e.g., direct reports, manager) to rate their performance against a set of leadership competencies. The feedback will display each leaders' strengths, development priorities, and general assessment findings. Each leader in the OTS Leadership Coaching Program is paired with a coach to help maximize their performance. OTS then surveys leaders to assess their experience and gather feedback to improve the program.

Furthermore, OTS expanded its staff management and capability-building efforts by implementing the FDA OO OTS Competency Framework.[72] The OTS Competency Framework has a total of 45 competencies divided into three main sets—Leadership, Core, and Technical—that apply to positions within the organization. The leadership and technical competencies are further broken down to accommodate leadership levels (i.e., Team Leader, Supervisor, Manager, Executive) and technical competency types (i.e., General, Specialized). OTS is still in the process of implementing the OTS Competency Framework and accompanying action learning plans to support OTS staff. In addition, CBER created CBER Human Capital, a function that includes a SharePoint site and Resource Hub that house training courses and standardized HR resources, as part of its FY20 hiring and recruiting strategy.[73] CDER and CBER each have unique competency models, with the same shared core competencies and a separate but similar list of technical competencies.

These competency frameworks and resources are more important than ever to support the growing need for knowledge transfer and onboarding at FDA. The OTS and OHCM workforce has experienced large shifts in gains, losses, and overall workforce growth since FY20.[74] Specifically, there have been 115 new hires and 61 losses from FY20 through FY21 Q3. Such a major transition places additional strain on the HR team through loss of historical knowledge and proficiency in addition to increased workload to backfill positions. Although hiring additional staff is beneficial, new staff require resources and sufficient transition plans to effectively transfer the knowledge they need to excel in their roles.

It is important to note that these initiatives to establish performance expectations and development for staff performing HR work are currently limited to separate organizations (i.e., OTS and CBER). Therefore, these efforts are unable to benefit the broader HR workforce, and they may even be adding further non-standardization since they are developed independently and do not apply to staff performing HR work if they are aligned to a different organization.

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[70] Sources: Team Development Report_DELIVERABLE_stage one, OTS; Team Development Report_DELIVERABLE_stage two, OTS.

[71] Sources: OO OTS Coaching Goal Plan Progress Report, OTS; OO OTS Leadership Coaching Satisfaction Report, OTS.

[72] Source: FDA OO OTS Competency Framework and Library, OTS.

[73] Source: CBER Human Capital Hiring and Recruiting Strategy, CBER OM.

[74] Sources: Post Hire Personnel Data FY20 – FY21 Q3, BIIS; FDA-wide Workforce Analysis Profile FY20 OTS.

F5.5 HR capability has improved, as evidenced by competency ratings, hiring manager satisfaction with the abilities of staff performing HR work, and OTS and OHCM performance against KPI targets.

Evidence shows that the performance of staff conducting HR work has improved since the Interim Assessment. In survey responses, CDER and CBER hiring managers indicated their level of satisfaction with support for hiring provided by staff from different organizations (Center OMs, Center Programs, and OTS). Compared to responses in the Interim Assessment, hiring manager satisfaction increased across the board in areas such as accuracy, coordination, timeliness, flexibility, communications, and problem solving for all three groups of staff performing HR work.

As illustrated in the heat map in Exhibit 34, darker green shades indicate a greater increase in the percent of managers who indicated that they are Satisfied or Very Satisfied with HR abilities related to hiring support. Consistent with patterns from the Interim Assessment, hiring managers tended to express higher satisfaction with the services of Center PM/AO staff than Center OM HC liaisons and OTS HR Specialists. Still, the heat chart in Exhibit 34 shows that hiring managers' satisfaction with CDER and CBER staff performing HR work has increased only slightly, while their satisfaction with OTS HR Specialists increased by about 10 points, compared with Interim survey ratings. While the hiring managers' overall satisfaction remains quite low for OTS HR Specialists, these positive trends indicate that the improvements OTS has been implementing are starting to have a measurable impact on its customers.

Exhibit 34: Increase in CDER and CBER Hiring Manager Satisfaction with the Abilities of Staff Performing HR Work in Different Organizations

Staff Performing HR Work in Different Organizations

| ABILITIES OF STAFF PERFORMING HR WORK		CENTER STAFF		FDA HR ORGANIZATION
		PMs/AOs (Programs)	HC Liaisons (OM)	OTS HR Specialists
Apply accurate knowledge of HR policies and procedures		+1	+3	+14
Coordinate with all HR parties necessary		+9	+8	+10
Meet timelines and commitments		+1	+3	+12
Provide appropriate options and alternative solutions		+5	+6	+9
Provide information to help me understand the hiring and recruitment process		+6	+4	+10
Take the initiative to solve problems that arise		+4	+6	+10
Percent Satisfied or Very Satisfied (range)	Interim	39-48%	13-21%	5-8%
	Final	44-49%	19-24%	15-22%

Respondents for the Final Assessment survey: CDER/CBER Hiring Managers (n=339-361). Survey item: "Based on your experiences with hiring new employees since the start of FY20 (October 2019), how satisfied are you with the abilities of HR Staff in various roles within FDA?" with a response scale of Very Dissatisfied, Dissatisfied, Neutral, Satisfied, Very Satisfied, and N/A. "N/A" responses were excluded from the Interim and Final analysis. Data shown reflects "Very Satisfied" and "Satisfied" responses only.

In addition, on the Final Assessment survey, managers of HR staff report an increase in HR staff proficiency on several technical competencies, compared with their Interim Assessment survey ratings. As shown in Exhibit 35, the largest increase in perceived satisfaction with HR staff technical competencies was in the Recruitment competency (33 percentage points), followed by Federal HR Technical Knowledge (18 percentage points), Classification (13 percentage points), and Project Management (13 percentage points).

The ratings for other competencies were relatively high and did not shift significantly. For example, on both the Interim and Final Assessment surveys, managers of HR staff reported that nearly 90 percent (89 to 98 percent) of HR staff meet or exceed the core competencies in Collaboration/Partnering, Problem Solving, Customer Service, Communication, Results Driven, and Organizational Awareness. Managers of HR staff in the CDER and CBER Program Offices also indicated that the vast majority of AOs and PMs meet or exceed their additional technical competencies on both the Interim and Final Assessment surveys (84 to 100

percent). However, there was a slight decrease in perceptions about the number of staff who meet or exceed expectations for Management Analysis (decreased from 89 to 84 percent), shown in Supplement Exhibit S-20.

Exhibit 35: HR Manager Ratings on Percentage of Staff Performing HR Work in OTS, OHCM, and Center OM that Meet or Exceed Technical Competencies
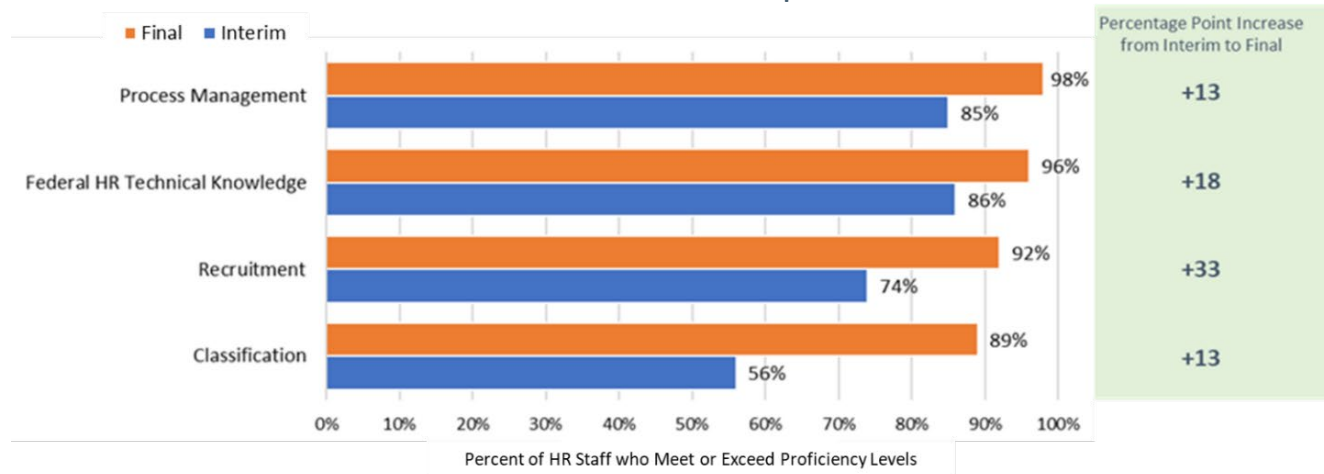
Respondents: HR Manager (Final: n=13, Interim: n=12-18). The number of HR staff being rated for each competency varies (Final: n=73-116, Interim: n=120-194). Survey item: "Consider all the Federal government employees who directly report to you and support recruiting, hiring, and retention of CDER or CBER employees. Please indicate the number of staff who exhibit each level of proficiency in each of the technical competencies: Process Management, Federal HR Technical Knowledge, Recruitment, Classification," with a response scale of Does Not Meet, Meets, Exceeds, Does Not Need. "Does Not Need This Competency" responses were excluded from the analysis. Data shown reflects "Meets" and "Exceeds" responses only.

Performance against KPIs provide an additional mechanism for evaluating the sufficiency of HR's capability to meet expectations and achieve specific outcomes. As of FY21 Q3, OHCM had met or exceeded all its KPI targets, and OTS had met five of its eight KPI targets (see Exhibit 36). The three unmet KPIs for OTS include the ability to work through Title 42(g) within 10 days, contacting selectees to extended final offers, and developing draft JOAs. OTS Corrective Actions Plans noted that two of the three unmet KPIs may require re-evaluation and revision because the candidate security clearance cycle, which falls outside of OTS's control, must be completed before a final offer can be extended.

Exhibit 36: OTS and OHCM Performance Against FY21 KPI Targets as of FY21 Q3

OTS/ OHCM	KEY PERFORMANCE INDICATORS (SLA TIMEFRAME)	FY21 TARGET	FY21 Q1-3 PERFORMANCE	PERFORMANCE AGAINST TARGET	
OHCM	Retirement Estimate Request (15 days)	95%	100%	▲	+5
	New Employee OPF Folder Creation (45 days)	90%	100%	▲	+10
	Annual FDA Workforce Profiles (April 30)	85%	n/a		n/a
	Training Satisfaction Surveys (post training session)	80%	98%	▲	+18
	ER Draft Notices (2 days)	80%	100%	▲	+20
	ER Draft Notices (5 days)	90%	100%	▲	+10
	LR Draft Step 1 Grievance Decisions (2 days)	80%	100%	▲	+20
	LR Draft Step 1 Grievance Decisions (5 days)	90%	100%	▲	+10
	LR Draft Step 2 Grievance Decisions (2 days)	80%	100%	▲	+20
	LR Draft Step 2 Grievance Decisions (5 days)	90%	100%	▲	+10
	LR Draft Step 3 Grievance Decisions (2 days)	80%	100%	▲	+20
	LR Draft Step 3 Grievance Decisions (5 days)	90%	100%	▲	+10
OTS	10-Day Work Flow for Physician Resources (10 days)	85%	92%	▲	+7
	10-Day Work Flow for Title 42(g) Resources (10 days)	90%	62%	▼	-28
	Contact Selectee to Extend Final Offer (3 days)	75%	60%	▼	-15
	Executive Submission (3 days)	90%	100%	▲	+10
	Personnel Orders of FDA Commissioned Corps Officers (2 days)	85%	100%	▲	+15
	Provide Certificate of Eligibles (20 days)	75%	78%	▲	+13
	Provide Draft JOA for Review (3 days)	75%	59%	▼	-16
	Staffing Classification (20 days)	80%	81%	▲	+1

Legend: ▲ Met or exceeded goal   ▼ Has not met goal

3. RECOMMENDATIONS

The assessment team provides FDA with recommendations aimed to further mature how the Agency recruits, hires, and retains human drug and biologics review program staff. These recommendations present data-driven ideas for continuing progress within the five assessment categories, based on this Final Assessment's findings and conclusions.

The first two recommendations involve multifaceted, cross-cutting concepts that apply to more than one of the assessment categories. Addressing these multifaceted recommendations is crucial for FDA to carry out the fundamental transitions needed to achieve impactful and sustainable improvement. The remaining recommendations are aligned to each of the assessment categories. Although they are presented singularly, FDA will likely achieve the greatest progress by recognizing these recommendations' interconnectedness and coordinating implementation efforts. Finally, in conjunction with addressing these recommendations, FDA should overlay a strong initiative to encourage acceptance and adoption to support the workforce through any change processes.

The assessment team incorporated Interim Recommendations into the Final Recommendations as needed, when the actions described in the recommendations are still required to help address current or ongoing issues identified in the assessment. To clarify the references, Final Assessment recommendations are labeled with an "RF" (e.g., RF-1), and Interim Assessment recommendations are labeled with an "R" (e.g., R-1).

3.1 Cross-cutting

RF-1. Engage leaders and stakeholders across HR organizations and CDER and CBER to collaboratively plan, develop, and institutionalize FDA's shift to a strategic service delivery model designed to meet customer requirements (e.g., human capital business partner model).

Incorporates Interim Recommendation R-10; see also HR Staff Capability and Capacity Recommendation RF-10

FDA should define and expand its HR service delivery model beyond administrative processing and compliance into a more collaborative, customer-focused approach to strategically delineate, coordinate, and modernize functions across the talent lifecycle. The service delivery model should establish an efficient and consistent approach, grounded in merit system principles and applicable laws and regulations, that is focused on delivering service outcomes that are defined in consultation with customers and strategically meaningful to FDA's business. The service model should also define and de-conflict the formal roles and responsibilities of the multiple groups of HR service providers and service customers (e.g., OTS and OHCM staff, staff in CDER and CBER OMs, and Program Offices who perform HR work, hiring managers, and Center leadership). Evolving to a strategic service delivery model also includes the concepts of a customer-driven mindset for HR services, integrated human capital functions (e.g., recruiting, hiring, and retention are considered a dynamic system, rather than independent functions), and alignment of HR strategies and actions to mission-centric outcomes.

- A key first step is holding a collaborative session with HR and Center leaders to define the service model with the level of customer engagement desired by FDA (see Section 2.2). Considering which target customer-focused stage (i.e., customer compliance to customer experience) FDA wants to incorporate into its service model, FDA's HR leaders should review and update processes, tools, practices, competencies, and technology so they are in alignment with the desired model.

- Hold senior leaders and managers of staff performing HR work accountable to act as executive sponsors and change agents to help remove barriers and facilitate a successful transition to the desired service model. Once FDA establishes a plan for transitioning to the service model, there must be clear delineation of roles, responsibilities, and decision authorities to support successful implementation. HR leaders must then work jointly and persistently to use the desired level of customer engagement as a

touchstone to drive all elements of the initiative, such as decision making, processes and workflows, resource allocations, metrics-that-matter, capability, and capacity requirements. FDA should clearly delegate decision rights to the appropriate (i.e., lowest possible) levels of leadership, including explicit guidance on the types of decisions and approval authorities granted to execute the plan.

