PDUFA VII/BsUFA III
Hiring and Retention Assessment

Final Report

July 7, 2025

Eastern Research Group, Inc. (ERG)

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Background

Congress first enacted the Prescription Drug User Fee Act (PDUFA) in 1992 to ensure timely review of new drugs and biologics by the U.S. Food and Drug Administration (FDA). Since the initial five-year term, Congress has reauthorized PDUFA every five years, with the most recent reauthorization (PDUFA VII) occurring in 2022 for fiscal years 2023–2027. Similarly, Congress first enacted the Biosimilar User Fee Amendments (BsUFA) in 2007 and has reauthorized it every five years, with the most recent reauthorization (BsUFA III) occurring in 2022. For these reauthorizations, FDA held meetings with industry and other interested parties to develop performance goals, procedures, and commitments. During the meetings, industry and FDA observed that the efficiency and effectiveness of FDA Human Resources (HR) and Human Capital (HC) operations are critical to successful PDUFA VII and BsUFA III performance. Several PDUFA VII and BsUFA III commitments relate to hiring and retaining enough technical and scientific experts to conduct reviews of product applications.

Previously, independent contractors conducted assessments of FDA's HR and HC operations. For PDUFA VI, the final assessment published in 2021[1] found that FDA improved its recruiting, hiring, and retention operations since the initial assessment in 2017[2] and made progress in several other areas. The assessment outlined ten recommendations for further improvement.

For PDUFA VII and BsUFA III, FDA committed to an independent assessment that builds on the findings of previous assessments, with a focus on changes that have improved FDA's hiring and retention outcomes and challenges that remain. FDA contracted Eastern Research Group, Inc. (ERG) to conduct the assessment. Key objectives of the assessment are to:

- Document and analyze any incremental enhancements/changes to FDA human drug review program hiring and retention since the final PDUFA VI assessment.
- Capture the current status of FDA recruiting, hiring, pre-employment onboarding, and retention and the effectiveness of current practices.
- Assess hiring process transparency from the perspective of interested parties within FDA.

Conclusions, Findings, and Recommendations

To address the key objectives for this assessment of FDA HR/HC operations under PDUFA VII and BsUFA III, ERG established a set of evaluation questions and metrics to guide data collection and analysis. This enabled us to generate meaningful, evidence-based conclusions as well as findings and recommendations for FDA's recruitment, hiring, pre-employment onboarding, and retention programs (see tables below).

ERG developed this assessment report using data collected and analyzed from October 2, 2023 to January 31, 2025. Changes to federal hiring, work, and staffing policies—and their effects on FDA's hiring and retention of staff—after January 31, 2025 are not accounted for in the conclusions, findings, and recommendations of this report.

[1] Final Assessment of FDA Hiring and Retention Report. *https://www.fda.gov/media/154873/download*
[2] Initial Assessment of FDA Hiring and Retention Report. *https://www.fda.gov/media/108866/download*

Note: Some assessment questions refer to the "last assessment" of FDA's HR/HC program. As noted above, FDA published the final report for that PDUFA VI HR/HC assessment in 2021.[3]

FDA HR/HC Overall

Table ES-1. Findings and recommendations for FDA HR/HC overall

No.	Finding	Recommendation
1-A	Overall, FDA's recruitment, hiring, pre-employment onboarding, and retention practices have improved since the last assessment. Processes are more effective and efficient, and FDA is generally able to attract and retain qualified staff.	None.
1-B	Due to its streamlined processes and flexibilities, use of the Title 21 (Cures Act) hiring authority is attractive to FDA staff involved in hiring, external candidates, and internal staff who convert to a Title 21 position.	None.
1-C	Communication and coordination across Offices and Centers continue to be a pain point for FDA staff involved in recruitment, hiring, pre-employment onboarding, and retention.	Focus on improving cross Office and Center communication and coordination in three areas: • Clarify roles and responsibilities, delineate handoff procedures, and establish clear touchpoints for processes that require cross Office/Center coordination. • Establish and consistently apply a procedure to communicate policy and process changes directly to affected staff, with documentation in a repository of current policies and procedures. Have changes take effect at predictable points (e.g., start of a pay period). • Explore further HR data system integration to improve tracking and access to status information (including reasons for delays) for hiring packages across Offices and Centers.

FDA HR Enhancements

Table ES-2. Answers to assessment questions about HR/HC enhancements

Assessment Question	Abbreviated Answer
What is the status of enhancements that were planned at the time of the last assessment?	ERG assessed the status of three planned enhancement areas: HR data systems, an integrated HR/HC service delivery model, and leadership succession planning. FDA has fully implemented the enhancements planned at the time of the last assessment. FDA is continuing to enhance and refine these initiatives on an ongoing basis.

[3] FDA Final Hiring and Retention Assessment and Addendum – December 2021 *https://www.fda.gov/media/154873/download*

Assessment Question	Abbreviated Answer
What were cause(s) of any delays to implementation?	FDA implemented the enhancement areas on schedule, without any significant delays.
To what extent were the enhancements implemented with fidelity?	FDA's implementation of the HR data systems, integrated service delivery model, and leadership succession planning initiatives closely align with the goals stated for these enhancement areas.
What is the impact of enhancements on hiring and retention outcomes?	All three enhancement areas have generated positive outcomes. The HR data systems have modernized and improved the efficiency and transparency of hiring-related activities – and contributed to a decrease in the average time to complete the portion of the hiring process tracked in ATLAS (Applicant Tracking Lifecycle Analysis Solution), which includes the final candidate package review and final offer, for new PDUFA and BsUFA employees. The integrated service delivery model has fostered collaboration, a positive workplace, and opportunities for skill building, all supported by data. FDA's leadership succession planning initiatives have helped the Agency identify and address succession risks and develop the leadership pipeline.

Table ES-3. Findings and recommendations for HR/HC enhancements

No.	Finding	Recommendation
2-A	FDA has successfully implemented each enhancement area with minimal to no delays and in alignment with stated goals.	For HR data systems, continue to implement updates and address missing or unintegrated workflows (including process that span Offices and Centers) and expand access for more staff in more roles where feasible.

FDA Recruiting, Hiring, Pre-Employment Onboarding, and Retention Status and Effectiveness of Current Practices

Table ES-4. Answers to assessment questions about current state of FDA recruitment, hiring, pre-employment onboarding, and retention

Assessment Question	Abbreviated Answer
What is the current status of FDA recruiting?	FDA's current practices yield a sufficient talent pool to produce skilled, qualified hires that meet CDER and CBER staffing needs. New hires report positive experiences with the recruitment process. FDA's Agency- and Center-level HR/HC staff generally agree that recruitment practices are effective, though they identify opportunities for further improvement—such as processes to avoid disagreements between OTS and Program Offices about whether candidates are qualified for a position.
What is the current status of FDA hiring?	FDA's current practices appropriately evaluate candidates and identify future employees to support FDA's public health mission. New hires generally report satisfaction with their experience in the hiring process. Hiring managers are generally satisfied with processes that are under their control, and less satisfied with processes that depend on other parties. HR/HC staff generally agree that hiring practices are effective, though they identify some opportunities for improvement—such as clarifying processes for the period from a package leaving the program office to its arrival in OTS. Center-level HR/HC staff and hiring

Assessment Question	Abbreviated Answer
	managers also noted that it can take several months for a candidate to receive a tentative offer from OTS.
What is the current status of FDA pre-employment onboarding?	FDA's current practices lead to successful completion of security (background) checks and ethics pre-clearances within expected timelines. Onboarding practices also provide sufficient education for new staff on FDA procedures and prepare them to perform their duties. Staff generally report positive experiences and satisfaction with the efficiency and effectiveness of pre-employment onboarding practices, though they identify opportunities for improvement—such as clarifying the responsibility for initiating clearances and streamlining the security process.
What is the current status of FDA retention of new hires?	Through FY2024, FDA's retention practices have contributed to high retention rates (low attrition rates). Belief in the FDA mission motivates employees to continue their current work, and most new staff report satisfaction with their position and Center. However, some staff report that a desire for improved salaries and promotion pathways could motivate them to leave the Agency. In addition, new federal policies (e.g., reduction or elimination of telework and flexible work options) and uncertainties (in potential changes to how FDA carries out its mission) have the potential to motivate more staff to leave.
How do FDA's hiring outcomes and retention rates compare to those of similar federal agencies and industry?	FDA performs comparably to similar federal agencies and industry in terms of HR/HC structure and hiring outcomes. FDA outperforms similar agencies and industry in terms of retention.

Recruiting = FDA's process of finding potential candidates who might be qualified to fill positions at the Agency and attracting qualified candidates to apply. This process includes the posting of job announcements.

Hiring = FDA's process of reviewing applications, selecting candidates to interview, interviewing candidates, making hiring decisions, and extending initial (or tentative) job offers.

Pre-employment onboarding = FDA's new hire orienting activities beginning after the tentative offer up to EOD. This includes pre-hiring paperwork and prompts, the badging process, security clearance, ethics, the tentative and final offer letters, and any other relevant activities that contribute to these pre-employment onboarding outputs.

Retention = FDA's strategies, programs, and other initiatives designed to encourage employees to continue their employment with the Agency. Examples include student loan repayment programs, retention allowances, flexible work schedules, telework, professional development opportunities, and employee networking groups.

CDER = Center for Drug Evaluation and Research. CBER = Center for Biologics Evaluation and Research. OTS = Office of Talent Solutions.

Table ES-5. Findings and recommendations for FDA recruitment, hiring, pre-employment onboarding, and retention

No.	Finding	Recommendation
3-A	FDA's use of a wide range of recruitment and outreach strategies is effective in making CDER and CBER job opportunities visible to prospective applicants.	None.

No.	Finding	Recommendation
3-B	FDA's hiring process is effective. Good practices such as standardized screening and interview promote fair, consistent treatment of candidates. FDA staff involved in hiring sometimes experience challenges with (1) which candidates are deemed qualified on certificates and (2) confusion about who is responsible for initiating security and ethics pre-clearance processes.	Take three actions: • Expand standardized screening and interview practices Agency-wide. • Address qualifications procedures to ensure hiring managers and OTS HR specialists share a common understanding of which candidates can be considered qualified. • Clarify roles and responsibilities for security and ethics pre-clearance initiation across all involved parties.
3-C	Due to the length of the overall hiring and pre-employment onboarding process and insufficient communication during that time, FDA loses some qualified candidates.	Add touchpoints with candidates to communicate status (even if status is unchanged) and next steps – and to convey that FDA values the candidates and appreciates their time and patience.
3-D	Agency- and Center-specific new employee orientations (NEOs) are effective in preparing staff to begin work at FDA.	None.
3-E	Most new hires are satisfied with their decision to work in their current position at their Center.	None.
3-F	FDA's retention initiatives are largely effective. Three challenges are: • Reduction or elimination of telework and flexible work schedules (which are highly valued). • Perceived insufficiency in promotion pathways. • Lower salaries compared to those available in industry.	To the extent possible: • Continue current retention initiatives and re-establish recently amended initiatives (especially flexible work arrangements). • Create and publicize opportunities for leadership skills development and promotion. • As budget allows, convert employees to Title 21.
3-G	FDA's data on time to hire currently exist in disparate systems, making it difficult to accurately calculate total time to hire (which anecdotally ranges from 5 to 18 months). Within specific elements of the hiring process tracked by ATLAS and for security clearance procedures, FDA generally meets service level agreements (SLAs).	Two actions: • Investigate mechanisms to enable calculation of data across disparate systems to reliably determine total time to hire and data for individual phases/steps in the overall process. • Develop an analysis of factors contributing to total time to hire outside of those related to SLAs, and identify opportunities to reduce the total time to hire.

FDA Hiring Process Transparency

Table ES-6. Answers to assessment questions about FDA hiring process transparency

Assessment Question	Abbreviated Answer
To what extent are hiring processes, goals, and expectations clear and understandable to FDA HR/HC staff?	Most HR/HC staff are clear about their roles and receive sufficient training and documentation to support them in performing their duties, although OHCM staff express a desire for more training. Roles, processes, communication, and collaboration across Offices and Centers are less transparent. Enhancements to HR data systems contribute significantly to transparency, however.
How transparent is the hiring process to other FDA staff (leadership, CDER/CBER review staff, others)?	For other FDA staff (including leadership, review staff, and hiring managers), transparency is often sufficient within an Office or Center. However, communication and collaboration across Offices and Centers are sometimes insufficient to create a sense of transparency in hiring timelines, statuses, and changes in policies and processes. In some cases, staff report losing candidates due to a lack of transparency (lack of status updates for candidates).
How transparent is the hiring process to new staff?	CDER and CBER new hires have mixed experiences with hiring process transparency. Many cite inconsistencies in communications (or prolonged periods without status updates) and non-transparent timelines and processes. This led some to consider other job opportunities, though ERG obtained feedback only from candidates that ultimately accepted a position with FDA.

Table ES-7. Findings and recommendations for FDA hiring process transparency

No.	Finding	Recommendation
4-A	New hires in CDER and CBER are generally satisfied with the hiring process and their decision to join FDA. However, lack of transparency about their status and next steps during the hiring process posed challenges and causes some candidates to look elsewhere for employment.	See Recommendation 3-C.
4-B	Staff involved in hiring generally understand their own roles and processes, but do not consistently find roles and processes in other Offices and Centers to be transparent.	See Recommendations 1-C and 3-B.
4-C	FDA's HR data system enhancements have contributed to significant improvements in the transparency of hiring actions and statuses, though opportunities for improvement still exist.	See Recommendations 1-C and 2-A.

1. Introduction

To ensure that safe and effective products are available to improve and protect the health of the public in the United States, the U.S. Food and Drug Administration (FDA) evaluates new drugs and conducts thorough reviews of marketing applications before product approval and release. For this process to occur effectively and efficiently, FDA must hire and retain a skilled staff of technical and scientific experts for the human drug review program. This becomes more challenging as the field of medicine evolves and product application reviews become more complex. FDA must ensure that its human resource (HR) and human capital (HC) activities can develop and maintain the necessary knowledgeable workforce—while competing with other federal and non-federal entities that seek to employ staff with the same talents.

To provide funding for the staff and other resources needed to ensure timely review of new drugs, Congress enacted the Prescription Drug User Fee Act (PDUFA) in 1992. Congress has reauthorized PDUFA every five years, with the most recent reauthorization (PDUFA VII) occurring in 2022 for fiscal years 2023–2027. Similarly, Congress enacted the Biosimilar User Fee Amendments (BsUFA) in 2007 and has reauthorized it every five years, with the most recent reauthorization (BsUFA III) occurring in 2022 for fiscal years 2023–2027. For each PDUFA and BsUFA reauthorization, FDA holds meetings with industry and other interested parties to develop performance goals, procedures, and commitments. During meetings for the current reauthorizations, industry and FDA observed that the efficiency and effectiveness of FDA HR/HC operations is critical to successful PDUFA VII and BsUFA III performance. Several PDUFA VII and BsUFA III commitments relate to hiring and retaining enough technical and scientific experts to conduct reviews of product applications.

Previously, independent contractors conducted assessments of FDA's HR and HC operations. For PDUFA VI, the final assessment published in 2021[4] found that FDA made notable advancements in its recruiting, hiring, and retention operations since publication of the initial assessment in 2017;[5] FDA made moderate[6] progress in each of five assessment categories during this four-year period.[7] The final assessment outlined ten recommendations to further improve how FDA recruits, hires, and retains human drug review program staff.

For PDUFA VII and BsUFA III, FDA committed to an independent assessment that builds on the findings of previous assessments, with a focus on changes that have improved FDA's hiring and retention outcomes and challenges that remain. FDA contracted Eastern Research Group, Inc. (ERG) to conduct the assessment. FDA specified three key assessment objectives, which ERG translated into questions to be answered by the assessment (Table 1-1).

[4] Final Assessment of FDA Hiring and Retention Report. *https://www.fda.gov/media/154873/download*
[5] Initial Assessment of FDA Hiring and Retention Report. *https://www.fda.gov/media/108866/download*
[6] Moderate defined as there being 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.
[7] The five assessment categories were: 1. Strategy; 2. Culture, Collaboration, and Communication; 3. Recruiting and Hiring Processes; 4. Data Management and Systems; 5. HR Staff Capability and Capacity.

Table 1-1. Assessment questions, by key objective

Key Objective 1: Document and analyze any incremental enhancements/changes made to FDA's human drug review program hiring and retention since the final PDUFA VI assessment
1a. What is the status of enhancements that were planned at the time of the last assessment?
1b. What were cause(s) of any delays to implementation?
1c. To what extent were the enhancements implemented with fidelity (i.e., faithful to the original vision/purpose)?
1d. What is the impact of enhancements on hiring and retention outcomes?
Key Objective 2: Capture the current status of FDA's recruiting, hiring, pre-employment onboarding, and retention of new hires and the effectiveness of current practices
2a. What is the current status of FDA recruiting?
2b. What is the current status of FDA hiring?
2c. What is the current status of FDA pre-employment onboarding?
2d. What is the current status of FDA retention of new hires?
2e. How do FDA's hiring outcomes and retention rates compare to those of similar federal agencies and industry?
Key Objective 3: Assess hiring process transparency from the perspective of interested parties within FDA
3a. To what extent are hiring processes, goals, and expectations clear and understandable to FDA HR/HC staff?
3b. How transparent is the hiring process to other FDA staff (leadership, CDER/CBER review staff, others)?
3c. How transparent is the hiring process to new staff?

CDER = Center for Drug Evaluation and Research. CBER = Center for Biologics Evaluation and Research.

ERG used a systematic methodology (Section 2) to identify, collect, and analyze comprehensive data for this assessment—which we distilled into answers to the assessment questions (Section 3) and a cohesive set of findings and recommendations (Section 4). To contextualize our conclusions, ERG prepared a list of acronyms and terms (Appendix A); an overview of FDA's human drug review program HR/HC structure, processes, hiring authorities, and data systems (Appendix B); and our detailed results (Appendix C).

ERG collected and analyzed data for this assessment from October 2, 2023 to January 31, 2025. On January 20, 2025, the White House announced several new federal policies (e.g., Hiring Freeze,[8] Return to In-Person Work[9]), which we expect will have significant effects on FDA's hiring and retention of staff under PDUFA and BsUFA. As such, additional changes to federal hiring, work, and staffing policies, and their effects on FDA's hiring and retention of staff after January 31, 2025, are not accounted for in our findings and recommendations.

[8] Presidential Action: Hiring Freeze. *https://www.whitehouse.gov/presidential-actions/2025/01/hiring-freeze*

[9] Presidential Action: Return to In-Person Work. *https://www.whitehouse.gov/presidential-actions/2025/01/return-to-in-person-work*

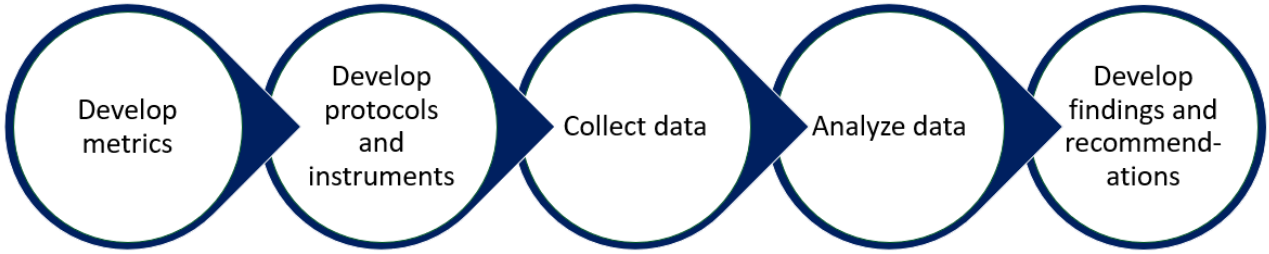
The remainder of this report includes:

- Section 2: Methods
- Section 3: Answers to Assessment Questions
- Section 4: Findings and Recommendations
- Appendix A: Acronyms and Glossary
- Appendix B: FDA Human Drug Review HR/HC Program
- Appendix C: Detailed Results

2. Methods

ERG used a systematic process to identify, collect, and analyze comprehensive data for this assessment. This process involved five key steps (Figure 2-1).

Figure 2-1: ERG's FDA HR/HC assessment process



2.1 Evaluation Metrics

ERG began by establishing a set of evaluation metrics directly related to FDA's key objectives and our assessment questions. Table 2-1 presents a summary of our metrics by key objective for this assessment.

Table 2-1. Assessment metrics by key objective

Key Objective	Metrics Category
Key Objective 1	• Status of enhancement implementation • Impacts of implementation • FDA feedback on successes and challenges
Key Objective 2	• Recruitment efforts, applicant interest, and candidate sourcing • Hiring goals, numbers, and time to hire • Security clearance and ethics pre-clearance times • Attrition rate and reasons • HR servicing ratios • Cross-office communication and collaboration • FDA feedback on successes and challenges
Key Objective 3	• Clarity of role expectations for HR/HC organizations and staff • Staff (overall and new staff) perspectives on transparency of hiring process • FDA feedback on successes and challenges

2.2 Protocols and Instruments

The evaluation metrics establish a structure for data needed for the assessment. ERG prepared protocols and instruments for collecting the data (Table 2-2).

Table 2-2. Data collection protocols and instruments for ERG's FDA HR/HC assessment

Data Collection Protocols	Data Collection Instruments	Purpose
HR/HC quantitative data calls	Data Request and Processing Guide • Public: FDA website, PDUFA/BsUFA reports, other agency websites, FedScope • FDA: FEVS, HR data systems (ATLAS, AOIS, PathHR) • FDA human capital reporting and analysis portal (attrition, WHAT, WAPOR, exit survey) • Other data calls (retention)	Obtain and process quantitative recruitment, hiring, pre-employment onboarding, and retention data from public and FDA HR/HC data systems to capture the current state of these activities
Surveys	CDER and CBER staff OTS and OHCM HR/HC staff FDA HR data system (ATLAS, AOIS, PathHR) users	Obtain HR/HC, CDER, and CBER staff perspectives on HR/HC processes and data systems, overall and by role in processes
Knowledge-sharing sessions, interviews, and focus groups	Scripts • OTS and OHCM HR/HC specialists • CDER and CBER HC liaisons • Administrative officers and program managers • CDER and CBER hiring managers • HR/HC leadership • Pre-employment onboarding security and ethics specialists • Topic-specific subject matter experts	Obtain qualitative insights into FDA HR/HC structures, processes, data systems, enhancements, challenges, successes, lessons learned, and suggestions for improvement
Document reviews	Policy, process, and procedure document reviews related to workforce development, leadership succession, and HR information technology • FDA strategic plans • Center- and Office-specific plans • Previous internal and third-party HR/HC assessments	Obtain information about goals for, implementation of, and status of FDA HR/HC structures, processes, data systems, and enhancements

FEVS = Federal Employment Viewpoint Survey. ATLAS = Applicant Tracking Lifecycle Analysis Solution. AOIS = Administrative Operations Information System. WHAT = FDA Workforce Hiring and Attrition Trends Report. WAPOR = Workforce Analysis Profiles Online Report. OTS = Office of Talent Solutions. OHCM = Office of Human Capital Management.

2.3 Data Collection

ERG collected qualitative and quantitative data (Table 2-3) in accordance with the procedures specified in our evaluation protocols and instruments. ERG developed data collection tools to store raw data and compute metrics values.

Table 2-3. Data collected for ERG's HR/HC assessment, by data collection and topic addressed

Data Collection	n	HR Enhancements	Recruitment	Hiring	Onboarding	Retention	HR Culture	Resources	Cross-Office Communication	HR Data Systems	Transparency	Similar Agencies
Public data sources	47		●	●		●						●
Private FDA Intranet	3	●	●			●		●		●		
FDA Human Capital Reporting and Analysis Portal	2			●								
FDA quantitative data calls	5		●	●	●	●						●
CDER and CBER staff surveys	2*		●	●	●	●	●	●	●	●	●	
OTS and OHCM staff surveys	2*		●	●	●	●	●	●	●	●	●	
FDA HR data system user surveys	3*	●	●	●	●					●	●	
Knowledge-sharing sessions	5	●	●	●	●	●	●	●	●	●	●	
Interviews	19	●	●	●	●	●	●	●	●	●	●	●
Focus groups	36	●	●	●	●	●	●	●	●	●	●	
Document reviews	78	●								●		●

*Number of respondents were: CDER staff survey, 2,285 (38% response rate). CBER staff survey, 427 (32% response rate). OTS staff survey, 47 (49% response rate). OHCM staff survey, 33 (32% response rate). Data system user survey, 103: ATLAS = 74 (6% response rate), PathHR = 9 (32% response rate), AOIS = 40 (17% response rate). In most cases, response rates exceeded the target of 30%. The data system survey took place in December 2024 to January 2025, when many staff were out on leave or distracted by other events.

To protect proprietary and non-public information, ERG performed all data collections and analyses on secure computers. To protect the privacy of interview and survey respondents, ERG maintained identifying information only for the purpose of sending surveys and scheduling interviews and kept this information in a secure environment that was inaccessible to anyone outside ERG's internal project team. ERG anonymized and aggregated survey and interview results for analysis and reporting purposes. All ERG personnel hold security clearances and signed non-disclosure agreements.

2.4 Data Analysis

Broadly, ERG conducted quantitative and qualitative analyses from a variety of data sources (Table 2-4) to produce two types of results for this assessment:

- **Answers to assessment questions**. To answer each assessment question, ERG synthesized metrics results and related quantitative and qualitative data to develop evidence-based explanations.
- **Findings and recommendations**. ERG integrated quantitative and qualitative information across all topics to distill results into findings and specific, actionable recommendations, categorized by key objective for this assessment.

Table 2-4. Data collected for ERG's HR/HC assessment, by key objective and data source

Key Objective / Assessment Question	Public Data	FDA Data Calls	CDER/CBER Surveys	OTS/OHCM Surveys	HR Data System User Surveys	Knowledge-Sharing Sessions	Interviews	Focus Groups	Document Reviews
FDA HR Enhancements									
Status of enhancements						●			●
Causes of any delays						●			●
Fidelity of implementation					●	●	●		●
Impacts of enhancements			●	●	●	●	●	●	●
Current HR/HC Status									
Recruitment		●	●	●		●	●	●	●
Hiring	●	●	●	●		●	●	●	●
Pre-employment onboarding		●	●	●		●	●	●	●
Retention	●	●	●	●		●	●	●	●
Comparison to other agencies/industry	●	●					●		●
Transparency									
HR/HC staff			●	●			●	●	
Other staff			●	●			●	●	
New hires			●	●			●	●	

3. Answers to Assessment Questions

This section provides answers to the assessment questions based on analysis and synthesis of assessment results (Appendix C). In some cases, the assessment questions refer to the "last assessment" of FDA's HR/HC program for human drug review staff. Specifically, the assessment questions ask about enhancements made since that time or changes in HR/HC outcomes since that time. The last assessment occurred during PDUFA VI; FDA published the final report for the PDUFA VI HR/HC assessment in 2021.[10] In our answers to the assessment questions, we refer to that assessment as the "2021 PDUFA VI HR/HC assessment" or "last assessment."

3.1 FDA HR/HC Enhancements Since Last Assessment

The findings of the 2021 PDUFA VI HR/HC assessment suggested a need for improvement in several aspects of FDA's HR/HC program for human drug review staff. FDA initiated a variety of changes to address the findings. In this report, ERG assesses the status and impacts of three main enhancement areas:

- **HR data systems (ATLAS, AOIS, and PathHR).** These data systems provide Agency- and Center-level HR/HC staff a platform to view and carry out hiring-related activities.
- **Integrated HR/HC service delivery model.** This model seeks to integrate HR processes across the full HR workforce to streamline and enhance workforce planning, recruitment, development, and retention efforts across FDA.
- **Leadership succession planning.** This planning seeks to manage (and mitigate) the potential impacts of attrition among senior FDA leaders.

Below is a high-level summary of our answers to the assessment questions related to these three enhancements, followed by more detailed information, organized by enhancement area.

Summary: In all three areas, FDA has fully implemented the enhancements planned at the time of the last assessment. FDA is continuing to enhance and refine these initiatives on an ongoing basis. FDA implemented the enhancement areas on schedule, without any significant delays. FDA's implementation closely aligns with the goals stated for these enhancement areas. All three enhancement areas have generated positive outcomes. The HR data systems have modernized and improved the efficiency and transparency of hiring-related activities – and contributed to a decrease in the average time to complete the portion of the hiring process tracked in ATLAS for PDUFA and BsUFA employees. The integrated HR/HC service delivery model has helped address workforce gaps by expanding the use of Title 21 and available training programs, advancing human capital data analytics, promoting collaboration across Centers and Offices, and creating a positive work environment. FDA's leadership succession planning initiatives have promoted cross-agency collaboration, yielded annual summary reports, and added professional development opportunities; these Agency-level activities have acted as a guide for Center-level activities.

[10] FDA Final Hiring and Retention Assessment and Addendum – December 2021 *https://www.fda.gov/media/154873/download*

HR Data Systems (ATLAS, AOIS, PathHR)

Since 2021, FDA has implemented or expanded three data systems to enhance its hiring and personnel management processes:

- First deployed in 2018 and subsequently expanded, the **Applicant Tracking and Lifecycle Analysis Solution (ATLAS)** is an FDA-wide system designed to streamline and standardize hiring workflows, improve transparency, and reduce hiring times. Over 3,500 staff throughout the Agency use ATLAS to track and manage hiring-related activities.
- First deployed in 2020 and subsequently expanded, the **CDER Administrative Operations Information System (AOIS)** automates over 150 administrative personnel actions and provides real-time dashboards and reports to facilitate decision-making in CDER. About 285 staff in CDER use AOIS to track and manage hiring and other personnel activities.
- With a phased rollout starting in 2021, **PathHR** is a new CBER system of record that centralizes that Center's HR data and integrates HR and payroll planning. About 55 staff in CBER use PathHR to track and manage hiring and other personnel activities.

At the Agency level, ATLAS is used to track actions by the Office of Talent Solutions (OTS), while AOIS and PathHR track Center-level actions in CDER and CBER. By automating and streamlining previously manual processes and by providing accurate real-time data, ATLAS, AOIS, and PathHR have each improved the efficiency and transparency of the hiring process for their users. Collectively, these systems have transformed FDA's hiring operations from a fragmented, manual state to a more integrated, efficient, and transparent state. As is typical for relatively new systems (and all systems), users continue to identify opportunities for improvement and FDA continues to refine all three systems on an ongoing basis.

Table 3-1 provides a high-level summary of answers to the assessment questions related to the HR data systems enhancement area. Below the table we provide more detailed answers to the assessment questions for each of the three HR data systems.

Table 3-1. High-level summary of answers to assessment questions for HR data systems enhancement area

Assessment Question	Answer	Explanation
Enhancement status	Fully implemented	FDA has implemented all planned enhancements and continues to refine the systems based on user feedback.
Causes of any delays	No significant delays	FDA has implemented most HR data system enhancements on schedule. FDA delayed and deprioritized one PathHR enhancement in favor of another enhancement.
Fidelity of implementation	High	FDA's implementation of the planned HR data system enhancements closely aligns with the stated goals.
Impact on hiring/retention outcomes	Positive	ATLAS, AOIS, and PathHR have automated and streamlined previously manual processes and provide real-time data for status checking and operational decision-making. Improved efficiency in these processes have likely contributed to a decrease in the average time to complete the portion of the hiring process tracked in ATLAS for PDUFA and BsUFA

Assessment Question	Answer	Explanation
		employees from FY2021 to FY2024. Some data system users would like FDA to make additional enhancements.

Sources: FY2021 data: 2021 PDUFA VI HR/HC assessment. FY2024 data: ATLAS data request (data received on 01/17/2025).

ATLAS

What is the status of ATLAS enhancements planned at the time of the last assessment?

FDA has fully implemented all enhancements that the Agency planned for ATLAS at the time of the last assessment; these enhancements aimed to further streamline and increase the transparency of the hiring process. FDA encountered some delays with reporting functionalities and data integration from other systems. FDA has also implemented enhancements to ATLAS, including integrating data across other administrative systems, automating and improving workflows (such as Title 21), automating manual processes, adding digitized checklists, providing Outlook notifications for pending and late tasks, offering electronic approval mechanisms, updating the FAST Report, and enhancing dashboards to streamline hiring and increase transparency.

In surveys, interviews, and focus groups, ATLAS data system users confirm that these enhancements are generally useful: the system is generally user-friendly, and the purpose of ATLAS and staff roles in the system are clear.

What were causes of any delays to implementation of ATLAS enhancements?

None. FDA implemented the data system enhancements on schedule.

To what extent were ATLAS enhancements implemented with fidelity?

FDA's implementation of ATLAS enhancements planned at the time of the 2021 PDUFA VI HR/HC assessment closely aligns with the stated goals for the enhancements (Table 3-2). As is typical with relatively new and enhanced (and all) data systems, ATLAS users continue to identify additional refinements that could further improve achievement of the agency's goals for ATLAS. For example, some users have identified gaps in workflows, would like further integration with other systems (e.g., USA Staffing), and would like more status flags and alerts for processes such as security and ethics. These staff state that they are sometimes unsure of progress on their actions because processes occurring outside of ATLAS are not reflected in the system.

Table 3-2. Fidelity of implementation of ATLAS enhancements to stated goals

ATLAS Enhancement Goal	Implementation Fidelity
Provide a comprehensive information technology solution to improve HR operations; address complex and inefficient processes.	FDA implemented planned integrations of several systems and automated previously manual processes; ATLAS now has over 3,500 users FDA-wide.
Modernize technology to improve the recruiting and hiring process.	FDA systematized and automated workflows for several hiring authorities.