- Address less tangible but more impactful cultural levers, such as creating a unified mindset among staff performing HR work across FDA who will collectively articulate and build shared commitments to the values and approaches that support different ways of thinking and interacting with customers. HR leaders must also identify and build the related competencies in staff who perform HR work (see HR Staff Capability and Capacity Recommendation RF-10).

- Implement additional tactics for establishing and sustaining the more collaborative, customer-focused culture previously recommended (Interim Recommendation R-10). These efforts could include conducting a series of structured, facilitated sessions with participants who represent diverse organizations and perspectives, including a mix of OC/OO, Center, OTS, and OHCM leaders to delve into the root causes of the current cultural challenges and, most importantly, generate solutions for shifting the culture and promoting more constructive interaction among groups based on shared goals. In a related effort, FDA should examine and challenge perceived limitations (e.g., funding constraints, FDA's cultural norms, HHS guidance) that hold the Agency back from taking bold action to address fundamental organizational challenges.

- Establish feedback mechanisms to assess whether noticeable, positive change is occurring at the desired velocity and with the groups identified as customers. These indicators could include the use of frequent pulse check surveys and real-time feedback from varied stakeholders (e.g., hiring managers, new hires, and staff who perform HR work in the Centers, OTS, and OHCM) on the adoption of a collaborative, customer-focused culture.

RF-2. Establish an enterprise-level HRIT system (e.g., through expanding ATLAS or using a single interface for multiple systems) that integrates the entire talent lifecycle; cultivate user adoption and leverage integrated data to support process automation and advanced analytics.

Incorporates Interim Recommendation R-4

Centers and OO should work together to unify data practices and develop a single enterprise solution that integrates data and HR processes across the talent lifecycle to drive greater vested interest, pooled resources, commitment, and accountability for delivering an optimized talent experience. This requires an HRIT infrastructure solution that includes advanced system capabilities and provides seamless workflows, tracking, and reporting for the entire talent experience lifecycle (from anticipated vacancy through separation) to address larger systemic integration and data management issues that continue to challenge service delivery. FDA should regularly review existing HRIT systems to make continual improvements to workflow, integrate additional functions, and identify additional technological solutions (preferably low-code/no-code applications that can be quickly and easily configured as needs change and can serve as a unifying user interface).

- Continue to review the HR system inventory to map the linkages among the current and upcoming HRIT solutions. Review existing data to uncover opportunities to standardize process workflows for all HR actions processed by staff in OTS, OHCM, CDER, and CBER. Specifically review pre- and post-pandemic workflows to pinpoint new areas of efficiency and improved processes (e.g., reporting requirements, hiring demand influx, data access). Update processes and workflows to incorporate these improvements into regular operations, rather than reverting to the previous processes.

- Fully implement the ATLAS system and expand functionality to increase integration with other systems and provide greater visibility into the status of actions and accountable party. Review HR data and reporting needs for the Centers and OO to maintain the appropriate data availability in ATLAS, increase transparency, and reduce the number of systems needed to track and report relevant HR data from across the talent lifecycle.

- Centers and OO should also collaborate to explore the benefits of a common solution that meets the collective data reporting and system access needs of all parties. Determine appropriate access restrictions for the purposes of data security and process efficiency. Also, consider alternatives to the daunting task of building or buying an end-to-end solution, such as developing a single-user interface that integrates disparate HR systems on the back end.

- Develop a talent analytics strategy to leverage the value of increased system integration, automated HR processing, and reporting functionality. Implement readily available digital solutions that support advanced analytics, workflow management, and workload management across the HR workforce including both Center and agency HR. For example:

    - Use advanced business process automation technologies (such as Robotic Process Automation [RPA]) to gain efficiencies in the HR workload, such as by automating the data entry that occurs with processing HR actions (e.g., pre-filling data fields in automated templates) or other steps that tend be routine and/or manually tracked for validation and compliance.

    - Use automated workflow management applications to integrate HR processes with other organizational touchpoints (such as IT, Security, Facilities, and Finance) to create a seamless experience for the customer and increase efficiency of the overall process. Integrating and automating workflows across the entire talent experience lifecycle can also serve as a force-multiplier to expand capacity by dramatically reducing the workload for completing some tasks. In addition, the use of integrated/automated workflows facilitates measurement and monitoring of metrics-that-matter, enhances transparency for customers (thereby enhancing customer trust), and helps identify workflow bottlenecks (thus promoting continual improvements).

    - Use predictive attrition analytics based on integrated tracking of applicant, employee, and position data to anticipate losses and inform recruiting and hiring actions, succession planning, career planning, and other talent management functions. For example, if average tenure for a specific position is 22 months, and FDA's average hire time for that same position is 6 months, then FDA could consider starting a recruiting action 16 months into an incumbent's tenure. Similarly, if predicative attrition analysis suggests that a specific Office is at risk for losing half of its staff over the next three years (e.g., due to retirements and resignations), FDA might wish to ramp up hiring just for that Office well before the vacancies begin to materialize.

    - Analyze long-term value of recruiting sources (e.g., track average tenure and salary of employees hired from different recruiting sources) to determine which sources generate employees who tend to stay with the Agency longer and calculate the average "cost" (in average salary) of candidates from each source. Use the resulting analytic insights to refine approaches for recruiting and hiring.

- Cultivate a transformative HR culture that can fully achieve the potential of digital solutions. The scope and impact of digital solutions FDA is implementing such as ATLAS have substantial cultural implications because they have the potential to fundamentally change the way services are provided to customers. For FDA to see meaningful impact from HRIT improvement initiatives, it is important for the Agency to not only roll out new tools but to also support *change enablement*, so staff will want to use the new tools. Without an investment in the human side of technology changes, users are prone to continuing to use old systems or to develop manual workaround processes. Accordingly, FDA should actively work to build, instill, and sustain an FDA-wide culture of change enablement that helps users keep pace with the frequency of introducing new digital solutions and to start using the solutions, so they provide value to customers as quickly as possible. A transformative HR culture must start with a focus on the customer and should view these digital solutions as a means to create value for customers, not merely as tools that can lighten the workload of staff performing HR work.

3.2 Strategy

See also Cross-cutting Recommendation RF-1

RF-3. Refine retention strategies to enable improved coordination and integration across the Agency, establish targets for effective use of strategies, and more proactively address succession needs.

FDA should review and refine existing retention strategies at the Center and Agency level to provide clearer linkages between strategies across functions (e.g., recruiting, HR analytics), identify opportunities to improve information sharing and coordination across the Agency, and enable more strategic targeting and customization of available incentives and hiring authorities. For example, CDER and CBER acquired many new hires during the pandemic, and these employees' complete experience with FDA has been under a highly flexible, remote, and mission-focused environment. Moreover, many people across the FDA workforce have valued the ability to work in a more flexible environment during the pandemic. In essence, FDA's value proposition to attract and retain employees, especially those hired during the pandemic, has changed, and retention strategies should be revisited and updated as needed to address emerging needs and motivators. FDA should strongly consider guidance from OPM's July 2021 memo regarding personnel policies and workplace environment following the Covid-19 pandemic and use trend data to tailor retention strategies and programs to the various needs and experiences of key employee groups.[75] For example, data trends may show that different retention tools are more effective for retaining employees with different characteristics (e.g., occupational series, age, tenure, retirement eligibility). FDA should develop guidance for using retention tools effectively, targeting usage depending on the situation, and making usage more consistent across the Agency. Similarly, FDA should continue to build and carry out succession planning to proactively manage the risk and impact of retirement and other attrition to MCOs, leadership, and specific at-risk organizations and occupations (e.g., shallow bench, high attrition rate).

3.3 Culture, Collaboration, and Communication

See also Cross-cutting Recommendation RF-1

RF-4. Continue developing a stakeholder engagement strategy to encourage two-way communication that will increase awareness and efficient adoption of recruiting and hiring process improvements.

Repeats Interim Recommendation R-11

The Interim Assessment provided the following recommendation, which continues to apply:

> *OTS should work collaboratively with the Centers to establish a stakeholder engagement strategy that is attuned to customer needs and that rebuilds their brand as the knowledgeable, communicative source of FDA's HR information. The strategy should document the cadence, channels for communications, and products that will promote better transparency about hiring process improvement efforts. This will increase awareness of progress and acknowledge challenges, such as the reasons behind certain HR practices (e.g., the need to review PDs, the need to practice more proactive position management to improve consistency and compliance). As part of the stakeholder engagement strategy, OTS and the Centers should also recalibrate the expectations held by all parties for customer service delivery. To accomplish this, they should hold sessions to determine the strengths and weaknesses of customer service delivery. During these sessions, stakeholders should mutually define the future state customer service standards and expectations.*

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[75] Source: Memo: Additional Guidance on Post-Reentry Personnel Policies and Work Environment, July 2021, OPM, https://chcoc.gov/sites/default/files/CPM%202021-17%20Additional%20Guidance%20on%20Post-Reentry%20Personnel%20Policies%20and%20Work%20Environment.pdf.

For example, FDA should revise external outreach materials and methods of communication to improve the candidate experience of learning about FDA, finding FDA jobs, and applying for positions. As part of this effort, FDA should conduct a review of its external website content, such as the available special hiring authorities and pay authorities (e.g., Title 21).

3.4   Recruiting and Hiring Processes

See also Cross-cutting Recommendations RF-1 and RF-2

RF-5.   Establish new service delivery metrics (e.g., collaboration, time to hire) based on the throughput and other hiring metrics achieved during the pandemic, while seeking to realize additional efficiencies.

In response to the pandemic, FDA more effectively made use of the array of tools and flexibilities at its disposal to meet urgent hiring needs for CDER and CBER. The timeliness of the hiring process achieved during the pandemic should be used as the baseline for hiring actions moving forward, even in a post-pandemic posture. HR productivity during the pandemic showed that faster hiring times and higher hiring throughputs are possible. As FDA transitions operations post-pandemic, it should use the pandemic timelines as the standard by which to compare future actions.

After institutionalizing the efficiencies gained during the pandemic, FDA should maintain a continual improvement mindset to sustain efficiencies over time and to look for further enhancements. FDA should subsequently continue to establish, measure, and monitor KPIs and continually strive to optimize the timelines associated with recruiting and hiring functions, mitigating risk through appropriate measures (e.g., adopting the "standard of adequacy" that OPM specifies in The Classifier's Handbook).[76]

RF-6.   Examine the disconnect between the large number of qualified candidate referrals provided by OTS and the low number of CDER and CBER selections from these referrals.

FDA should investigate the dynamics involved in the high volume of qualified candidate referrals on certificates, the low numbers of selections relative to referrals, and the relatively high number of announcements that produce selections (discussed in Finding F3.5). Potential areas to review include the following: current OTS qualification review practices and procedures to develop referrals of qualified candidate; CDER and CBER input on whether requirements and standards for qualified candidates were met (especially in instances where no selection was made); the impact of multiple certificates per vacancy and shared certificates use; the potential disconnect between OTS's and Center hiring managers' views and expectations of candidate quality and qualifications. FDA should also consider conducting a rigorous, legally defensible job analysis for selection for key CDER and CBER jobs, which should always comport with the Equal Employment Opportunity Commission's (EEOC's) Uniform Guidelines on Employee Selection Procedures. It is also recommended that hiring managers play an active role in the job analysis process such as collaborating directly with OTS staff to share knowledge of the job role or performance level expectations. The resulting selection factors could be used as a basis to establish mutually agreed-upon quality ranking factors. Ultimately, asking hiring managers and OTS staff to develop a common understanding and procedures for the qualification review and selection and sharing accountability for selection from the resulting certificates will improve both the applicant screening stage (i.e., to generate referrals) and the selection stage.

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[76] Source: The Classifier's Handbook, OPM.

3.5   Data Management and Systems

See also Cross-cutting recommendation RF-2

RF-7.   Continue to infuse more uniformity and structure into data management and reporting practices for recruiting, hiring, and retention data.

Incorporates Interim Recommendation R-4

As presented in Interim Recommendation R-4, FDA should continue to infuse more uniformity and structure into data management and reporting practices for recruiting, hiring, and retention data (e.g., shared data dictionaries, common nomenclature, and data management protocols) to improve data integrity, access to data, and the confidence others have in data to drive business decisions. FDA should stand up an HR Data Management Board that holds formal responsibility for overseeing how recruiting and hiring data are managed. The Board should be comprised of OC/OO, Center, OTS, and OHCM leaders and other representatives who have direct involvement in HR data management. The board should identify existing best practices that could be replicated, identify any significant gaps, and prioritize the data management and reporting practices to be addressed. The group should establish a formal plan for creating, vetting, finalizing, and communicating the data management and reporting practices. Along with establishing and enacting strong data management practices, the group will need to monitor and update these practices so that they continue to be beneficial across the organization. The board should meet regularly (e.g., monthly, quarterly) to oversee decisions on how data are managed and to adjudicate outstanding issues. By instituting a formal forum for these discussions, FDA can work to resolve data management issues before they escalate into more significant challenges.

3.6   HR Staff Capability and Capacity

See also Cross-cutting Recommendations RF-1 and RF-2

RF-8.   Continue to refine workload management processes for assessing and distributing work across the HR workforce, with consideration for adopting an Agile workflow management technique, such as Kanban.

Incorporates Interim Recommendation R-8

As FDA continues working toward Interim Recommendation R-8, it is worth noting that the issue of HR workload management is much more complex than simply finding the "right" ratio between the number of recruiting and hiring actions and the resources available to complete them (e.g., HR headcount). Factors such as how work is assigned, to whom it is assigned (and why), how the work is performed (e.g., the relative level of manual processes versus automated workflows), the relative level of proficiency of those to whom work is assigned, the standard of quality to which work is performed (e.g., "adequate," "absolute"), how work is tracked, how workflows are monitored, the desired level of customer focus, and several others must be assessed to truly understand and optimize workload. As these factors evolve, HR leaders must re-evaluate the projected target for HR staffing ratio or HR workforce strength (considering staff in OTS and OHCM as well as CDER and CBER.

In considering workload management, the assessment team would further recommend that FDA consider applying an Agile workflow management technique such as Kanban (with its powerful core tenet of work-in-progress [WIP] limits) for assigning HR work to staff. WIP limits recognize that staff can only work on a fixed number of actions at any one time, that number being a function of both the individual and the complexity of work assigned to them. This effort could start with establishing a business plan to capture the myriad reasons for applying a Kanban process (with WIP limits) to HR workload management.

RF-9. **Continue to hold managers of staff performing HR work—across OTS, OHCM, CDER, and CBER— accountable for actively managing staff performance by establishing standardized performance management goals.**

Incorporates Interim Recommendation R-9

As FDA works on implementing Interim Recommendation R-9, HR leaders should bear in mind that—while performance goals aligned to customer outcomes and organizational priorities are important—those goals are not an end unto themselves. FDA should incorporate these standardized performance goals into its Performance Management Appraisal Program (PMAP) to enhance organizational effectiveness and align to Agency mission and goals. Achieving such improvements requires not only clear and measurable goals but also the active participation of managers who 1) frequently engage in two-way dialogue with employees to communicate and clarify priorities, 2) identify and address developmental needs, and 3) listen with empathy to employee aspirations and challenges. Such active participation rarely happens organically. It takes strong messaging, modeling, and metrics. It also requires that managers have the appropriate competencies (primarily the so-called "soft skills" versus technical skills) to partner with, empower, and support employees in achieving goals valuable for both organizational performance and employee career development.

RF-10. **Create and implement an updated, unified HR competency model for all FDA staff performing HR work, aligned to the customer-focused performance expectations and expanding use of technology.**

Incorporates Interim Recommendation R-10; see also Cross-cutting Recommendations RF-1 and RF-2, and Recruiting and Hiring Processes Recommendation RF-6

FDA should review, update, and expand its HR competency model to align with decisions about transitioning to a customer-focused service delivery model discussed in Cross-cutting Recommendation RF-1. Different customer-focused models require different competencies. While many of the technical competencies may be common across models, key behaviors and so-called "soft-skill" competencies will vary considerably. As a result, FDA should define a unified competency model for all FDA staff performing HR work that includes behavioral indicators and target proficiency levels, incorporating the Center-specific technical competencies, as appropriate. In addition, FDA should refine the model as needed to align with the level of customer focus it wishes to provide. The updated competency model should also reflect factors such as the expanding use of technology solutions (e.g., ATLAS), talent analytics, and other considerations for HR works, develops insights, and collaborates to support customer objectives (see also Cross-cutting Recommendation RF-2).

Once roles and responsibilities are defined to support the customer-focused service delivery model (discussed in Cross-cutting Recommendation RF-1), the updated HR competency model should then be implemented within the Individual Development Plans of all staff performing the relevant HR work. The associated development opportunities should reflect diverse, tailored options that include not only training but also options such as experiential learning, micro-learning, and cross-training details. Furthermore, the competency model can also support skill monitoring and performance management, workforce planning, and succession planning for staff performing HR work. Ideally, if the updated competency model is based on a legally defensible job analysis that comports with the EEOC's Uniform Guidelines on Employee Selection Procedures (see also Recruiting and Hiring Processes Recommendation RF-6), it could also be used to set FDA-unique selective factors and quality ranking factors to improve the assessment, selection, and hiring of staff to perform HR work, who have the critical skills to meet FDA's needs.

APPENDIX: REPORT SUPPLEMENT

LIST OF EXHIBITS

This Appendix provides supplemental information for the Food and Drug Administration (FDA) Final Hiring and Retention Assessment. This supplemental information includes additional results from data analyses that are referenced in the report to provide further insight to the report content. The main report references the relevant exhibit as "see Supplement Exhibit S-X." Supplement Exhibits are presented herein in numerical order Exhibits S-1 to S-21).

Exhibit S-1: Interview Themes – Alignment of Recruiting, Hiring, and Retention in FDA Strategic Planning

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Alignment of Recruiting, Hiring, and Retention in FDA Strategic Planning	There is alignment at a high level, but FDA's formal and informal strategic plans do not always translate into practice (e.g., plans do not link to the operational guidance, integrated processes, or other resources needed to achieve them. the work is so fast-paced that staff are trying to strike a balance between planning and flexibility).	Int: 1st out of 2
	FDA and CDER/CBER leaders recognize that recruiting, hiring, and retention are strategic priorities, demonstrated by establishing collaborative working groups and including these priorities in planning documents, such as budget, risk management, talent acquisition, and diversity and inclusion documents.	Int: 2nd out of 2

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Exhibit S-2: Interview Themes – Potential Impact of Improved Integration of Recruiting, Hiring and Retention Functions

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Potential Impact of Improved Integration of Recruiting, Hiring and Retention Functions	An integrated strategy would help leaders and operational staff organize and allocate resources to HR priorities (e.g., assessment of STEM and mission critical occupations, access to more timely information, use of analytics to identify the root causes of turnover, enterprise level coordination).	Int: 1st out of 2
	Better integration would improve process quality by enabling more thoughtful planning and coordination (e.g., partnerships between managers and HR, more accurate candidate screening, more clarity for candidates, a recruiting pipeline for specialized positions, a well-planned approach to classification, compensation, and diversity and inclusion).	Int: 2nd out of 2

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Exhibit S-3: Interview, Focus Group, and Survey Feedback – How COVID-19 Impacted Recruiting, Hiring, and Retention

Themes from Interview and Focus Groups on Impact of COVID-19

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
FDA Advantages – COVID-19 Impact on Recruiting, Hiring, and Retention (Interviews)	The flexibility and stability of government work, including the ability to telework during COVID-19, helps with recruiting, hiring, and retention.	Int: 1st out of 2
	A commitment to FDA's mission and the sense of purpose related to protecting public health are meaningful for staff and job candidates alike.	Int: 2nd out of 2
FDA Advantages – COVID-19 Impact on Recruiting, Hiring, and Retention (Focus Groups)	From an FDA workforce perspective, there have been positive outcomes related to the COVID-19 pandemic including the adaption to teleworking, adoption of virtual recruiting, and the use of COVID-related retention incentives.	FG: 1st out of 2
	FDA employees and job candidates identify with the agency's mission of protecting public health and share a sentiment for contributing to the greater good.	FG: 2nd out of 2

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
FDA Challenges – COVID-19 Impact on Retention	There is a risk of increased turnover (now or in the near future) due to overwhelming workload and burnout, in part due to the surge of work related to COVID-19.	Int: 1st out of 3
	There is a potential for increased turnover after temporary arrangements related to COVID-19 are over (e.g., end of telework, fear of being expected to relocate).	Int: 3rd out of 3
FDA Challenges – COVID-19 Overall Impact on HR	Workload increases related to the COVID-19 pandemic, have been particularly challenging for staff in CDER and CBER.	FG: 2nd out of 2

Themes from Open-ended Survey Responses on Impact of COVID-19

SURVEY RESPONDENTS	MOST COMMON THEMES FROM OPEN-ENDED RESPONSES	FREQUENCY
CDER/CBER Staff Survey Themes	There is a risk of increased turnover (now or in the near future) due to overwhelming workload and burnout, in part due to the surge of work related to COVID-19	26
	The flexibility and stability of government work, including the ability to telework during COVID-19, helps with recruiting, hiring, and retention	20
	There is a potential for increased turnover after temporary arrangements related to COVID-19 are over (e.g., end of telework, fear of being expected to relocate)	17
	There is more awareness of FDA's stature/profile	8
HR Staff Survey Theme	There is a potential for increased turnover after temporary arrangements related to COVID-19 are over (e.g., end of telework, fear of being expected to relocate).	5
HR Manager Survey Theme	The flexibility and stability of government work, including the ability to telework during COVID-19, helps with recruiting, hiring, and retention.	7

Respondents:

- *CDER and CBER staff (n=183). Survey item: "Please share more information about your perspective on the impact of COVID-19 on recruiting, hiring, or retention of CDER/CBER staff."*
- *HR Staff (n=11). Survey item: "Please share more information about your perspective on the impact of COVID-19 on recruiting, hiring, or retention of CDER/CBER staff."*
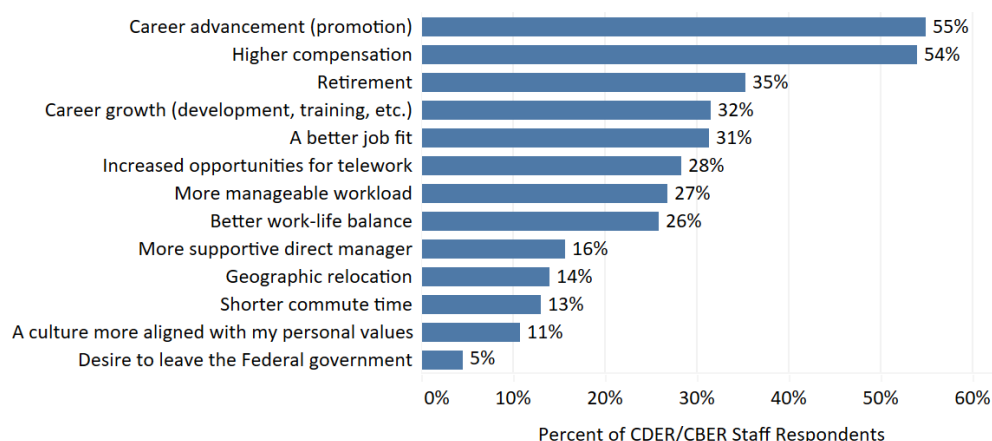- *Respondents: HR Manager (n= 19). Survey item: "Please share more information about your perspective on the impact of COVID-19 on recruiting, hiring, or retention of CDER/CBER staff."*
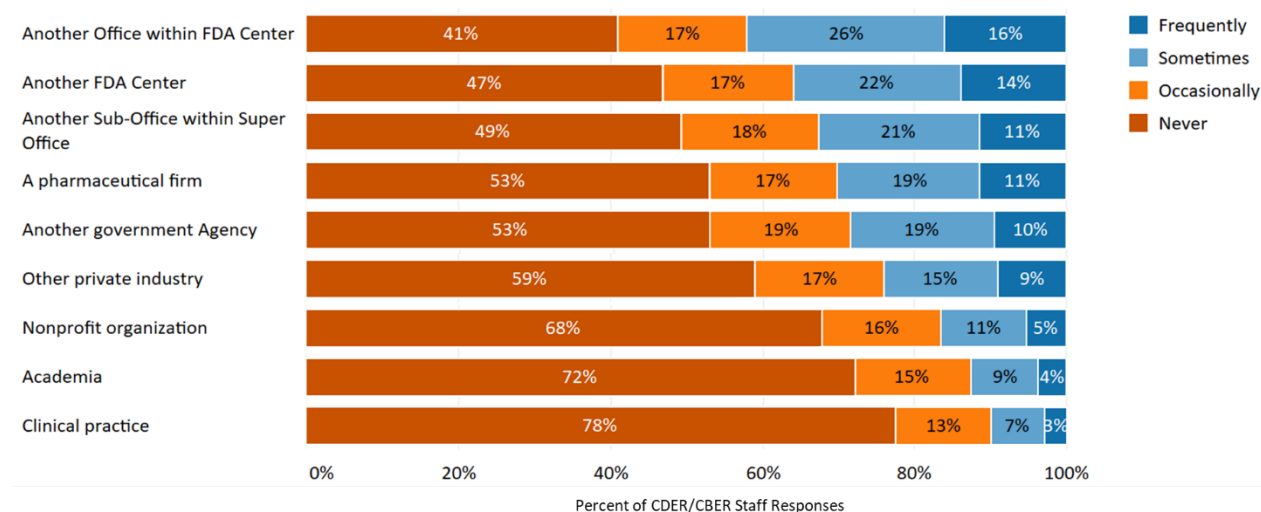
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Exhibit S-4: Survey Results – Reasons CDER and CBER Staff Would Leave Center and Other Places They Consider Working

Reasons CDER/CBER Staff Would Leave Current Center

Reason	Percent
Career advancement (promotion)	55%
Higher compensation	54%
Retirement	35%
Career growth (development, training, etc.)	32%
A better job fit	31%
Increased opportunities for telework	28%
More manageable workload	27%
Better work-life balance	26%
More supportive direct manager	16%
Geographic relocation	14%
Shorter commute time	13%
A culture more aligned with my personal values	11%
Desire to leave the Federal government	5%

Percent of CDER/CBER Staff Respondents

Respondents: CDER and CBER staff (n=2251). Survey Item: "For which of the following reasons would you consider leaving your current Center? Please select all that apply." This item type is Select All That Apply, so the response numbers count all selections provided by survey participants.

Sources of Workforce Competition

	Never	Occasionally	Sometimes	Frequently
Another Office within FDA Center	41%	17%	26%	16%
Another FDA Center	47%	17%	22%	14%
Another Sub-Office within Super Office	49%	18%	21%	11%
A pharmaceutical firm	53%	17%	19%	11%
Another government Agency	53%	19%	19%	10%
Other private industry	59%	17%	15%	9%
Nonprofit organization	68%	16%	11%	5%
Academia	72%	15%	9%	4%
Clinical practice	78%	13%	7%	3%

Percent of CDER/CBER Staff Responses

Respondents: CDER and CBER staff (n=1833-2274). Survey item: "In the past six months, how often have you considered looking for another position in:" A "Not Applicable" response option was also provided; those responses are not included in this analysis.

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Exhibit S-5: Focus Group Theme – Effective Retention Related Practices

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Effective Retention-related Practices	Financial benefits, including retention incentives, student loan repayment, and salary increases due to promotion and Cures allowances are all effective for retaining CDER and CBER staff.	FG: 1st out of 3
	Non-financial benefits, particularly workplace flexibilities including telework, administrative leave, and flexible hours have been effective for retaining CDER and CBER staff.	FG: 2nd out of 3

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Exhibit S-6: Interview and Focus Group Themes – Effective Coordination Between Groups Performing HR Work

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Effective Coordina-tion Between Groups* (Interviews)	There has been a noticeable improvement due to OTS's efforts to increase communication with CDER and CBER and to provide targeted solutions to support the Centers' needs.	Int: 2nd out of 3
FDA-Fostered Collaboration Among Groups*	Efforts to increase collaboration between OTS, OHCM, CDER/CBER Staff performing HR work, and Hiring Managers have been effective (e.g., regular working group meetings, consultative HR discussions for recruiting and hiring efforts), and more frequent touchpoints with assigned points of contact and having people with decision-making authority participating in groups would further improve the impact of collaboration.	Int: 1st out of 2
Effective Coordination Between Groups* (Focus Groups)	Although challenges still exist with the hiring process, there have been some improvements to communication and collaboration (e.g., collaborative meetings to operationalize Cures; commitment to diversity, equity, and inclusion initiatives; focused efforts by HR Liaisons).	FG: 3rd out of 3

Groups performing HR work were defined as staff performing work related to recruiting, hiring, and retention across FDA organizations (e.g., OTS, OHCM, CDER/CBER OM, CDER/CBER Program Offices).