ATLAS Enhancement Goal	Implementation Fidelity
Provide tracking and reporting capabilities to manage the complete end-to-end talent management lifecycle.	FDA added HR task and service level agreement tracking, along with real-time dashboards and reports.
Standardize hiring workflows across FDA.	As above.
Increase transparency and accountability in the hiring process.	FDA added service level agreement tracking and real-time dashboards; ATLAS users report improvements in transparency and accountability.
Foster engagement and buy-in to accelerate system adoption; enhance user experience and support through training and strategic communications.	In ERG's surveys, interviews, and focus groups, ATLAS users report receiving sufficient communications and training to be able to use ATLAS effectively.
Continuously refine and enhance the system based on user feedback.	FDA has implemented over 60 updates since ATLAS entered the operating and maintenance stage.
Improve satisfaction with processes and technology.	In ERG's surveys, interviews, and focus groups, ATLAS users report increased satisfaction.
Ensure mission-critical vacancies are filled in a timely and efficient manner with high-quality hires.	ATLAS automates workflows from several hiring authorities.
Reduce the overall time to hire.	FY2021 to FY2024, the average time to complete the portion of the hiring process tracked in ATLAS for PDUFA and BsUFA employees decreased by 1 to 54 business days, depending on the hiring authority.

Sources: FY2021 data: 2021 PDUFA VI HR/HC assessment. FY2024 data: ATLAS data request (data received on 01/17/2025).

What is the impact of ATLAS enhancements on hiring and retention outcomes?

Implementation of ATLAS enhancements has improved outcomes in terms of both HR business operations and time to hire for new employees:

- **HR business operations:** In surveys, interviews, and focus groups, ATLAS users generally agreed that ATLAS is user-friendly and has streamlined their work (increasing efficiency), improved access to data and alerts (increasing transparency, auditability, and accountability), and improved data accuracy and security. Some users noted that human error or delays in entering data can lead to data accuracy issues, but those are user (not system) issues.
- **Time to hire for new employees:** Overall, the average time to complete the portion of the hiring process tracked in ATLAS for new PDUFA and BsUFA employees decreased from FY2021 to FY2024. Although ERG cannot establish a causal relationship, the evidence suggests that ATLAS enhancements contributed to improved efficiency and a decrease in average time to hire. The average time to conduct the portion of the hiring process tracked in ATLAS improved for most hiring authorities.

AOIS

What is the status of AOIS enhancements that were planned at the time of the last assessment?

FDA initially developed AOIS to rectify workflow and data gaps from tracking HR data and activities among disparate systems and processes in CDER. The last assessment identified a need for additional capabilities. Since then, FDA has implemented capabilities such as automated administrative personnel actions, streamlined Personnel Action Requests (PAR), real-time dashboards and data reports, system integration with other systems (e.g., CDER Budget & Acquisition Planning System [CBAPS]), and addition of an Office Space Request (OSR) module and the Return to Facilities (RTF) program.

In surveys, interviews, and focus groups, AOIS data system users confirm that these enhancements are useful. AOIS users generally report positive experiences, stating that the system is quick and easy to learn, actions are easy to track and access, and data are easy to obtain.

What were causes of any delays to implementation of AOIS enhancements?

None. FDA implemented the data system enhancements on schedule.

To what extent were AOIS enhancements implemented with fidelity?

FDA's implementation of AOIS enhancements closely aligns with the stated goals for the enhancements (Table 3-3). As is typical for relatively new (and all) data systems, some AOIS users continue to identify additional refinements that could help further achieve CDER's goals for AOIS. For example, some suggest greater integration with ATLAS to improve access to and the accuracy of statuses throughout the talent lifecycle.

Table 3-3. Fidelity of implementation of AOIS enhancements to stated goals

AOIS Enhancement Goal	Implementation Fidelity
Improve the overall efficiency, accuracy, and user experience of AOIS.	In ERG's surveys, interviews, and focus groups, users generally reported satisfaction with these elements of AOIS, though some would like additional refinements.
Enhance the PAR approval process.	AOIS has automated over 150 administrative personnel actions, improving efficiency and data accuracy.
Improve the user functionalities and system views.	In ERG's surveys, interviews, and focus groups, AOIS users felt the system was easy to use and learn and provides needed reports and dashboards.
Provide new user roles and dashboards.	The OSR module provides new user roles and dashboards to better manage facilities and resources.
Streamline the office space planning process.	The OSR module supports CDER's hybrid workplace and the RTF initiative by automating office space planning and approvals.
Automate and improve efficiency of various administrative actions.	In ERG's surveys, interviews, and focus groups, users generally agreed that AOIS improves process efficiency, though they would also like additional refinements.
Ensure data integrity and accuracy.	In ERG's surveys, interviews, and focus groups, users agreed that the data are accurate and displayed as intended, though they would also like additional refinements.

AOIS Enhancement Goal	Implementation Fidelity
Facilitate timely approvals and reduce bottlenecks.	AOIS streamlines the PAR approval process, reducing average approval time and improving operational efficiency.
Provide real-time interactive dashboards for better data access and monitoring.	AOIS provides real-time dashboards and reports, enhancing user experience and decision-making capabilities.
Offer continuous system improvements based on user feedback.	FDA continues to refine AOIS based on user feedback.

What is the impact of AOIS enhancements on hiring and retention outcomes?

Implementation of AOIS has improved HR/HC processes by providing a centralized platform for data, tracking, reporting, and communication. This increases accountability, efficiency, and transparency in recruitment, hiring, and onboarding processes. Some users would like AOIS to provide more detailed reports and greater integration of systems to avoid duplicative processes (e.g., the need to enter data from AOIS to ATLAS) that can lead to data errors and delays in updating statuses.

PathHR

What is the status of PathHR enhancements that were planned at the time of the last assessment?

FDA has fully deployed PathHR, the HR system of record for CBER. As with AOIS in CDER, FDA initially developed PathHR to address workflow gaps and provide tracking for CBER's HR work. Previously, CBER used the HR Management system and other manual processes.

With FDA's implementation of the enhancements planned at the time of the last assessment, PathHR now centralizes CBER HR data, integrates HR and payroll planning, and replaces manual processes with automated workflows. Position Management, Employee Profiles, PAR Actions, and Recruitment & Onboarding Tracker modules provide real-time data and improve the accuracy and speed of HR processes. Dashboards and reports provide information about recruitment status, position management, and workforce planning, which assists staff with data-driven decision-making. These enhancements have improved the efficiency and transparency of CBER HR operations.

In surveys, interviews, and focus groups, PathHR users confirmed that these enhancements are useful, enabling staff to access and track assignments quickly and easily.

What were causes of any delays to implementation of PathHR enhancements?

FDA implemented most PathHR enhancements without delays. Based on user input, FDA postponed the User Pending Action Dashboard in favor of other priorities (e.g., Talent Acquisition Plan enhancements).

To what extent were PathHR enhancements implemented with fidelity?

FDA's implementation of PathHR closely aligns with the stated goals for the enhancements (Table 3-4). As is typical for relatively new (and all) data systems, some users continue to identify additional refinements that could help further achieve CBER's goals for PathHR. For example, some suggest greater integration with ATLAS to address remaining workflow gaps and improve efficiency.

Table 3-4. Fidelity of implementation of PathHR enhancements to stated goals

PathHR Enhancement Goal	Implementation Fidelity
Access a single centralized platform with real-time HR data.	PathHR provides a centralized platform for managing and tracking HR actions, reducing manual processes.
Make data-driven workforce decisions.	The system offers dashboards and reports for tracking key performance indicators, supporting data-driven workforce decisions.
Leverage an integrated solution that replaces manual processes.	In ERG's surveys, interviews, and focus groups, over half agreed that PathHR is an improvement, while also stating that some workflow gaps remain due to limited access at the program manager level.
Validate gaps between department and agency source systems.	PathHR has integrated with Agency-level HR data (ATLAS), reducing manual workload, and improving data accuracy and efficiency.
Improve payroll forecasting accuracy by automating integration with the Biologics Planning, Execution, and Reporting Solution (BPERS).	Enhancements to cost projections, dashboards, and reports help the Budget Team track and update data related to payroll and vacancies.

What is the impact of PathHR enhancements on hiring and retention outcomes?

Implementing PathHR enhancements has provided a centralized tracking and reporting platform. In interviews, focus groups, and surveys, users agreed that PathHR increases accountability and transparency in recruitment, hiring, and onboarding. As noted above, some users continue to cite a need for further improvement in addressing workflow gaps stemming from user access roles and privileges that necessitate duplicative processes that can lead to delays or errors.

Integrated HR/HC Service Delivery Model

The integrated HR/HC service delivery model at FDA, implemented through the 2023-2027 Strategic Workforce Plan (SWFP), aims to create a more collaborative, customer-focused approach to HR services – to ensure that FDA has the right talent at the right time to meet its mission, improve process efficiency, and enhance service quality. Previously, HR functions were fragmented, with inconsistencies in processes and limited collaboration across FDA Offices and Centers. The integrated service delivery model fosters a more unified approach, with the Integrated Strategic Human Capital Planning Council (ISHCPC) guiding workforce planning.

Table 3-5 provides a high-level summary of answers to the assessment questions related to the integrated service delivery model. Below the table we provide more detailed answers to the assessment questions.

Table 3-5. High-level summary of answers to assessment questions for Integrated HR/HC Service Delivery Model enhancement area

Assessment Question	Answer	Explanation
Enhancement status	On schedule	As of October 2024, 70% of the FY2024 SWFP action items complete and 30% of FY2024 action items on track.
Causes of any delays	None	When needed, FDA has adjusted its strategy to address potential delays.
Fidelity of implementation	High	FDA's implementation closely aligns with its stated goals.
Impact on hiring/retention outcomes	Positive	The model has contributed to increased training and development programs, succession management activities, FEVS targets, expanded Title 21 use, improved human capital data analytics and integration, and initiatives like the Recruitment Community of Practice and ISHCPC.

What is the status of the integrated HR/HC service delivery model enhancements planned at the time of the last assessment?

The 2021 PDUFA VI HR/HC assessment concluded that FDA had made progress toward a more effective HR/HC service delivery model, but needed to enhance the model to be more unified, proactive, accountable, collaborative, and customer-centric – to improve and modernize service delivery. FDA planned enhancements to:

- Improve alignment of HR processes with strategic priorities.
- Enhance transparency and accountability through real-time data dashboards.
- Improve coordination across Centers.
- Increase satisfaction among interested parties, leading to more effective recruitment, development, and retention.

Since that time, FDA has established the ISHCPC guide enhancements and initiated several programs that have helped address hiring, retention, and development gaps for mission-critical occupations and specialized job families, such as the following:

- The Office of Digital Transformation (ODT) has continued the DataForward program to train FDA staff in data science and data analytics. Several cohorts of participants have engaged in data science and analytics training courses.
- ODT has advanced the UpTech Program to include a comprehensive IT Skills Inventory aimed at upskilling and reskilling FDA IT professionals. The UpTech Program has created 20 competency-based learning paths for the top 20 technology roles and increased ODT's instructor-led course and certification offerings by 25%.
- FDA has extended the Team Engagement Program to support supervisors with team building and engagement activities that engage with teams across the organization.

- FDA has maintained the Digital Strategic Leaders Program, focusing on enhancing the digital leadership capabilities of the FDA technology workforce with training modules and workshops.
- In April 2024, FDA established the Research and Science Traineeship Program to build a strong talent pipeline by providing training and development opportunities for scientists to prepare them for roles within the Agency.

What were causes of any delays to implementation of integrated HR/HC service delivery model enhancements?

FDA has not encountered any significant delays in implementation. When needed, the Agency has adjusted its strategies to address potential delays.

To what extent were integrated HR/HC service delivery model enhancements implemented with fidelity?

FDA's implementation of the service delivery model aligns with its stated goals (Table 3-6). FDA encountered some challenges and resource constraints, but effectively adapted its strategies to maintain fidelity with its goals.

Table 3-6. Fidelity of implementation of the Integrated HR/HC Service Delivery Model to stated goals

Integrated Service Delivery Model Enhancement Goal	Implementation Fidelity
Fully addressing current and anticipated critical workforce gaps.	FDA has made progress in training and development, succession management, and addressing hiring and retention gaps for Mission Critical Occupations and Specialized Job Families. Initiatives like the Title 21 Transition Plan and Annual TAPs are on track.
Ensuring FDA continues to be an outstanding place to work.	FDA has met or exceeded targets for FEVS index values and works to foster a culture of respect and communication. Specific actions include the Civility Strategic Plan.
Advancing workforce infrastructure and systems.	FDA has advanced human capital data analytics systems, evaluation and refinement of the SWFP, and proactive management of vacancies. One example of this is integration of AOIS with CBAPS and development of real-time interactive dashboards.
Facilitating collaboration across Centers/Offices.	Leveraging the Recruitment Community of Practice and supporting the FDA ISHCPC facilitates collaborative efforts across Centers and Offices, while creation of outreach plans and recruitment calendars demonstrate a coordinated approach.

What is the impact of integrated HC service delivery model enhancements on hiring and retention outcomes?

Thus far, implementation of the integrated HR/HC service delivery model has contributed to positive impacts:

- **Improved collaboration:** FDA has a more collaborative approach towards HR functions. This is made possible through initiatives like the Recruitment Community of Practice and the ISHCPC, which shares leading practices and creates a repository of workforce planning guides, tools, and templates.

- **Improved data analytics and systems:** FDA has expanded its human capital data analytics capabilities by incorporating exit survey data and Workforce Analysis Profiles Online Report (WAPOR) data into its internal executive hiring dashboard, which provides leadership with insights into hiring patterns, workforce trends, and departure reasons. . This has facilitated data-driven decision-making and improved strategic workforce planning.
- **Strong talent pipeline:** FDA has increased its use of Title 21 in hiring positions that support review of new drugs. The Agency has expanded job families and developed career paths for positions like Consumer Safety Officers, with competitive pay. STEM fellowships, the FDA Research and Science Traineeship Program, and other traineeships and partnerships have contributed to retention of scientists who have completed these programs.
- **Improved training opportunities:** By implementing and continuing training and development programs, such as the DataForward and UpTech programs, FDA has upskilled its staff in key areas like data science and information technology. This has helped address hiring, retention, and development gaps for mission-critical occupations and specialized job families. Additionally, the IT Skills Inventory provides a detailed assessment of the current skill levels of IT professionals and identifies areas for improvement.
- **Improved leadership development opportunities:** FDA continued its Leadership Development Program and has focused on professional development and leadership succession through initiatives like the launch of an enterprise-wide leadership development program for GS-9 through GS-12 employees. The Digital Strategic Leaders Program has received positive feedback from participants.
- **Positive work environment:** FDA launched new initiatives like the FDA Team Engagement Program and the Anti-Harassment Program to foster team building, engagement, and a harassment-free workplace. Participation in the Team Engagement Program has increased. FDA has also met Federal Employee Viewpoint Survey (FEVS) targets.

Leadership Succession Planning

The FDA FY2021-FY2024 Succession Management Plan aims to ensure leadership continuity and organizational excellence by identifying and preparing high-potential candidates for critical roles. The plan's purpose is to align with FDA's strategic priorities, support workforce and succession planning initiatives within FDA centers, and build on current work products. Previously, succession planning efforts were fragmented, with varying levels of maturity across centers. The current state reflects a more integrated approach, with establishment of a cross-agency Succession Planning Workgroup (SPW) that promotes collaboration and co-creation of recommendations. This has led to improved data collection, better understanding of bench readiness, and identification of risks and opportunities.

Table 3-7 provides a high-level summary of answers to the assessment questions related to the leadership succession planning enhancement area. Below the table we provide more detailed answers to the assessment questions.

Table 3-7. High-level summary of answers to assessment questions for Leadership Succession Planning enhancement area

Assessment Question	Answer	Explanation
Enhancement status	On schedule	FDA has made progress in implementing SWFP initiatives, with 100% implementation of FDA's FY2021-FY2024 Succession Management Strategic Plan action items completed.
Causes of any delays	None	No delays in implementation.
Fidelity of implementation	High	Implementation aligns with strategic priorities and supports workforce initiatives.
Impact on hiring/retention outcomes	Mostly positive	Trainings and programs are available to develop needed skills. Agency-level planning provides guidance for Center-level activities. Center-level succession planning is less robust than Agency-level planning; unexpected leadership vacancies and resource limitations add challenges.

What is the status of the leadership succession planning enhancements planned at the time of the last assessment?

The 2021 PDUFA VI HR/HC assessment noted that FDA had initiated strategies to advance succession planning, focusing on establishing a robust framework to ensure leadership continuity and organizational excellence. It highlighted plans and measurable objectives that formed a framework for strategic initiatives for recruiting, hiring, and retention. However, it suggested that FDA further integrate these strategies and take a more proactive approach to managing attrition of mission critical skills in CDER and CBER. Since that time, FDA has:

- Established templates for center summary reports and developed annual summary reports.
- Enhanced leadership development programs.
- Enhanced experiential learning and internal development, resulting in a more prepared and qualified leadership pipeline.

In addition, FDA established the SPW to examine succession planning analytics and reporting and created a repository of best practices and resources related to succession planning at the human capital council level. Better data integration and process standardization are still needed to fully benefit from these initiatives. At the time of this assessment, 80% of FDA, 100% of CDER, and 54% of CBER leadership positions had one or more well-prepared and qualified candidates ready to assume vacated positions.[11]

[11] The 2024 FDA Succession Planning Workgroup Summary Reports categorized leadership positions as "SPW defined Center/Office leadership positions" and "additional defined Center/Office leadership positions" without further detail.

Despite advancements at the Agency-level, CDER and CBER succession planning need further development (discussed further below). FDA plans to address these issues in the next draft of the succession plan while continuing to enhance the Agency's initiatives towards succession planning.

What were causes of any delays to implementation of leadership succession planning enhancements?

FDA has experienced no delays in leadership succession planning at the Agency level. CDER and CBER have experienced four challenges that impact the efficacy of planning efforts (see discussion of impacts of implementation, below).

To what extent were leadership succession planning enhancements implemented with fidelity?

Despite some challenges, implementation of FDA's Succession Management Strategic Plan closely aligns with stated goals and strategic priorities (Table 3-8).

Table 3-8. Fidelity of implementation of the Leadership Succession Planning enhancement to stated goals

Leadership Succession Planning Enhancement Goal	Implementation Fidelity
Align with FDA's strategic priorities.	Integration of regulatory requirements and alignment with strategic plans, such as FDA's and HHS's strategic plans, have provided a robust framework for succession planning.
Build on work products currently under development at the department and federal levels.	Leveraging data from summary reports to draft the next succession plan, creation of a repository for best practices, and implementation of bright spot meetings help FDA make data-driven decisions and contribute to a culture of knowledge sharing and collaboration.
Support workforce and succession planning initiatives within FDA Centers.	Center-level summary reports and the SPW help facilitate cross-agency collaboration and provide a comprehensive understanding of the succession planning landscape across Centers and Offices. The SPW has engaged succession planning leads across the Agency, promoting diverse perspectives and a deeper understanding of variabilities and similarities across Centers.

What is the impact of leadership succession planning enhancements on hiring and retention outcomes?

FDA's leadership succession planning involves developing and expanding talent pools; providing training on a wide variety of skills (e.g., soft skills, leadership skills, technical training); analyzing and assessing current and future needs; and providing annual summary reports as a basis for planning. Notable achievements include:

- **Planning and collaboration:** The SPW and its work in creating consolidated summary reports provide a comprehensive view of cross-Agency efforts. This facilitates benchmarking, development of cohesive approaches, and identification of emerging risks for succession.
- **Identifying key risks and challenges to succession planning:** Identification of "undefined" elements (e.g., cultural differences, varying maturity levels, and internal politics) has helped FDA recognize the need for more support, training, and monitoring of cultural shifts at the Center-

level. Integration of succession management with broader HC and workforce planning efforts has also helped identify social factors, political factors, and organizational realignments that impact senior executive positions.

- **Implementing training and leadership development opportunities:** Mentorship programs, training opportunities, rotational details, leadership skills building further down the chain of command, and proactive assessment of staffing needs help staff progress in their career at FDA.

In total, the result of all this work is an increase in qualified candidates prepared to move up the career ladder. Nevertheless, CDER and CBER have encountered particular challenges that make succession planning more difficult:

- The unpredictability of leadership departures.
- In CBER, a relatively high proportion of staff eligible to retire (21% of workforce eligible to retire in CBER compared to 16% FDA-wide),[12] posing a potential risk to retaining mission-critical skills.
- Difficulty competing with industry to recruit, retain, and develop leadership talent.
- Additional complexity to succession planning with use of various hiring authorities (including Title 21), though this is counterbalanced by increased flexibility in hiring.
- Budgetary constraints that hinder the ability to further develop the bench of potential leaders.

Changes in federal policy made after January 2025—such as orders to return to work onsite—and uncertainties in how policies, priorities, directions, and climate at FDA are impacting recruitment, hiring, and retention of skilled staff. Depending on how these issues evolve, this situation is likely to impact the bench of potential leaders as well.

3.2 Recruiting, Hiring, Pre-Employment Onboarding, and Retention Status and Effectiveness of Current Practices

For this assessment of FDA's HR/HC program for human drug review staff, ERG examined four phases of FDA's talent lifecycle: recruiting, hiring, pre-employment onboarding, and retention. Table 3-9 presents a high-level summary of the current status of these activities. Below that are answers to assessment questions related to each category of HR/HC activity.

Table 3-9. High-level summary of status of recruiting, hiring, pre-employment onboarding, and retention

Status at Time of Last Assessment (FY2021)	Current Status (FY2024)	Explanation
Recruitment strategies from OTS and Center-level HR/HC staff successfully identify candidates.	**Still working well**	Current recruitment strategies successfully make a talented candidate pool aware of FDA job openings.
Hiring challenges exist, including lengthy hiring times and differences in perspective on applicant qualifications.	**Progress made**	Some aspects of hiring duration are outside FDA's control; FDA meets most service level agreements (SLAs) within their control, though the overall hiring process can take several months. Disagreements about qualification of candidates still occur in some cases.

[12] 2024 FDA Succession Planning Workgroup Summary Report.

Status at Time of Last Assessment (FY2021)	Current Status (FY2024)	Explanation
Pre-employment onboarding not a major topic of the last assessment.	**Generally working well**	CDER/CBER new hires are satisfied with the clearance process and new employee orientation (NEO). Some confusion remains about who initiates clearance processes. Overall timeline for security procedures can be lengthy due to fingerprinting and badging steps, which are dependent on applicant responsiveness and appointment scheduling limitations.
Attrition is relatively low for CDER and CBER.	**Still working well**	Attrition remains relatively low for CDER and CBER.
Special hiring and pay authorities benefit FDA hiring and retention.	**Still working well**	FDA continues to lean on Title 21 to hire and retain skilled scientific staff.

What is the current status of FDA recruiting?

Summary: For CDER and CBER human drug review program staff, FDA's current recruiting practices yield a sufficient talent pool to produce skilled, qualified hires that meet the needs of the Centers. Moreover, new hires report positive experiences with the recruitment process. FDA's Agency- and Center-level HR/HC staff generally agree that recruitment practices are effective, though they identify opportunities for further improvement—such as processes to avoid disagreements between OTS and Program Offices about whether candidates are qualified for a position.

At FDA, recruiting consists of:

- **Talent launch**—identifying vacancy requirements, developing a recruitment strategy, and announcing the vacancy. The CDER/CBER hiring manager, a CDER/CBER management analyst, and an FDA OTS HR specialist collaborate on these activities.
- **Talent sourcing**—conducting outreach and implementing and assessing the recruitment strategy. An OTS HR Specialist leads the vacancy posting effort after it is reviewed by an OTS quality reviewer and CDER/CBER hiring manager. A CDER/CBER human capital liaison (HCL) may also support with social media postings. The hiring manager, quality reviewer, HR specialist, and HCL collaborate on these activities.
- **Initial steps of talent evaluation**—analyzing candidates' qualifications and issuing certificates for qualified candidates, conducted by the OTS HR specialist. The CDER/CBER hiring manager, quality reviewer, and HR specialist collaborate on these activities.

Please see FDA Human Drug Review HR/HC Program for more details.

The 2021 PDUFA VI HR/HC assessment described FDA's recruiting activities as largely successful in generating a talent pool sufficient to enable FDA to identify skilled, qualified staff that meet each Center's needs. In our assessment, ERG found that this continues to be true. Practices that contribute to effective recruiting of CDER and CBER human drug review staff include:

- Increasing use of hiring authorities that enable FDA to be more competitive—especially Title 21, which appeals to potential applicants because it provides for greater flexibility and speed in the hiring process as well as more competitive salaries.
- Leveraging the work of the Scientific Staffing and Outreach Branch (SSOB), which has increased the number of strategic partnerships from 60 in 2021 to 333 in 2024.
- Conducting direct outreach at conferences and hiring events.
- Using social media (especially LinkedIn) to advertise positions. In tracking social media analytics, the SSOB reports an average of 180,000 views per job posting and 16,000 clicks to apply per job posting.[13]

In ERG's surveys, interviews, and focus groups, OTS staff generally describe the recruitment process as effective and efficient. Both OTS and Center hiring managers report satisfaction with recruitment processes that they control (e.g., reporting the need for a new hire, reviewing the vacancy announcement). Furthermore, new hires report high rates of satisfaction with their experience with the recruitment process, including learning about the job opportunity and applying for the job. They also report high rates of satisfaction with their decision to work in their current position in their Center.

While FDA's recruiting of human drug review staff is largely effective, ERG did observe some challenges:

- **Candidate qualification determinations:** OTS and Center hiring managers sometimes have differing opinions about whether candidates are qualified for a position. This can occur when OTS deems a candidate not to be qualified due to subtle differences between the candidate's academic or professional experience and the position description (PD); this removes skilled candidates from the hiring pool. Conversely, OTS sometimes issues certificates of qualification to candidates who hiring managers do not believe are qualified. These differences in opinion can result in a need to seek more applicants, reducing the efficiency of the recruitment process. The 2021 PDUFA VI HR/HC assessment noted this challenge as well.
- **Posting of jobs under Title 21:** Currently, the standard procedure for positions being filled under Title 21 does not involve posting to USAJobs, which limits the reach of these job openings to potential applicants. Applicants learn about these positions through word of mouth (especially in the case of conversion of existing CDER and CBER staff from another hiring authority to Title 21), LinkedIn, or the *FDA Title 21 postings website*.

What is the current status of FDA hiring?

Summary: FDA's current hiring practices appropriately evaluate candidates and identify future employees to support FDA's public health mission. New hires report satisfaction with their experience in the hiring process. Hiring managers express positive sentiments about the portions of the hiring process that are under their control (e.g., interviewing). However, hiring managers give lower satisfaction ratings for elements that depend on other parties, like OTS. FDA's Agency- and Center-level HR/HC staff generally agree that hiring practices are effective, though they identify some opportunities for improvement—such as clarifying processes for the period from a package leaving the program office to

[13] FDA OTS Scientific Staffing Outreach Branch Data Request.

its arrival in OTS. Center-level HR/HC staff and hiring managers also noted that it can take several months for a candidate to receive a tentative offer from OTS.

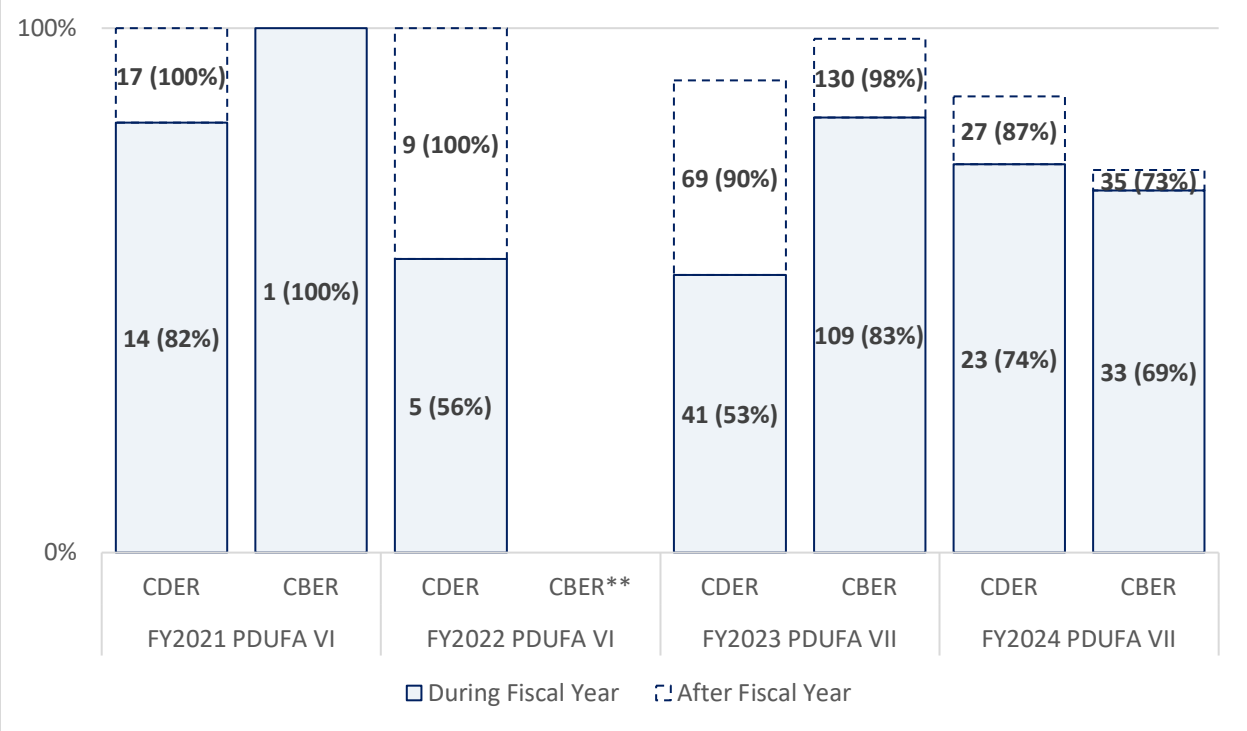
At FDA, hiring consists of:

- **Remainder of talent evaluation**—reviewing resumes of candidates on the certificate of qualification for the position. The CDER/CBER hiring manager performs this review.
- **Interview and selection**—meeting with candidates, evaluating their talent and skills, speaking with references, and making a selection to fill the position. The CDER/CBER hiring manager leads this process, with support from the CDER/CBER HCL to submit the selection to the OTS HR specialist and quality reviewer.
- **Initial portion of tentative offer**—issuing the tentative offer and negotiating salary. The OTS HR specialist issues the tentative offer and notifies the Center about salary negotiation if requested. The Center/Office hiring manager completes the current supervisor reference check. The HR specialist also approves the salary adjustment determined by the Center. The CDER/CBER HCL then initiates clearances.

Please see FDA Human Drug Review HR/HC Program for more details.

Figure 3-1 presents FDA's fulfillment of PDUFA hiring goals at the time of the last assessment (PDUFA VI, FY2021) and currently (PDUFA VII, FY2024). For BsUFA, hiring goals did not exist in FY2021 and FY2022. As of December 31, 2024, FDA reached 93% of its BsUFA III hiring goal of 14 people in FY2023, and did not fulfill the FY2024 BsUFA III hiring goal of 1 employee. In general, both at the time of the last assessment and currently, FDA has been meeting or been close to meeting its PDUFA and BsUFA hiring goals each fiscal year. FDA hires most staff within the fiscal year; because hiring for individual positions begins at different points throughout the year and the hiring process is lengthy, entrance on duty (EOD) for some staff occurs after the end of the fiscal year. For FY2024, insufficient time has elapsed to determine the extent to which FDA will meet its PDUFA and BsUFA hiring goals. However, ERG does have comparable data for the previous year, FY2023, which shows that FDA achieved 90% or more of its hiring goal.

Figure 3-1. Percent of PDUFA hiring goals fulfilled within or after the fiscal year, for FY2021, FY2023, and FY2024*



Sources: *FDARA Hiring Data*; *PDUFA and BsUFA Quarterly Hiring Updates*.

*For hires after the fiscal year for FY2021, FDA assessed completion of the hiring goal as of September 30, 2022 (four quarters after the end of the fiscal year). For FY2022, FDA assessed completion of the hiring goal as of September 30, 2023 (four quarters after the end of the fiscal year). For FY2023, FDA assessed completion of the hiring goal as of December 31, 2024 (five quarters after the end of the fiscal year). For FY2024, data has been updated through December 31, 2024 (one quarter after the end of the fiscal year).

**The hiring goal for CBER in FY2022 was zero.

The 2021 PDUFA VI HR/HC assessment described FDA's hiring as an evolving process, noting a shift towards hiring and converting employees using authorities like Title 21 and Direct Hire. Under these initiatives and through the use of shared certificates (to enable sharing of qualified candidates across positions), the last assessment cited an improvement in average time to hire, especially among Title 21 and Title 42(g) hires. In our assessment, ERG found that this continues to be true:

- In FY2023 and FY2024, FDA hired most new PDUFA and BsUFA staff using Title 21 for physicians and non-physician/non-executive positions.
- Agency- and Center-level HR/HC staff report that Title 21 is a faster process than Title 5.