Exhibit S-7: Interview and Focus Group Themes – Challenges with Coordination Between Groups Performing HR Work

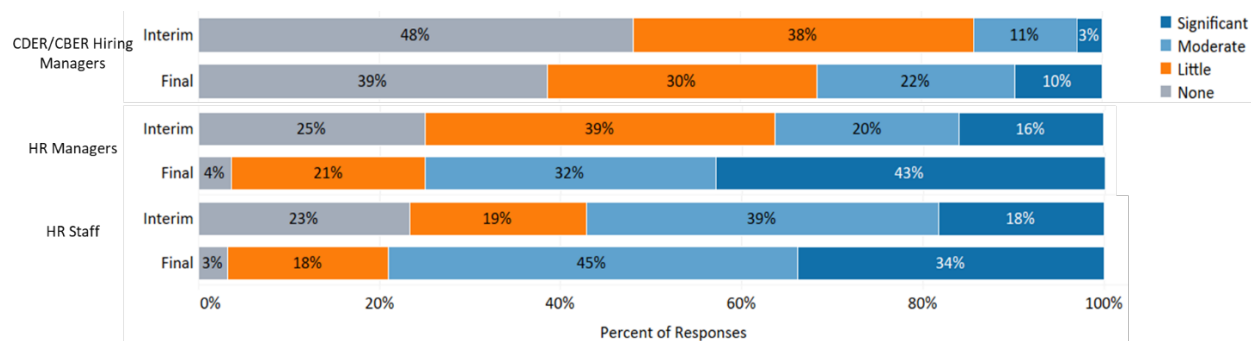| INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Challenges with Coordination Between Groups* (Focus Groups)	Inconsistent communication and lack of collaboration between the parties involved in recruiting, hiring, and retention (e.g., OTS, OHCM, CDER/CBER OM, PMs/AOs, Hiring Managers) is hampering processes.	FG: 1st out of 3
	HR support to CDER and CBER is not consistent nor standardized; processes differ, timelines vary, and HR works on challenges in isolation and operates in siloes.	FG: 2nd out of 3
Challenges with Coordination Between Groups* (Interviews)	There are challenges with effective handoffs and coordination (e.g., lack of visibility into HR process leading to frustration and bottlenecks, inconsistent guidance and procedures, turnover of OTS points of contact, duplication of efforts across OTS staff and CDER/CBER staff performing HR work, and difficulty for recruiters to plan ahead for upcoming hiring needs).	Int: 1st out of 3
	The effectiveness of coordination varies for different CDER and CBER Offices (e.g., many administrative staff in CDER with siloed roles and layers of review/approval, difficulty for OTS staff to exchange information and convey consistent guidance with multiple CDER POCs, CDER/CBER desire to expedite the process by making exceptions to HR policy).	Int: 3rd out of 3

Groups performing HR work were defined as staff performing work related to recruiting, hiring, and retention across FDA organizations (e.g., OTS, OHCM, CDER/CBER OM, CDER/CBER Program Offices).

Exhibit S-8: Survey Results – Extent of Improved Satisfaction with Recruiting and Hiring due to OTS and OHCM Support

Respondents: HR Staff (n=73); HR Managers (n=32); Center (CDER and CBER Hiring Managers only n=449,). Response scale: None, Little, Moderate, Significant, and Don't know. "Don't Know" responses were excluded from the analysis. Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Support provided by the Agency's HR Organization (OTS/OHCM) to the Centers has improved your overall satisfaction with FDA's recruiting and hiring processes."

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Exhibit S-9: Survey Results – Extent of Agreement that Recruiting, Hiring, and Retention Meets FDA Needs

Interim Survey Results

Final Survey Results
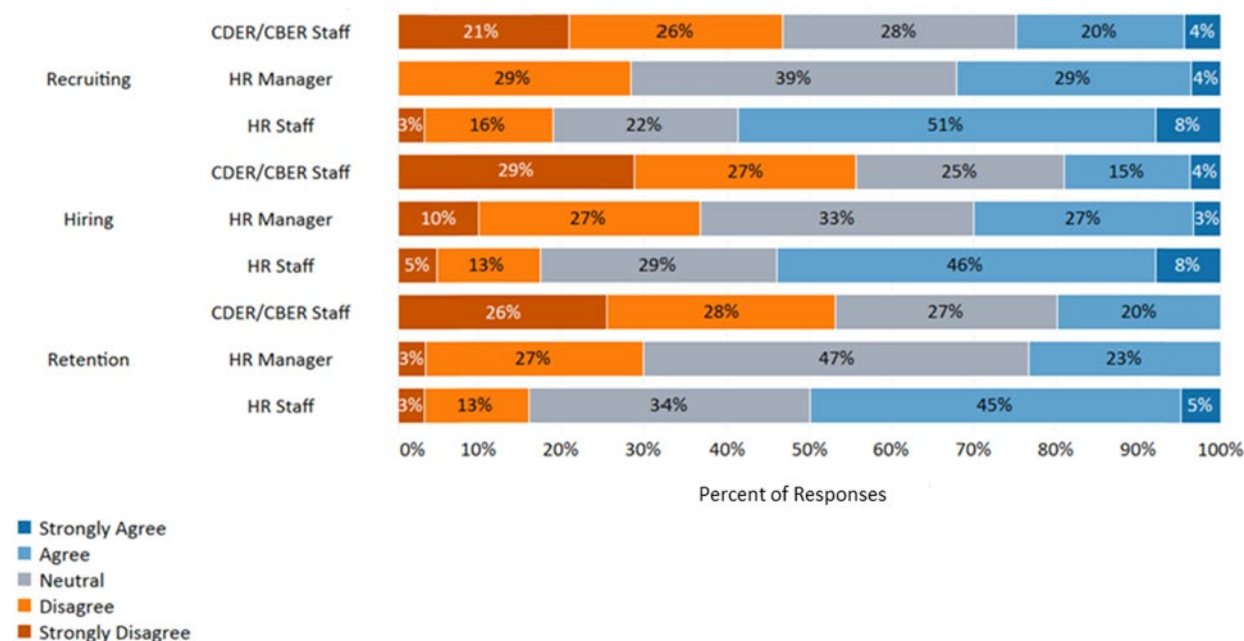

Respondents: CDER and CBER staff (Final: n=2315, Interim: n=1805); HR managers (Final: n=35, Interim: n=52); HR Staff (Final: n=77, Interim: n=120). Survey item: "Survey items: "Overall, I believe the FDA's current recruiting process for human drug and biologics review program staff meets the needs of the Agency"; "Overall, I believe the FDA's current hiring process for human drug and biologics review program staff meets the needs of the Agency"; and "Overall, I believe the FDA's current retention strategies for human drug and biologics review program staff meets the needs of the Agency," with a response scale of Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree. Chart reflects" Strongly Agree" and "Agree" responses only.

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Exhibit S-10: Interview and Focus Group Themes – Additional Resources Needed

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
FDA Support for Collaboration (Need for Additional Resources)	Additional resources would help foster effective collaboration (e.g., up-to-date SOPs and policies, clear and consistent information about hiring authorities, roles and responsibilities, performance goals and expectations, tracking systems that support both transparency and compliance).	FG: 1st out of 1
Need for Additional Resources (Interviews)*	Additional staff and resources (e.g., training, change management, shared repository of up-to-date documents) are needed for the overall cadre of staff performing HR work to be more efficient and effective, more proactive, and better able to meet targets for recruiting, hiring, and retention.	Int: 1st out of 2
	Rather than needing additional resources, there is a need for better allocation of resources and alignment of work to help avoid overload, thus allowing staff performing HR work to support recruiting, hiring, and retention work more effectively.	Int: 2nd out of 2
Need for Additional Resources (Focus Groups)*	Both OTS/OHCM staff and CDER/CBER staff supporting HR work require training on HR processes to keep up with changing processes and to perform their roles successfully.	FG: 2nd out of 3
	OTS/OHCM staff and CDER/CBER staff supporting HR work need additional resources, including improved processes, process documentation and guidance, and clearly defined roles and responsibilities.	FG: 3rd out of 3
	CDER and CBER need additional staff to support the increased HR workload (e.g., COVID-related hiring surge, developing 21st Century Cures packages); OTS needs additional staff to handle the increased number of hiring actions being submitted by the Centers	FG: 1st out of 3

Feedback for these themes come from HR Managers only.

Exhibit S-11: Survey Results – Additional Resources Needed to Make HR Processes More Successful

RESPONSE OPTION	CDER/CBER STAFF	HR STAFF	HR MANAGERS
More direct engagement FDA's HR organization (i.e., OTS and OHCM)	89%	45%	50%
Documented process guidance (e.g., process maps, steps, roles, timelines)	77%	83%	86%
Checklists and "job aids" for conducting hiring process work	73%	66%	71%
More direct engagement with the Human Capital Liaison in your Center's Office of Management	71%	21%	32%
Reliable Information Technology (IT) system that provides easy access to the status of hiring actions	66%	48%	50%
Training on FDA's hiring processes	52%	55%	61%
Web page or centralized area with information on conducting hiring process work	52%	55%	57%
More direct engagement with the Program Manager/Administrative Officer in your Office	39%	21%	36%
Training on Federal hiring laws, Federal regulations, and/or Office of Personnel Management (OPM) processes	33%	45%	54%
Access to designated Office of Personnel Management (OPM) and FDA HR policy experts	N/A	38%	68%

Respondents: CDER and CBER staff (n=241), HR Staff (n=28), HR Manager (n=29). This item type is Select All That Apply, so the response numbers count all selections provided by survey participants.

- *CDER/CBER Staff Survey Item: "What additional resources do you need to be more efficient and effective in the hiring process? Please select all that apply."*
- *HR Staff Survey Item: "What additional resources would help you be more successful when performing work related to the recruiting and hiring processes and/or retention initiatives? Please select all that apply."*
- *HR Manager Survey Item: "What additional resources would help your HR staff be more successful when working on recruiting and hiring processes and/or retention initiatives? Please select all that apply"*

- *Other: When applicable, the "other" responses were allocated to existing categories. For the remaining responses, the most common themes are listed below:*
  - *CDER/CBER Staff Survey. Accountability from HR Staff, More Efficient Operations/Transparent processes, Transaction time improvement, and Other (e.g., more funding, more staff, more qualified candidates, diversity and inclusion, pay equity, more collaboration, more openness for new policies, HR reform).*
  - *HR Staff Survey. Individualized guidance, additional funds, more training on SharePoint sites, and need to hire more employees. The table above shows the most common response themes out of the remaining comments.*
  - *HR Manager Survey. Timelines and accountability, additional funding for HR transformation, and additional HR specialists for labor relations.*

Exhibit S-12: Interview Themes – Effectiveness of the Recruiting Process

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Recruiting Process Effectiveness	Recruitment and outreach processes need more refinement. FDA has been able to pivot and adjust to recruiting practices brought on by the pandemic to recruit hard to fill positions but there is opportunity to improve and further diversify the talent pool through better coordination and communication.	Int: 1st out of 4
	Recruiting outreach and messaging needs to be more coordinated and targeted.	Int: 4th out of 4

Exhibit S-13: Feedback from Interviews, Focus Groups, and Surveys – Effectiveness of Recruiting Sources

Interview and Focus Group Themes on Recruiting Effectiveness

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Effective Recruiting Sources/Practices (Interviews)	Effective external sources for recruiting and outreach include professional societies, social media, various job sites, longstanding networks, and FDA alumni.	Int: 2nd out of 4
Effective Recruiting Sources/Practices (Focus Groups)	The most effective outreach methods include the traditional word of mouth and conference attendance and advertisements in academic media.	FG: 1st out of 3
	Less traditional recruiting sources that are useful but not used as widely include social media (e.g., LinkedIn, Facebook, and Twitter) and job posting websites (e.g., Monster.com).	FG: 2nd out of 3*
	When FDA staff make a one-on-one connection with candidates (e.g., attending academic conferences, connecting with personal and professional networks), they are able to understand candidates' passions and interests, which enables recruiters to identify appropriate jobs and opportunities.	FG: 2nd out of 3*
Ineffective Recruiting Sources/Practices	USAJOBS, OPM's primary recruiting platform, is not useful for recruiting.	FG: 1st out of 2

Note: These two themes emerged from an equal number of source comments, so they both ranked in second place.

Survey Results on Most Productive Recruiting Channels

RESPONSE OPTION	CDER/CBER STAFF	HR STAFF	HR MANAGERS
Referrals by FDA employees	68%	39%	54%
Informal outreach/word of mouth	41%	21%	31%
Job searches on USAJOBS	36%	58%	38%
Professional events (e.g., conferences, career fairs, speaking engagements)	25%	21%	31%
Social media (e.g., LinkedIn, Twitter, Facebook)	17%	24%	26%
Advertisements in professional journals	15%	27%	26%
None of the above	11%	28%	21%
Job boards (e.g., Glassdoor, Indeed, university job boards)	9%	14%	21%
Campus visits (e.g., campus job fairs, professorships, panel discussions)	5%	7%	8%
Executive search firms	4%	1%	0%
Advertisements in general publications (e.g., newspapers, news magazines)	3%	6%	5%
Public advertisements (e.g., Metro ads, highway billboards)	1%	6%	N/A
*Other (please describe):	6%	1%	8%

Respondents: CDER and CBER staff (n=368), HR Staff (n=71), HR Manager (n=39). Survey Item: "Please select the recruitment channels that have been most productive for you in generating highly qualified candidates since the start of FY20 (October 2019). Please select all that apply." This item type is Select All That Apply, so the response numbers count all selections provided by survey participants.

Other responses. When applicable, responses were allocated to existing categories. For the remaining responses, the most common themes for each survey are summarized below.

- *CDER/CBER Staff Survey: FDA Notices and Other (e.g., Sharing Certs, Internal Candidates, Letters Training Programs).*
- *HR Staff Survey: Individualized guidance, additional funds, more training on SharePoint sites, and need to hire more employees.*
- *HR Manager Survey: Hire Now.*

Exhibit S-14: Survey, Interview, and Focus Group Feedback – Impact of Classification Reform on Overall Satisfaction

Extent of Improved Satisfaction with Recruiting and Hiring due to Classification Reform/Optimization
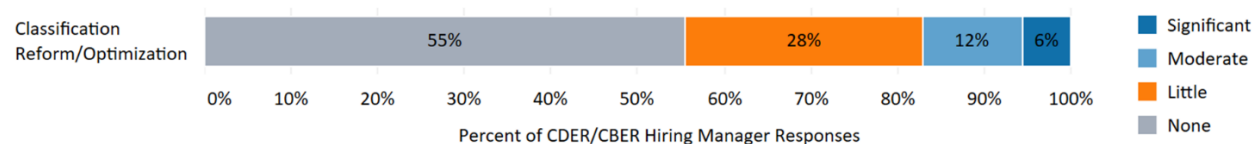
Respondents: Center (CDER and CBER Hiring Managers only n=439,). Response scale: None, Little, Moderate, Significant, and Don't know. "Don't Know" responses were excluded from the analysis. Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Classification Reform/Optimization to the Centers has improved your overall satisfaction with FDA's recruiting and hiring processes."

Effectiveness of Classification Reform/Optimization

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Classification Reform/Optimization	While efforts to reform and optimize classification have led to advancements in the process, there is still room for improvement.	Int: 1st out of 4
	Reforming the classification process provided opportunities for streamlining and standardizing the system, thus improving the overall process and helping the agency as a whole.	Int: 2nd out of 4
	Classification is less of an issue now due to the use of the Cures hiring authority.	Int: 3rd out of 4
	There is a lack of awareness on the initiative and/or if any progress has been made since announced.	Int: 4th out of 4

Includes one focus group comment on classification reform and optimization

Exhibit S-15: Focus Group Themes – Effective Hiring Related Practices

| INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Effective Hiring-related Practices	DHA has been effective in helping to hire CDER and CBER staff. It allows for direct contact with the candidates, is quicker end-to-end, and offers salary/compensation that otherwise would not be available.	FG: 1st out of 2
	Alternatives to Title 5—specifically Title 38 and Title 21 (Cures)—allow for hiring talent we would not have otherwise been able compensate based on industry level expectations.	FG: 1st out of 2

Note: Theme counts tied for first place.

Exhibit S-16: Survey Results – Satisfaction with Recruiting and Hiring due to Title 21 and Direct Hire

Expanded Direct Hire Authority of 2018
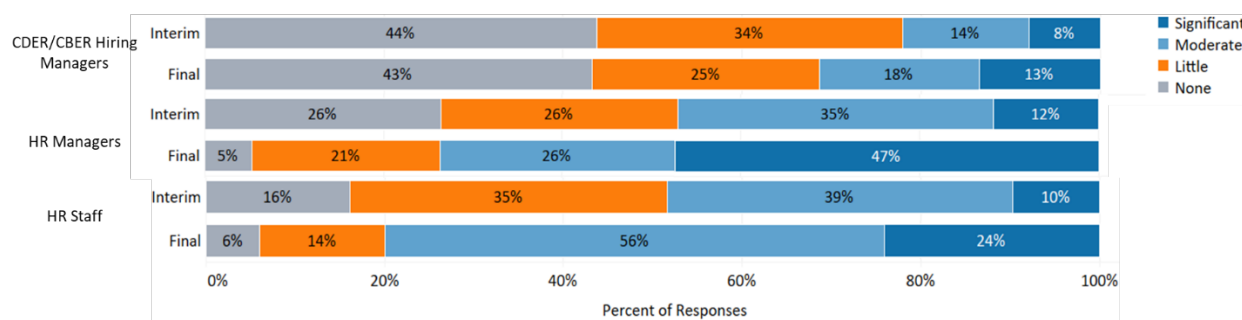
Title 21 (21st Century Cures Act)
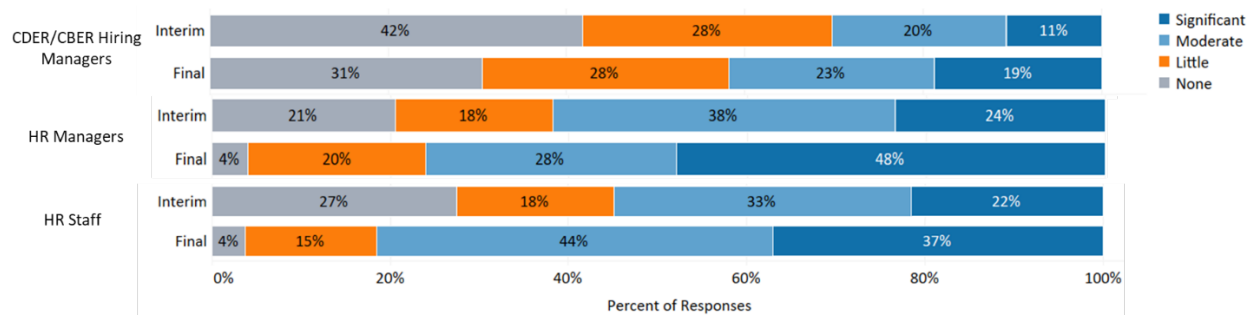
Respondents to the Direct Hire Authority question: HR Staff (n=74); HR Managers (n=33); Center (CDER and CBER Hiring Managers only n=436). Respondents to the Title 21 question: HR Staff (n=73); HR Managers (n=33); Center (CDER and CBER Hiring Managers only, n=446). Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Use of special hiring authorities through Title 21 (21st Century Cures Act)/Expanded Direct Hire Authority of 2018 (inclusion of additional scientific occupational series) has improved your overall satisfaction with FDA's recruiting and hiring processes." Response scale: None, Little, Moderate, Significant, Don't Know. "Don't Know" responses were excluded from the analysis.

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### Exhibit S-17: Interview and Focus Group Themes – Effectiveness of Hiring Process

INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Hiring Process Effectiveness	Recent improvements such as reform initiatives, collaborative processes, and dedicated HR support have been helpful in making hiring more effective.	Int: 2nd out of 4
Challenges with the Hiring Process	The traditional hiring process (i.e., Title 5) is too slow, and leads to the loss of good candidates.	Int: 3rd out of 4
	There is a lack of process clarity, quality assurance, and accountability in the current hiring process.	Int: 4th out of 4
Challenges with Coordination Between Groups* (Interviews)	There are challenges with effective handoffs and coordination (e.g., lack of visibility into HR process leading to frustration and bottlenecks, inconsistent guidance and procedures, turnover of OTS points of contact, duplication of efforts across OTS/OHCM staff and CDER/CBER staff supporting HR work).	Int: 1st out of 3
Challenges with Coordination Between Groups* (Focus Groups)	Inconsistent communication and lack of collaboration between the parties involved in recruiting, hiring, and retention (e.g., OTS, OHCM, CDER/CBER OM, PMs/AOs, Hiring Managers) is hampering processes.	FG: 1st out of 3

Groups performing HR work were defined as staff performing work related to recruiting, hiring, and retention across FDA organizations (e.g., OTS, OHCM, CDER/CBER OM, CDER/CBER Program Offices).

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Exhibit S-18: Survey Results – New Hire Feedback on Hiring Process Time

Weeks Elapsed in Hiring Process
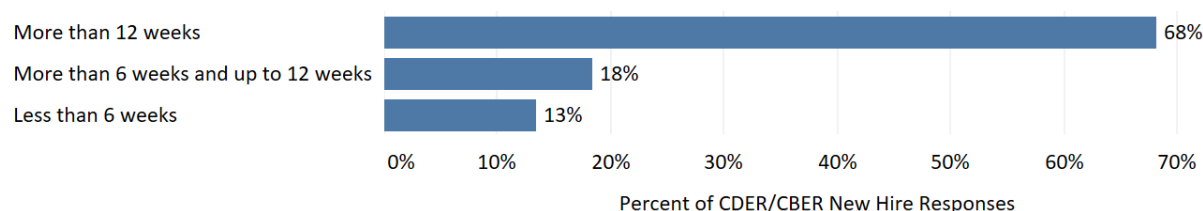
Respondents: Center (CDER and CBER New Hires only, n=529). Survey Item: "Approximately how many weeks elapsed from when you started the hiring process with FDA (e.g., submitted your application, resume, or curriculum vitae (CV)) to the time you received an initial (or tentative) job offer from FDA?" Response Option "I do not remember" was excluded from the analysis.

CDER/CBER New Hire Perceptions on Hiring Process Time
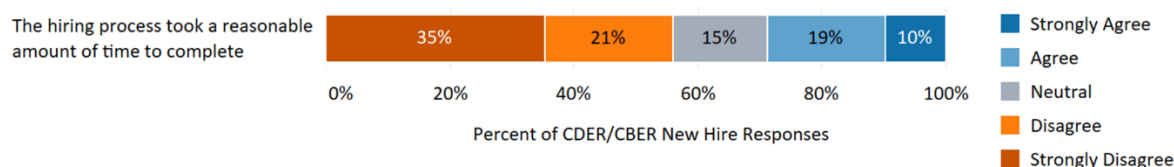
Respondents: Center (CDER and CBER New Hires only, n=504). Response scale: Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree, N/A. "N/A" responses were excluded from the analysis. Survey Item: "Based on your experiences since the start of FY20 (October 2019) with the recruiting and hiring processes, please rate your level of agreement with each statement below: The hiring process took a reasonable amount of time to complete."

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Exhibit S-19: Interview and Focus Group Themes – HR Systems, Data, and Reporting Needs

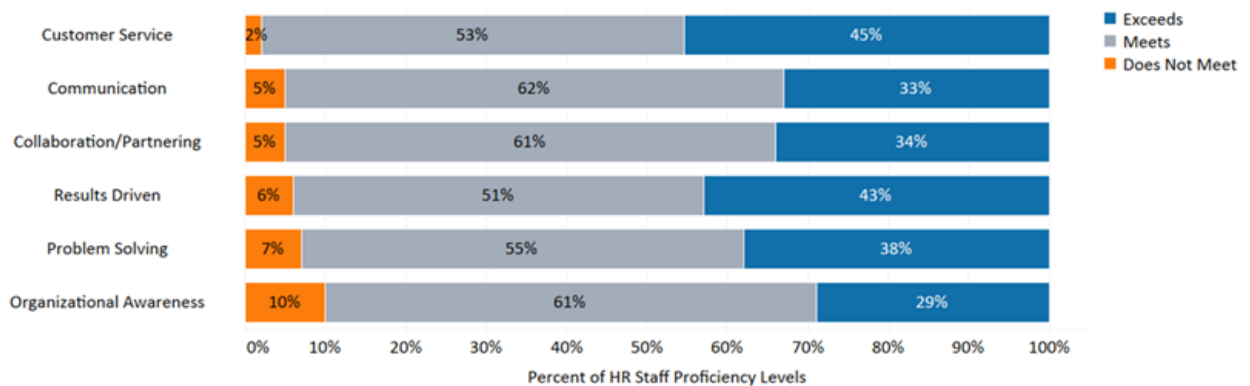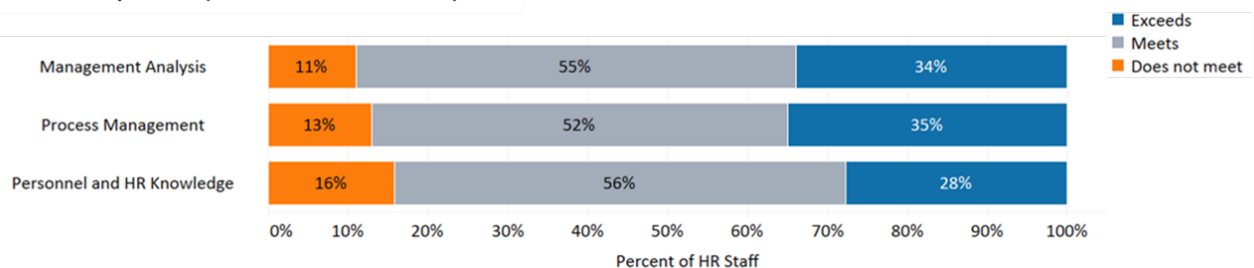| INTERVIEW/FOCUS GROUP TOPIC	THEME	RANK ORDER OF THEME
Current HR Systems Overall	There are many systems (e.g., USAStaffing, EHCM, BISS, HREPS, Center-specific systems) that track different data elements; staff have to use time-consuming manual processes to validate, clean, and combine the data needed for HR actions and reporting.	Int: 1st out of 4
	The current HR systems lack integration, but necessary change requires a stratified agency-wide approach and investment (e.g., buying or building a system) which is a complex challenge given the need to fulfill many different regulatory, procedural, and organizational requirements.	Int: 2nd out of 4
Data Capture, Maintenance, and Reporting	Systems vary across FDA—some effectively capture, maintain, and report relevant information for specific aspects of HR processes (but are not necessarily integrated with each other), and others rely on cumbersome, non-integrated manual processing.	Int: 1st out of 2
	FDA does not have the ability to capture, maintain, and report relevant information to support decision making.	Int: 2nd out of 2
Current HR Systems	Relying on multiple IT systems to complete HR actions leads to major problems; the lack of integration between systems, the associated manual processes result in duplicative efforts, process bottlenecks, decreased HR action transparency, increased system errors, and limited data reporting capabilities.	FG: 1st out of 4
	HR system inefficiencies are more related to processes and resources than limitations of the systems themselves; there is inadequate end-user input during system development, insufficient training, budget constraints, and a need for more defined processes.	FG: 2nd out of 4
	HHS/FDA should consider investing in existing HR systems by purchasing additional already developed capabilities (e.g., USA jobs payroll capability).	FG: 4th out of 4

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Exhibit S-20: Survey Results – HR Manager Ratings of HR Staff on Technical Competencies for OTS and OHCM and Center OM

Interim Survey Results

Core Competencies (for all staff supporting HR work)

Competency	Does Not Meet	Meets	Exceeds
Customer Service	2%	53%	45%
Communication	5%	62%	33%
Collaboration/Partnering	5%	61%	34%
Results Driven	6%	51%	43%
Problem Solving	7%	55%	38%
Organizational Awareness	10%	61%	29%

Percent of HR Staff Proficiency Levels

Technical Competencies (for CDER AOs and CBER PMs)

Competency	Does not meet	Meets	Exceeds
Management Analysis	11%	55%	34%
Process Management	13%	52%	35%
Personnel and HR Knowledge	16%	56%	28%

Percent of HR Staff

Final Survey Results

Core Competencies (for all staff supporting HR work)

Competency	Does Not Meet	Meets	Exceeds
Customer Service	2%	41%	57%
Communication	4%	52%	44%
Collaboration/Partnering	5%	45%	49%
Results Driven	6%	39%	55%
Problem Solving	8%	47%	46%
Organizational Awareness	11%	47%	42%

Percent of HR Staff Proficiency Levels

Technical Competencies (for CDER AOs and CBER PMs)

Competency	Does not meet	Meets	Exceeds
Process Management	0%	37%	63%
Personnel and HR Knowledge	9%	41%	50%
Management Analysis	16%	27%	57%

Percent of HR Staff

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Respondents:

- *Core Competencies Survey Item: HR Manager (Final: n=26, Interim: n=30-37) The number of HR staff being rated for each competency varies (Final: n=182-190, Interim: n=262-275). Survey item: "Consider all the Federal government employees who directly report to you and support recruiting, hiring, and retention of CDER or CBER employees. Please indicate the level of proficiency in each of the core competencies: Collaboration/Partnering, Communication, Customer Service, Organizational Awareness, Problem Solving, Results Driven" with a response scale of Does Not Meet, Meets, Exceeds, Does Not Need. "Does Not Need This Competency" responses were excluded from the analysis. Data shown reflects "Meets" and "Exceeds" responses only.*
- *Technical Competencies Survey Item: HR Manager (Final: n=15, Interim: n=17-18) The number of HR staff being rated for each competency varies (Final: n=88-94, Interim: n=164-179). Survey item: "Consider all the Federal government employees who directly report to you and support recruiting, hiring, and retention of CDER or CBER employees. Please indicate the number of staff who exhibit each level of proficiency in each of the technical competencies: Personnel and HR Knowledge, Management Analysis, Process Management," with a response scale of Does Not Meet, Meets, Exceeds, Does Not Need. "Does Not Need This Competency" responses were excluded from the analysis. Data shown reflects "Meets" and "Exceeds" responses only.*

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ATTACHMENT: EXHIBIT DESCRIPTIONS FOR ASSISTIVE TECHNOLOGY USERS

Exhibit 1: Assessment Design

There is a description of each assessment time period and a list the improvement activities included in each time period.