- From FY2021 to FY2024, the average time from when a candidate's package is received by OTS to when the candidate's EOD is finalized, as tracked in ATLAS for PDUFA and BsUFA employees, decreased under multiple hiring authorities with average times for individual process steps well below service level agreements.
    - *Direct Hire* (time in OTS only) – 64 business days in FY2021, to 10 business days in FY2024.
    - *Title 21* (time in OTS only) – 47 business days in FY2021, to 43 business days (Executives), 27 business days (Physicians), and 26 business days (Non-Executives/Non-Physicians) in FY2024.
    - *Title 42(g)* (time in OTS only) – 29 business days in FY2021, to 28 business days in FY2024.
- Anecdotally, Agency- and Center-level staff anticipate that a new Title 21 announcement process, currently being piloted to expand awareness of these positions on USAJobs, will produce a broad, qualified applicant pool to be reviewed during the hiring phase.

Practices that contribute to efficient and effective hiring of human drug review staff include:

- Utilizing standardized interview questions to evaluate candidate skills fairly and consistently.
- Performing a standardized screening process using phone calls or other tools (e.g., HireVue).

In interviews, focus groups, and surveys conducted for this assessment, CDER and CBER hiring managers generally reported satisfaction with the elements of the hiring process that are under their control, like the interview and selection process. They reported less satisfaction with elements that depend on OTS, like receiving the certificate of qualification and waiting for OTS to issue the tentative offer to the candidate. Most OTS staff rated the hiring process as effective and efficient, while CDER and CBER HR/HC staff generally did not. CDER and CBER HR/HC staff and hiring managers commented on the length of time it takes to generate and receive a certificate and issue a tentative offer to candidates, noting that it can take months for a candidate to receive an offer.

Time to Hire

In this report, ERG presents data on achievement of service level agreements for each step in the recruitment and hiring process that is tracked in ATLAS, beginning with "Program Submission" and ending with "Final Offer & EOD." This provides a comparison to the time-to-hire data available in the last assessment. Data on the total time to hire from start to finish (including time that elapses in steps that take place in individual Centers and Offices outside of the steps tracked in ATLAS) were not available from FDA at the time of this assessment. Therefore, ERG could not calculate the average or range for total time to hire, create a picture of the time that elapses for all the individual elements in the process, or conduct an analysis of opportunities to reduce the total time to hire. Anecdotally, the overall time to hire ranged from 5 to 18 months, with some exceptions above and below this range.

In our assessment, CDER and CBER new hires reported satisfaction with their experience in most elements of the hiring process; they reported less satisfaction with salary negotiation (see Appendix C, Figure C-23). Some new hires stated that they were unsure when the salary negotiation was meant to take place, which might influence the satisfaction score; not receiving the desired salary could also

impact the satisfaction score for some new hires. For the hiring process as a whole, new hires described frustration with the overall length of the hiring process, sometimes with long periods of no communication. Many factors outside FDA's control contribute to the length of the hiring process.

While FDA's hiring practices for PDUFA and BsUFA staff are largely effective, three challenges are:

- **Lack of tracking mechanism between Center Office of Management (OM) and OTS:** CDER and CBER HR/HC staff and hiring managers experience a gap in status tracking from the time a hiring package leaves their data system (AOIS or PathHR) until OTS enters information into ATLAS. Understanding package status and when it will reach the next stage would be beneficial.
- **Qualifications for Title 21:** Currently, Title 21 bypasses the standard recruitment process and begins in earnest with selection of a candidate during the hiring phase. Word of mouth, posts on social media such as LinkedIn, and internal boards generate applications, which go directly to the CDER/CBER hiring manager; these applications are sent to OTS for qualifications after the Center hiring manager has made a selection. Center staff (GS-343s) are not HR specialists (GS-201s) like in OTS, so they do not have the authority to formally determine the qualifications of a candidate. As a result, Center staff might not learn that they cannot proceed with a candidate until several labor hours have been dedicated to processing the candidate.
- **Length of hiring process and lack of communication:** New hires reported that the length of the hiring process coupled with minimal communication from FDA led them to believe that they were passed over for the position, causing them to seek other opportunities. This is also frustrating for HR/HC staff and hiring managers as they may lose high quality candidates who seek other work. While the length of the hiring process is largely outside of FDA's control, an opportunity for improvement might be to provide additional status updates to candidates so they know definitively that they are still being considered for the position.

What is the current status of FDA pre-employment onboarding?

Summary: For CDER and CBER human drug review program staff, FDA's current pre-employment onboarding practices lead to successful completion of security (background) checks and ethics pre-clearances within expected timelines. Onboarding practices also provide sufficient education for new staff on FDA procedures and prepare them to perform their duties. Newly hired staff and Agency-level HR/HC staff generally report positive experiences and satisfaction with the efficiency and effectiveness of pre-employment onboarding practices, though they identify opportunities for improvement—such as clarifying the responsibility for initiating clearances and streamlining the security process.

At FDA, pre-employment onboarding consists of:

- **Remainder of tentative offer**—completing security clearance (background check) and ethics pre-clearance processes.
- **Final offer and Entrance on Duty (EOD)**—verifying completion of clearances, issuing final offer to the candidate, and closing the case. A CDER/CBER HCL submits required clearance documentation, and the OTS HR specialist follows up to ensure completion. The HR specialist also issues the final offer and closes the case.

Please see FDA Human Drug Review HR/HC Program for more details.

The 2021 PDUFA VI HR/HC assessment described the pre-employment onboarding process (both as a whole and specific elements) as pain points. In our assessment, ERG has observed improvements:

- Most CDER and CBER new hires report satisfaction with ethics and security screening processes.
- In calendar year 2024, the Office of Security and Passport Operations (OSPO) [14] cleared candidates through eArrive in an average of 11 days (CDER) and 13 days (CBER), which is under the 14-day service level agreement. ERG was unable to obtain complete data, but the data we received suggest that the Office of Ethics and Integrity similarly completes ethics pre-clearances well within their service level agreements.
- Most CDER and CBER new hires are satisfied with FDA New Employee Orientation (NEO) and Center-specific NEO.

In ERG's surveys, interviews, and focus groups, the Office of Human Capital Management (OHCM) and OTS staff generally reported that the pre-employment onboarding process is effective and efficient, and Agency- and Center-level staff described the current pre-employment onboarding process as being standardized and straightforward with minimal confusion, particularly when it comes to the orientation and training of new staff. While HR/HC staff and new hires agreed that the Agency-wide NEO adequately educates staff on Agency policies and benefits, they also agreed that these sessions present more information than staff can reasonably be expected to recall. However, NEO resources are available on insideFDA (available to staff once they receive their badge and computer equipment). These serve as a crucial first step for new staff to obtain answers to questions.

While many elements of FDA's pre-employment onboarding of human drug review staff are largely effective, ERG observed some challenges:

- **Security and ethics clearance initiation:** In CDER/CBER program offices, some staff are uncertain about who is responsible for initiating security and ethics clearances. Center OM staff sometimes submit the ethics package because program offices do not do so consistently, but this can lead to duplicative work and requests.
- **Security eArrive delays:** Factors outside FDA's control sometimes cause delays with eArrive and security clearance initiation procedures. For example, delays can occur if candidates do not return paperwork promptly, cannot be fingerprinted promptly because they live far from FDA facilities, or need to meet drug testing or other requirements.
- **Overall security timeline:** While data show that OSPO completes the eArrive processing within the 14-day service level agreement on average, OTS and CDER/CBER staff describe the overall timeline, including fingerprinting and badging, as a pain point. Security staff have a plan to allow candidates to book their own fingerprinting appointments rather than having a personnel security specialist schedule them.

What is the current status of FDA retention of new hires?

Summary: Through FY2024, FDA's retention practices have contributed to high retention rates (low attrition rates). Belief in FDA's mission and public health work motivate employees to continue their

[14] As part of the reorganization that occurred at the end of FY2024, FDA divided the Office of Security and Emergency Management (OSEM) into two groups; security clearance and badging processes remain in the Office of Operations (OO) in the newly renamed "OSPO," and emergency management services now occur in the Office of Inspections and Investigations (OII).

current work, and the majority of newly hired CDER and CBER staff report satisfaction with their position or Center. However, some staff report that a desire for improved salaries and promotion pathways could motivate them to leave the Agency. In addition, new federal policies (e.g., reduction or elimination of telework and flexible work options) and uncertainties (in potential changes to how FDA carries out its mission) have the potential to motivate more staff to leave.

At FDA, retention consists of the measures, benefits, and incentives designed to keep employees in their current role at the Agency. Please see FDA Human Drug Review HR/HC Program for more details.

At the time of the 2021 PDUFA VI HR/HC assessment, FDA's attrition for CDER and CBER remained low and predictable, averaging 6% for CDER and 8% for CBER from FY2018 to FY2020. The COVID-19 pandemic began during that time and impacted the entire talent lifecycle, with a notable shift toward flexible schedules and telework. In our assessment, ERG found similar retention outcomes:

- From FY2024 through the first quarter of FY2025, attrition rates were low: 4.6% for CDER and 5.4% for CBER.
- In our surveys, 93% of newly hired CDER and CBER staff reported satisfaction with their decision to work in their current position and Center.
- In surveys and focus groups, staff cited that belief in FDA's mission of strengthening public health influences their decision to stay with the Agency.

In surveys, OTS and OHCM staff reported agreement with statements about HR/HC culture, practices, and principles being shared and cultivated at the Agency and Center levels. Furthermore, in focus groups, they stated that FDA work-life balance and programs positively impact staff retention.

While FDA's retention of human drug review staff is largely effective, ERG observed the following challenges during our data collection period (October 2023 to January 2025):

- **Lack of promotion pathways:** Staff would like more opportunities for upward growth in responsibilities and leadership at FDA, citing a lack of promotion pathways as a reason that they would consider leaving FDA.
- **Salaries:** FDA cannot offer salaries as high as those available in industry.
- **Flexible schedules and telework:** Most CDER and CBER staff report that full-time telework and flexible schedules influence their decision to stay in their Center. Anecdotally, the termination of remote work arrangements and a requirement for employees to return to work in-person on a full-time basis (as of late January 2025) is having a negative impact on retention (and recruitment and hiring, to the extent that the Agency can hire). The evidence suggests that attrition is likely to increase substantially in calendar year 2025.

How do FDA's hiring outcomes and retention rates compare to those of similar federal agencies and industry?

Summary: FDA performs comparably to similar federal agencies and industry in terms of HR/HC structure and hiring outcomes. FDA outperforms similar agencies and industry in terms of retention.

To support our understanding of FDA hiring and retention outcomes, ERG collected publicly available data on similar federal agencies and private industry (see Appendix C, Table C-11). The other federal agencies we used for comparison are the National Aeronautics and Space Administration (NASA),

National Institutes of Health (NIH), National Oceanic and Atmospheric Administration (NOAA), and the Securities and Exchange Commission (SEC). ERG also collected available data from the pharmaceutical industry, which is a major competitor for talent. Table 3-10 presents an overview of FDA's performance in key HR/HC metrics compared to similar federal agencies and industry. For more details, see Detailed Results.

Table 3-10. Comparison of FDA HR/HC performance with other federal agencies and industry

HR/HC Metric	FDA Compared to Similar Federal Agencies	FDA Compared to Industry
HR/HC structure	Comparable	Sometimes comparable (variable)*
Number of employees	Sometimes comparable	Sometimes comparable (variable)*
Mean length of federal service	Sometimes comparable	N/A
Percent of hires who are transfers in | new hires	Comparable	N/A
Percent of personnel loss: transfers out	Comparable	N/A
Accession rate	Comparable	N/A
Attrition rate	**Better (lower)**	**Better (lower)**
Net staffing change rate (2020-2024)**	N/A	Comparable
Percent of employees who quit federal service during fiscal year	Comparable	N/A

Sources: FedScope FY2024 through March 2024 and public-facing pharmaceutical industry websites (see Appendix C, Table C-11, for a full list of sources).

*Within private industry, HR/HC structure, size, and outcomes vary more from one organization to the next than they do within the federal government.

**Net staffing change rate measures overall change in number of employees during a specific period, calculated by dividing the annual change in staff count by the average staff count during that period.

Overall, FDA performs comparably to other federal agencies and industry in terms of HR/HC structure and hiring outcomes. Notably, FDA outperforms similar federal agencies and industry in terms of retention. Additionally, ERG compared FEVS data for FDA, CDER, and CBER with those for similar federal agencies; values for global satisfaction index (GSI), performance confidence index (PCI), and employee engagement index (EEI) are similar across these agencies.

3.3 Hiring Process Transparency

For this assessment, ERG evaluated the transparency of FDA hiring processes for HR/HC staff, new staff, and other staff. Table 3-11 presents a high-level summary of the current status of hiring process transparency. Below that are answers to assessment questions related to hiring process transparency.

Table 3-11. High-level summary of status of hiring process transparency

Status at Time of Last Assessment (FY2021)	Current Status (FY2024)	Explanation
Hiring managers, HR managers, and HR staff need process guidance (e.g., processes steps, roles) to make HR processes more successful.	**Significant improvement**	HR/HC staff and hiring managers are clear on their own roles. Most HR/HC staff feel they have sufficient resources; OHCM staff would like more resources (e.g., training, documentation).
Data systems improve HR/HC processes, but many more integrations and workflows are needed.	**Significant improvement**	Systems have modernized, streamlined, and improved transparency and accountability of hiring processes. Users would like further integrations and broad access.
HR managers and HR staff need more direct communication between Offices and positions, and resources on roles and processes.	**Progress made**	Communication has increased. Some challenges remain, such as unclear HR/HC contacts and processes in some cases.
Hiring managers need more resources and coordination with other HR staff to improve hiring processes.	**Progress made**	Resources have improved, though still need further improvement. Cross-Office and cross-Center communication, collaboration, and coordination remain challenging.
New hires experience inconsistencies in communication, processes, and documentation.	**Progress made**	Some communication, processes, and documentation have improved. Some candidates still experience inconsistencies in communication or contradicting information.

To what extent are hiring processes, goals, and expectations clear and understandable to FDA HR/HC staff?

Summary: Most HR/HC staff are clear about their roles and receive sufficient training and documentation to support them in performing their duties, although OHCM staff express a desire for more training. Roles, processes, communication, and collaboration across Offices and Centers are less transparent. Enhancements to HR data systems contribute significantly to transparency, however.

At the time of the 2021 PDUFA VI HR/HC assessment, HR managers and HR staff expressed a need for (1) more direct communication between Offices (e.g., OTS and OHCM) and positions (e.g., HC Liaisons and Center OM staff), (2) more resources (e.g., process guidance, checklists, job aids), and (3) improved HR data systems and data integration. In our assessment, ERG observed substantial improvements for most staff who play a role in recruiting, hiring, pre-employment onboarding, and retention. Their roles are clear, and they receive sufficient training and documentation to perform their duties. However, a greater proportion of OHCM staff feel a need for more resources (e.g., training) to assist them in performing their role effectively.

Though transparency is satisfactory within an Office or Center, transparency is lower for communication, collaboration, and points of contact across Offices and Centers. In surveys, OTS staff gave the highest ratings for transparency, OHCM staff generally gave neutral ratings, and CDER and CBER HR/HC staff gave low ratings. Across organizational units, staff are not always sure of the roles of other parties. In addition, changes to organizational charts can make it hard to identify and obtain a timely response from points of contact, resulting in a feeling that not much cross-office communication occurs.

Although cross-Office meetings do occur, these methods of communication do not appear to be sufficient to meet staff needs. In some cases, communications go through multiple touchpoints before they reach staff, which can create communication delays and inconsistencies—and thus staff not being adequately informed of statuses, new policies and processes, or changes to existing policies and processes.

On the other hand, enhancements to HR data systems (ATLAS, AOIS, PathHR) have been successful in improving transparency—by providing a mechanism to track ownership and status of actions (with time stamps). Automated alerts from these systems can improve transparency and accountability, though some staff would like fewer alerts (to avoid clogging inboxes) while others would like more alerts.

How transparent is the hiring process to other FDA staff?

Summary: For other FDA staff (including leadership, review staff, and hiring managers), transparency is often sufficient within an Office or Center. However, communication and collaboration across Offices and Centers are sometimes insufficient to create a sense of transparency in hiring timelines, statuses, and changes in policies and processes. In some cases, staff report losing candidates due to a lack of transparency (lack of status updates for candidates).

At the time of the 2021 PDUFA VI HR/HC assessment, hiring managers expressed a need for more resources (e.g., process guidance, checklists, job aids), more clearly defined roles for those involved in HR processes, more direct engagement with OTS and OHCM, and improved coordination to advance customer service. In our assessment, ERG observed that some of these cross-Office and cross-Center communication, collaboration, and coordination challenges remain. In general, hiring managers are more satisfied with HR/HC staff within their Offices/Centers than in other Offices/Centers; however, even within an Office/Center, satisfaction is not as high as desired.

Challenges in communication and collaboration impact transparency in three main ways:

- **Changing policies and processes:** Changes in policy can appear to be last-minute, arbitrary, or lacking sufficient documentation, leading to inconsistencies in how hiring packages are reviewed and causing avoidable delays in the hiring process.
- **Unclear statuses and timelines:** Lack of clarity about the status of hiring packages and other actions or steps in the hiring process can similarly cause confusion or avoidable delays in the hiring process.
- **Lack of transparency for candidates:** Some candidates exit the FDA hiring process to seek other opportunities during periods of prolonged uncertainty.

Like HR/HC staff, staff in this cohort indicate that enhancements to HR data systems contribute to transparency and accountability. They encourage additional integration of HR data systems (to provide

more information about steps outside their Office/Center) and greater access for staff involved in the hiring process.

How transparent is the hiring process to new staff?

Summary: CDER and CBER new hires have mixed experiences with hiring process transparency. Many cite inconsistencies in communications (or prolonged periods without status updates) and non-transparent timelines and processes. This led some to consider other job opportunities, though ERG obtained feedback only from candidates who ultimately accepted a position with FDA.

At the time of the 2021 PDUFA VI HR/HC assessment, new hires had several issues with hiring process transparency, including inconsistent communication, non-standardized processes and documentation, and slow processes that led to candidates seeking other opportunities. For our assessment, ERG defined new staff as employees who have worked in their current position at FDA for less than one year at the time of our staff surveys. We find that the challenges cited in the last assessment largely remain:

- **Insufficient timeliness in communication:** When they were job candidates, new staff found it difficult to know the status of their application or what steps they should expect next or when. It would have been helpful to have reference documentation that outlines FDA's hiring process, particularly during periods of little communication.
- **Contradictory information and redundant processes:** When they were job candidates, new staff observed a lack of communication and collaboration between FDA Offices and staff on shared elements of the hiring process. This would sometimes result in contradictory information from HR staff and hiring managers, as well as multiple requests for the same forms or information. This made it hard to understand what FDA needed from them and what their expectations should be for their potential position at FDA.
- **Unclear Title 21 pay:** Lack of transparency about salaries led some new hires to perceive discrepancies in pay for comparable positions across Offices or Centers.
- **Seeking other opportunities:** A lack of transparency (including long timelines and long periods without communication) left candidates unsure of their hiring status, which sometimes resulted in candidates considering and applying for other opportunities.

4. Findings and Recommendations

This section presents ERG's findings and recommendations based on our results (Appendix C) and answers to the assessment questions (Section 3).

4.1 FDA HR/HC Overall

Table 4-1. Findings and recommendations for FDA HR/HC overall

No.	Finding	Recommendation(s)
1-A	Overall, FDA's recruitment, hiring, pre-employment onboarding, and retention practices have improved since the last assessment. Processes are more effective and efficient, and FDA is generally able to attract and retain qualified staff.	None.
1-B	Due to its streamlined processes and flexibilities, use of the Title 21 (Cures Act) hiring authority is attractive to FDA staff involved in hiring, external candidates, and internal staff who convert to a Title 21 position.	None.
1-C	Communication and coordination across Offices and Centers continue to be a pain point for FDA staff involved in recruitment, hiring, pre-employment onboarding, and retention.	Focus on improving cross Office and Center communication and coordination in three areas: • Clarify roles and responsibilities, delineate handoff procedures, and establish clear touchpoints for processes that require cross Office/Center coordination. • Establish and consistently apply a procedure to communicate policy and process changes directly to affected staff, with documentation in a repository of current policies and procedures. Have changes take effect at predictable points (e.g., start of a pay period). • Explore further HR data system integration to improve tracking and access to status information (including reasons for delays) for hiring packages across Offices and Centers.

4.2 FDA HR Enhancements

Table 4-2. Findings and recommendations for FDA HR enhancement areas

No.	Finding	Recommendation
2-A	FDA has successfully implemented each enhancement area with minimal to no delays and in alignment with stated goals.	For HR data systems, continue to implement updates and address missing or unintegrated workflows (including process that span Offices and Centers) and expand access for more staff in more roles where feasible.

4.3 FDA Recruitment, Hiring, Pre-Employment Onboarding, and Retention Status and Effectiveness of Current Practices

Table 4-3. Findings and recommendations for FDA recruitment, hiring, pre-employment onboarding, and retention

No.	Finding	Recommendation
3-A	FDA's use of a wide range of recruitment and outreach strategies is effective in making CDER and CBER job opportunities visible to prospective applicants.	None.
3-B	FDA's hiring process is effective. Good practices such as standardized screening and interview promote fair, consistent treatment of candidates. FDA staff involved in hiring sometimes experience challenges with (1) which candidates are deemed qualified on certificates and (2) confusion about who is responsible for initiating security and ethics pre-clearance processes.	Take three actions: • Expand standardized screening and interview practices Agency-wide. • Address qualifications procedures to ensure hiring managers and OTS HR specialists share a common understanding about which candidates can be considered qualified. • Clarify roles and responsibilities for security and ethics pre-clearance initiation across all involved parties.
3-C	Due to the length of the overall hiring and pre-employment onboarding process and insufficient communication during that time, FDA loses some qualified candidates.	Add touchpoints with candidates to communicate status (even if status is unchanged) and next steps – and to convey that FDA values the candidates and appreciates their time and patience.
3-D	Agency- and Center-specific NEOs are effective in preparing staff to begin work at FDA.	None.
3-E	Most new hires are satisfied with their decision to work in their current position at their Center.	None.
3-F	FDA's retention initiatives are largely effective. Three challenges are: • Reduction or elimination of telework and flexible work schedules (which are highly valued). • Perceived insufficiency in promotion pathways. • Lower salaries compared to those available in industry.	To the extent possible: • Continue current retention initiatives and re-establish recently amended initiatives (especially flexible work arrangements). • Create and publicize opportunities for leadership skills development and promotion. • As budget allows, convert employees to Title 21.
3-G	FDA's data on time to hire currently exist in disparate systems, making it difficult to accurately calculate total time to hire (which anecdotally ranges from 5 to 18 months). Within specific elements of the hiring process tracked by ATLAS	Two actions: • Investigate mechanisms to enable calculation of data across disparate systems to reliably determine total time to hire and data for individual phases/steps in the overall process. • Develop an analysis of factors contributing to total time to hire outside of those related to

No.	Finding	Recommendation
	and for security clearance procedures, FDA generally meets SLAs.	SLAs, and identify opportunities to reduce the total time to hire.

4.4 FDA Hiring Process Transparency

Table 4-4. Findings and recommendations for FDA hiring process transparency

No.	Finding	Recommendation(s)
4-A	New hires in CDER and CBER are generally satisfied with the hiring process and their decision to join FDA. However, lack of transparency about their status and next steps during the hiring process posed challenges and causes some candidates to look elsewhere for employment.	See Recommendation 3-C.
4-B	Staff involved in hiring generally understand their own roles and processes, but do not consistently find roles and processes in other Offices and Centers to be transparent.	See Recommendations 1-C and 3-B.
4-C	FDA's HR data system enhancements have contributed to significant improvements in the transparency of hiring actions and statuses, though opportunities for improvement still exist.	See Recommendations 1-C and 2-A.

Appendix A. Acronyms and Glossary

Table A-1. Acronyms used in this report

Acronym	Meaning
AOIS	Administrative Operations Information System
ATLAS	Applicant Tracking Lifecycle Analysis Solution
BIIS	Business Intelligence Information System
BLS	Bureau of Labor Statistics
BPERS	Biologics Planning, Execution, and Reporting Solution
BsUFA	Biosimilar User Fee Amendments
CBAPS	CDER Budget and Acquisition Planning System
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
EASE	Enterprise Administrative Support Environment
EEI	Employee Engagement Index
EHCM	Enterprise Human Capital Management
eMedCred	Electronic Medical Credentialing System
EOD	Entrance on Duty
ePMAP	Electronic Performance Management Appraisal Program
ERG	Eastern Research Group, Inc.
FDA	Food and Drug Administration
FEVS	Federal Employment Viewpoint Survey
GS	General Schedule
GSI	Global Satisfaction Index
HCL	Human Capital Liaison
HC	Human Capital
HHS	Department of Health and Human Services
HR	Human Resources
IBAPS	Integrated Budget and Performance System
ISHCPC	Integrated Strategic Human Capital Planning Council
JA	Job Analysis
JOA	Job Opportunity Announcement
KPI	Key Performance Indicator
LDP	Leadership Development Program

Acronym	Meaning
LSP	Leadership Succession Plan
MCO	Mission Critical Occupation
NASA	National Aeronautics and Space Administration
NEO	New Employee Orientation
NIH	National Institutes of Health
NOAA	National Oceanic and Atmospheric Administration
NTIA	National Telecommunications and Information Administration
OAO	Office of Administrative Operations
OCE	Oncology Center of Excellence
ODT	Office of Digital Transformation
OEI	Office of Ethics and Integrity
OGE	Office of Government Ethics
OHCM	Office of Human Capital Management
OII	Office of Inspections and Investigations
OM	Office of Management
OO	Office of Operations
OPM	Office of Personnel Management
OSEM	Office of Security and Emergency Management
OSPO	Office of Security and Passport Operations
OSR	Office Space Request
OTS	Office of Talent Solutions
PAR	Personnel Action Request
PCI	Performance Confidence Index
PD	Position Description
PDUFA	Prescription Drug User Fee Act
RTF	Return to Facilities
SBRS	Senior Biomedical Research Services
SEC	Securities and Exchange Commission
SES	Senior Executive Service
SJF	Specialized Job Family
SL	Senior Level
SLA	Service Level Agreement
SME	Subject Matter Expert
SMP	Succession Management Plan

Acronym	Meaning
SOD	Statement of Duties
SPW	Succession Planning Workgroup
SSOB	Scientific Staffing and Outreach Branch
ST	Scientific Professional
SWFP	Strategic Workforce Plan
TAP	Talent Acquisition Plan
TLQ	Talent Launch Questionnaire
WAPOR	Workforce Analysis Profiles Online Report
WHAT	Workforce Hiring and Attrition Trends

Table A-2. Assessment terms and definitions

Term	Definition
Accession	A personnel action resulting in the addition of an employee to the organization; in federal agencies, accession occurs by transfer in or new hire.
Accession rate	Percent of new employees hired within a specified period of time (i.e., number of new employees divided by number of existing employees during the specified period, multiplied by 100).
Applicant	Person who submitted a resume and application but has yet to be vetted or deemed qualified.
Attrition rate	Percent of staff who leave an agency or organization within a specified period of time (i.e., number of separations divided by number of existing employees during the specified period, multiplied by 100). For the purpose of this assessment, attrition has the same meaning as separations.
Benchmarking	For the purpose of this assessment, comparing program performance and HR/HC models against similar agency and industry outcomes, standards, best practices, and relevant initiatives.
Candidate	Applicant who has been deemed qualified for the position.
Certificate	The list of qualified candidates for a position, generated by OTS after screening and assessing applicants. Also known as a "certificate of eligibles" or "cert."
Employee	A selectee who has completed onboarding and entrance on duty (EOD) (i.e., is working at FDA).
Employee Engagement Index (EEI)	An output of FEVS that serves as a quantitative measure of critical conditions conducive for employee engagement, such as effective leadership, meaningful work, and the opportunity for employees to learn and grow on the job.
Federal Employee Viewpoint Survey (FEVS)	A climate survey administered by the Office of Personnel Management (OPM) that assesses how federal employees experience the policies, practices, and procedures of their agency and its leadership.
Global Satisfaction Index (GSI)	An output of FEVS that serves as a quantitative measure of overall satisfaction with job responsibilities, pay and compensation, and the working environment.

Term	Definition
Hiring	FDA's process of reviewing applications, selecting candidates to interview, interviewing candidates, making hiring decisions, and extending initial (or tentative) job offers.
HR/HC model	An abstract representation of how an organization's HR/HC department functions. Examples include centralized and supporting HR/HC structures.
Integrated Human Capital (HC) Service Delivery Model	A comprehensive framework adopted by FDA to streamline and enhance workforce planning, recruitment, development, and retention efforts across the Agency. It involves collaboration among Centers and Offices, guided by the Integrated Strategic Human Capital Planning Council (ISHCPC), to ensure alignment with strategic goals and effective human capital management.
Interested parties	For the purpose of this assessment, refers to FDA leadership, HR/HC staff, and CDER/CBER staff.
Involuntary Loss	Leaving involuntarily, such as an expiration of temporary/term appointment, termination during the probationary/trial period, etc.
New hire	*General meaning:* An employee who has worked for an organization for less than a specified period (e.g., 60 days, one year). *In the context of this assessment:* A new employee who has worked in their current position at FDA for less than one year. *In the context of accession in a federal agency:* Addition of a new employee from outside the federal government.
Performance Confidence Index (PCI)	An output of FEVS that serves as a quantitative measure of employees' perception of their work units' ability to achieve goals and produce work at a high level.
Pre-employment onboarding	FDA's new hire orienting activities beginning after the tentative offer up to EOD. This includes pre-hiring paperwork and prompts, the badging process, security clearance, ethics, the tentative and final offer letters, and any other relevant activities that contribute to these pre-employment onboarding outputs.
Prospective employee	Candidates that are near the top of the certification for the position.
Recruiting	FDA's process of finding potential candidates who might be qualified to fill positions at the Agency and attracting qualified candidates to apply. This process includes the posting of job announcements.
Retention	FDA's strategies, programs, and other initiatives designed to encourage employees to continue their employment with the Agency. Examples include student loan repayment programs, retention allowances, flexible work schedules, telework, professional development opportunities, and employee networking groups.
Selectee	Candidate who has officially received a job offer.
Separation (attrition)	A personnel action resulting in the loss of an employee from the organization; in federal agencies, separations occur by transfers out, voluntary resignations (quitting), retirement, and involuntary resignations.
Succession Planning	A systematic process to identify and prepare high-potential candidates for critical roles within an organization, ensuring readiness and continuity by reducing leadership vacuums and promoting smooth transitions when leaders leave. It includes planning, training, and experiential activities to develop capable individuals for advancement.
Transfer in	In the context of accession in a federal agency: addition of a new employee from another federal agency.

Term	Definition
Transfer Out	Transfer of an existing employee to another federal agency.
USA Staffing	The federal government's integrated talent acquisition system that automates the federal hiring process.
WHAT Report	Report that tracks monthly workforce gains and losses and provides hiring and attrition metrics and risks.
Workforce Analysis Profiles Online Report (WAPOR)	Report that provides data on workforce counts, personnel gains and losses, attrition rates, retirement eligibility, workforce demographics, and workforce locations. WAPOR users can filter data by work unit, pay plan, and occupational series.

Appendix B. FDA Human Drug Review HR/HC Program

To ensure that safe and effective products are available to improve and protect the health of the public in the United States, FDA evaluates new drugs and conducts thorough reviews of marketing applications before product approval and release. For this process to occur effectively and efficiently, FDA must hire and retain a skilled staff of technical and scientific experts for the human drug review program. This becomes more challenging as the field of medicine evolves and product application reviews become more complex. FDA must ensure that its HR and HC activities can develop and maintain the necessary knowledgeable workforce—while competing with other federal and non-federal entities that seek to employ staff with the same talents.

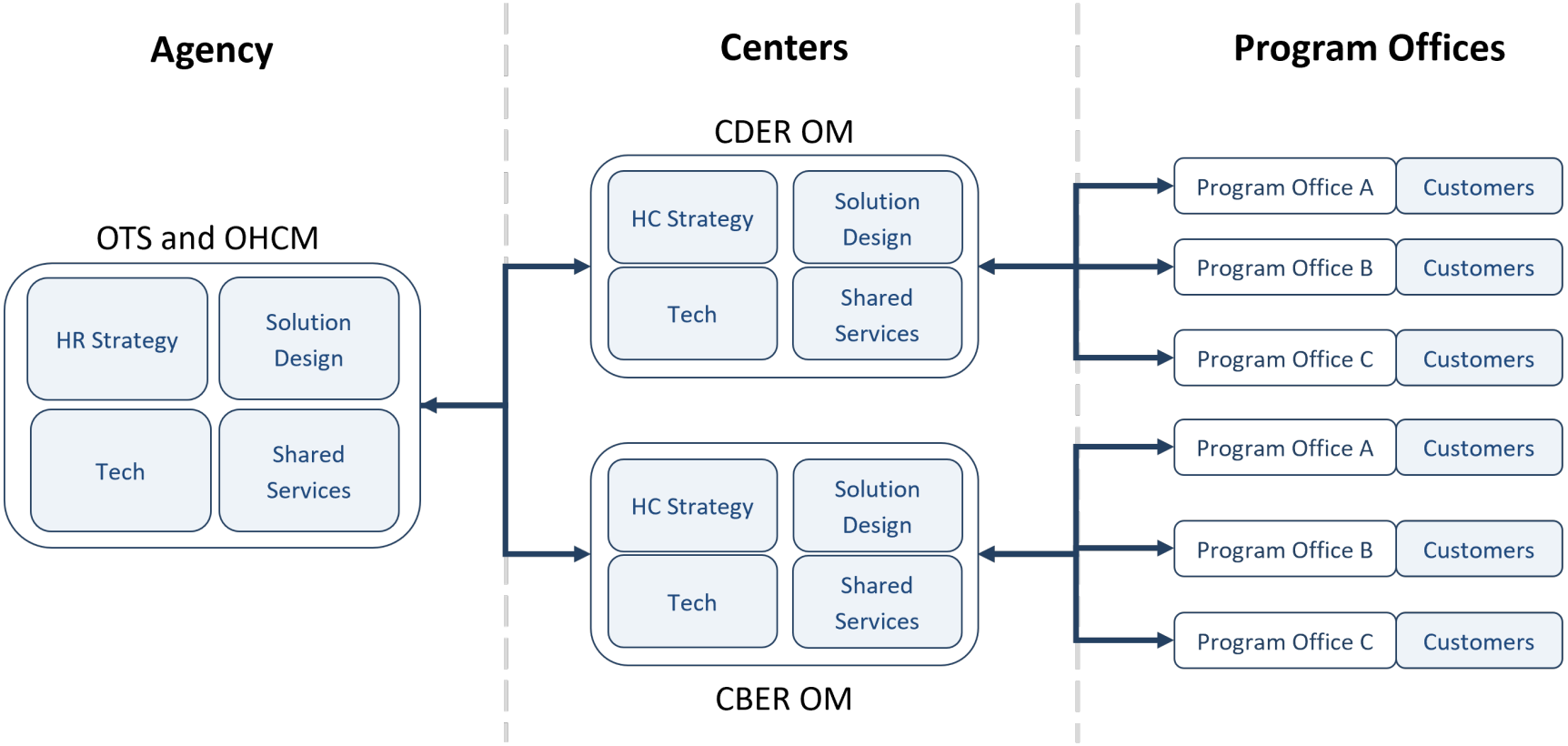
Operating Structure

At FDA, HR and HC activities take place at several levels (Figure B-1). FDA's central HR/HC function—which resides in OTS and OHCM—serves as a core resource for activities throughout the agency. FDA's CDER and CBER each have an OM that provides HC functions for its Center. Program Offices within each Center also conduct HC activities. HR/HC strategy is based on shared principles and processes across all levels of the Agency; each line of business (Centers and Offices) can craft a unique strategy to meet its specific needs. Similarly, data systems such as ATLAS serve staff at all levels of the agency—and the Centers have additional systems such as PathHR and AOIS to address their specific requirements.

Processes

The HR/HC functions that are the subject of this assessment are recruitment, hiring, pre-employment onboarding, and retention. Please see Appendix A for definitions of these terms. Figure B-2 presents an overview of these processes.

Figure B-1. FDA HR/HC operating structure*



*Program Office customers are hiring managers and potential hires.

Figure B-2. FDA's recruiting, hiring, and pre-employment onboarding process

Phase Steps					
• Approve talent acquisition strategy • Develop and communicate talent acquisition strategy • Review and approve vacancy announcement • Complete vacancy announcement and supporting documents	• Conduct outreach as needed • Assess strategy • Monitor vacancy	• Ensure candidate quality • Evaluate candidates and process certificate • Choose candidates to interview	• Support interview strategy • Interview and make selection • Support interview process	• Confirm selection • Support offer process • Manage offer	• Oversee candidate screening and final offer • Prepare for onboarding • Process hiring action
Relevant Parties					
• OTS • CDER/CBER OM • CDER/CBER Program Office	• OTS • CDER/CBER OM • CDER/CBER Program Office	• OTS • CDER/CBER OM • CDER/CBER Program Office	• OTS • CDER/CBER OM • CDER/CBER Program Office	• OTS • CDER/CBER OM • CDER/CBER Program Office • OEI • OSPO	• OTS • CDER/CBER OM • CDER/CBER Program Office • OEI • OSPO

Recruitment

Talent Launch

The recruitment process begins with the talent launch phase (Figure B-3). During this time, the Program Office hiring manager and management analyst complete the job analysis (JA) and talent launch questionnaire (TLQ), which the management analyst submits to the OTS HR specialist for final approval. The JA and TLQ identify the basic duties and responsibilities of the position; the knowledge, skills, and abilities required to perform these duties and responsibilities; and any other factors important for identifying and evaluating candidates. With this information, the hiring manager, management analyst, and HR specialist determine an advertising and talent acquisition strategy and conduct a pre-consult meeting. Once the hiring manager approves the strategy, the HR specialist develops a draft vacancy announcement, which concludes the talent launch. During this time, the hiring manager is also responsible for identifying whether the position grade and sensitivity will require the selected candidate to go through the ethics pre-clearance process.

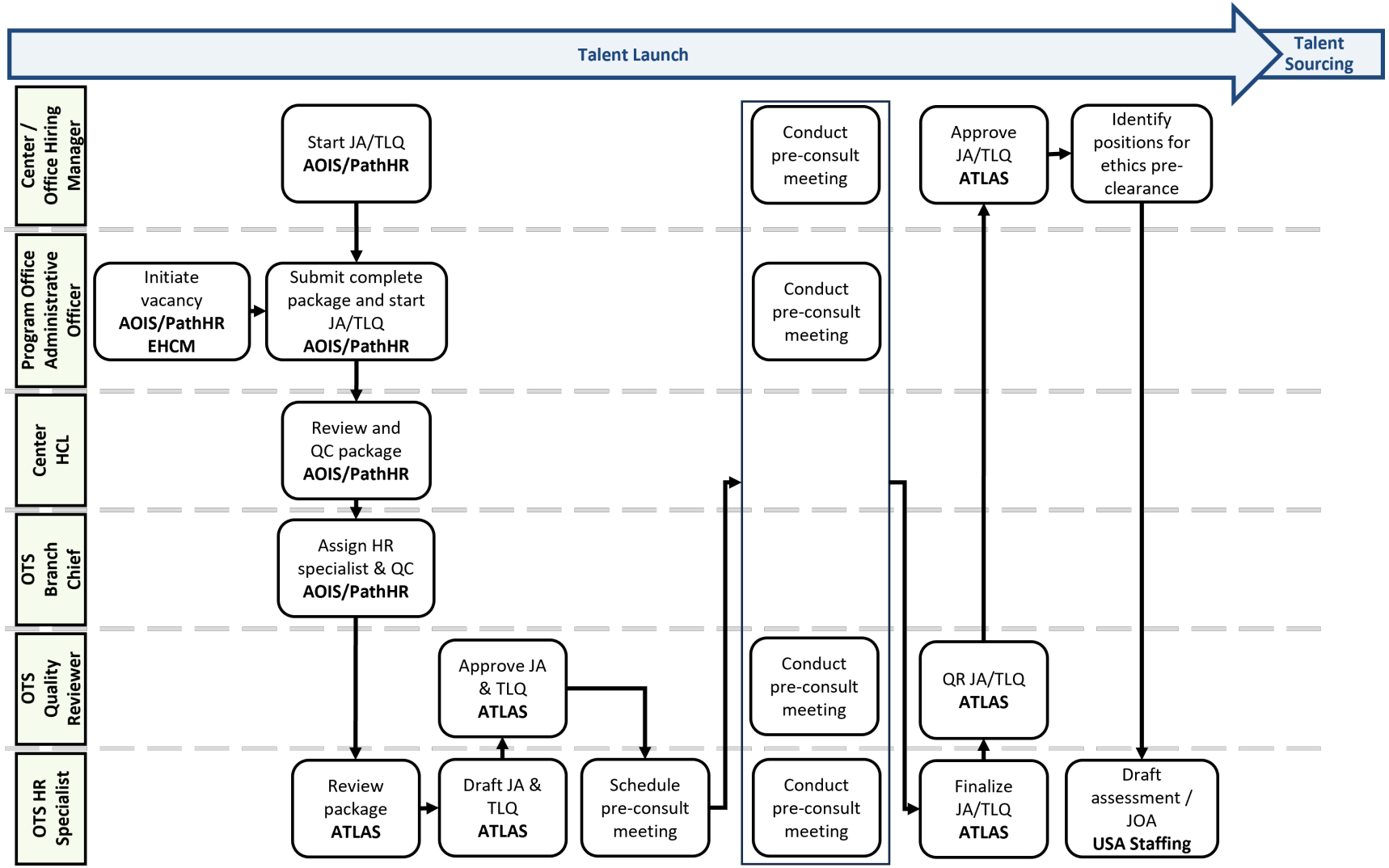
Talent Sourcing

The recruitment process continues with the talent sourcing phase (Figure B-4). After the OTS quality reviewer and Center/Office hiring manager review and approve the vacancy announcement, the HR specialist posts it to USA Staffing. The HCL in the Center may also support the vacancy with social media postings. The hiring manager and other Program Office recruitment staff conduct additional outreach as needed to support the announcement until it is closed by the HR specialist, which concludes the talent sourcing phase.

Talent Evaluation

The recruitment process concludes with the talent evaluation phase (Figure B-5). During this time, the HR specialist analyzes the qualifications of the candidates, which the quality reviewer approves. After approval, the HR specialist issues the certificate to the hiring manager in the Program Office. At this point, recruitment is over, and the remainder of the talent evaluation phase occurs as part of the hiring process.

Figure B-1. Recruitment - talent launch



JA = Job Analysis. TLQ = Talent Launch questionnaire. EHCM = Enterprise Human Capital Management. HCL = Human Capital Liaison. JOA = Job Opportunity Announcement.

Figure B-2. Recruitment - talent sourcing

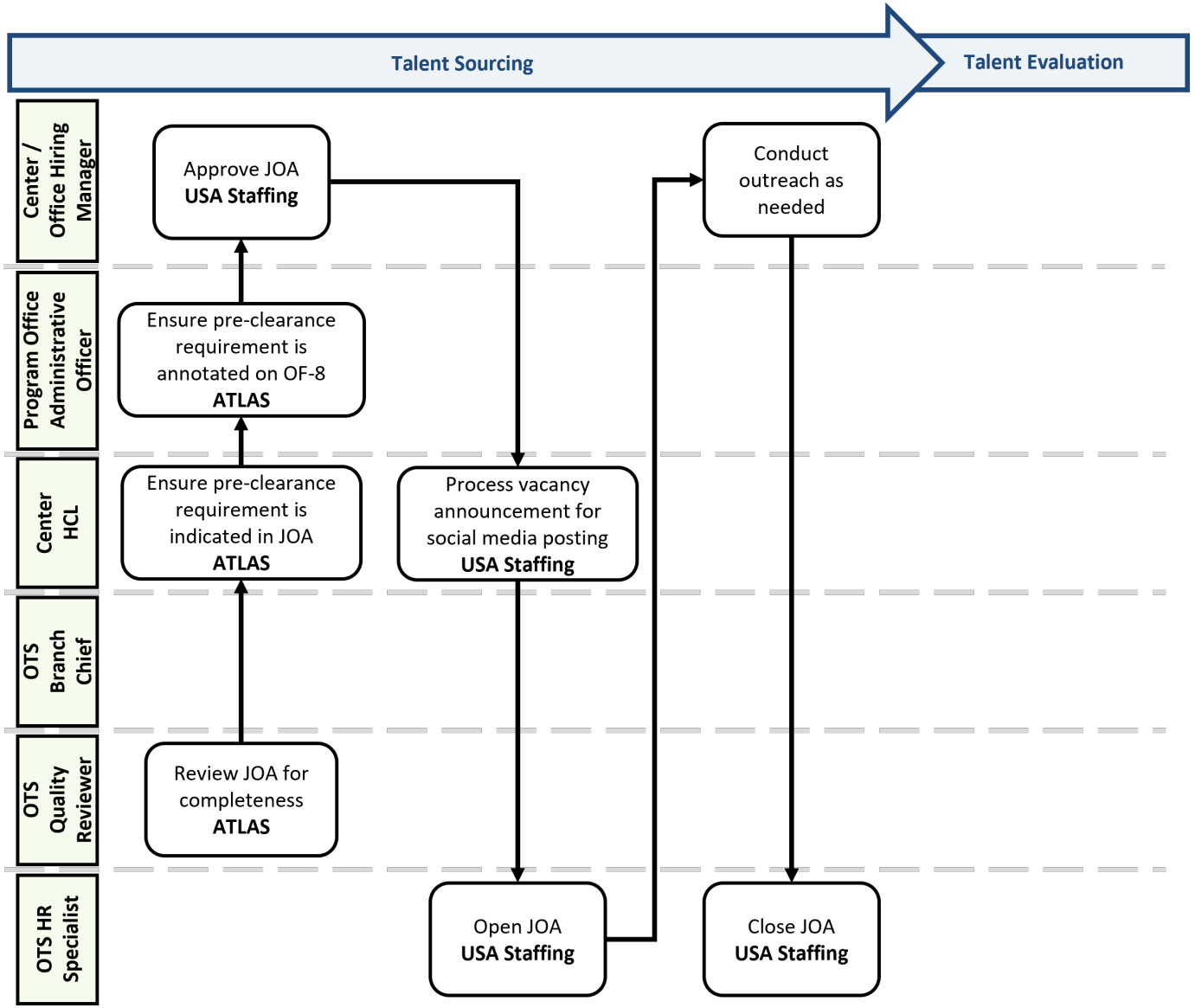
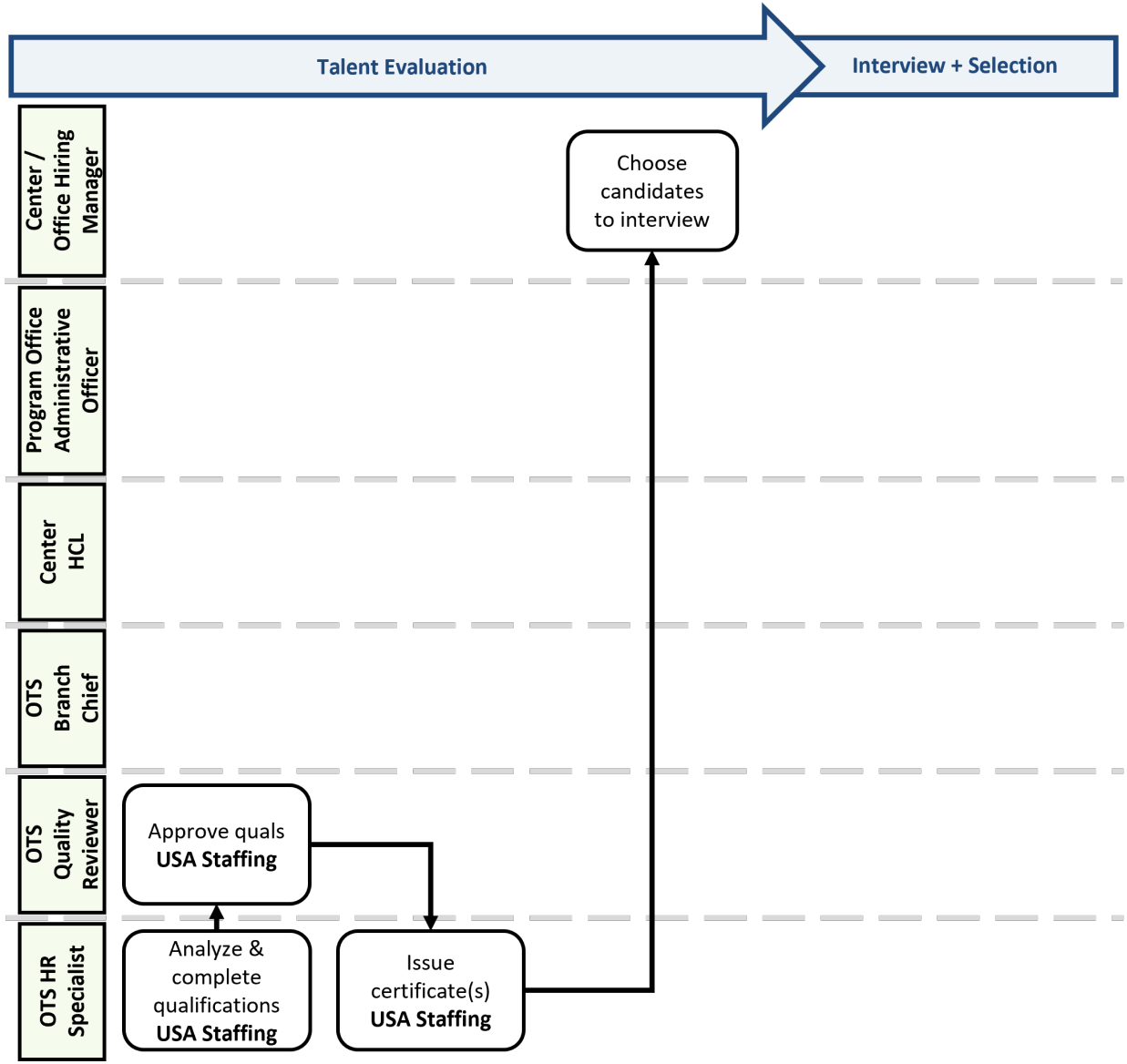


Figure B-3. Recruitment - talent evaluation



Hiring

Talent Evaluation

The last step of the talent evaluation phase begins the hiring process (Figure B-5). During this time, the hiring manager chooses candidates to interview.

Interview and Selection

The interview and selection phase continues the hiring process (Figure B-6). During this phase, the hiring manager and their team interview the candidates selected in the previous phase, the hiring manager checks references, and makes a selection. At this point, the administrative officer submits the selection package to the HR specialist, who determines if the selection is valid. The quality reviewer then confirms this determination and passes the process back to the hiring manager to ensure that the selectee is informed of any pre-clearance requirement, if applicable.

For Title 21, the process begins with the selection of a candidate from a pool of applicants. The selected candidate is then sent to OTS for qualifications and, if the candidate is qualified, the process continues as described. If not, the hiring manager must make a new selection and repeat the qualifications step with OTS.

Tentative Offer

The tentative offer phase continues the hiring process (Figure B-7). The HR specialist issues the tentative offer via USA Staffing, and the hiring manager conducts a current supervisor reference check. The candidate can accept, deny, or request negotiation. If the candidate chooses to negotiate salary, the HR specialist will mark that it has been requested and the final determination is made by staff in the Center and Program Office. If this is approved by the HR specialist and accepted by the candidate, the administrative officer in the Program Office can initiate clearances in eArrive, which ends the hiring process. The tentative offer phase continues into the hiring process.

Figure B-1. Hiring - interview and selection

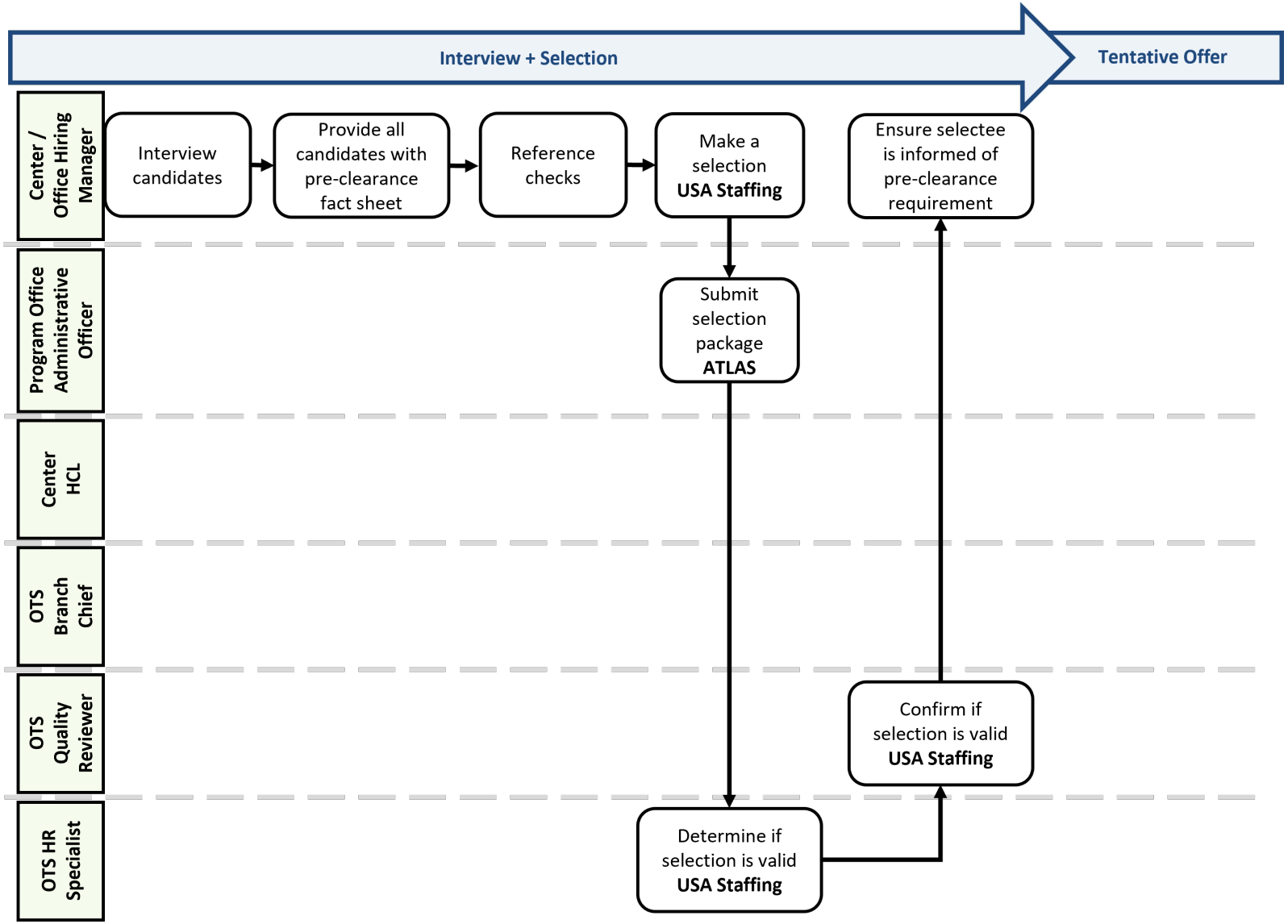
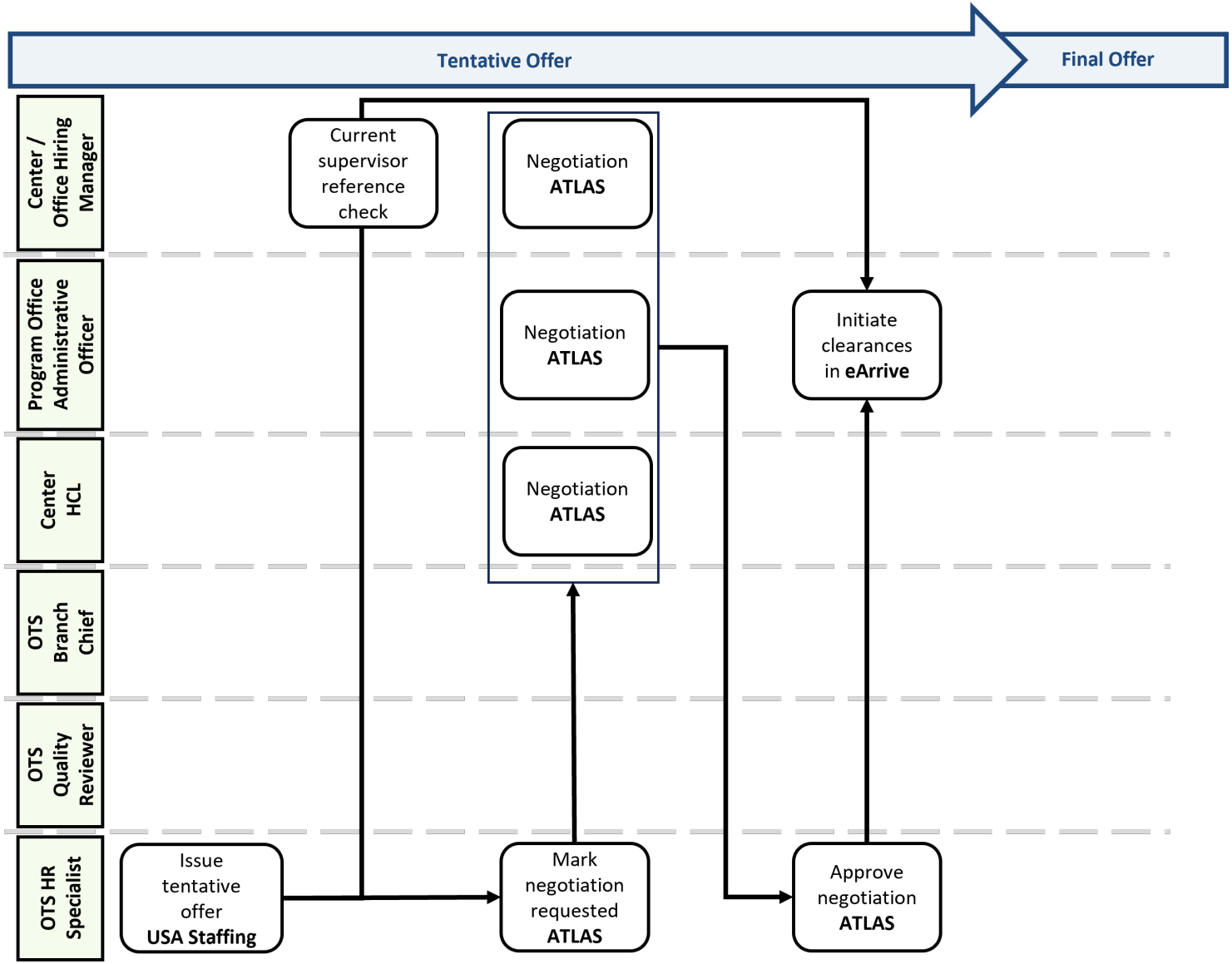


Figure B-2. Hiring - tentative offer



Pre-Employment Onboarding

Tentative Offer

The tentative offer continues with the security clearance and ethics pre-clearance processes, as applicable for the position.

The security clearance steps are conducted by an OSPO personnel security specialist and are therefore not pictured in Figure B-7. This process begins after the candidate accepts the tentative offer and is entered into the eArrive system by Center staff. The case remains under OSPO jurisdiction for the entirety of the pre-employment vetting process, during which time the candidate completes their paperwork to initiate the background investigation that the personnel security specialist then processes. After successfully completing the background investigation, the candidate will work with OSPO to complete the fingerprinting and badging process.

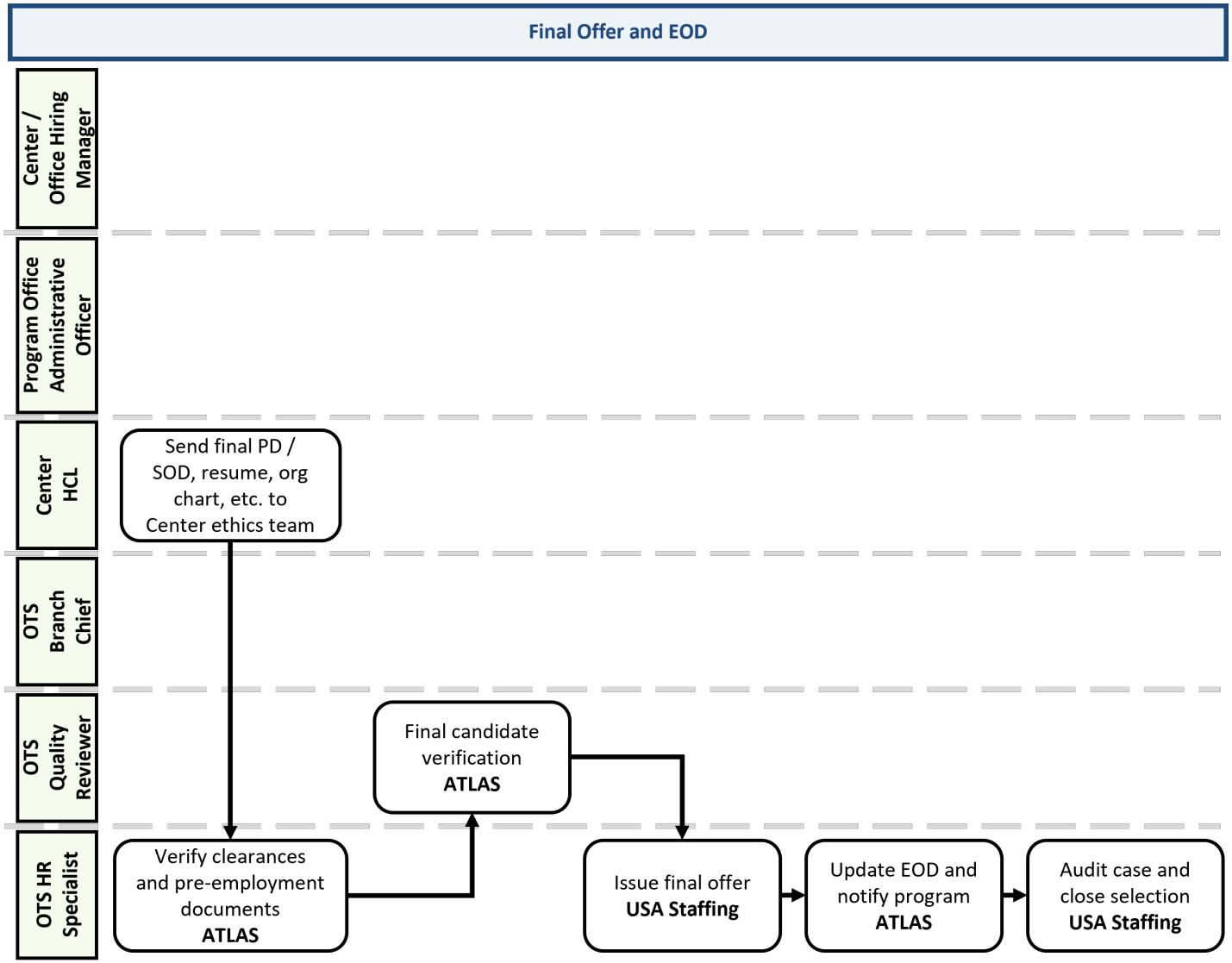
The ethics pre-clearance steps are conducted by the ethics liaison team in the Center and the ethics specialists from the Office of Ethics and Integrity (OEI) prior to a candidate's entry into a new position. When working with a case in ATLAS for a position at a GS-15 level equivalent, or higher position, Center staff should select the flag for requiring ethics pre-clearance and submit the case to their ethics liaisons in the Center. Once the candidate is selected and the tentative start date is known, the ethics liaison sends the request and associated paperwork to the OEI preclearance mailbox for a final preclearance decision to be made before OTS issues the final offer.

Final Offer and EOD

The final offer and EOD phase comprise the remainder of the pre-employment onboarding process (Figure B-8). During this phase, the HCL in the Center sends the required documentation to the Center ethics team. The HR specialist follows up to verify completion of the ethics and security clearances and all required pre-employment documents so the quality reviewer can complete the final candidate verification. Once this has occurred, the HR specialist issues the final offer to the candidate, notifies the program, and closes the case.

To start their time with the FDA, all employees complete the Agency-wide NEO. This two-day training orients the new employee to FDA policies and benefits before they begin their work. The Centers also offer their own orientation to familiarize new employees with practices that are specific to their area of work.

Figure B-1. Pre-employment onboarding - final offer and EOD



SOD = Statement of Duties.

Retention

Retention. Once FDA has hired skilled, qualified staff, the Agency must implement strategies to maintain and motivate the workforce. Examples of retention strategies include student loan repayment programs, retention allowances, flexible work schedules and telework, and professional development opportunities.

Hiring Authorities

While these HR/HC processes apply to all FDA hires, processes vary slightly by hiring authority. FDA uses several hiring and pay authorities (Table B-1).

Table B-1. Hiring authorities used at FDA

Hiring Authority	Description
Commissioned Corps https://www.usphs.gov/	Service in the Public Health Service Commissioned Corps is considered active military service. These staff deliver the nation's public health promotion and disease prevention programs and advance public health science.
Senior Executive Service (SES) https://www.opm.gov/policy-data-oversight/senior-executive-service/	The Senior Executive Service (SES) includes employees who lead the workforce. They have executive skills, a broad perspective on government, and a public service commitment that is grounded in the Constitution.
Title 5 Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	Employees hired through Title 5 fall under the General Schedule (GS) pay plan. This classification and pay system covers most civilian white-collar federal employees in professional, technical, administrative, and clerical positions. Their pay is assigned according to grade from grades 1 to 15, each of which includes 10 different steps of pay. These positions follow the traditional recruitment, hiring, and onboarding processes described above.
Title 21 Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	Enacted in 2017, the 21st Century Cures Act grants FDA a streamlined hiring authority to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products."[15] The Consolidated Appropriation Act of 2023 amended the 21st Century Cures Act to give FDA authority to appoint qualified candidates to scientific, technical, or professional positions, including cross-cutting operational positions, that support development, review, and regulation of medical productions and regulation of food and cosmetics.[16] Title 21 has a more streamlined recruiting process that does not require extensive vacancy announcement. It offers an 18-Band pay system with salaries generally higher than GS pay due to the essential and competitive nature of these positions.