The Initial Assessment, published in November 2017, assessed the current state of the Hiring Process.

The Interim Assessment, published in June 2020, assessed the current state, progress, and trend analysis for the Recruiting Process, Hiring Process, and Retention Strategies.

Implementation of Improvement Activities included **in the Interim Assessment**:

- STRS Hiring Pilot including ATLAS (pivoted to have a different focus in the Final Assessment)
- Title21/CURES Act Hiring and Pay Authority (continued into the Final Assessment)
- Expansion of Direct Hire Authority (continued into the Final Assessment)
- Scientific Staffing Team (continued into the Final Assessment)
- OHR Reorganization into OTS and OHCM (completed and therefore not included in the list of improvement activities for the Final Assessment)

The Final Assessment, to be published in December 2021, is currently assessing the current state, progress, and trend analysis for the Recruiting Process, Hiring Process, and Retention Strategies.

Implementation of Improvement Activities included **in the Final Assessment**:

- STRS Team – CDER and CBER Support, Continued development of ATLAS (pivoted to have a different focus than it had in the Interim Assessment)
- Title 21/Cures Act Hiring and Pay Authority (continued from the Interim Assessment)
- Expansion of Direct Hire Authority (continued from Interim Assessment)
- Scientific Staffing Outreach Branch (continued from Interim Assessment)
- Temporary COVID-related Hiring Authorities (new for the Final Assessment)
- ATLAS, CDER-AOIS, and CBER PathHR (new for the Final Assessment)
- Classification Reform/Optimization (new for the Final Assessment)
- FDA Delegated Examining Unit (new for the Final Assessment)

Exhibit 2: Data Collection by the Numbers

3 Center and HR Workforce Surveys were conducted, this included:

- CDER/CBER Staff Survey with a 32% response rate
- HR Staff Survey with a 48% response rate
- HR Manager Survey with a 59% response rate

50+ FDA Data Files were collected

24 HR Stakeholder Focus Groups were conducted, this included:

- HR Stakeholders in OTS, OHCM, CDER, and CBER

- 131 Participants
- 1,186 Comments

135+ FDA Documents were collected

22 Leadership Interviews were conducted, this included:

- Leaders in OC/OO, CDER, and CBER
- 30 Participants
- 576 Comments

2 Data Calls were conducted, this included:

- HR Workload Data Call with HR Managers in OTS, OHCM, CDER, and CBER
- HR Servicing Ratio Benchmarking Request from external agencies

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Exhibit 3: Assessment Stakeholders: FDA HR Service Providers and Recipients

HR Service Providers include staff that make up the FDA HR Workforce who are aligned to three Centers including:

- OO: OTS and OHCM HR Specialists and other staff supporting official FDA HR work
- CBER: Human Capital Liaisons (OM) and Program Managers (Programs)

HR Service Recipients include staff in two Centers:

- CDER: Human Drug Review Program Staff
- CBER: Human Biologics Review Program Staff

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Exhibit 6: Integrated Talent Lifecycle

Seven organizational factors further influence the talent experience:

Recruiting and Workforce Management influences the Attract, Hire, and Develop talent experience phases

Onboarding influences the Hire and Develop talent experience phases

Direct Supervisor/Office Leadership influences the Hire and Develop talent experience phases

Career Progression influences the Hire, Develop, and Retain talent experience phases

Way of Working influences the Attract, Hire, Develop, and Retain talent experience phases

Employee Value Proposition influences the Attract, Hire, Develop, and Retain talent experience phases

Process and Systems Transformation influences the Attract, Hire, Develop, and Retain talent experience phases

Integrated Planning is woven throughout each phase of the talent lifecycle, with feedback loops so that information from one phase can help refine and improve the other phases.

Governance and Accountability provides a solid foundation that cuts across the entire talent lifecycle.

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Exhibit 7: Survey Results on the Extent of COVID-19 Impact on Recruiting, Hiring, and Retention

This bar charts shows CDER and CBER Staff, HR Managers, and HR Staff responses to survey items on the extent of COVID-19 impact on recruiting, hiring, and retention captured during final assessment in three separate stacked bars.

CDER/CBER Staff responses for Recruiting include: No Impact 15%, Little Impact 27%, Moderate Impact 28%, High Impact 30%; HR Managers responses for Recruiting include: No Impact 21%, Little Impact 18%, Moderate Impact 32%, High Impact 29%; HR Staff responses for Recruiting include: No Impact 39%, Little Impact 19%, Moderate Impact 19%, High Impact 23%. CDER/CBER Staff responses for Hiring include: No Impact 14%, Little Impact 26%, Moderate Impact 29%, High Impact 31%; HR Managers responses for Hiring include: No Impact 21%, Little Impact 21%, Moderate Impact 26%, High Impact 32%; HR Staff responses for Hiring include: No Impact 33%, Little Impact 24%, Moderate Impact 6%, High Impact 36%. CDER/CBER Staff responses for Retention include: No Impact 21%, Little Impact 29%, Moderate Impact 23%, High Impact 27%; HR Managers responses for Retention include: No Impact 21%, Little Impact 29%, Moderate Impact 23%, High Impact 27%; HR Staff responses for Retention include: No Impact 35%, Little Impact 26%, Moderate Impact 23%, High Impact 16%.

Exhibit 10: Conceptual Framework of Cultural Elements that Support a Customer-focused Mindset

The Customer-focused Mindset model shows seven cultural elements as progressively larger circles. The cultural elements, from smallest to largest include: Policies and SOPs, Tools and Forms, Practices, Principles, Values, and Mindset. As the circles get larger, the cultural elements represented by each circle become less visible in the organization but more impactful on Mission Success, Organizational Resilience, and Adaptability and Agility. Solutions are also associated with the first three cultural elements: Policies and SOPs, Tools and Forms, and Practices. The graphic also shows that, as the cultural elements progress, they support increasing levels of customer-focused mindset. The progressive complexity of customer-focused mindset include: customer compliance (aligned with Tools and Forms), customer service (aligned with Practices), customer support (aligned with Principles), customer care and customer success (both aligned with Values), and customer experience (aligned with Mindset).

Exhibit 11: Increased Satisfaction with Recruiting and Hiring due to OTS and OHCM Support **(bar chart)**

Specific responses from CDER/CBER Hiring Managers, HR Managers, and HR Staff are each presented separately for Interim and Final (Significant and Moderate responses only). CDER/CBER Hiring Managers: Interim responses include Significant 3%, Moderate 11%; Final responses include Significant 10%, Moderate 22%; HR Managers: Interim responses include Significant 16%, Moderate 20%; Final responses include Significant 43%, Moderate 32%. HR Staff. Interim responses include: Significant 18%, Moderate 39%; Final responses include: Significant 34%, Moderate 45%.

Combined Significant and Moderate responses show that satisfaction increased for all survey audiences from the Interim to the Final survey. **CDER/CBER Hiring Managers** show a percentage point increase of 18 from Interim to Final. **HR Managers** show a percentage point increase of 39 from Interim to Final. **HR Staff** show a percentage point increase of 22 from Interim to Final.

Exhibit 12: Increased Agreement that Hiring, Recruiting, and Retention Meet FDA's Needs **(3 bar charts)**

Results are presented in three separate bar charts, one each for survey responses on Recruiting, Hiring, and Retention.

Results about Recruiting. CDER/CBER Staff: Interim responses include Agree 13%, Strongly Agree 3%; Final responses include Agree 20%, Strongly Agree 4%. HR Managers: Interim responses include Agree 0%, Strongly Agree 0%; Final responses include Agree 29%, Strongly Agree 4%. HR Staff: Interim responses include Agree 22%, Strongly Agree 5%; Final responses include Agree 51%, Strongly Agree 8%.

Agreement that the recruiting process meets the needs of the increased for all survey audiences from the Interim to the Final survey. **CDER/CBER Staff** agreement increased by 8 percentage points from Interim to Final; **HR Managers** agreement increased by 33 percentage points from Interim to Final; **HR Staff** agreement increased by 32 percentage points from Interim to Final

Results about Hiring. CDER/CBER Staff: Interim responses include Agree 9%, Strongly Agree 3%; Final responses include Agree 15%, Strongly Agree 4%. HR Managers: Interim responses include Agree 0%, Strongly Agree 0%; Final responses include Agree 27%, Strongly Agree 3%. HR Staff: Interim responses include Agree 18%, Strongly Agree 5%; Final responses include Agree 46%, Strongly Agree 8%.

Agreement that the hiring process meets the needs of the Agency (Agree and Strongly Agree responses combined) increased for all survey audiences from the Interim to the Final survey. **CDER/CBER Staff** agreement increased by 7 percentage points from Interim to Final. **HR Managers** agreement increased by 30 percentage points from Interim to Final. **HR Staff** agreement increased by 31 percentage points from Interim to Final.

Results for Retention. CDER/CBER Staff: Interim responses include Agree 13%, Strongly Agree 3%; Final responses include Agree 20%, Strongly Agree 0%. HR Managers: Interim responses include Agree 2%, Strongly Agree 0%; Final responses include Agree 23%, Strongly Agree 0%. HR Staff: Interim responses include Agree 15%, Strongly Agree 5%; Final responses include Agree 45%, Strongly Agree 5%.

Agreement that the retention strategies meet the needs of the Agency (Agree and Strongly Agree responses combined) increased for all survey audiences from the Interim to the Final survey. **CDER/CBER Staff** agreement increased by 4 percentage points from Interim to Final. **HR Managers** agreement increased by 21 percentage points from Interim to Final. **HR Staff** agreement increased by 30 percentage points from Interim to Final.

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Exhibit 13: Stakeholder Needs for Additional Resources to Make HR Processes More Successful

Responses are presented for the CDER/CBER Hiring Managers' top five resources, including responses from CDER/CBER Hiring Managers, HR Staff, and HR Managers.

More Direct engagement with OTS/OHCM: CDER/CBER Hiring Manager responses 89%, HR Staff responses 45%; HR Manager responses 50%.

Process guidance (e.g., process maps, roles, timelines): CDER/CBER Hiring Manager responses 77%, HR Staff responses 83%; HR Manager responses 86%.

Checklists and job aids for the hiring process: CDER/CBER Hiring Manager responses 73%, HR Staff responses 66%; HR Manager responses 71%.

More direct engagement with the HC Liaison in your Center's OM: CDER/CBER Hiring Manager responses 71%, HR Staff responses 21%; HR Manager responses 32%.

Reliable IT system that shows the status of hiring actions: CDER/CBER Hiring Manager responses 66%, HR Staff responses 48%; HR Manager responses 50%

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Exhibit 16: SSOB External Strategic Partnerships Growth from FY18 to FY21 Q3

The cumulative total of SSOB external strategic partnerships are presented for FY18, FY19, FY20, and FY21 Q3. Academic Partnerships: 26 in FY18, 53 in FY19, 71 in FY20, 90 in FY21 Q3; Government Partnerships: 16 in FY18, 21 in FY19, 22 in FY20, 24 in FY21 Q3; Association Partnerships: 9 in FY18, 14 in FY19, 19 in FY20, 19 in FY21 Q3; Organization Partnerships: 0 in FY18, 2 in FY19, 6 in FY20, 10 in FY21 Q3; Other Partnerships: 3 in FY18, 6 in FY19, 6 in FY20, 6 in FY21 Q3.

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Exhibit 17: OTS Classification of CDER and CBER Position Descriptions from FY20 to FY21 Q3

These bar charts show the average time (in business days) to classify CDER and CBER position descriptions for FY20 and FY21 (Q1-Q3). Specific responses for FY20 include: 35 business days for CDER, 34 business days for CBER; responses for FY21 Q1-Q3 include: 36 business days for CDER, 39 business days for CBER. This graphic shows the FY20 KPI is 22 business days and 20 business days for FY21 KPI.

In FY20, CDER classified 822 PDs, meeting 48% of the FY20 KPI. CBER classified 150 PDs, meeting 49% of the FY20 KPI. The FY20 target is 75%

In FY21 Q1-Q3, CDER classified 534 PDs, meeting 45% of the FY21 KPI. CBER classified 109 PDs, meeting 36% of the FY21 KPI. The FY21 target is 80%

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Exhibit 18: Number of CDER and CBER Hires by Hiring and Pay Authority FY20 to FY21 Q3

These bar charts show the count of hires in FY20 and FY21 Q1-3 for Title 38, Title 21, Title 5, Title 42, Senior Executive Service, presented separately for CDER and CBER. CDER: Title 38 FY20 56, FY21 47; Title 21 FY20 200, FY21 309; Title 5 FY20 181, FY21 123; Title 42 FY20 88, FY21 52 Senior Executive Service FY20 1, FY21 0. CBER: Title 38 FY20 16, FY21 14; Title 21 FY20 2, FY21 2; Title 5 FY20 62, FY21 69; Title 42 FY20 26, FY21 15; Senior Executive Service FY20 0, FY21 0.

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Exhibit 20: Use of Title 21 in CDER and CBER from FY18 to FY21 Q3

These bar charts show the count of Title 21 Hires categorized as Conversion, Internal Hire, and External Hire in FY18 through FY21 Q3, presented separately for CDER and CBER. CDER: External Hire: FY18 0, FY19 10, FY20 97, FY21 Q3 102; Internal Hire: FY18 2, FY19 7, FY20 103, FY21 Q3 207; Conversion: FY18 1, FY19 21, FY20 15, FY21 Q3 43. The second bar chart shows CBER data as follows: External Hire: FY18 0, FY19 10, FY20 1, FY21 Q3 2; Internal Hire: FY18 2, FY19 7, FY20 1, FY21 Q3 0; Conversion: FY18 1, FY19 2, FY20 6, FY21 Q3 9.

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Exhibit 22: Increased Satisfaction with Recruiting and Hiring due to Title 21 and Direct Hire

These bar charts show Interim and Final survey results on the level of increased satisfaction with Recruiting and Hiring (Significant and Moderate responses only) due to Title 21 and Expanded Direct Hire Authority of 2018. Specific responses from CDER/CBER Hiring Managers, HR Managers, and HR Staff are each presented separately for Interim to Final in two separate stacked bar charts for Title 21 and Direct Hire of 2018.