[15] 21st Century Cures Act (Public Law 114-255), https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf
[16] Consolidated Appropriations Act, 2023 (Public Law 117-328), *https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf*

Hiring Authority	Description
Title 38 Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	Title 38 is a pay authority only; it applies to physicians and dentists. These staff are hired under Title 5 and paid under Title 38.
Title 42(f) Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	This excepted service pay system covers special consultants, senior science managers, and senior science advisors. While they are non-executive staff and are exempt from inclusion in the SES, their duties are broad and complex enough to be classified the GS-15 level.
Title 42(g) Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	Like Title 42(f), this excepted service pay system covers service fellows, staff fellows, and visiting scientists who fall outside of alternative competitive pay systems.
Senior Biomedical Research Services (SBRS) Source: Senior Biomedical Research Service (SBRS) SharePoint Site, insideFDA	Used to retain and recruit the highest-level scientific researchers and product/clinical reviewers essential to fulfill the scientific mission of FDA.
Senior Level (SL) Scientific Professional (ST) Source: "Title 21 Basics" Presentation, Office of Talent Solutions, December 2023	Used to recruit and retain staff in non-executive positions whose duties are broad and complex enough to be classified above the GS 15 but statutorily exempt from inclusion in the SES

Hard-to-Hire Positions

Talent recruitment, hiring, and retention are especially challenging for scientific and technical positions, which are critical to mission success at FDA. FDA also experiences its own unique challenges in the investment of time to train new professionals in specific human drug review program practices. Thus, FDA prioritizes certain mission critical occupations (MCOs) and specialized job families (SJFs) that are essential to main functions at FDA, which may change year to year depending on the needs of the Agency. CDER and CBER also maintain their own lists of MCOs and SJFs that are specific to their goals.

Table B-2 presents the MCOs and SJFs of interest to this assessment. In the surveys that ERG conducted for this assessment, respondents indicated whether they belong to any of these positions or groups.

Table B-2. MCOs and SJFs of relevance to this assessment

MCOs	SJFs
0301 Data Scientist	Business Informaticist
0401 Biologist	Health Informaticist
0403 Microbiologist	Epidemiologist
0405 Pharmacologist	General Health Scientist
0415 Toxicologist	Government Information Specialist
0602 Physician	Pharmaceutical Scientist
0696 Consumer Safety Officer	Regulatory Policy Analyst
1320 Chemist	Regulatory Counsel
1515 Operations Research Analyst	Regulatory Health Project Manager
1529 Mathematical Statistician	
1530 Statistician	
1550 Computer Scientist	

Source: Conversation with CDER Leadership, 5/13/2024.

Data Systems

Processes associated with hiring and retaining staff are tracked and completed in several data systems. USAJobs is a public-facing website where prospective employees may apply for jobs at federal agencies, including FDA. HR staff can utilize USA Staffing to recruit, evaluate, assess, certify, select, and onboard for FDA positions. FDA also utilizes several internal systems to manage and streamline specific process related to recruiting, hiring, and onboarding. eClass and eArrive are used for classification and security onboarding, respectively. Enterprise Human Capital Management (EHCM) is used across the Agency to create an electronic personnel record for every employee. Additionally, of particular interest to this assessment are the following three data systems:

- ***ATLAS.*** FDA developed ATLAS as its new human capital system of record to modernize technology, increase transparency, and reduce hiring time. ATLAS replaces manual HR processes and increases data availability, both of which were critical burdens reported in the PDUFA VI HR/HC assessment. ATLAS tracks hiring-related actions by OTS at the Agency level. At this time, ATLAS exists in an operations and maintenance state, and it continues to receive updates based on user feedback.
- ***AOIS.*** AOIS is CDER's system for tracking and fulfilling personnel administrative processes. Its main function is to streamline the PAR process by automating administrative operations. OM and OTS established AOIS in December 2020, and it continues to receive updates based on user feedback.
- ***PathHR.*** PathHR is CBER's centralized platform with real-time HR data to allow HR staff to manage and track positions, employees, recruitment, and HR actions. Since its initial deployment in 2020, CBER has released nine enhanced versions.

Narrative Versions of Figures

Figure B-1. FDA HR/HC operating structure

The first level of the operating structure is the Agency-level, which includes OTS and OHCM. These offices together oversee HR strategy, solution design, tech, and shared services. These items are delivered to the next level, the Center-level, which includes CDER OM and CBER OM. Each of these offices oversees their HC strategy, solution design, tech, and shared services, which they deliver to their customers, the program offices, within the program office-level.

Figure B-2. FDA's recruiting, hiring, and pre-employment onboarding process

At FDA, the recruiting process includes talent launch, talent sourcing, and the start of talent evaluation phase. The hiring process includes the remainder of talent evaluation, interview and selection, and the start of the tentative offer phase. The pre-employment onboarding phase includes the remainder of the tentative offer and the final offer and EOD phase.

The following list represents the phases of FDA's talent lifecycle, the phase steps, and the relevant parties:

- **Talent Launch**
  - Phase steps:
    - Approve talent acquisition strategy
    - Develop and communicate talent acquisition strategy
    - Review and approve vacancy
    - Complete vacancy announcement and supporting documents
  - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office
- **Talent Sourcing**
  - Phase steps:
    - Conduct outreach as needed
    - Assess strategy
    - Monitor vacancy
  - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office
- **Talent Evaluation**
  - Phase steps:
    - Ensure candidate quality
    - Evaluate candidates and process
    - Choose candidates to interview
  - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office
- **Interview and Selection**
  - Phase steps:
    - Support interview strategy
    - Interview and make selection
    - Support interview process
  - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office
- **Tentative Offer**
  - Phase steps:
    - Confirm selection
    - Support offer process

        - Manage offer
    - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office, OEI, OSPO
- **Final Offer and EOD**
    - Phase steps:
        - Oversee candidate screening and final offer
        - Prepare for onboarding
        - Process hiring action
    - Relevant parties: OTS, CDER/CBER OM, CDER/CBER Program Office, OEI, OSPO

Figure B-3. Recruitment – talent launch

The talent launch phase includes the following steps:

1. Either the Program Office administrative officer initiates the vacancy (AOIS/PathHR, EHCM) or the Center/Office hiring manager starts the JA/TLQ (AOIS/PathHR).
2. The Program Office administrative officer submits the complete package and starts the JA/TLQ (AOIS/PathHR).
3. The Center HCL reviews and QCs the package (AOIS/PathHR).
4. The OTS branch chief assigns the HR specialist and QRs (AOIS/PathHR).
5. The OTS HR specialist reviews the package (ATLAS).
6. The OTS HR specialist drafts the JA and TLQ (ATLAS).
7. The OTS quality reviewer approves the JA and TLQ (ATLAS).
8. The OTS HR specialist schedules the pre-consult meeting.
9. The OTS HR specialist, OTS quality reviewer, Program Office administrative officer, and Center/Office hiring manager conduct the pre-consult meeting.
10. The OTS HR specialist finalizes the JA/TLQ (ATLAS).
11. The OTS quality reviewer QRs the JA/TLQ (ATLAS).
12. The Center/Office hiring manager approves the JA/TLQ (ATLAS).
13. The Center/Office hiring manager identifies positions for ethics pre-clearance.
14. The OTS HR specialist drafts the assessment/JOA (USA Staffing).

After the conclusion of the talent launch, the process proceeds into talent sourcing.

Figure B-4. Recruitment – talent sourcing

The talent sourcing phase includes the following steps:

1. The OTS quality reviewer reviews the JOA for completeness (ATLAS).
2. The Center HCL ensures the pre-clearance requirement is indicated in the JOA (ATLAS).
3. The Program Office administrative officer ensures the pre-clearance requirement is annotated on the OF-8 (ATLAS).
4. The Center/Office hiring manager approves the JOA (USA Staffing).
5. The Center HCL processes the vacancy announcement for social media posting (USA Staffing).
6. The OTS HR specialist opens the JOA (USA Staffing).
7. The Center/Office hiring manager conducts outreach as needed.
8. The OTS HR specialist closes the JOA (USA Staffing).

After the conclusion of the talent sourcing, the process proceeds into talent evaluation.

Figure B-5. Recruitment – talent evaluation

The talent evaluation phase includes the following steps:

1. The OTS HR specialist analyzes and completes the qualifications (USA Staffing).
2. The OTS quality reviewer approves qualifications (USA Staffing).
3. The OTS HR specialist issues the certificate(s) (USA Staffing).
4. The Center/Office hiring manager chooses candidates to interview.

After the conclusion of talent evaluation, the process proceeds into interview and selection.

Figure B-6. Hiring – interview and selection

The interview and selection phase includes the following steps:

1. The Center/Office hiring manager interviews candidates.
2. The Center/Office hiring manager provides all candidates with pre-clearance fact sheet.
3. The Center/Office hiring manager checks references of candidates.
4. The Center/Office hiring manager makes a selection (USA Staffing).
5. The Program Office administrative officer submits the selection package (ATLAS).
6. The OTS HR specialist determines if the selection is valid (USA Staffing).
7. The OTS quality reviewer confirms if the selection is valid (USA Staffing).
8. The Center/Office hiring manager ensures the selectee is informed of the pre-clearance requirement.

After the conclusion of interview and selection, the process proceeds into the tentative offer.

Figure B-7. Hiring – tentative offer

The tentative offer phase includes the following steps:

1. The OTS HR specialist issues the tentative offer (USA Staffing).
2. The Center/Office hiring manager completes the current supervisor reference check.
3. If negotiation is requested:
    a. The OTS HR specialist marks negotiation as requested (ATLAS).
    b. The Center HCL, Program Office administrative officer, and Center/Office hiring manager collaborate on the negotiation.
    c. The OTS HR specialist approves the negotiation.
    d. The Program Office administrative officer initiates clearances in eArrive.
4. If negotiation is not requested:
    a. The Program Office administrative officer initiates clearances in eArrive.

After the conclusion of the tentative offer, the process proceeds into the final offer and EOD.

Figure B-8. Hiring – final offer and EOD

The final offer includes the following steps:

1. The Center HCL sends the final PD/SOD, resume, org chart, etc. to the Center ethics team.
2. The OTS HR specialist verifies clearances and pre-employment documents (ATLAS).
3. The OTS quality reviewer completes final candidate verification (ATLAS).
4. The OTS HR specialist issues the final offer (USA Staffing).
5. The OTS HR specialist updates the EOD and notifies the program (ATLAS).
6. The OTS HR specialist audits the case and closes the selection (USA Staffing).

Appendix C. Detailed Results

This section presents results from ERG's data collections, organized by assessment objective:

- Section C.1: FDA HR/HC Enhancements.
- Section C.2: Status of FDA Recruitment, Hiring, Pre-Employment Onboarding, and Retention and Effectiveness of Current Practices.
- Section C.3: FDA Hiring Process Transparency.

Throughout this section, results pertain to all organizational units (CDER, CBER, OTS, OHCM), funding programs (PDUFA, BsUFA), roles in talent lifecycle activities, and hiring authorities except when otherwise specified.

C.1 FDA HR/HC Enhancements

ERG collected data and opinions about three categories of enhancements to FDA's HR/HC program for the human drug review program that the agency initiated following the last assessment of this program:

- **Development of three HR data systems**: ATLAS, which staff in OTS, CDER, and CBER use to manage the hiring process across various hiring authorities, with the aim of improving efficiency, transparency, and accountability; PathHR, which CBER staff use to centralize and track recruitment and HR actions, with the aim of improving data accuracy and decision-making capabilities; and AOIS, which CDER staff use to automate and manage personnel administrative processes, with the aim of improving efficiency and providing real-time data for decision-making.
- **Implementation of an Integrated HC Service Delivery Model**: A framework aimed at streamlining and enhancing workforce planning, recruitment, development, and retention efforts across FDA. Guided by the ISHCPC, it involves collaboration across Centers and Offices to promote alignment with strategic goals and effective human capital management.
- **Leadership succession planning (LSP)**: A process aimed at systematically identifying and preparing high-potential individuals to transition into critical roles within FDA to ensure organizational readiness and continuity by reducing leadership vacuums and promoting smooth transitions when leaders leave. It involves planning, training, and experiential activities to develop individuals who can advance and take on new roles effectively.

HR Data Systems (ATLAS, AOIS, PathHR)

ERG assessed the status, fidelity, and impacts of HR data system enhancements by:

- Reviewing FDA's enhancement goals.
- Reviewing FDA's enhancement plans and investigated their implementation status.
- Investigating the status of planned integration of the data systems.
- Conducting surveys, interviews, and focus groups to obtain opinions about the data systems.

Below are our results, organized by data system: ATLAS, AOIS, PathHR, and all HR data system collectively.

ATLAS

In this section, we present the following results related to our assessment of FDA's enhancement of ATLAS:

- Enhancement plan and implementation status (Table C-1).
- ATLAS enhancements implemented (Table C-2).
- User experience with ATLAS (Figure C-1).
- User opinions about ATLAS fulfillment of system goals (Figure C-2).
- OTS staff opinions about ATLAS impacts on hiring efficiency and transparency (Figure C-3).

For context, below is a list of FDA's goals for ATLAS:

- Provide comprehensive solution to improve HR operations; address complex, inefficient processes.
- Modernize technology to improve the recruiting and hiring process.
- Increase transparency and accountability in the hiring process.
- Reduce the overall time to hire.
- Improve satisfaction with processes and technology.
- Standardize hiring workflows across FDA.
- Provide tracking and reporting capabilities to manage talent management lifecycle.
- Ensure mission-critical vacancies are filled in a timely and efficient manner with high-quality hires.
- Foster engagement to accelerate system adoption; enhance user experience and support.
- Continuously refine and enhance the system based on user feedback.

Collectively, the data provide evidence that FDA has implemented ATLAS enhancements as planned (on time and consistent with goals) and that these enhancements have been effective in streamlining hiring processes to improve efficiency and transparency. The evidence (including average time to conduct hiring process steps in ATLAS data shown in Section C.2) suggests that ATLAS enhancements have also contributed to a decrease in the overall average time to hire.

Table C-1. ATLAS enhancement plan and implementation status

Enhancement Plan	Consistent with Goals	Contains Goals	Contains Approach	Identifies Responsible Parties	Contains Timeline	Contains Approach to Measure Success	Status	Delays
ATLAS One-Pager; *Comprehensive Report*	✓	✓	✓	✓	✓	✓	Fully Imple-mented	None

Sources: ATLAS One-Pager (OTS ATLAS Intranet page, retrieved 01/30/2025); ATLAS Comprehensive Report (December 2024).

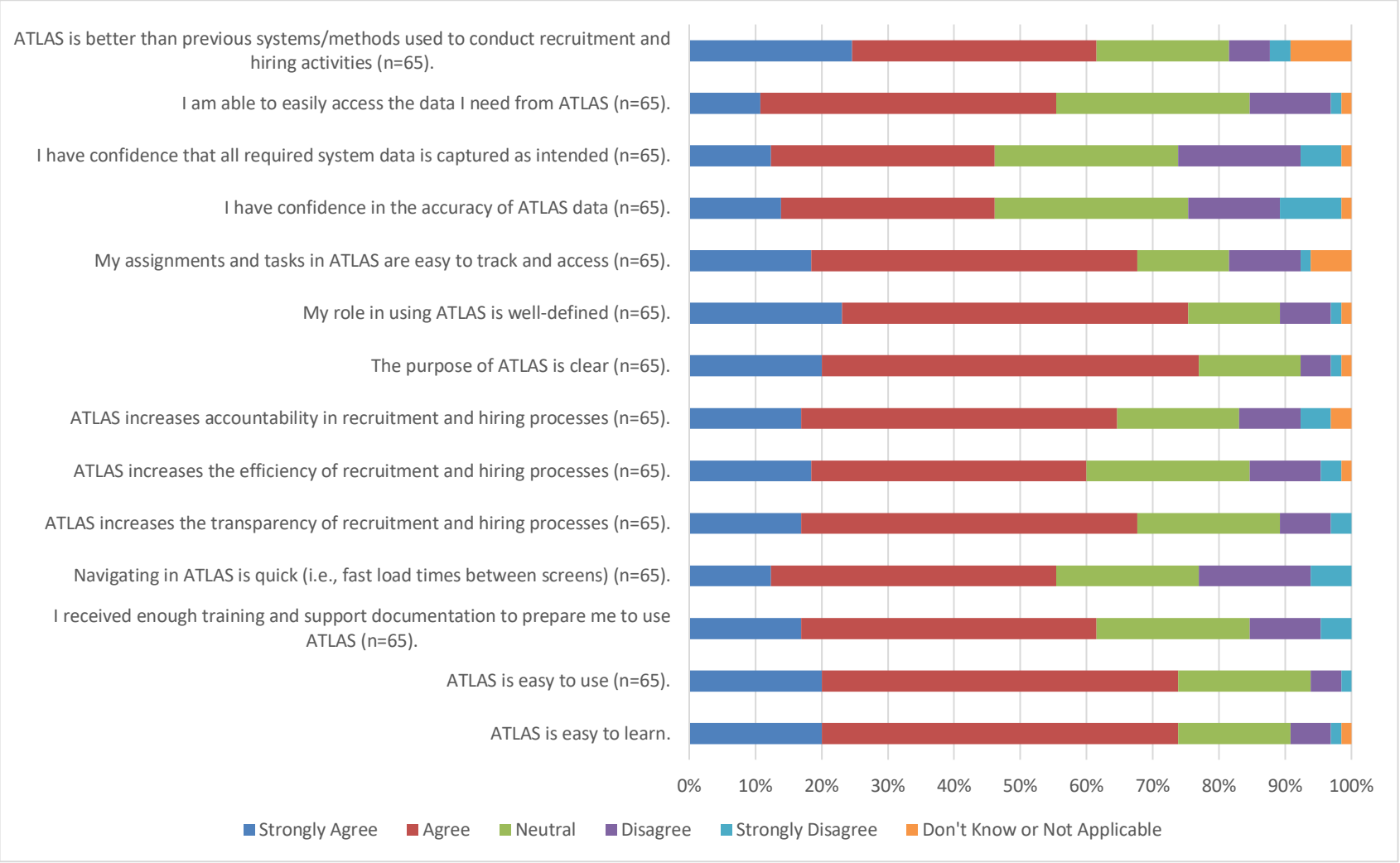
Table C-2. ATLAS System Enhancements

Enhancement Category	Enhancements Implemented Between 2018 and 2024
Workflow deployment	• Deployment to five offices in CDER and CBER for Title 5 Merit Promotion (Dec 2018) • Delegated Examining Single Candidate, Title 21 Non-Physician/Non-Exec workflows (Feb 2021) • Title 21 Physician and Exec, Title 42 (f), Title 42 (g) workflows (Jun 2021) • Title 5 hiring workflows (Merit Promotion, Direct Hire, Non-Competitive) (Sep 2021) • SES workflow (Nov 2021) • Title 38 workflow and Direct Hire Authorities (Jan 2022) • Named Actions workflow (Mar 2022) • Development of OTS PAR Processing Teams and process workflows (Mar 2022) • FDA-wide implementation of all 19 hiring workflows (Sep 2022)
System integration and modernization	• Development of ATLAS (2018) • Integration of additional hiring processes (ongoing) • Integration of eClass for classification support (Jan 2022) • EHCM (EASE API) integration (Sep 2022) • Integration with FDA's Oncology Center of Excellence administrative system (Sep 2024)
User experience improvements	• Roles, talent phases, and process workflows (Feb 2021) • Journey maps (Feb 2021) • Enhancements to Title 21 Non-Physician/Non-Executive workflow (Jun 2021) • Development of user personas (Sep 2022) • Approver dashboard for real-time review and action (Sep 2024) • Outlook notifications for recruitment actions (Sep 2024) • User requested task refinements, email notifications, and advanced filters (2023 - 2024)
Process efficiency enhancements	• Modifications to existing USA Staffing queries (Jun 2021) • Updates to checklists (Jun 2021) • Implementation of electronic signature approvals (Jun 2021) • Standardization of Title 5 workflows across FDA (Sep 2021) • Automated system email notifications (May 2022) • Title 5 JA and JOA refinement (May 2022) • Over 110 updates to add reporting capabilities and streamline processes (Mar 2023) • Digitized 21st Century Cures checklist with electronic signatures (Sep 2024) • HyperCare Support and Operations & Maintenance (Release 4.5) • User requested FDA Accelerated Staffing Track (FAST) report refinements, task routing updates, and checklist modifications (Mar 2023 - Nov 2024)
Reporting and feedback integration	• User experience surveys (2022) • Refined consolidated reports (Jun 2022) • Implementation of reporting capabilities (Mar 2023) • Evolution with newly implemented 21st Century Cures policies (Mar 2023) • Enhancements based on user feedback (ongoing) • User requested new report developments and updates to existing reports (2023 - 2024)

Sources: ATLAS Development Roadmap. ATLAS Comprehensive Report (December 2024).

EASE = Enterprise Administrative Support Environment.

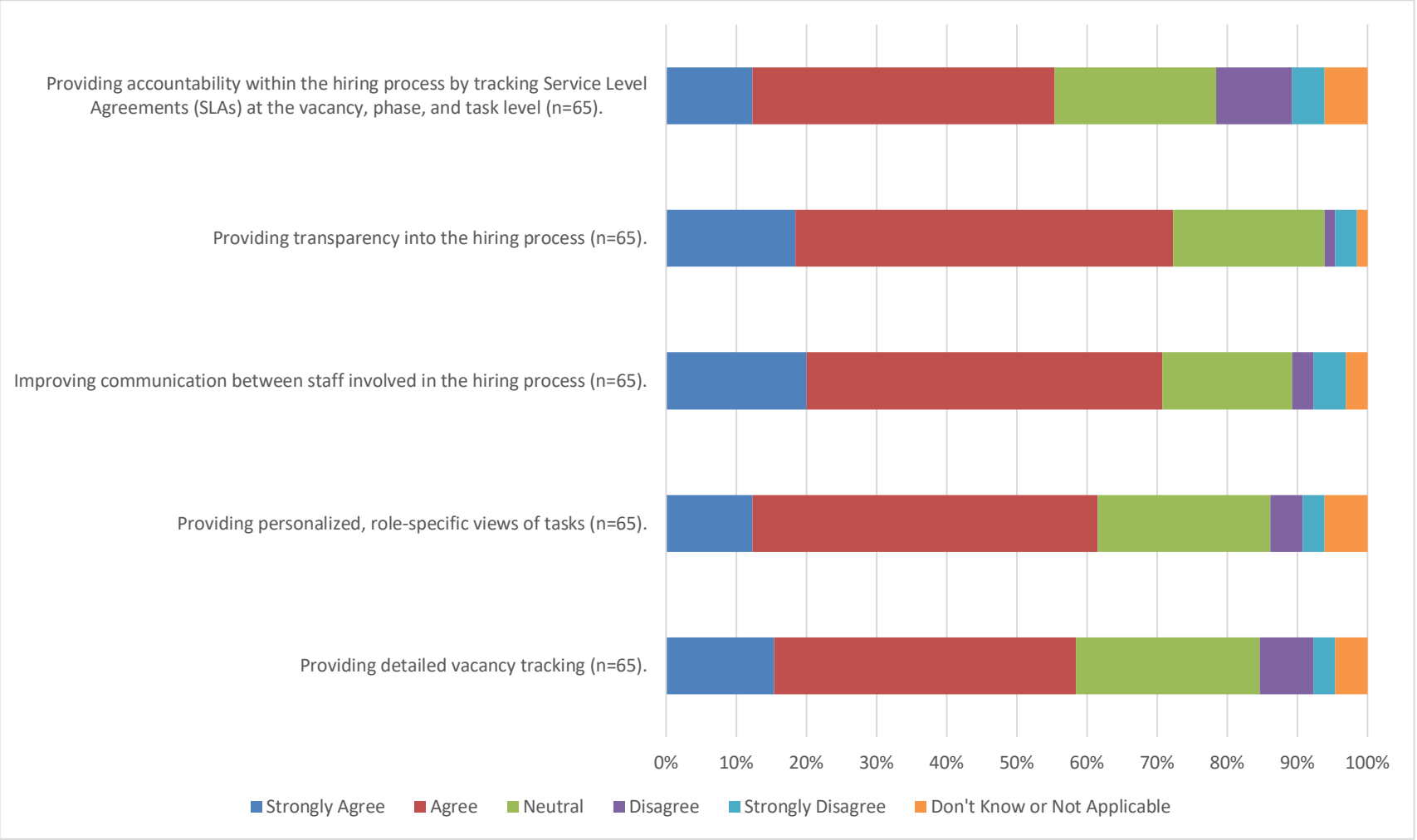
Figure C-1. User opinions about their experience with ATLAS (n=65)*



Source: HR Data System User Survey conducted by ERG (December 2024) for this assessment.

*Patterns: OTS/DTS offices show slightly higher agreement than CDER and CBER. Hiring managers show slightly higher agreement than staff in other roles for most questions.

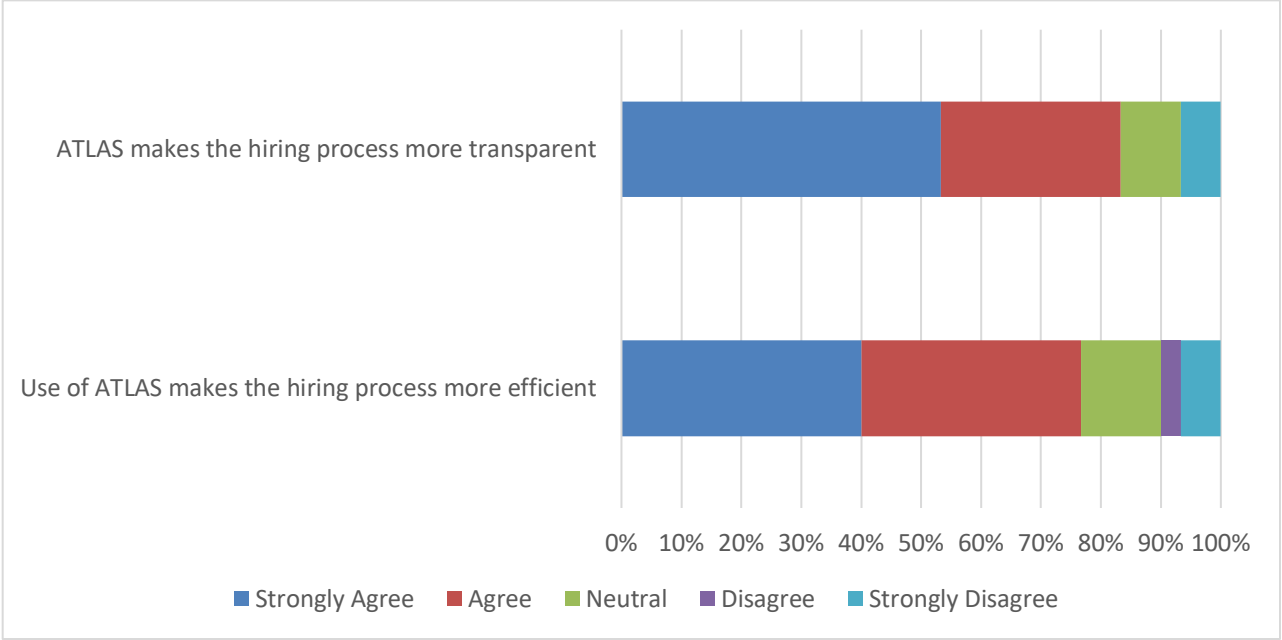
Figure C-2. User opinions about ATLAS fulfillment of system goals (n=65)*



Source: HR Data System User Survey conducted by ERG (December 2024) for this assessment.

*Patterns: Hiring Managers show slightly higher agreement than staff in other roles for most questions.

Figure C-3. OTS staff opinions about the effects of ATLAS on hiring process efficiency and transparency (n=30)*



Source: OTS HR/HC Staff Survey conducted by ERG (September 2024) for this assessment.
*"Don't Know or Not Applicable" responses were excluded from analysis.

AOIS

In this section, we present the following results related to our assessment of FDA's enhancement of AOIS:

- Enhancement plan and implementation status (Table C-3)
- User experience with AOIS (Figure C-4)
- User opinions about AOIS fulfillment of system goals (Figure C-5)

For context, FDA's goals for AOIS enhancements are to improve overall efficiency, accuracy, and user experience by:

- Enhancing the PAR approval process.
- Improving user functionalities and system views.
- Providing new user roles and dashboards.
- Streamlining the office space planning process.
- Automating and improving the efficiency of various administrative operations.
- Ensuring data integrity and accuracy.
- Facilitating timely approvals and reducing bottlenecks.
- Providing real-time interactive dashboards for better data access and monitoring.
- Enhancing the user experience with updated user interfaces.
- Offering continuous system improvements based on user feedback.

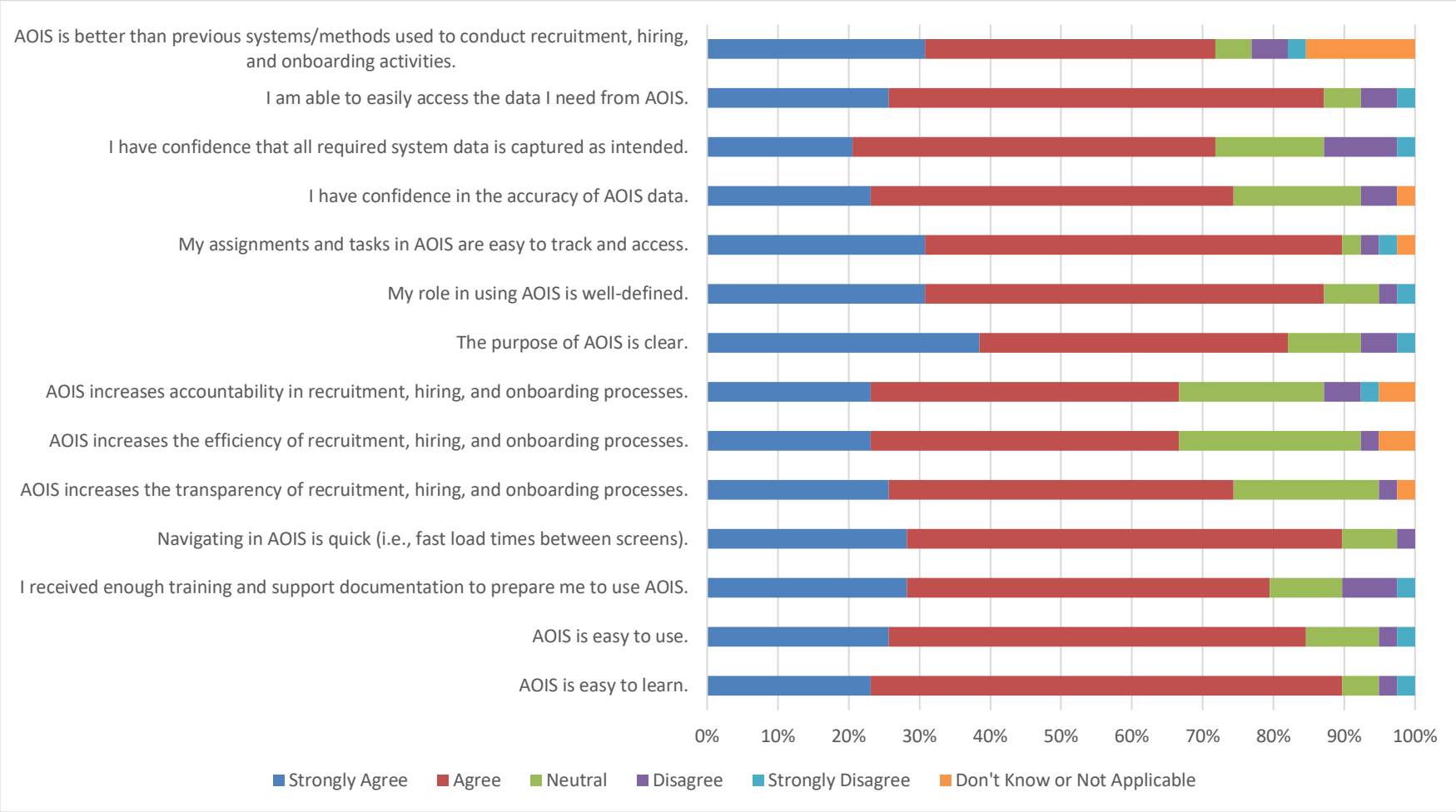
Collectively, the data provide evidence that FDA has implemented AOIS enhancements as planned (on time and consistent with goals), and that these enhancements have been effective in streamlining CDER processes to improve efficiency and transparency.

Table C-3. AOIS enhancement plan and implementation status

Enhancement Plan	Consistent with Goals	Contains Goals	Contains Approach	Identifies Responsible Parties	Contains Timeline	Contains Approach to Measure Success	Status	Delays
AOIS *AOIS Future Functionality (FY 2024);* *FY 2024 Project Timeline*	✓	✓	✓	✓	✓	✖	Fully Imple-mented	None

Sources: CDER-OM AOIS Intranet page (retrieved 01/30/2025); FY2024 Project Timeline.