The first bar chart shows survey results for Title 21. CDER/CBER Hiring Managers: Interim responses include Significant 11%, Moderate 20%; Final responses include Significant 19%, Moderate 23%. HR Managers: Interim responses include Significant 24%, Moderate 38%; Final responses include Significant 48%, Moderate 28%. HR Staff: Interim responses include Significant 22%, Moderate 33%; Final responses include: Significant 37%, Moderate 44%.

Combined Significant and Moderate responses show that satisfaction increased for all survey audiences from the Interim to the Final Survey for Title 21. **CDER/CBER Hiring Managers** show a percentage point increase of 11 from Interim to Final. **HR Managers** show a percentage point increase of 14 from Interim to Final. **HR Staff** show a percentage point increase of 26 from Interim to Final.

The second bar chart shows survey results for Expanded Direct Hire Authority of 2018. CDER/CBER Hiring Managers: Interim responses include Significant 8%, Moderate 14%; Final responses include Significant 13%, Moderate 18%. HR Managers: Interim responses include Significant 12%, Moderate 35%; Final responses include Significant 47%, Moderate 26%. HR Staff: Interim responses include Significant 10%, Moderate 39%; Final responses include Significant 24%, Moderate 56%.

Combined Significant and Moderate responses show that satisfaction increased for all survey audiences from the Interim to the Final Survey for Expanded Direct Hire Authority of 2018. **CDER/CBER Hiring Managers** show a percentage point increase of 9 from Interim to Final. **HR Managers** show a percentage point increase of 26 from Interim to Final. **HR Staff** show a percentage point increase of 31 from Interim to Final.

Title 21 Respondents: HR Staff (Final: n=73, Interim: n=90); HR Managers (Final n=33, Interim: n=47); Center (CDER and CBER Hiring Managers only; Final: n=446, Interim: n=337). Direct Hire Respondents: HR Staff (Final: n=74, Interim: n=91); HR Managers (Final n=33, Interim: n=46); Center (CDER and CBER Hiring Managers only; Final: n=436, Interim: n=339).

- Final Assessment Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Use of special hiring authorities through Title 21 (21st Century Cures Act)/Expanded Direct Hire Authority of 2018 (inclusion of additional scientific occupational series) has improved your overall satisfaction with FDA's recruiting and hiring processes."
- Interim Assessment Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to Access to special hiring authorities through the 21st Century Cures Act/Expanded Direct Hire Authority options (e.g., inclusion of additional scientific occupational series) in terms of your overall satisfaction."
- Response scale: None, Little, Moderate, Significant, Don't Know. "Don't Know" responses were excluded from the analysis. Data shown reflects "Moderate" and "Significant" responses only. For all response data see Supplement Exhibit S-16.

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Exhibit 25: FDA Certificate Log—Number of Qualified and Selected Applications

The first bar chart shows the total number of Referrals, Selections, and Hires from Certificates from FY20 – FY21 Q3, presented separately for CDER and CBER. CDER: Referrals 12,209, Selections 891, Hires 390. CBER: Referrals: 9,996, Selections 487, Hires 161.

The second bar chart shows the total number of Selections from VAs from FY20 – FY21 Q3, presented separately for CDER and CBER. CDER: Total VAs 349, VAs with Selections 70. CBER: Total VAs 141, VAs with Selections 52.

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Exhibit 27: Conceptual View of FDA HR Data Integration

This graphic shows a conceptual view of FDA's current state of HR data integration for recruiting, hiring, and retention. The graphic depicts the phases of the talent lifecycle, as well as the systems and manual data collection efforts that are used during each phase. The first phase is Workforce Planning, which uses eClass, CBER PathHR, and CDER-AOIS systems, as well as manual data collection efforts around strategic recruiting partnerships. The next phase is Recruiting and Outreach, which uses eClass and EHCM systems, along with manual data collection for recruiting and outreach tracking, and HR support POCs. The following phase is the

Application and Hiring Workflow, which is supported by ATLAS, USA Staffing, eClass, and EHCM systems; it also utilizes manual processes for collecting data for interviews and scheduling, HR workload tracking, and hiring process reporting. FDA currently uses Excel and SharePoint to manually track until ATLAS Reporting is fully functional. The next phase in the lifecycle is Onboarding, which uses eMedCred, eArrive, and EHCM systems and relies on manual KPI performance tracking and customer feedback data. The next phase of Employee Experience and Performance uses the following systems: BIIS, EHCM, and ePortal (which is branded as "One HR" and further integrates source data from an eSolutions suite of applications that include: eMedCred, ePMAP, eIncentive, and eTelework). It also relies on manual attrition risk assessments and succession plans. Lastly, the Offboarding phase uses iBAPS, EHCM, and eDepart systems, and relies on manual exit survey data. Boxes with a green background indicate that data from the system is currently integrated, including ATLAS, USA Staffing, and eClass. Boxes with a teal background indicate that data from the system will be integrated by March 2022; these include: EHCM, ATLAS Hiring Process Reporting, BIIS, and ePortal (branded as "OneHR"). ePortal further integrates source data from an eSolutions suite of applications that include: eMedCred, ePMAP, eIncentive, and eTelework). Boxes with a navy-blue background indicate that data integration is planned but is pending approval and funding; they include: CDER-AOIS, CBER PathHR, eArrive, and eDepart. And finally, boxes with a yellow background indicate that data integration capabilities exist but there are no current plans for integration; they include: recruiting and outreach trackers/ spreadsheets, strategic recruiting partnerships, HR support POCs, interview and scheduling data, HR workload tracking, KPI performance trackers, customer feedback data, attrition risk assessments and succession plans, exit survey data, and data housed in the iBAPS system.

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Exhibit 31: HR Manager Survey Responses on HR Staff Capacity

HR Managers responses to three survey questions related to HR Staff Capacity. "On average, my HR staff can effectively accomplish their workload within normal working hours": Strongly Disagree 10%, Disagree 27%, Neutral 33%, Agree 27%, Strongly Agree 3%. "There is an effective process by which recruiting, hiring, and retention work is distributed": Strongly Disagree 16%, Disagree 25%, Neutral 28%, Agree 22%, Strongly Agree 9%. "HR Staff have access to sufficient resources (e.g., HR IT systems, budget, job aids) to manage their work": Strongly Disagree 9%, Disagree 47%, Neutral 28%, Agree 16%, Strongly Agree 0%.

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Exhibit 33: Time Spent on HR work in OTS/OHCM, CDER, and CBER

OTS spent 62 percent of time on HR work for CDER and/or CBER and 38 percent of time spent on Other Work. The breakdown of OTS work time by function includes: Job Analysis 11%, Classification 7%, Recruiting and Outreach 6%, Interview and Selection 13%, Onboarding 6%, Retention 0%, Other Recruiting/Hiring/ Retention work for CDER/CBER 11%, Other HR Work for CDER/CBER 7%; Other Non-HR work 5%, Support to other Centers 33%.

OHCM spent 39 percent of time on HR work for CDER and/or CBER and 61 percent of time spent on Other Work. The breakdown of OHCM work time by function includes: Job Analysis 0%, Classification 0%, Recruiting and Outreach 0%, Interview and Selection 0%, Onboarding 2%, Retention 25%, Other Recruiting/Hiring/ Retention work for CDER/CBER 2%, Other HR Work for CDER/CBER 10%; Other Non-HR work 17%, Support to other Centers 44%.

CDER HR Staff spent 75 percent of time on HR work for CDER and/or CBER and 25 percent of time spent on Other Work. The breakdown of CDER HR Staff work time by category includes: Recruiting and Hiring 36%, Staffing 27%, Other HR Work 12%; Other Non-HR work 25%.

CBER HR Staff spent 70 percent of time on HR work for CDER and/or CBER and 30 percent of time spent on Other Work. The breakdown of OHCM work time by function includes: Recruiting and Hiring 35%, Staffing 19%, Other HR Work 15%, Other Non-HR work 30%.

Exhibit 35: HR Manager Ratings on Percentage of Staff Performing HR Work in OTS, OHCM, and Center OM that Meet or Exceed Technical Competencies

This bar chart shows HR Manager ratings on the proficiency of staff performing HR work in OTS, OHCM, and Center OM, showing the combined percentage of those who meet or exceed technical competencies. Results are presented separately for Interim and Final survey results. Process Management Interim 85%, Final 98%; Federal HR Technical Knowledge Interim 86%, Final 96%; Recruitment Interim 74%, Final 92%; Classification Interim 56%, Final 89%.

The increased percentage points from the Interim to the Final survey include: **Process Management**, **Federal HR Technical Knowledge** 18, **Recruitment** 33, **Classification** 13.

Exhibit S-4: Survey Results – Reasons CDER and CBER Staff Would Leave Center and Other Places They Consider Working

Reasons CDER/CBER Staff Would Leave Current Center

This bar chart shows the CDER/CBER Staff Survey results on the reasons why CDER/CBER staff would leave their current Center. CDER/CBER Staff responses include: career advancement 55%, higher compensation 54%, retirement 35%, career growth 32%, a better job fit 31%, increased opportunities for telework 28%, more manageable workload 27%, better work-life balance 26%, more supportive direct manager 16%, geographic location 14%, shorter commute time 13%, culture more aligned with my personal values 11%, desire to leave the Federal government 5%.

Respondents: CDER and CBER staff (n=2251). Survey Item: "For which of the following reasons would you consider leaving your current Center? Please select all that apply." This item type is Select All That Apply, so the response numbers count all selections provided by survey participants.

Sources of Workforce Competition

This graphic shows how often CDER/CBER staff have considered looking for a new job with specific organization types. Another Office within FDA Center: Never 41%, Occasionally 17%, Sometimes 26%, Frequently 16%; Another FDA Center: Never 47%, Occasionally 17%, Sometimes 22%, Frequently 14%; Another Sub-Office within Super Office: Never 49%, Occasionally 18%, Sometimes 21%, Frequently 11%; A Pharmaceutical firm: Never 53%, Occasionally 17%, Sometimes 19%, Frequently 11%; Another Government Agency: Never 53%, Occasionally 19%, Sometimes 19%, Frequently 10%; Other private industry: Never 59%, Occasionally 17%, Sometimes 15%, Frequently 9%; Nonprofit organization: Never 68%, Occasionally 16%, Sometimes 11%, Frequently 5%; Academia: Never 72%, Occasionally 15%, Sometimes 9%, Frequently 4%; Clinical Practice: Never 78%, Occasionally 13%, Sometimes 7%, Frequently 3%.

Respondents: CDER and CBER staff (n=1833-2274). Survey item: "In the past six months, how often have you considered looking for another position in:" A "Not Applicable" response option was also provided; those responses are not included in this analysis.

Exhibit S-8: Survey Results – Extent of Improved Satisfaction with Recruiting and Hiring due to OTS and OHCM Support

This graphic shows survey results on the extent of improved satisfaction with recruiting and hiring due to OTS and OHCM support. Responses for CDER/CBER Hiring Managers, HR Managers, and HR Staff are presented separately. CDER/CBER Hiring Managers responses at Interim include: None 48%, Little 38%, Moderate 11%, Significant 3%; CDER/CBER Hiring Manager responses at Final include: None 39%, Little 30%, Moderate 22%, Significant 10%. HR Manager responses at Interim include: None 25%, Little 39%, Moderate 20%, Significant 16%; HR Manager responses at Final include: None 4%, Little 21%, Moderate 32%, Significant 43%. HR Staff responses at Interim include: None 23%, Little 19%, Moderate 39%, Significant 18%; HR Staff responses at Final include: None 3%, Little 18%, Moderate 45%, Significant 34%.

Respondents: HR Staff (n=73); HR Managers (n=32); Center (CDER and CBER Hiring Managers only n=449,). Response scale: None, Little, Moderate, Significant, and Don't know. "Don't Know" responses were excluded from the analysis. Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Support provided by the Agency's HR Organization (OTS/OHCM) to the Centers has improved your overall satisfaction with FDA's recruiting and hiring processes."

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Exhibit S-9: Survey Results – Extent of Agreement that Recruiting, Hiring, and Retention Meets FDA Needs

Interim Survey Results. The first bar chart shows Interim survey responses about whether Recruiting, Hiring, and Retention meet the Agency's needs. Specific responses are provided separately for each function by each survey audience. Recruiting: CDER/CBER Staff responses Strongly Disagree 28%, Disagree 30%, Neutral 26%, Agree 13%, Strongly Agree 3%; HR Manager responses Strongly Disagree 25%, Disagree 27%, Neutral 48%, Agree 0%, Strongly Agree 0%; HR Staff Strongly Disagree 10%, Disagree 15%, Neutral 47%, Agree 22%, Strongly Agree 5%. Hiring: CDER/CBER Staff responses Strongly Disagree 37%, Disagree 32%, Neutral 20%, Agree 9%, Strongly Agree 2%; HR Manager responses Strongly Disagree 26%, Disagree 35%, Neutral 40%, Agree 0%, Strongly Agree 0%; HR Staff responses Strongly Disagree 14%, Disagree 15%, Neutral 47%, Agree 18%, Strongly Agree 5%. Retention: CDER/CBER Staff responses Strongly Disagree 29%, Disagree 31%, Neutral 24%, Agree 13%, Strongly Agree 3%; HR Manager responses Strongly Disagree 21%, Disagree 21%, Neutral 56%, Agree 0%, Strongly Agree 2%; HR Staff responses Strongly Disagree 9%, Disagree 21%, Neutral 49%, Agree 15%, Strongly Agree 5%.

Final Survey Results. The second bar chart shows Final survey responses about whether Recruiting, Hiring, and Retention meet the Agency's needs. Specific responses are provided separately for each function by each survey audience. Recruiting: CDER/CBER Staff responses Strongly Disagree 21%, Disagree 26%, Neutral 28%, Agree 20%, Strongly Agree 4%; HR Manager responses Strongly Disagree 0%, Disagree 29%, Neutral 39%, Agree 29%, Strongly Agree 4%; HR Staff responses Strongly Disagree 3%, Disagree 16%, Neutral 22%, Agree 51%, Strongly Agree 8%. Hiring: CDER/CBER Staff responses Strongly Disagree 29%, Disagree 27%, Neutral 25%, Agree 15%, Strongly Agree 4%; HR Manager responses Strongly Disagree 10%, Disagree 27%, Neutral 33%, Agree 27%, Strongly Agree 3%; HR Staff responses Strongly Disagree 5%, Disagree 13%, Neutral 29%, Agree 46%, Strongly Agree 8%. Retention: CDER/CBER Staff responses Strongly Disagree 26%, Disagree 28%, Neutral 27%, Agree 20%, Strongly Agree 0%; HR Manager responses Strongly Disagree 3%, Disagree 27%, Neutral 47%, Agree 23%, Strongly Agree 0%; HR Staff responses Strongly Disagree 3%, Disagree 13%, Neutral 34%, Agree 45%, Strongly Agree 5%.