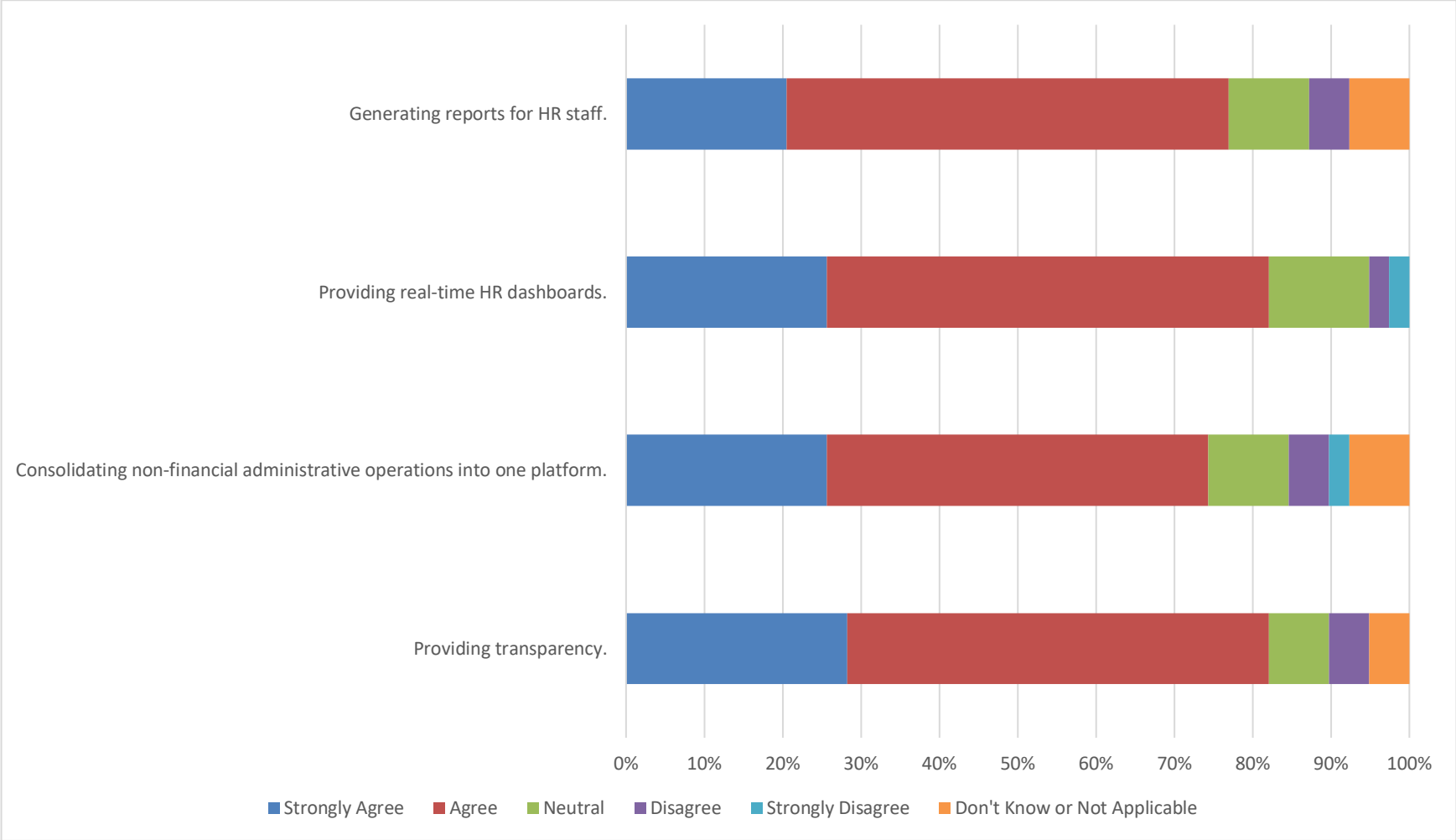
Figure C-4. User opinions about their experience with AOIS (n=39)*



Source: HR Data System User Survey conducted by ERG (December 2024) for this assessment.

*Patterns by role: Hiring Managers (n=9) showed higher, nearly 100%, agreement among respondents with the statements above.

Figure C-5. User opinions about AOIS fulfillment of system goals (n=39)*



Source: HR Data System User Survey (December 2024) conducted by ERG for this assessment.

*Patterns by role: Hiring Managers (n=9) show 100% agreement with these statements.

PathHR

In this section, we present the following results related to our assessment of FDA's enhancement of PathHR:

- Enhancement plan and implementation status (Table C-4).
- User experience with PathHR (Figure C-6).
- User opinions about PathHR fulfillment of system goals (Figure C-7).

For context, below is a list of FDA's goals for PathHR:

- Access a single centralized platform with real-time HR data.
- Make data-driven workforce decisions.
- Leverage an integrated solution that replaces manual processes.
- Validate gaps between department and agency source systems.
- Improve payroll forecasting accuracy by automating integration with the Biologics Planning, Execution, and Reporting Solution (BPERS).

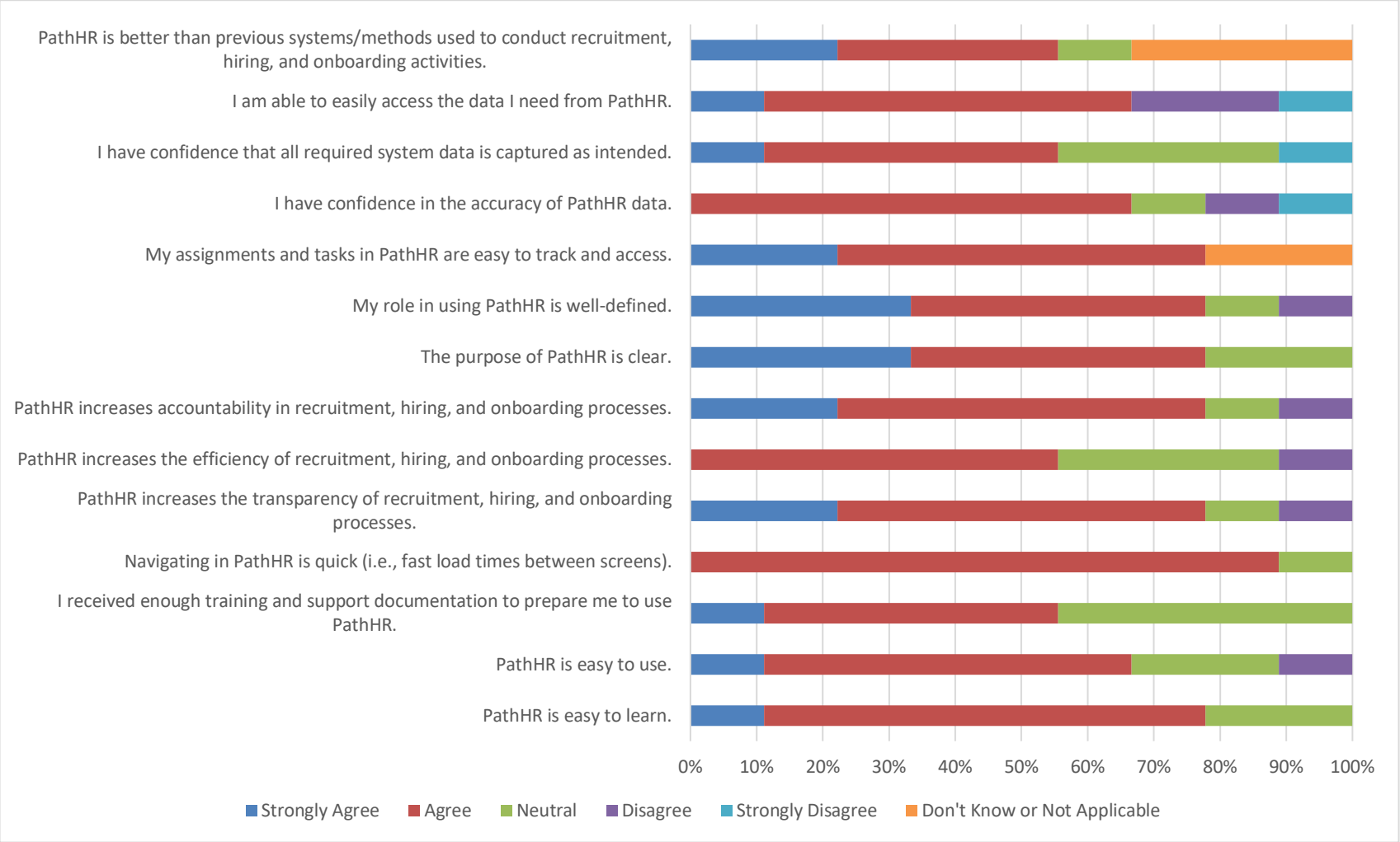
Collectively, the data provide evidence that FDA has implemented PathHR enhancements as planned (on time and consistent with goals), and that these enhancements have been effective in streamlining CBER processes to improve efficiency and transparency.

Table C-4. PathHR enhancement plan and implementation status

Enhancement Plan	Consistent with Goals	Contains Goals	Contains Approach	Identifies Responsible Parties	Contains Timeline	Contains Approach to Measure Success	Status	Delays
PathHR *System Overview*	✓	✓	✓	×	×	×	Fully Imple-mented	None

Source: PathHR System Overview.

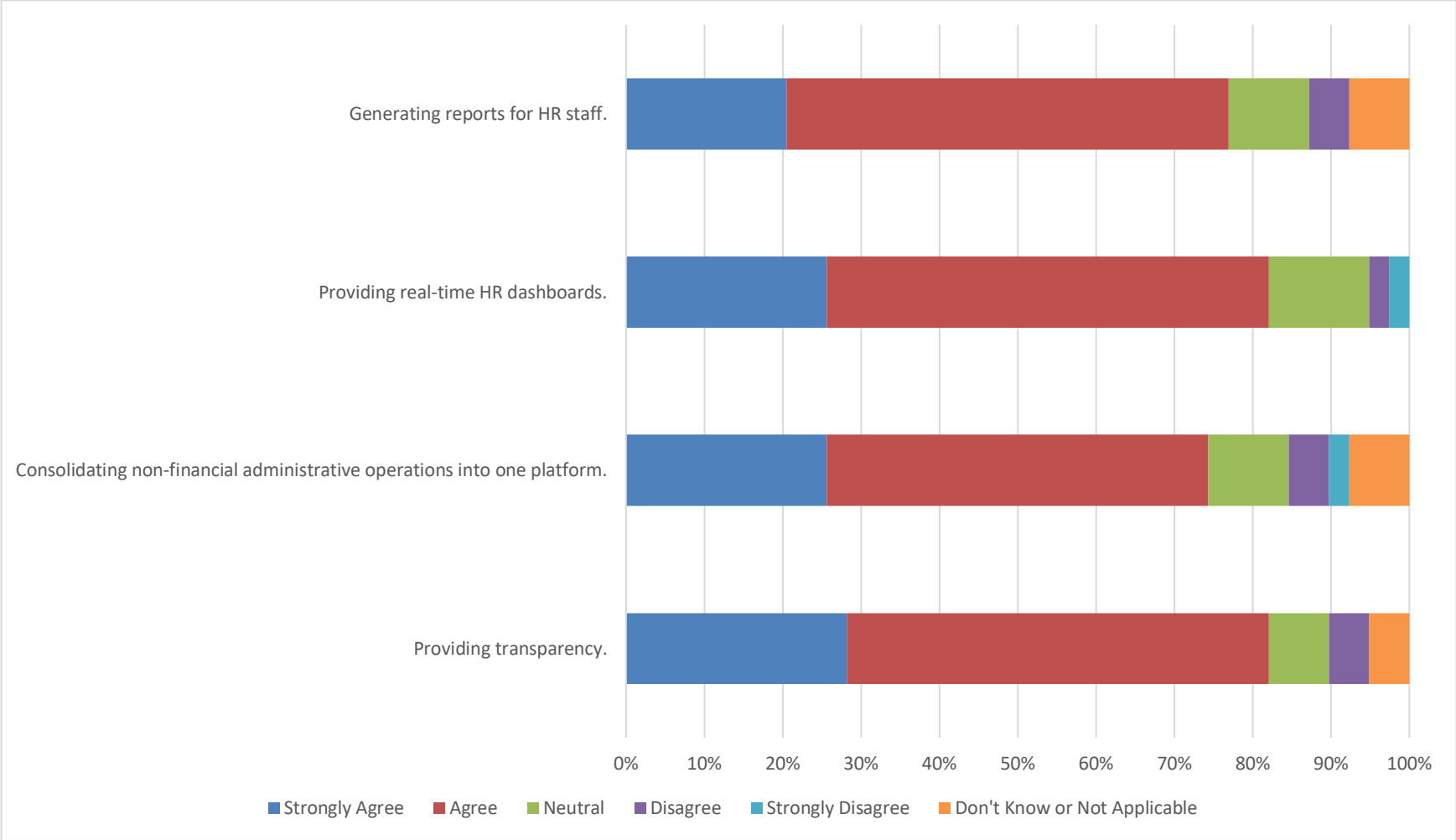
Figure C-6. User opinions about their experience with PathHR (n=9)*



Source: HR Data System User Survey conducted by ERG (December 2024) for this assessment.

*Patterns: Hiring Managers (n=2) show 100% agreement with these statements. Staff with roles related to pre-employment onboarding (n=4), and retention (n=9) showed less agreement and more disagreement with these statements (especially statements that PathHR increases efficiency and transparency and PathHR data are accurate and easily accessible).

Figure C-5. User opinions about AOIS fulfillment of system goals (n=39)*



Source: HR Data System User Survey (December 2024) conducted by ERG for this assessment.

*Patterns by role: Hiring Managers (n=9) show 100% agreement with these statements.

FDA HR Data Systems Collectively

In addition to collecting data on each HR data system (ATLAS, AOIS, PathHR) individually, ERG collected information and feedback about the state of HR data systems collectively. In this section, we present:

- A summary of progress made between 2021 and 2024 (Table C-5).
- Staff opinions about FDA's HR data systems (Figure C-8 and Table C-6).

Collectively, the data provide evidence FDA has implemented HR data system enhancements as planned, and that these enhancements have been effective in streamlining CDER processes to improve efficiency and transparency. As is typical with relatively new systems, users would like further refinements to (1) further integrate systems and provide easier access to data on processes that cross Offices and Centers, and (2) expand system access to more staff in more roles so that they can also benefit from streamlining and transparency of HR/HC processes.

Table C-5. Progress of FDA HR data system integration for recruiting, hiring, and retention since last assessment

Data Source or System	Owner	Purpose	Integrated* at Time of Last Assessment (2021)	Currently Integrated* (2025)
Administrative Officer Information System (AOIS)	CDER	Standardize and automate workflows, provide transparency, track process timeliness, and provide system communication	Planned	•
Applicant Tracking and Lifecycle Analysis Solution (ATLAS)	FDA	Track recruitment and hiring activities	•	•
ATLAS Hiring Process Reporting	FDA	Report on hiring process	Planned	•
Business Intelligence Information System (BIIS)	HHS	Track post-hire personnel data	Planned	•
eArrive	FDA	Automate and track employee onboarding processes and data	Planned	•
eClass	FDA	Create, maintain, and store PDs, classifications, and personnel actions	•	•
eDepart	FDA	Automate and track employee exit processes and data	Planned	•
eIncentive	FDA	Automate employee awards (incentives) nomination development, submission, review, and approval processes	Planned	•
Electronic Performance Management Appraisal Plan (ePMAP)	FDA	Automate performance management system and process	Planned	•
eMedCred	FDA	Automate verification of certifications and credentials of FDA physicians	Planned	•
Enterprise Administrative Support Environment (EASE)	FDA	Manage location, personnel, and sensitive data for employees and non-employees		•

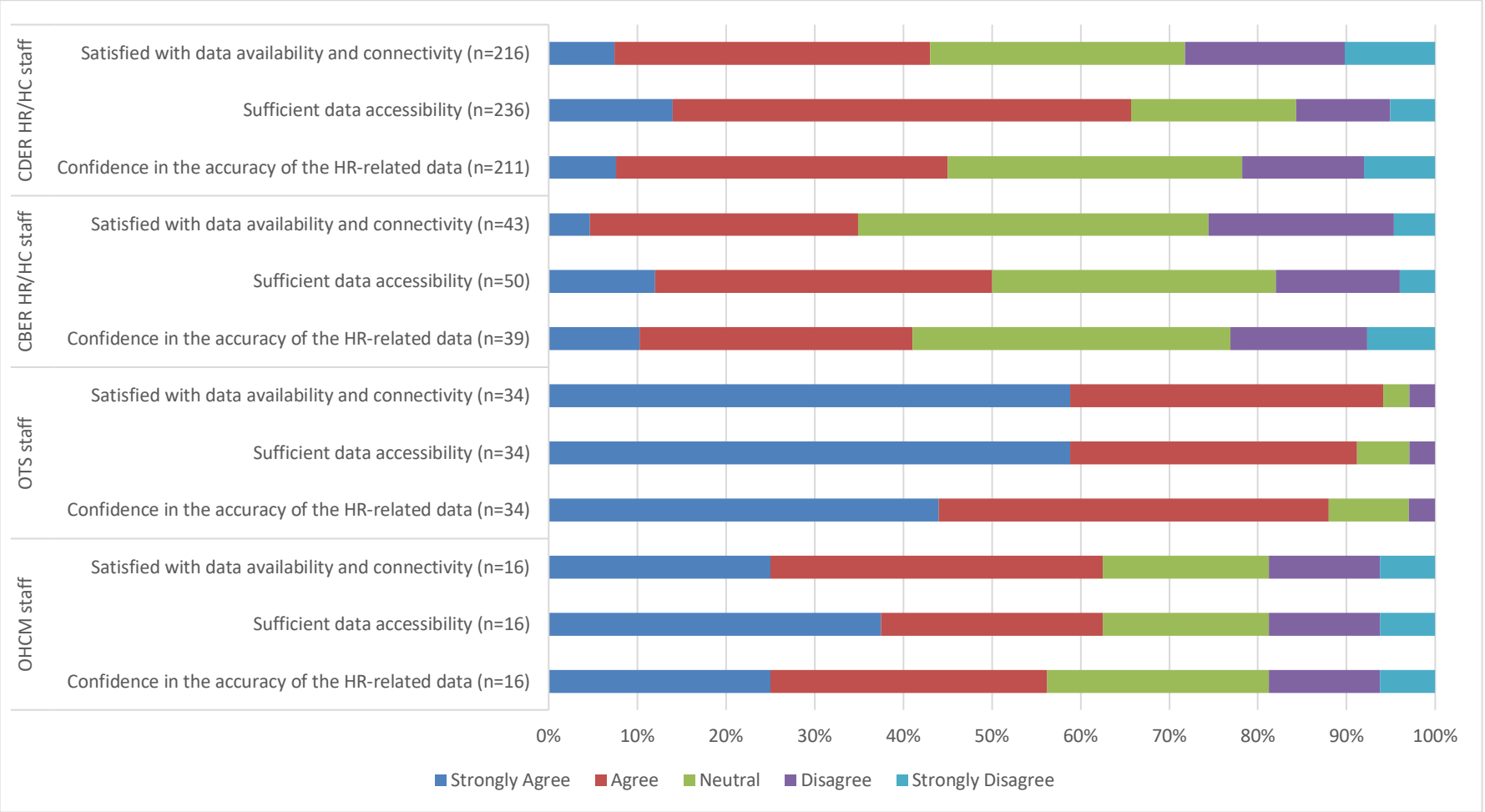
Data Source or System	Owner	Purpose	Integrated* at Time of Last Assessment (2021)	Currently Integrated* (2025)
Enterprise Human Capital Management system (EHCM)	HHS	Track employee profiles, appointments, recruitment, workforce administration, benefits, positions, and vacancies	Planned	•
ePortal "OneHR"	FDA	Provide self-service employee portal, data warehouse, and HelpDesk with news, employee information, policies, and procedures	Planned	•
eTelework	FDA	Automate telework agreement processes	Planned	•
Exit Survey Data	FDA	Tracks employee exit survey data to understand reasons for departure		•
HR Workload Tracking	FDA	Monitor and manage HR staff workload, tasks, assignments, and productivity		•
Integrated Budget and Performance System (IBAPS)	FDA	Manage employee benefits, payroll, and related information		•
KPI Performance Trackers	FDA	Measure and monitor HR-related KPIs and assess HR performance		•
PathHR	CBER	Tracks CBER's HR work	Planned	•
USA Staffing	OPM	Track recruitment activities, including job requisitions	•	•

Source: FDA System Environment mapping: current as of 11/1/24 (received 01/2025)].

HHS = U.S. Department of Health and Human Services. OPM = Office of Personnel Management.

*Data systems are integrated, at least to some extent, in FDA's larger HR data system environment (not necessarily integrated with each other).

Figure C-8. Staff opinions about FDA's HR/HC data systems by staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: "Based on activities you are involved with, please rate your level of agreement with the following statements regarding FDA's HR/HC data systems: I have access to the data I need to perform the duties of my role; I am satisfied with data availability and connectivity to other HR data; I have confidence in the accuracy of the HR-related data I access." "Don't Know or Not Applicable" responses were excluded from analysis.

Table C-6. Qualitative data on HR data system implementation from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others
Working Well											
Centralize data, communication tracking, and/or document retrieval		●	●				●	●	●		
Modernize previously manual processes		●	●				●	●			
Increase transparency and awareness throughout hiring process		●	●				●	●			
Challenges											
Need additional integration across data systems to streamline full talent lifecycle and reduce redundant work		●	●		●		●	●	●		
Not all staff involved in HR/HC processes have adequate access to systems (e.g., hiring manager access to ATLAS)		●	●				●	●	●		
Depend on human inputs (e.g., timely updates for actions and checklists, missing/lack of detail, data entry errors) that impact timeliness and accuracy of data			●		●		●	●		●	
Need more comprehensive workflows that reflect the overall talent lifecycle		●	●		●		●	●			

*Survey open responses, interviews, and focus groups.

Integrated HR/HC Service Delivery Model

ERG assessed the status, fidelity, and impacts of Integrated HR/HC Service Delivery Model by:

- Reviewing FDA's enhancement goals.
- Reviewing FDA's enhancement plans and action items and investigating their implementation status.
- Assessing staff opinions about implementation of the model.

For context, FDA's goals for the integrated HR/HC service delivery model are as follows:

- Fully address current and anticipated critical workforce gaps.
- Ensure FDA continues to be an outstanding place to work.
- Advance workforce infrastructure and systems to ensure FDA builds the workforce of the future.
- Facilitate collaboration across Centers/Offices to improve practices to recruit, develop, and retain highly qualified talent.

In this section, we present the following results:

- Enhancement plan and implementation status (Table C-7).
- Status of planned FY2024 action items (Table C-8).

Collectively, the data here and throughout this appendix provide evidence that FDA has implemented the integrated HR/HC service delivery model as planned (on time and consistent with goals), and that this has contributed to improved service delivery, though further improvements can be made (as described in other sections).

Table C-7. Integrated HR/HC service delivery model enhancement plan and implementation status

Enhancement Plan	Consistent with Goals	Contains Goals	Contains Approach	Identifies Responsible Parties	Contains Timeline	Contains Approach to Measure Success	Status	Delays
Strategic Workforce Plan FYs 2023 to 2027	✓	✓	✓	✓	✓	✓	Fully Imple-mented	None

Source: Strategic Workforce Plan FY2023 to FY2027.

Table C-8. Status of FY2024 action items for implementation of integrated HR/HC service delivery model

No.	Objective	# of Action Items	% Complete	% On Track
1.1	Develop prioritized capabilities via targeted training and development	6	100%	100%
1.2	Build succession management activities and develop leadership capabilities to prepare next generation of FDA leaders	4	75%	25%
1.3	Improve staff's ability to collaborate and access specialized expertise	3	100%	100%

No.	Objective	# of Action Items	% Complete	% On Track
1.4	Address hiring, retention, and development gaps for priority MCOs and SJFs	8	88%	13%
2.1	Achieve HHS's annual targets for FEVS	3	67%	33%
2.3	Strive for an environment free of harassment	2	50%	50%
3.1	Add Title 21 hiring/pay authorities to newly eligible Centers/Offices	2	50%	50%
3.2	Advance HC data analytics systems for enhanced data-driven workforce planning and decision making	3	67%	33%
3.3	Evaluate and refine SWFP annually	2	100%	100%
4.1	Continue to convene ISHCPC to identify and showcase recruiting and development practices from Centers and Offices	1	100%	100%
4.2	Create and maintain repository of shared workforce planning guides, tools, and templates created by OHCM, OTS, or Center staff	2	100%	100%

Source: Strategic Workforce Plan FYs 2023 to 2027 - Action Planning Update for FY24 and FY25.

Leadership Succession Planning

ERG assessed the status, fidelity, and impacts of FDA leadership succession planning by:

- Reviewing FDA's enhancement goals.
- Reviewing FDA's enhancement plans and action items and investigating their implementation status.
- Assessing staff opinions about plan implementation.

For context, FDA's goals for leadership succession planning are as follows:

- Align with FDA's strategic priorities.
- Build on work products currently under development at the department and federal levels.
- Support workforce and succession planning initiatives within FDA Centers.

In this section, we present the following results:

- Enhancement plan and implementation status (Table C-9).
- Status of FY2024 action items (Table C-10).

Collectively, the data here and throughout this appendix provide evidence that FDA has implemented the leadership succession planning initiative as planned (on time and consistent with goals), and that this is contributing to improved capacity to fill leadership positions.

Table C-9. Leadership succession planning enhancement plan and implementation status

Enhancement Plan	Consistent with Goals	Contains Goals	Contains Approach	Identifies Responsible Parties	Contains Timeline	Contains Approach to Measure Success	Status	Delays
Succession Management Plan FYs 2021 to 2024	✓	✓	✓	✓	✓	✓	Fully Imple-mented	None

Source: Succession Management Strategic Plan FY2021 - FY2024.

Table C-10. Status of FY2024 action items for leadership succession planning

No.	Objective	# of Action Items	% Complete	% On Track
1.1	Consider future needs: Explore future readiness for FDA senior executives and leadership bench for FY2021-2024 planning cycle	1	100%	100%
1.2	Optimize executive bench strength: Expand and diversify leadership pipeline by preparing aspiring successors and senior contributors for next-level experiences	4	100%	100%
1.3	Resource planning: Plan and allocate resources effectively to support succession planning activities, considering budget and resource needs	2	100%	100%
2.1	Summary report: Generate annual report outlining cross-agency succession planning efforts, compliance, risks, potential successors, and outcomes	1	100%	100%
2.2	Senior executive position assessment: Assess senior executive positions to understand demands, future shifts, and success factors	1	100%	100%
3.1	Cross-agency planning review and alignment: Establish review body to examine succession planning analytics, provide recommendations, and ensure alignment with FDA and Center mission planning	1	100%	100%

Source: 2024 FDA Succession Planning Workgroup Summary Reports.

C.2 Status of FDA Recruitment, Hiring, Pre-Employment Onboarding, and Retention and Effectiveness of Current Practices

In this section, ERG builds on the findings of the 2021 PDUFA VI HR/HC assessment to present a current snapshot of FDA's recruitment, hiring, pre-employment onboarding, and retention of new hires, with an emphasis on the effectiveness of current practices, regardless of whether those factors are in FDA's control. ERG begins with an analysis of the overall talent lifecycle before delving into results for each phase of the talent lifecycle.

Overall Talent Lifecycle and Comparison with Other Agencies

The talent lifecycle encompasses all the stages that an individual experiences with an organization, from an initial expression of interest in the organization through completion of service. ERG's assessment focused on four stages: recruitment, hiring, pre-employment onboarding, and retention. Definitions of these stages

of the talent lifecycle vary by organization. For the definitions we used for the purpose of this assessment, please see Appendix A (Glossary); for more details, please see Appendix B (FDA's Human Drug Review HR/HC Program).

To develop data on the overall talent lifecycle and comparison with outcomes in other agencies (i.e., NASA, NIH, NOAA, SEC) and industry, ERG gathered information from many FDA, other government, and other public sources—and conducted interviews, focus groups, and surveys with FDA staff.

In this section, we present the following results:

- HR/HC structure and hiring and retention outcomes for FDA, other federal agencies, and industry (Table C-11).
- Distribution of workforce gains by type (Figure C-9) and accession rates by fiscal year (Figure C-10).
- Average time to hire in ATLAS for PDUFA and BsUFA staff compared to SLAs (Table C-12) and compared to the time of the last assessment (Table C-13).
- Number of new hires compared to hiring goals for FDA, CDER, and CBER overall (Figure C-11) and for PDUFA and BsUFA positions (Figure C-12).
- New staff opinions about their FDA hiring experience (Figure C-13).
- Hiring manager opinions about the hiring process experience (Figure C-14).
- Key themes and feedback about the overall talent lifecycle from all sources (Table C-14).

Collectively, these data provide evidence that FDA is able to attract, hire, and retain a skilled workforce to meet Center needs for PDUFA and BsUFA. Overall, FDA's performance is at least comparable to similar agencies and industry. Between the time of the last assessment (FY2021) and this assessment (FY2024), average time to hire as reported by ATLAS has decreased—both overall and at each stage of recruitment/hiring. However, challenges remain in communication, collaboration, and coordination across Offices and Centers.

Table C-11. HR/HC structure and hiring and retention outcomes for FDA, other federal agencies, and industry (for FY2024 unless otherwise specified)

Metric	Data Source	FDA	CDER	CBER	Other Agencies*	Industry
HR/HC structure	Interviews	Centralized, with decentralized components	Centralized, with decentralized components	Centralized, with decentralized components	Centralized, with decentralized components	Variable
HR servicing ratio	WAPOR	1:75	1:75	1:75	N/A	N/A
Number of federal employees	WAPOR	N/A	6,029	1,370	N/A	N/A
Number of federal employees	FedScope	20,912	N/A	N/A	5,000 – 20,000	N/A
Number of employees	BLS	N/A	N/A	N/A	N/A	681,000
Percent of hires who are transfers in | new hires	WAPOR	N/A	7% | 79%	10% | 68%	N/A	N/A

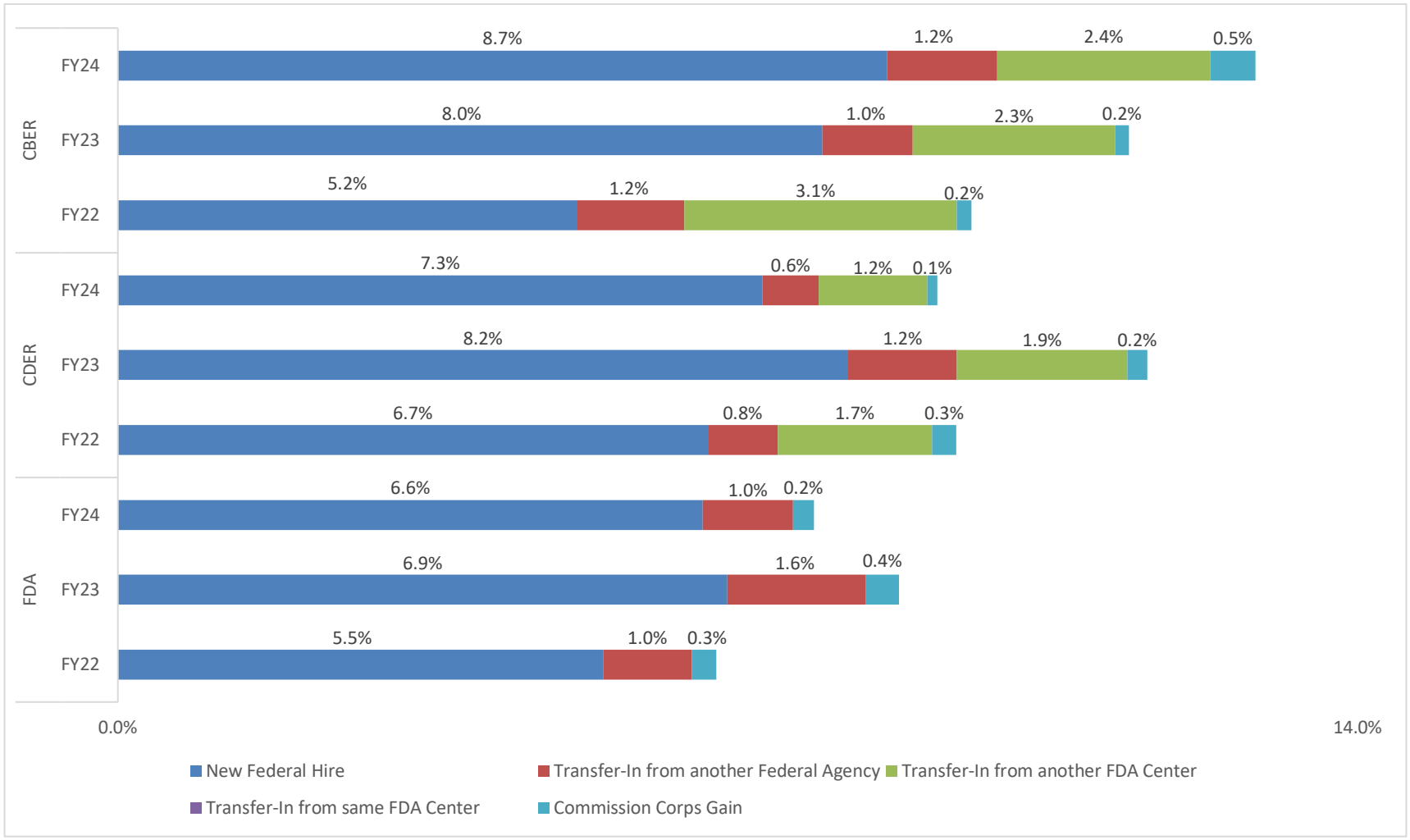
Metric	Data Source	FDA	CDER	CBER	Other Agencies*	Industry
Percent of hires who are transfers in | new hires	FedScope	9% | 91%	N/A	N/A	3-19% | 81-97%	N/A
Accession rate	WAPOR	N/A	9%	13%	N/A	N/A
Accession rate	FedScope (FY2024 to Q1 2024)	4%	N/A	N/A	3.3 – 5.7%	N/A
Attrition (separation) rate	WAPOR	N/A	5%	6%	N/A	N/A
Attrition (separation) rate	FedScope (FY2024 to Q1 2024)	3%	N/A	N/A	3.4 – 4.9 %	N/A
Attrition (separation) rate	AceNgage	N/A	N/A	N/A	N/A	15-20%
Net staffing change rate (2020-2024)	WAPOR	N/A	3%	4%	N/A	N/A
Net staffing change rate (2020-2024)	FedScope	2%	N/A	N/A	N/A	N/A
Net staffing change rate (2020-2024)	BLS	N/A	N/A	N/A	N/A	1%
Percent of personnel loss transfers out | involuntary	WAPOR	N/A	10% | 6%	14% | 8%	N/A	N/A
Percent of personnel loss transfers out | involuntary	FedScope (Mar 2024)	15% | 16%	N/A	N/A	11.8 – 18.8%	N/A
Percent of employees who quit federal service during fiscal year	WAPOR	N/A	1%	0.9%	N/A	N/A
Percent of employees who quit federal service during fiscal year	FedScope (FY2024 – Q1 2025)	0.7%	N/A	N/A	0.6 – 0.8%	N/A
Length of service: mean | median	WAPOR (Nov 2024)	N/A	12.2 | 11.0	14.1 | 13.0	N/A	N/A
Mean length of federal service (years)	FedScope (Mar 2024)	12.9	N/A	N/A	13.1 – 15.6	N/A

Source: WAPOR, data updated as of 01/23/2025, retrieved 02/03/2025. *FedScope* Updated September 2024 unless otherwise specified, accessed 03/12/2025. *BLS* Updated January 29, 2025, accessed 03/12/2025. AceNgage. (2024). Tackling Pharma Attrition: Why Employees Are Leaving. LinkedIn.

*NASA, NIH, NOAA, SEC.

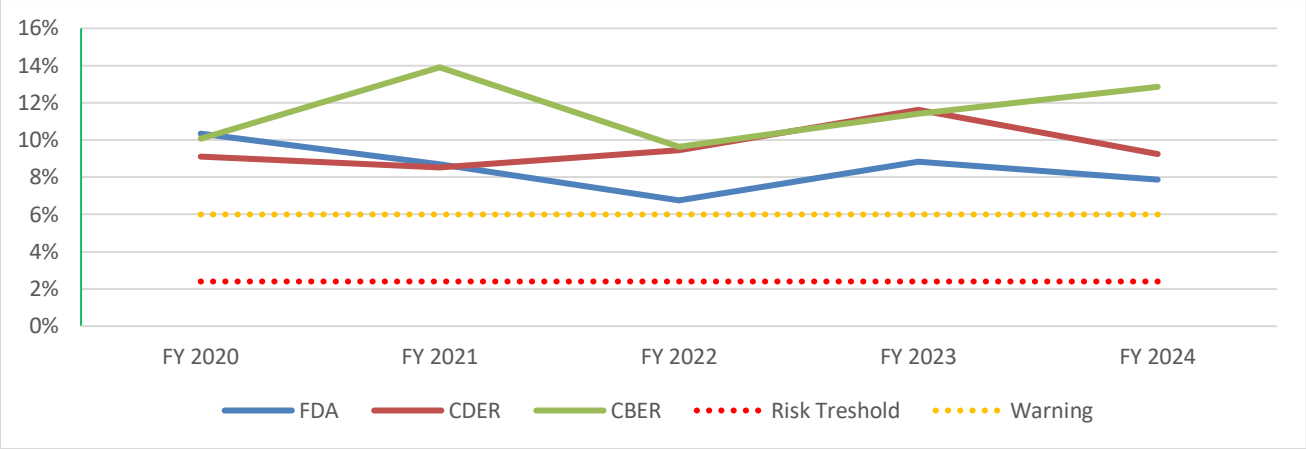
HR servicing ratio = Number of HR Staff 201s and 203s in OTS and OHCM divided by total number of full-time equivalents; our FDA-wide, CDER, and CBER data were updated on 12/20/2024. Net staffing change rate measures overall change in number of employees during a specific period, calculated by dividing annual change in staff count by average staff count during the specified period. N/A = Not Available or Not Applicable. BLS = Bureau of Labor Statistics.

Figure C-9. FDA, CDER, and CBER workforce gains as a percentage of total workforce by type for FY2022, FY2023, and FY2024



Source: WAPOR, data updated as of 01/23/2025; retrieved 02/03/2025. Note: FDA-level data do not include Center-level transfers.

Figure C-10. Accession rate by fiscal year, FY2020 to FY2024



Sources: WAPOR, data updated as of 01/23/2025, retrieved 02/03/2025. FDA Workforce Hiring and Attrition Trends (WHAT) Report, data updated 01/21/2025, retrieved 02/04/2025.

Accession risk threshold, 2.4%, and accession warning threshold, 6.0% (adapted from FDA WHAT report). FDA defines accession risk threshold as the lowest acceptable rate of growth to meet staffing demands, and FDA also includes a warning threshold (yellow).

Table C-12. Average time to complete OTS portion of hiring process in ATLAS* for PDUFA/BsUFA staff compared to SLAs in FY2023-FY2024, by hiring authority

Hiring Authority	SLA (bus. days)	FY2023 Vacancies	FY2023 Actual Avg (bus. days)	FY2023 Avg % of SLA Used	FY2024 Vacancies	FY2024 Avg Actual (bus. days)	FY2024 Avg % of SLA Used
Title 21 Non-Physicians / Non-Executives	114	409	44	38%	372	36	32%
Title 21 Physicians	118	183	31	26%	168	27	23%
Title 21 Executives	116	6	28	24%	10	43	37%
Title 5 Merit Promotion	221	73	194	88%	25	162	73%
Title 5 Direct Hire	221	4	165	74%	0	N/A	N/A
Title 5 Non-Competitive	76	22	57	75%	23	33	43%
Delegated Examining	227	2	76	34%	0	N/A	N/A
Title 38 Merit Promotion	135	0	N/A	N/A	0	N/A	N/A
Title 38 Direct Hire	57	52	22	39%	0	10	18%
Title 42 (f) Name Select	49	0	N/A	N/A	24	-	-
Title 42 (f) Position Advertised	152	0	N/A	N/A	0	N/A	N/A
Title 42 (g) Name Select	53	54	25	46%	47	28	53%
SES	219	0	N/A	N/A	0	N/A	N/A
Named actions (PARs)	0	0	N/A	N/A	0	N/A	N/A

Source: ATLAS Data Request received 01/17/2025.

*Time to complete portion of hiring process in ATLAS: Measured from when a candidate's package is received by OTS to when the candidate's EOD is finalized, as tracked in ATLAS. "N/A" = Not applicable because there were no

vacancies that fiscal year. "-" = Data not provided. Note: FDA met SLAs for most positions across all hiring authorities.

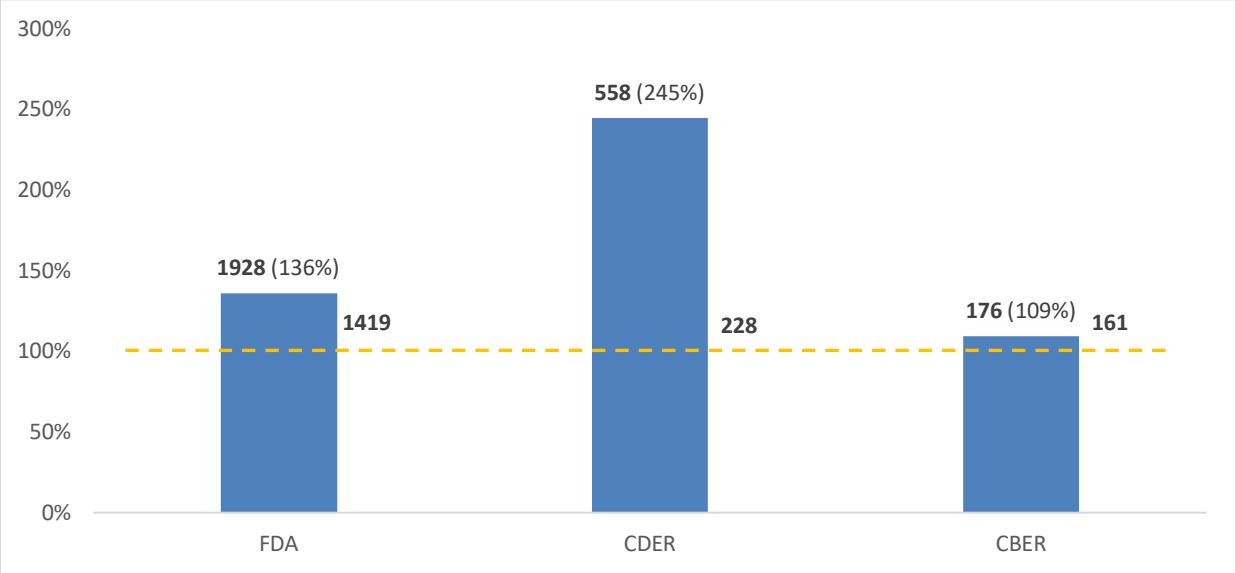
Table C-13. Average time to complete OTS portion of hiring process in ATLAS for PDUFA and BsUFA staff in business days in FY2024, by phase in hiring process and by hiring authority

Hiring Authority	Program Submission*	Talent Launch**	Talent Sourcing***	Talent Evaluation	Interview & Selection***	Tentative Offer	Final Offer & EOD	Overall Average	Number of Vacancies
Title 21 Non-Physicians / Non-Executives	2	3	N/A	5	N/A	7	19	36.35	**372**
Title 21 Physicians	2	2	N/A	7	N/A	3	14	27.06	**168**
Title 21 Executives	0	3	N/A	5	N/A	3	32	42.83	**10**
Title 38 Direct Hire	2	1	N/A	4	N/A	1	3	10.36	**24**
Hiring Authority	**Program Submission***	**Talent Launch**	**Talent Sourcing*****	**Talent Evaluation**	**Interview & Selection*****	**Tentative Offer**	**Final Offer & EOD**	**Overall Average**	**Number of Vacancies**
Title 42 (g)	0	N/A	N/A	5	N/A	16	6	28.08	**47**
Title 5 Merit Promotion	N/A	17	14	32	79	4	15	162.24	**25**
Title 5 Non-Competitive	N/A	3	N/A	10	N/A	2	19	33.03	**23**
Title 5 Direct Hire	N/A	-	-	-	-	-	-	-	**-**
Delegated Examining	N/A	-	-	-	-	-	-	-	**-**
Title 38 Merit Promotion	-	-	-	-	-	-	-	-	**-**
Title 42 (f) Name Select	N/A	N/A	N/A	-	N/A	-	-	-	**-**
Title 42 (f) Position Advertised	N/A	-	-	-	-	-	-	-	**-**
SES	N/A	-	-	-	-	-	-	-	**-**
Named Actions (i.e., PARs)	-	-	-	-	-	-	-	-	**-**

Source: ATLAS data request received 01/17/2025.

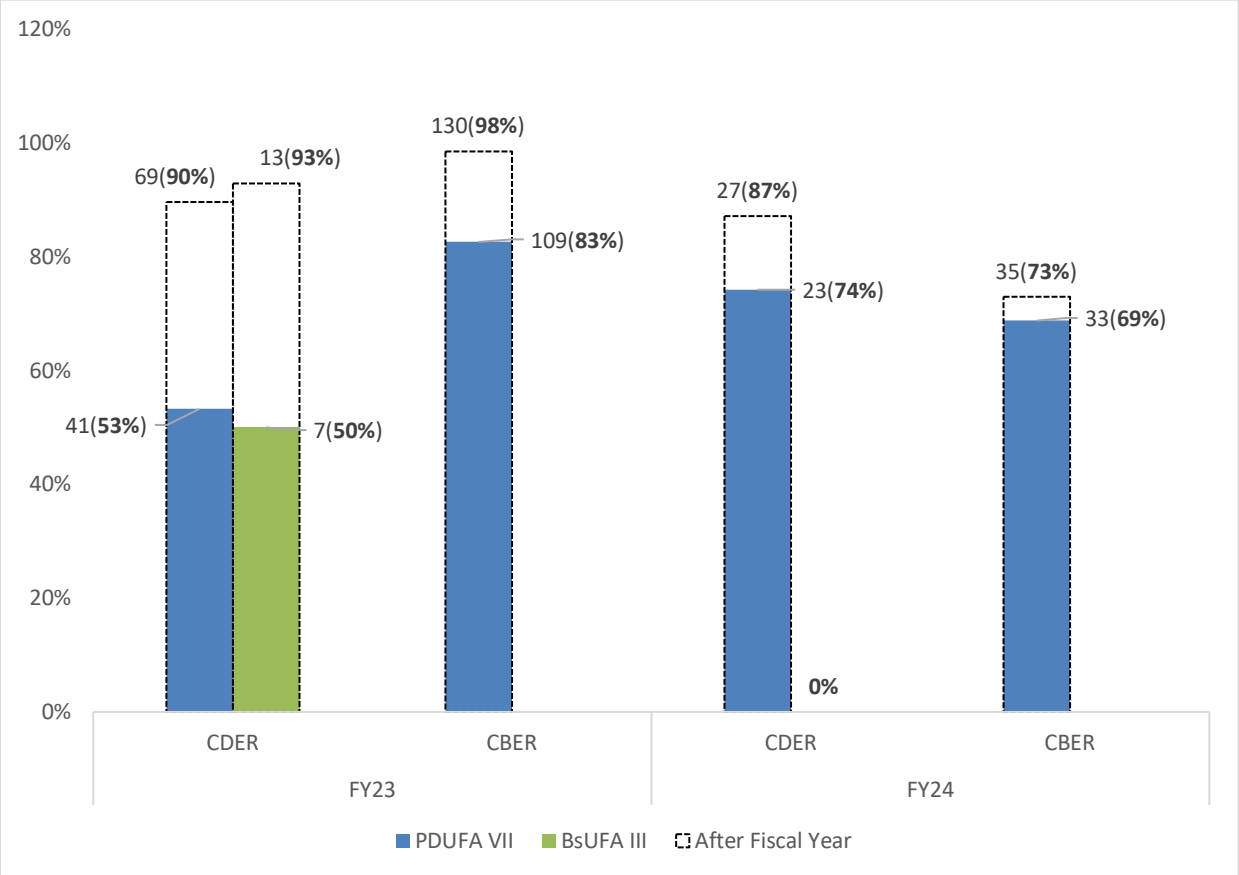
*"Program Submission" phase includes OTS receipt and review of a candidate's package for completeness. See Appendix B, Figure B-2 for information on activities performed in "Talent Launch" through "Final Offer and EOD" phases. **For some hiring authorities, "Talent Launch" phase includes assignment of an HR specialist and confirmation of the action. ***For most hiring authorities/actions, "Talent Sourcing" and "Interview & Selection" are handled at the CDER/CBER Program Office level or do not apply. "N/A" = Phase not applicable to hiring authority. "-" = Data not provided.

Figure C-11. FDA, CDER, and CBER number of new hires compared to hiring goals for FY2024



Source: Data request. Yellow dotted line indicates 2024 hiring goals: FDA = 1,419, CDER = 228, CBER = 161.

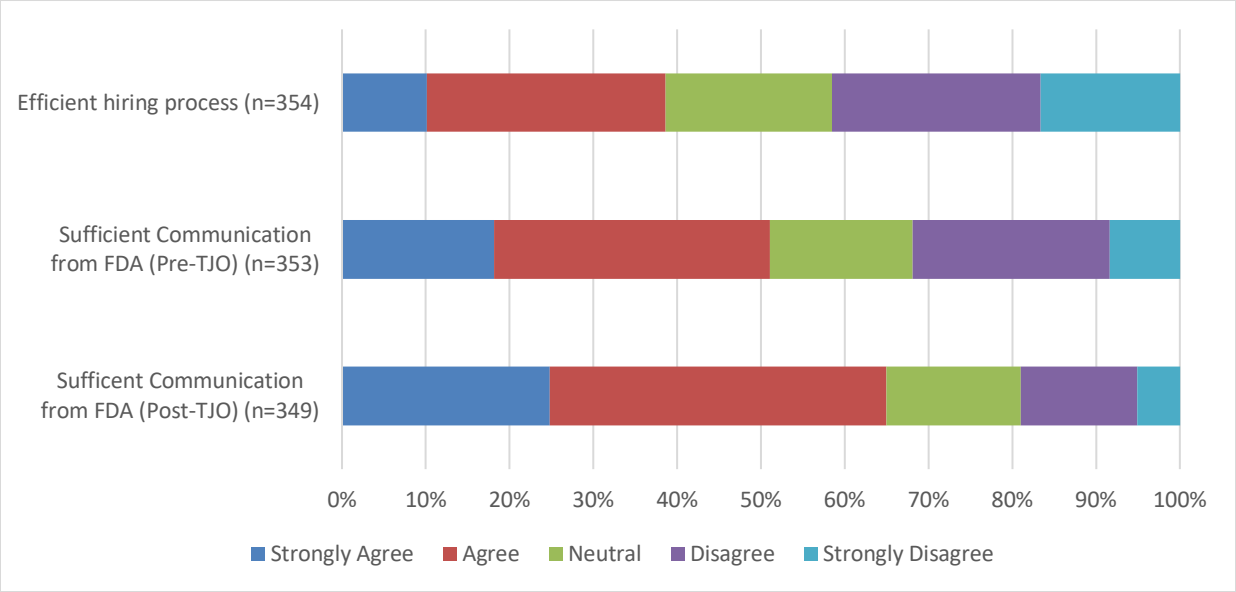
Figure C-12. PDUFA and BsUFA number of new hires compared to hiring goals for FY2023 and FY2024, by Center



Source: *PDUFA and BsUFA Quarterly Hiring Updates*

Note: FDA did not establish BsUFA hiring goals for CBER in FY2023 or FY2024.

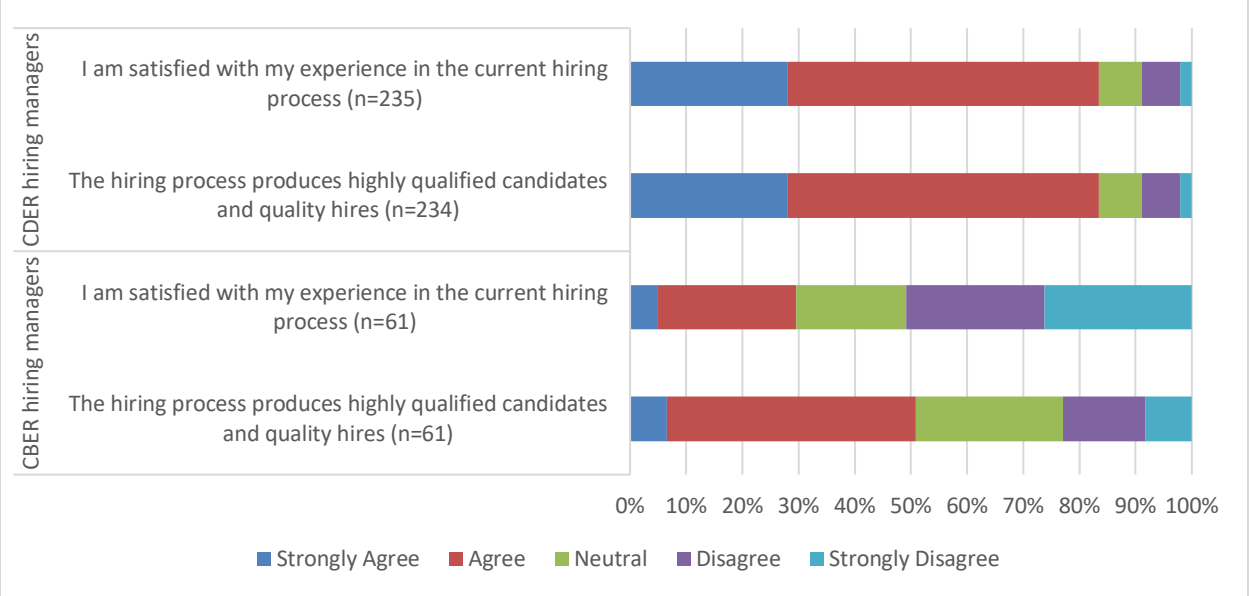
Figure C-13. CDER and CBER staff opinions about hiring process experience*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey items: "Rate your level of agreement with the following statements related to your experience with FDA's hiring and pre-employment onboarding process: The hiring process was efficient (i.e., well organized and timely); Communication from the FDA was sufficient throughout the hiring process (Up to receiving the tentative offer); Communication from the FDA was sufficient throughout the pre-employment onboarding process (From receiving the tentative offer through EOD])". Response patterns are similar across CDER and CBER new hires.

Figure C-14. CDER and CBER hiring manager opinions about hiring process experience*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey items: "Rate your level of agreement with the following statements related to your experience as a hiring manager." "Don't Know or Not Applicable" responses were excluded from analysis.

Table C-14. Overall talent lifecycle qualitative data from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others	Within FDA Control
Working Well												
ATLAS, PathHR, and AOIS for greatly improved hiring process effectiveness and transparency		•	•				•		•			•
Clear expectations about roles		•				•						•
Satisfaction with decision to accept positions at FDA				•								
Challenges												
Collaborating and communicating across Offices and Centers		•	•				•	•				•
Title 21: Frequent changes in processes and policies, with changes not communicated effectively to all staff, leading to delays and frustration		•	•				•		•			•
Overall hiring process efficiency and transparency (better for Title 5 than Title 21)				•				•				**

*Survey open responses, interviews, and focus groups.

**While the overall Federal recruiting and hiring process has mandatory steps over which FDA does not have control, FDA is responsible for completing these steps in a timely manner. Certain factors that are within FDA control (e.g., avoiding understaffing, properly training employees, providing clear expectations of roles) impact FDA's ability to maintain an efficient process.

Recruitment

The recruitment phase begins the talent lifecycle. In this phase, Center, OTS, and OHCM staff collaborate to reach and identify individuals with applicable skills and experiences who can succeed in available vacancies. To develop data for our assessment of FDA recruitment for PDUFA and BsUFA positions, ERG conducted interviews, focus groups, and surveys of FDA staff involved in recruitment as well as new staff who experienced FDA recruiting processes; we also collected data on talent sourcing.

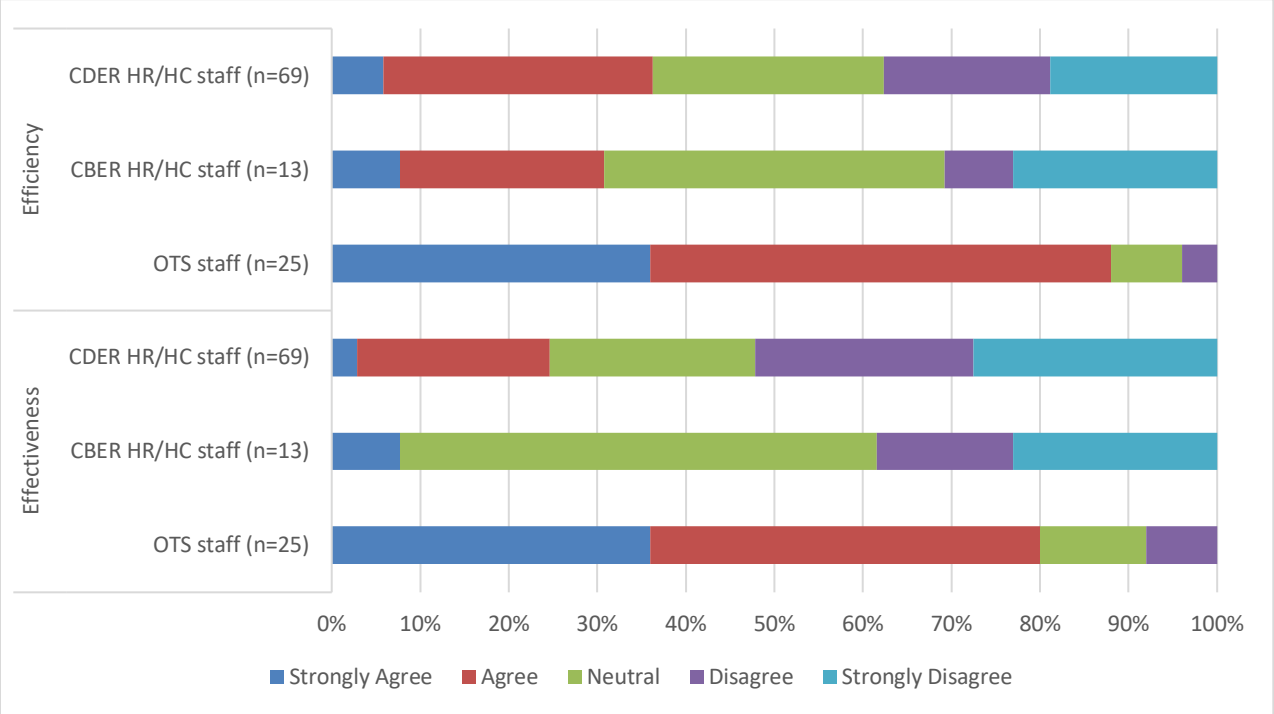
In this section, ERG presents the following results:

- Opinions of Center HR/HC staff and OTS staff about recruitment effectiveness and efficiency (Figure C-15).
- Satisfaction of hiring managers (Figure C-16) and new hires (Figure C-17) with recruitment processes.

- Growth in strategic partnerships[17] for recruitment (Figure C-18) and how new hires learned about PDUFA and BsUFA vacancies (Figure C-19).
- Key themes and feedback about the recruitment process from all sources (Table C-15).

Collectively, these data provide evidence that FDA is able to make vacancies visible to and attract individuals with the skills needed for PDUFA and BsUFA positions, and new hires are generally satisfied with recruitment (especially under Title 21). OTS staff are much more likely than Center staff to consider recruitment processes to be effective and efficient, and hiring managers are most satisfied with processes under Center control.

Figure C-15. Opinions about recruitment from staff involved in HR/HC processes*

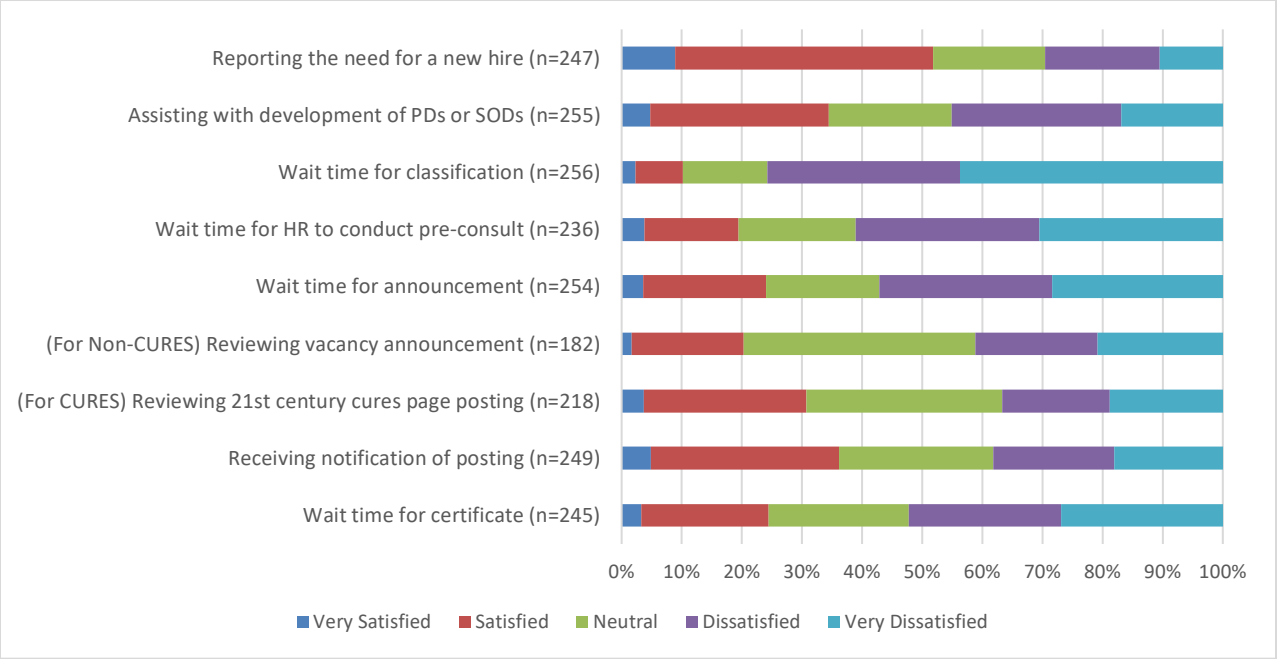


Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: Please rate your level of agreement with the following statements regarding FDA's recruiting, hiring, pre-employment onboarding, and retention activities. Select 'Don't Know or N/A' for the activities that you don't actively support as a primary function of your job: The FDA recruitment process is effective; The FDA recruitment process is efficient." "Don't Know or Not Applicable" responses were excluded from analysis. The data for effectiveness and efficiency include all survey respondents (across all surveyed organizational units and roles) from CDER, CBER, OTS, and OHCM who indicated they spend at least 25% of their time in recruitment processes, also resulting in no OHCM survey responses used for this figure.

[17] To support FDA's ability to attract talent to scientific positions that are essential to the Agency's mission, the Scientific Staffing and Outreach Branch (SSOB) establishes strategic partnerships to facilitate direct engagement and sustained interactions with academic and government institutions, professional associations, organizations, and consortiums. These collaborations support outreach and recruitment for MCOs by expanding and leveraging FDA's talent pool to attract specialized professionals. The SSOB emphasizes quality rather than quantity of partnerships, though the number of partnerships has grown substantially.

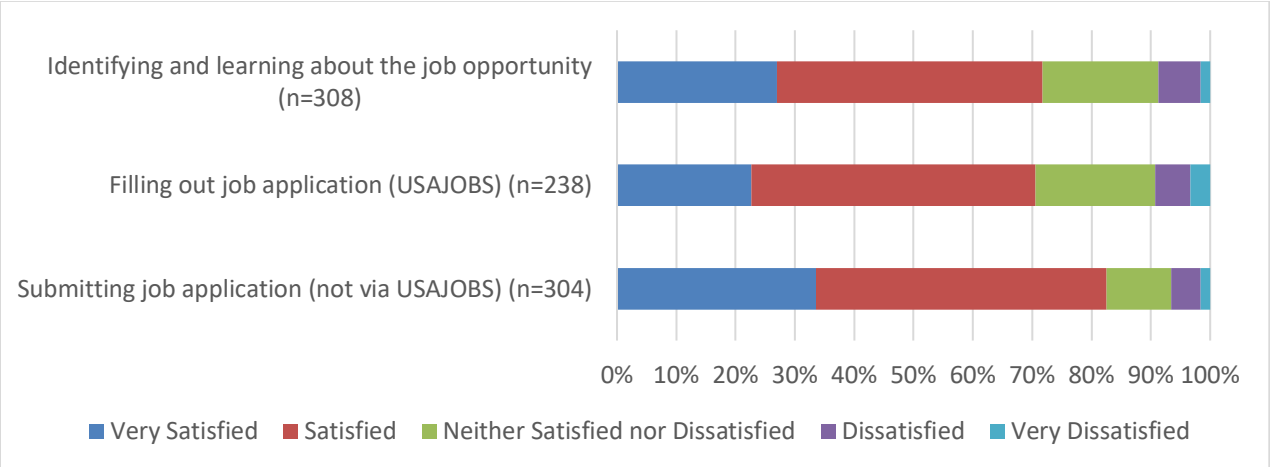
Figure C-16. CDER and CBER hiring manager satisfaction with recruitment processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Listed below are elements of the hiring process you might have experienced as a hiring manager. Please rank your satisfaction with these elements." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across organizational units and roles except as follows: CDER hiring managers were less satisfied with assisting with development of PDs or SODs at 30% (n=195) satisfaction than CBER hiring managers at 49% (n=60), less satisfied with reviewing CURES postings at 27% (n=170) than CBER hiring managers at 46% (n=48), and less satisfied with receiving posting notifications at 33% (n=191) than CBER hiring managers at 44% (n=58) satisfaction.