Respondents: CDER and CBER staff (Final: n=2315, Interim: n=1805); HR managers (Final: n=35, Interim: n=52); HR Staff (Final: n=77, Interim: n=120). Survey item: "Survey items: "Overall, I believe the FDA's current recruiting process for human drug and biologics review program staff meets the needs of the Agency"; "Overall, I believe the FDA's current hiring process for human drug and biologics review program staff meets the needs of the Agency"; and "Overall, I believe the FDA's current retention strategies for human drug and

biologics review program staff meets the needs of the Agency," with a response scale of Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree. Chart reflects" Strongly Agree" and "Agree" responses only.

Exhibit S-16: Survey Results – Satisfaction with Recruiting and Hiring due to Title 21 and Direct Hire

The first bar chart shows Interim survey results on the extent of satisfaction with recruiting and hiring processes has improved due to Direct Hire Authority, with results from CDER/CBER Hiring Managers, HR Managers, and HR Staff presented separately. CDER/CBER Hiring Managers: Interim responses include None 44%, Little 34%, Moderate 14%, Significant 8%; Final responses include None 43%, Little 25%, Moderate 18%, Significant 13%. HR Managers: Interim responses include None 26%, Little 26%, Moderate 35%, Significant 12%; Final responses include None 5%, Little 21%, Moderate 26%, Significant 47%. HR Staff: Interim responses include None 16%, Little 35%, Moderate 39%, Significant 10%; Final responses include None 6%, Little 14%, Moderate 56%, Significant 24%.

The second bar chart shows Final survey results on the extent of satisfaction with recruiting and hiring processes has improved due to Title 21. Responses are presented for CDER/CBER Hiring Managers, HR Managers, and HR Staff. CDER/CBER Hiring Managers: Interim responses include None 42%, Little 28%, Moderate 20%, Significant 11%; Final responses include None 31%, Little 28%, Moderate 23%, Significant 19%. HR Managers: Interim responses include None 21%, Little 18%, Moderate 38%, Significant 24%; Final responses include None 4%, Little 20%, Moderate 28%, Significant 48%. HR Staff: Interim responses include None 27%, Little 18%, Moderate 33%, Significant 22%; Final responses include None 4%, Little 15%, Moderate 44%, Significant 37%.

Title 21 Respondents: HR Staff (n=73); HR Managers (n=33); Center (CDER and CBER Hiring Managers only, n=446). Direct Hire Respondents: HR Staff (n=74); HR Managers (n=33); Center (CDER and CBER Hiring Managers only n=436). Survey item: "Thinking about your experiences since the start of FY20 (October 2019), please indicate the extent to which Use of special hiring authorities through Title 21 (21st Century Cures Act)/Expanded Direct Hire Authority of 2018 (inclusion of additional scientific occupational series) has improved your overall satisfaction with FDA's recruiting and hiring processes." Response scale: None, Little, Moderate, Significant, Don't Know. "Don't Know" responses were excluded from the analysis.
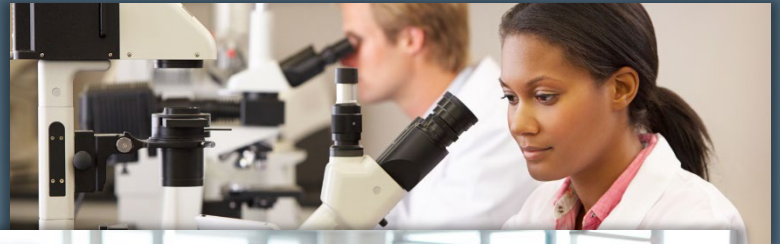
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FDA Final Hiring and Retention Assessment

Report Addendum

CONTRACT NO. HHSF223201510027B

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April 12, 2022

1. INTRODUCTION

Background

The Food and Drug Administration (FDA) is authorized to collect user fees from sponsors and applicants to help expedite the development, review, and approval processes of human drugs and biologics. As part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II commitments, FDA committed to a series of three assessments of the efficiency and effectiveness of its recruiting, hiring, and retention of human drug and biologics review program staff (i.e., all staff within the Center for Drug Evaluation and Research [CDER] and the Center for Biologics Evaluation and Research [CBER]).[1] FDA contracted with Booz Allen—as a third-party evaluator—to conduct the Interim and Final Assessments. Accordingly, Booz Allen delivered a report on December 10, 2021 that summarized the findings, conclusions, and recommendations of the assessment.

Stakeholders for the Assessment

FDA's official Human Resources (HR) organization includes HR staff aligned to the Office of Talent Solutions (OTS) and the Office of Human Capital Management (OHCM) within FDA's Office of Operations (OO). In addition, Center-based staff provide HR support, including Human Capital Liaisons within each Centers' Office of Management (OM), and staff in the Centers' program offices who perform administrative HR duties in addition to other program support. Collectively, these staff comprise FDA's HR workforce.

2. PURPOSE OF THE ADDENDUM AND EXPLANATION OF CHANGES

Part of the assessment involved identifying the staff performing this HR support across organizations and specifying the HR workload of these staff members. Because the Center staff are not consistently identifiable as having HR responsibilities in a system of record, Booz Allen conducted an HR workload data call in March 2021. In this manual data call effort, managers of HR staff in OTS, OHCM, CDER OM, and CBER OM reported the headcount of their staff who perform HR work and estimated their workload allocation for different HR functions and other non-HR work. Our approach included providing specific definitions of HR functions, example activities, and one-on-one follow-up with each respondent to clarify the data call instructions and understand the information they provided on headcount of and workload distribution of staff performing HR activities.

Following publication of the Final Assessment Report on December 10, 2021, CBER inquired about potentially inconsistent results from the HR workload data call. Upon review and further validation with CDER and CBER, Booz Allen recognized the data call yielded non-comparable numbers for the CDER and CBER HR workforce. For example, CBER data call participants included staff in their program offices who perform aspects of administrative HR support, while CDER data call participants excluded their approximately 180 program office staff given that the program provides administrative support on a wide variety of functional activities including non-human capital support to hiring managers.

In March 2022, Booz Allen worked with CDER and CBER HR leadership to recalculate the tally using comparable data populations, while maintaining consistent use of original data call criteria. Recognizing that data about Center program staff are not comparable for CDER and CBER, those numbers were removed from the HR workforce totals. The results now present the more reliable and comparable totals of the HR workforce in each Center's Offices of Management. Estimated numbers of program staff performing HR activities in CDER and CBER are referenced separately; however, they are not incorporated into the tallied results related to HR workload.

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[1] Sources: FDA Reauthorization Act of 2017 (FDARA), FDA.gov; PDUFA VI Commitment Letter FY2018 to FY2022, FDA.gov; BsUFA II Commitment Letter, FDA.gov.

In addition, to clarify the size of the Center-based HR workforce, this addendum shows the proportion of CBER and CDER OM staff time dedicated to HR work. These figures, shown as Full Time Equivalent (FTE), represent the *portion of staff time* spent on HR work rather than the *numbers of staff* who spend time on HR work. For example, if two staff members each spend half their time on HR work, that would count as one FTE. This validation exercise underscores the difficulties in estimating the amount of time staff in the Centers' program offices spend working on administrative HR support, because it is often a small part of their overall responsibilities. See Section 3 of this addendum for these updated and clarified results.

As referenced in the Final Report, accurate accounting of both the HR workload and workforce is essential to improving process efficiency and effectiveness and can also support initiatives such as predictive modeling of workload and more sophisticated methods of assigning and performing work. In addition, the ability to track HR workforce and workload across FDA would help the Agency pinpoint and calibrate the appropriate HR workforce size relative to the workload, adjust to changes in workload demand (e.g., work surges, seasonal variation), and identify the capabilities needed for the HR workforce to effectively carry out the work.

3. REVISIONS TO REPORT CONTENT

The revised content in this section replaces in full the current report Finding F5.2.

Findings and Conclusions: HR Staff Capability and Capacity (Report Section 2.5)

A substantial number of CDER and CBER staff provide HR support in addition to the HR Specialist workforce, and their roles are not clearly defined and distinguished from OTS and OHCM staff. (Report Finding F5.2)

OTS and OHCM serve as the Agency's official HR organization. Essentially, OTS is responsible for recruiting and hiring staff, and OHCM works to support and retain the onboard workforce. CDER and CBER also have dedicated staff who perform HR activities—aligned within the Centers' Office of Management (OMs) and the program offices. Clearly defining the nature and volume of HR work that these different groups of staff perform and how these groups work together is essential to fully understanding both the opportunities to enhance quality and efficiency and the risk of duplication and disorganization.

Because of the FDA-wide HR servicing ratio's specificity (i.e., counting only the HR Specialists), it does not account for staff performing HR work in CDER and CBER or the range of support provided by OTS and OHCM staff in occupational series other than 0201 and 0203. Results from an HR workload data call provided the number of CDER and CBER OM FTE dedicated to performing HR work. In addition, data from HR workload trackers and relative size of the Centers formed the basis to estimate the number of OTS and OHCM FTE dedicated to supporting CDER and CBER.

As presented in the revised Report Exhibit 32, results from those analyses showed that approximately 172 dedicated FTEs across OTS, OHCM, CDER OM, and CBER OM, perform HR work for the recruiting, hiring, and retention of human drug and biologics review program staff. These numbers include vacancies and contractors. The official HR staff in OTS and OHCM provide about three-fourths of this HR support (122 FTEs), and 50 FTEs are aligned to CDER and CBER OMs. This constitutes a considerable investment by CDER and CBER, as the total salaries for just the 50 FTEs in their Offices of Management represent an expenditure of approximately $6.3 million annually.[2] That figure does not account for any of the staff in the program offices who also spend a portion of their time on HR administrative support.

Estimated FTE HR Support to CDER and CBER by Organization (Report Exhibit 32)

| ORGANIZATION	FTE[1]
OTS	83
OHCM	39
CDER OM	36
CBER OM	14
Total	172

The staff within the CDER and CBER program offices who perform administrative and operational support work are referred to as Administrative Officers and Program Managers, respectively. Their work includes a

[2] Based on average salary of $127,297 for FDA employees; FedScope, September 2020 data cube (the most current quarter in the data cube as of 9/24/2021).

wide array of administrative tasks—from budget, contracts, and travel to facilities, space management, and human resources support. In CBER, there are an estimated 24 Program Managers, whose time dedicated to HR work equates to approximately 17 FTE. In CDER—which is a much larger Center than CBER—there are approximately 180 Administrative Officers who spend varying amounts of time on HR support activities. Therefore, it was difficult for CDER to estimate the time Administrative Officers spend on HR-support (to present as FTE) with confidence and accuracy. Establishing a reliable way to identify program staff who perform administrative HR work and track their workload will help FDA accurately monitor and manage the size of its entire HR workforce.

Although the Agency does not currently track HR workload at the functional level, managers of staff in OTS, OHCM, CDER OM, and CBER OM, who primarily perform HR work, responded to an HR workload data call to provide estimates of how much time their teams spend on different kinds of work. Managers of OTS and OHCM staff distributed work time across a more detailed list of HR activities, because these organizations support a wide range of specialized functions. Managers of staff in CDER and CBER distributed the work time for their staff against a broader set of HR-related work categories. These data call results show that in the breakdown of time spent supporting HR work for CDER and/or CBER, managers estimate that OTS staff dedicate 63 percent of their work time and OHCM staff spend 37 percent of their work time to supporting HR work for the two specific Centers. The comparatively low percent for OHCM staff likely results from the fact that they provide general support to the entire Agency, rather than dedicated support to specific Centers. For the Center OM staff identified as performing HR work, CDER OM staff spend 84 percent of their time on HR work and CBER OM staff spend 95 percent of their time on HR work (see revised Report Exhibit 33). Work classified as "other HR work" includes functions, such as HRIT, workplace flexibility programs (e.g., telework), and awards. Work classified as "other non-HR work" includes administrative, operational, or technical activities not related to HR support.

Time Spent on HR work in OTS/OHCM, CDER OM, and CBER OM[3] (Report Exhibit 33)

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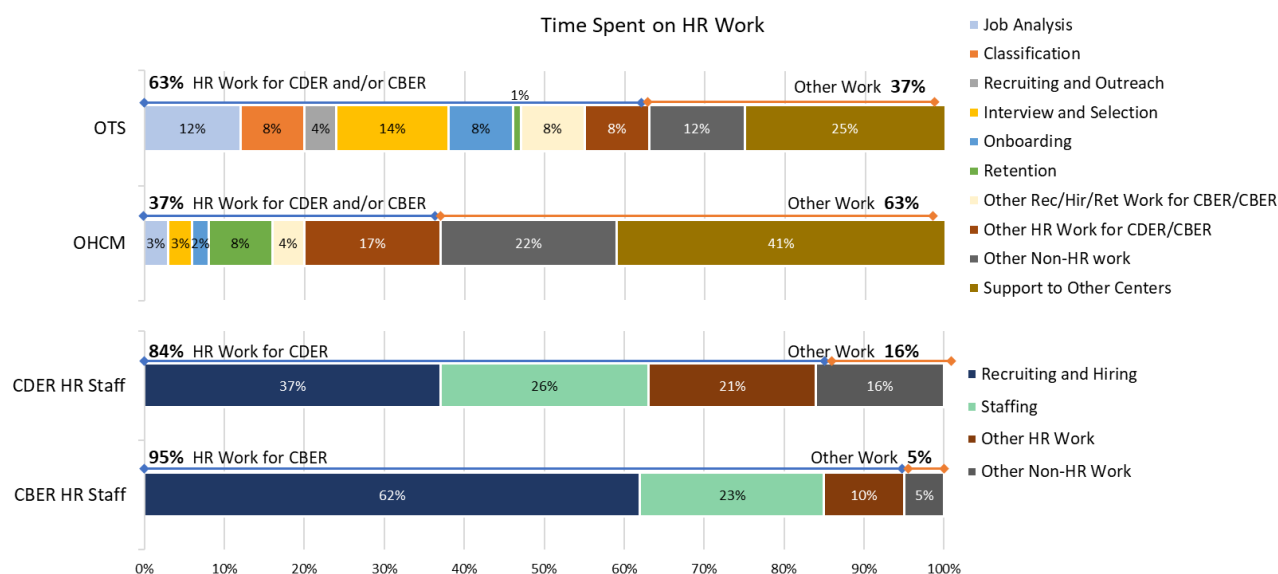
[3] Results presented for CDER and CBER have been updated from the Final Assessment Report. Staff outside of CBER OM and several CBER individuals who only performed "Other Non-HR Work" were removed from the tally. CDER OM also reallocated some workload that was originally tallied under "Other Non-HR Work" to the category of "Other HR Work". These updates changed the CBER workload breakdown to be 95 percent "HR Work" / 5 percent "Other Non-HR Work" (previously CBER's breakdown was 70 percent "HR Work" / 30 percent "Other Non-HR Work") and the CDER workload breakdown to be 84 percent "HR Work" / 16 percent "Other Non-HR Work" (previously CDER's breakdown was 75 percent "HR Work" / 25 percent "Other Non-HR Work").