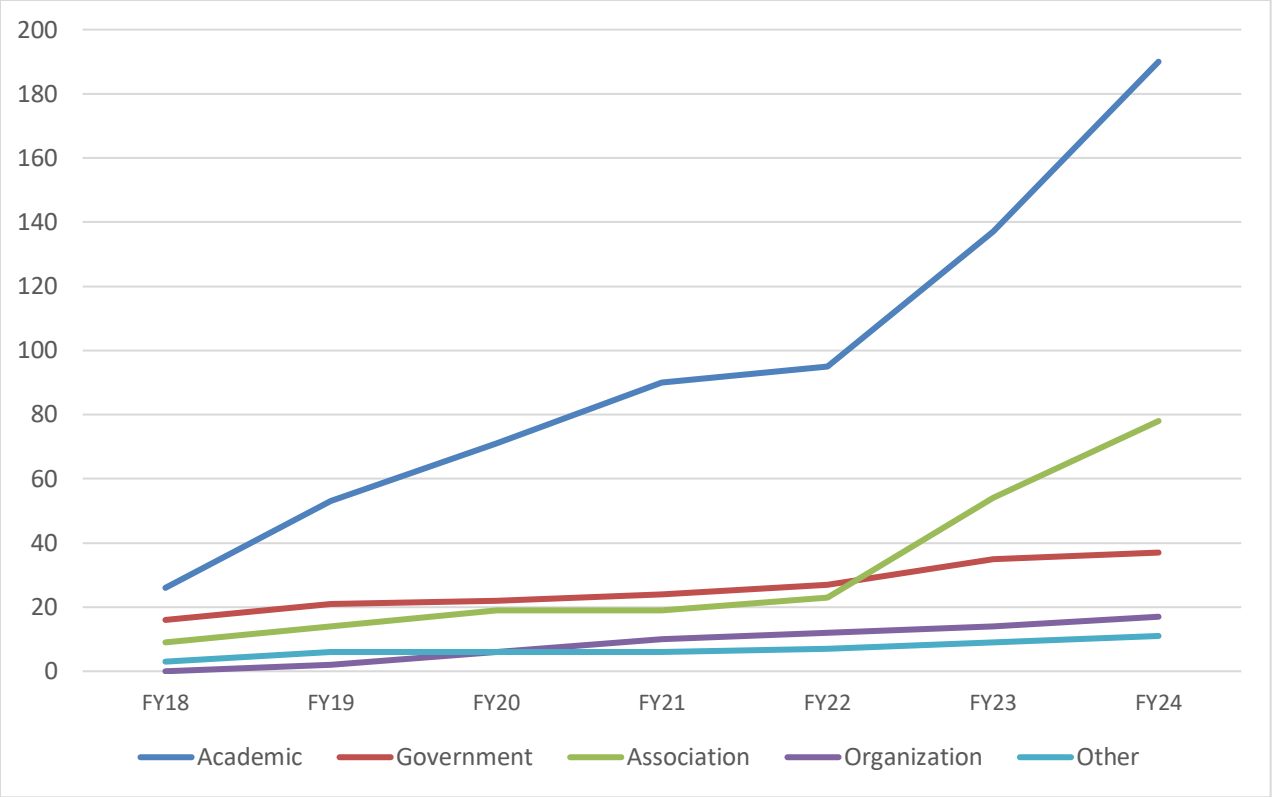
Figure C-17. CDER and CBER new hire satisfaction with recruitment processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

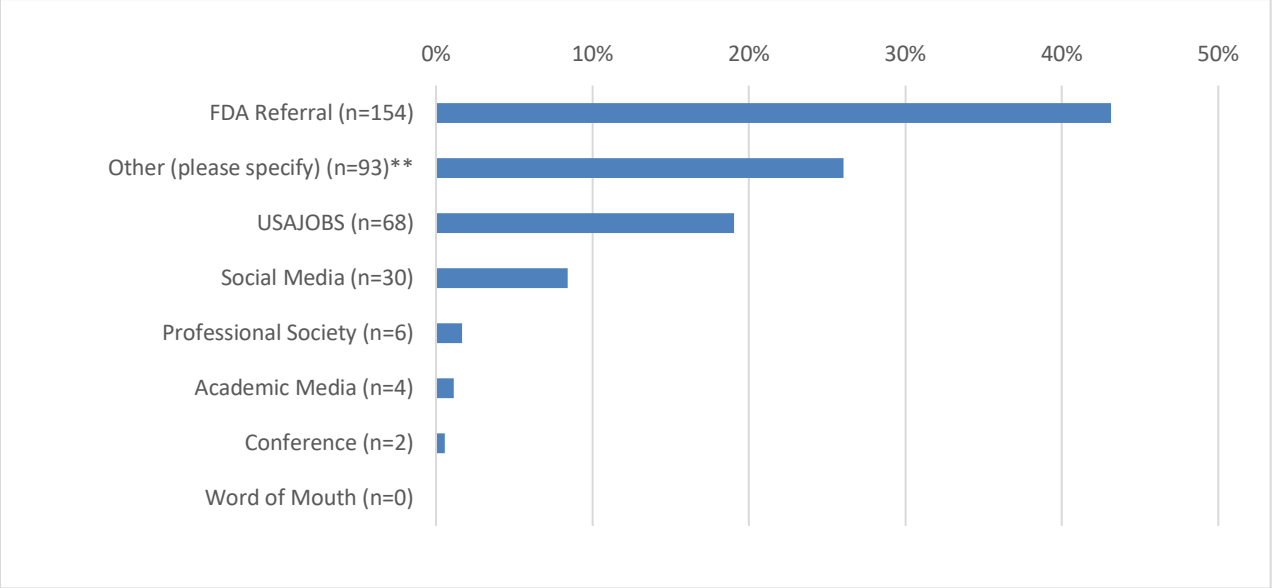
*Survey item: "Listed below are elements of the hiring process you might have experienced as a candidate. Please rank your satisfaction with these elements:" Response patterns are similar across organizational units. "Don't Know or Not Applicable" responses were excluded from analysis.

Figure C-18. Growth in number of strategic partnerships FY2018 to FY2024



Source: FDA OTS SSOB data request, December 2024.

Figure C-19. How newly hired CDER and CBER staff first heard about current position (n=357)*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: How did you first hear about your current position?

**Responses for "Other (please specify)" include FDA website (particularly the FDA Title 21 postings page) (n<20) or contact from a recruiter (n<10).

Table C-15. Qualitative data on recruitment from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others	Within FDA Control
Working Well												
Collaboration between OTS, AO, and hiring manager to identify position needs		●	●				●	●	●			●
Recruiting outside of USAJobs (e.g., LinkedIn)		●	●	●			●	●				●
Direct outreach (e.g., conferences)		●		●	●		●	●	●			●
Announcement of vacancies		●					●		●			●
Challenges												
Program Office / OTS disagreements about whether specific candidates are qualified (resulting in delays or need to identify other candidates)		●	●				●	●	●			**
Telework inflexibility			●				●	●				

AO = Administrative Officer.

*Survey open responses, interviews, and focus groups.

**Partially under FDA control. Focus group participants described disagreements over minute details, like the wording of a course description in a candidate's transcript. While certain portions of qualifications are defined by OPM, certain elements of interpretation are under FDA control.

Hiring

Following recruitment, the talent lifecycle continues with the hiring phase. During this time, qualified candidates who were identified in the recruitment phase are further vetted and interviewed until a selection is ultimately made. To develop data for our assessment of FDA hiring for PDUFA and BsUFA positions, ERG analyzed FDA hiring data and conducted interviews, focus groups, and surveys with staff involved in hiring.

In this section, ERG presents the following results:

- A recap of progress toward achieving CDER/CBER and PDUFA/BsUFA hiring goals for FY2024 (Table C-16).
- Distribution of FY2023 and FY2024 hires by hiring authority (Figure C-20).
- Center HR/HC staff and OTS staff opinions about hiring process effectiveness and efficiency (Figure C-21).
- Satisfaction with hiring processes among hiring managers (Figure C-22) and new staff (Figure C-23).
- Key themes and feedback about hiring processes from all sources (Table C-17).

The data provide evidence that FDA is generally able to achieve (or come close to achieving) its hiring goals for CDER/CBER and PDUFA/BsUFA. OTS staff are much more likely than Center HR/HC staff to believe that hiring is effective and efficient, and hiring managers are most satisfied with elements of hiring process that are in their control (e.g., reviewing resumes, interviewing candidates, answering candidate questions, speaking to references, and communicating the selection to HR contact). New hires generally view the hiring process favorably but report the least satisfaction with salary negotiation phase; this might be attributable more to the salary determination itself than the process of negotiating salary.

Table C-16. Progress toward achieving CDER/CBER and PDUFAVII/BsUFAIII hiring goals in FY2024

Metric	CDER	CBER	PDUFA	BsUFA
Number of vacancies in fiscal year	334*	16*	NA	NA
Hiring goal	32*	48*	79	1
Percent of hiring goal achieved during fiscal year	72%*	69%*	71%	0%
Percent of hiring goal achieved as of 12/31/2024**	84%*	73%*	78%	0%

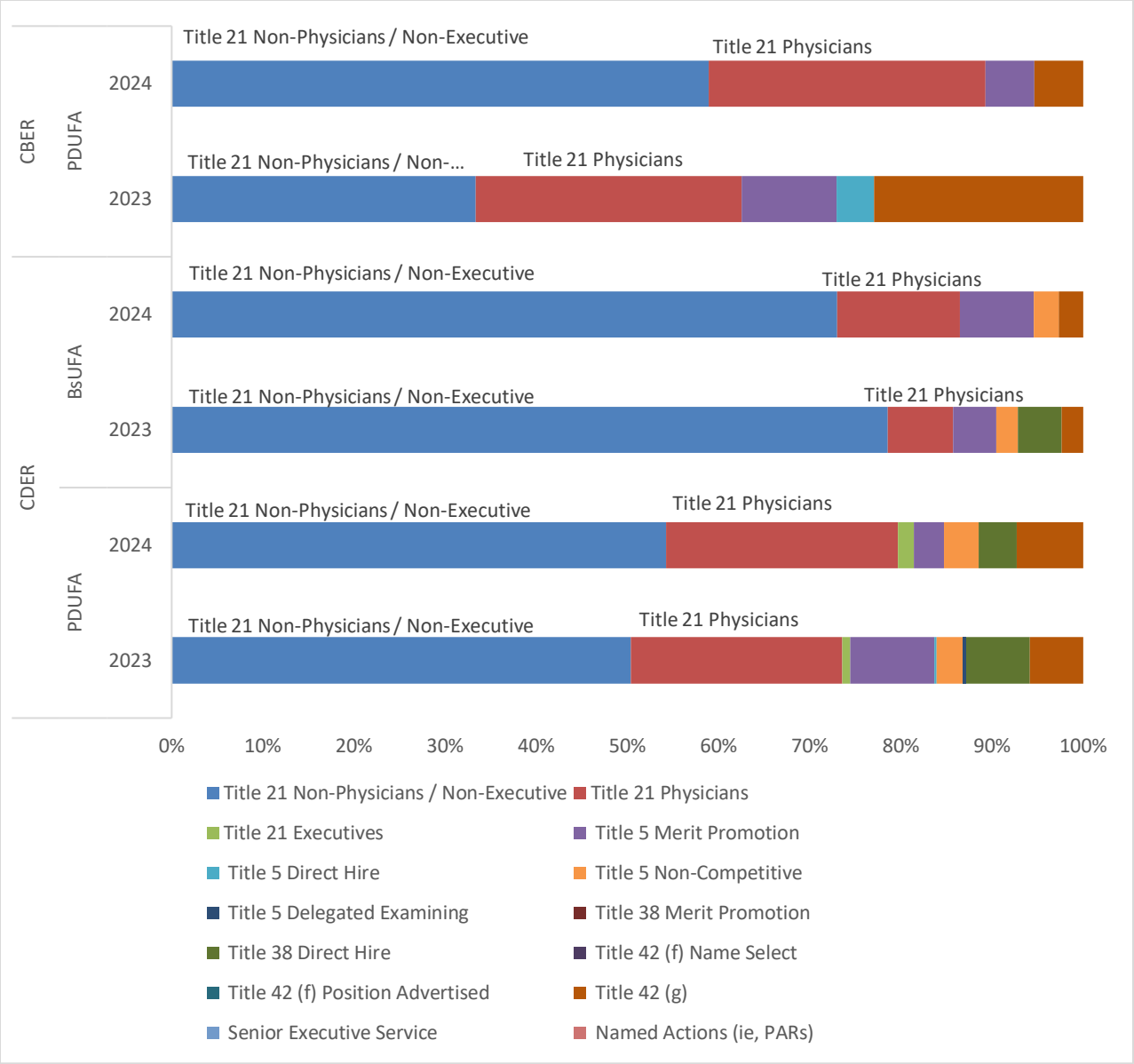
Sources: ATLAS Data Request received 01/17/2025 (vacancies, number of hires, distribution of hires by authority). PDUFA and BsUFA Quarterly Hiring Updates (hiring goals).[18] WHAT Report.[19]

*PDUFA and BsUFA data combined, not Center-wide.

**Because hiring for new positions begins at different points throughout a fiscal year and the hiring process is lengthy, a significant percent of new staff begins work after the end of the fiscal year. This has been true every fiscal year since FDA began establishing and reporting on hiring goals. This is why FDA continues to provide quarterly updates on hiring for previous fiscal years for a substantial period of time after a fiscal year ends. Insufficient time has elapsed to know whether FDA will achieve FY2024 hiring goals; a pause in hiring with the election of a new President might hinder FDA's ability to achieve its FY2024 hiring goals.

[18] PDUFA and BsUFA Quarterly Hiring Updates, Performance Reports (content current as of 10/08/2024; https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates)
[19] Workforce Hiring and Attrition Trends (WHAT) Report, accessed 01/03/2025, Data current as of November 2024

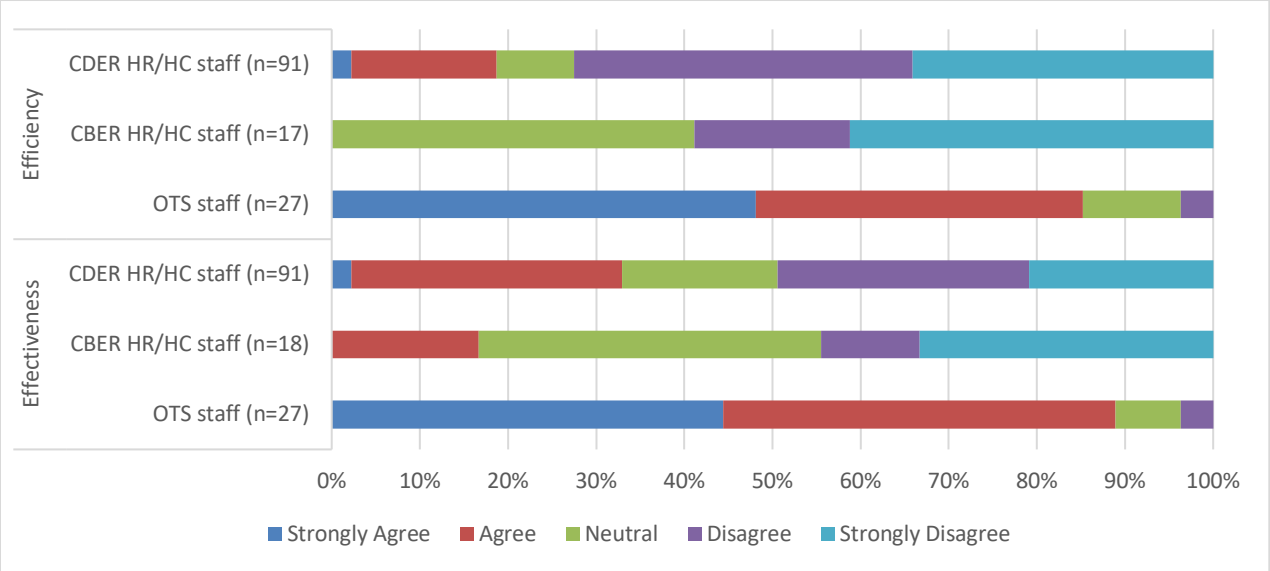
Figure C-20. Distribution of FY2023 & FY2024 hires by hiring authority*



Source: ATLAS Data Request received 01/17/2025.

*CDER PDUFA 2023 Hires: n=715, 2024 Hires: n=575; CDER BsUFA 2023 Hires: n=42, 2024 Hires: n=37. CDER PDUFA Title 21 Non-Physicians / Non-Executive Hires were 50.3% of total hires in 2023, and 54.3% of total hires in 2024. CDER BsUFA Title 21 Non-Physicians / Non-Executive Hires were 78.6% of total hires in 2023, and 73.0% of total hires in 2024. CBER PDUFA Title 21 Non-Physicians / Non-Executive Hires were 33.3% of total hires in 2023, and 58.9% of total hires in 2024. CDER PDUFA Title 21 Physicians Hires were 23.2% of total hires in 2023, and 25.4% of total hires in 2024. CDER BsUFA Title 21 Physicians Hires were 7.1% of total hires in 2023, and 13.5% of total hires in 2024. CBER PDUFA Title 21 Physicians Hires were 29.2% of total hires in 2023, and 30.4% of total hires in 2024. There were no CBER BsUFA hires in 2023 or 2024.

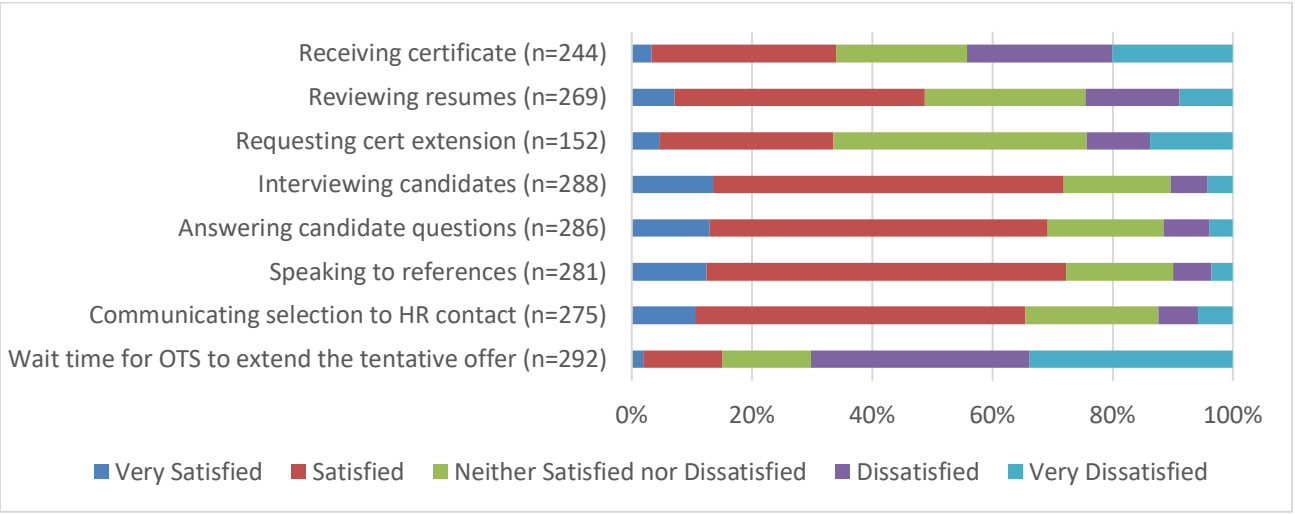
Figure C-21. Opinions about hiring from staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: Please rate your level of agreement with the following statements regarding FDA's recruiting, hiring, pre-employment onboarding, and retention activities. Select 'Don't Know or N/A' for the activities that you don't actively support as a primary function of your job: The FDA hiring process is effective; The FDA hiring process is efficient". "Don't Know or Not Applicable" responses were excluded from analysis. The data for effectiveness and efficiency include all survey respondents (across all surveyed organizational units and roles) from CDER, CBER, OTS, and OHCM who indicated they spend at least 25% of their time in hiring processes, also resulting in no OHCM survey responses used in this figure.

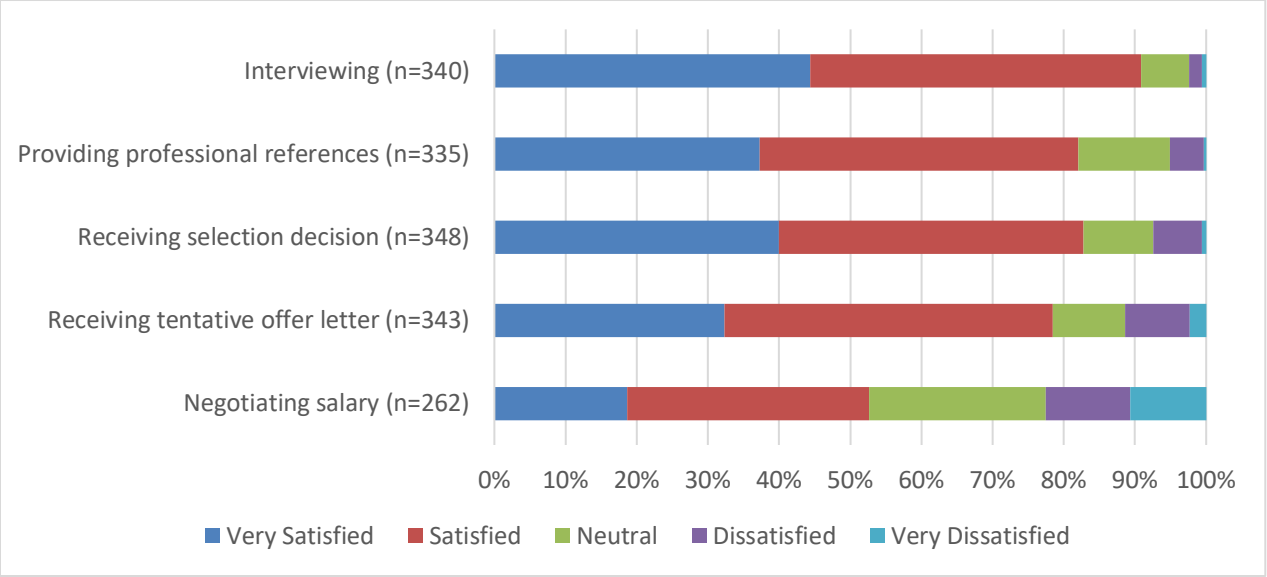
Figure C-22. CDER and CBER hiring manager satisfaction with hiring processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Listed below are elements of the hiring process you might have experienced as a hiring manager. Please rank your satisfaction with these elements." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across organizational units.

Figure C-23. CDER and CBER new hire satisfaction with hiring processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Listed below are elements of the hiring process you might have experienced as a candidate. Please rank your satisfaction with these elements." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across CDER and CBER new hires except for CDER new hires who are more satisfied with providing professional references at 85% (n=266) than CBER new hires at 72% (n=69) satisfaction, as well as receiving the selection decision at 85% (n=271) satisfaction in comparison to CBER new hires at 75% (n=77) satisfaction.

Table C-17. Qualitative data on hiring from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others	Within FDA Control
Working Well												
Screening process (e.g., phone calls, HireVue)			●				●	●				●
Interviewing candidates			●				●	●				●
Standardized interview approach			●				●					●
Challenges												
Lengthy time to process internal hires			●	●			●	●				
Lack of tracking mechanism for package between program office and OTS		●	●				●	●				●
Title 21: Program Office / OTS disagreements about whether specific candidates are qualified**							●					***
Inconsistencies in timeline and review of packages in OM and OTS			●				●	●				●
Loss of candidates due to length of process		●	●				●	●				
Frequently changing policies and processes			●				●	●				
Lack of collaboration between OAO, OM, and OTS		●					●					●
Particularly for more specialized positions, certificates can be very long with mostly unqualified candidates			●				●	●				
Candidates have difficulty navigating the salary negotiation process				●				●				

OAO = Office of Administrative Operations

*Survey open responses, interviews, and focus groups.

** For a Title 5 hire, OTS qualification determinations typically occur during the recruitment phase. For a Title 21 hire, it occurs after the hiring manager selects a candidate, which is why we include this theme in the hiring section.

***Partially under FDA control. Focus group participants described disagreements over very minute details, like the wording of a course description in a candidate's transcript. While certain portions of qualifications are defined by OPM, certain elements of interpretation are under FDA control.

Pre-Employment Onboarding

Following hiring, the talent lifecycle continues with the pre-employment onboarding phase. To develop data for our assessment of pre-employment onboarding, ERG analyzed data from FDA about their security background checks and ethics pre-clearance processes and conducted interviews, focus groups, and surveys with staff involved in various onboarding activities.

In this section, ERG presents the following results:

- For security clearance, average number of days for OSPO to clear candidates through eArrive (Figure C-24).
- For ethics pre-clearance, average number of days for OEI to complete pre-clearances for certain senior positions (Table C-18).
- Center HR/HC staff and OTS staff opinions about pre-employment onboarding effectiveness and efficiency (Figure C-25).
- Satisfaction with pre-employment onboarding processes among hiring managers (Figure C-26) and new hires (Figure C-27).
- Key themes and feedback about pre-employment onboarding from all sources (Table C-19).

Collectively, these data provide evidence that FDA has improved pre-employment onboarding processes that were pain points at the time of the last assessment. OSPO now completes most security clearances through eArrive, and OEI completes most ethics pre-clearances in timeframes well below their SLAs. OTS and OHCM staff are more likely than Center staff to agree that pre-employment onboarding processes are effective and efficient; hiring managers tend to be frustrated with wait times for these processes. New hires are generally satisfied with their experiences.

Figure C-24. Average number of days for OSPO to clear candidates through eArrive, CY2021-2024*

Source: OSPO data request, January 2025.

*The SLA for this activity is 14 days. It starts when the candidate is entered into eArrive by Center staff and ends when the paperwork is cleared by an OSPO personnel security specialist. The SLA does not include fingerprinting and badging, which occur after eArrive approval and background investigation clearance.

Table C-18. Ethics pre-clearance metrics for CDER and CBER, CY2024

Metric	CDER	CBER
OGE Form 278		
Number of pre-clearances completed	9	1
Average days to complete pre-clearance*	40.44	29.00
Average days to EOD**	58.67	67.00
OGE Form 450		
Number of pre-clearances completed	91	7
Average days to complete pre-clearance*	14.84	21.14
Average days to EOD**	38.32	56.14

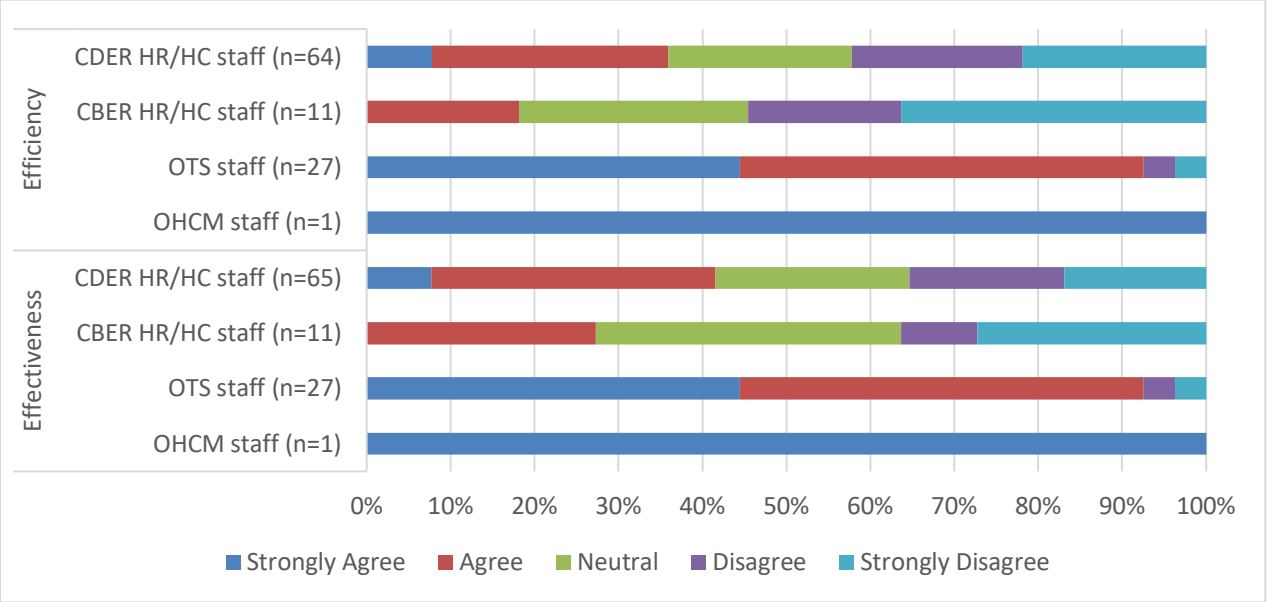
Source: OEI data request, January 2025.

The most senior positions at FDA file U.S. Office of Government Ethics (OGE) form 278, and other high-level positions (e.g., directors, Center directors) file OGE form 450. ERG was unable to obtain ethics pre-clearance metrics for other positions or years.

*The SLA for this activity is 60 days.

**If OEI completes a pre-clearance too far in advance of the candidate's EOD (i.e., more than 60 days before EOD), certain details (e.g., holdings) might change and pre-clearance might need to be re-done closer to the EOD.

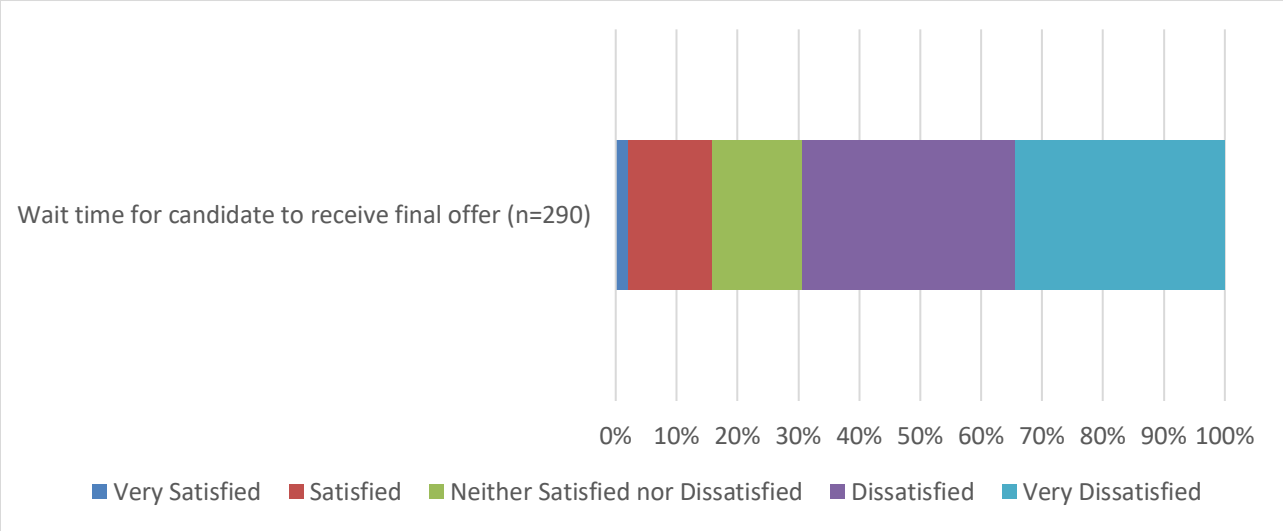
Figure C-25. Opinions about pre-employment onboarding from staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: "Please rate your level of agreement with the following statements regarding FDA's recruiting, hiring, pre-employment onboarding, and retention activities. Select 'Don't Know or N/A' for the activities that you don't actively support as a primary function of your job: The FDA pre-employment onboarding process is effective; The FDA pre-employment onboarding process is efficient." "Don't Know or Not Applicable" responses were excluded from analysis. The data include all survey respondents from CDER, CBER, OTS, and OHCM who indicated they spend at least 25% of their time in pre-employment onboarding processes, where one OHCM staff response qualified and indicated 100% agreement (n=1).

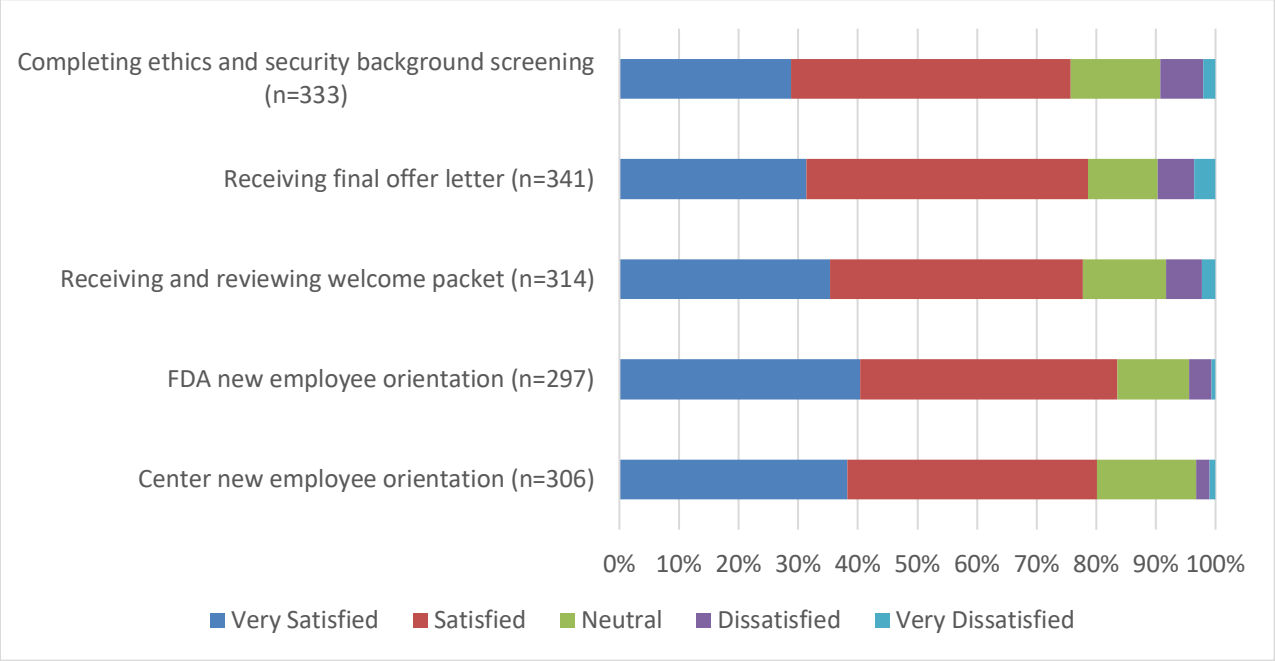
Figure C-26. CDER and CBER hiring manager satisfaction with pre-employment onboarding processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Listed below are elements of the hiring process you might have experienced as a hiring manager. Please rank your satisfaction with these elements." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across CDER and CBER hiring managers.

Figure C-27. CDER and CBER new hire satisfaction with pre-employment onboarding processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Listed below are elements of the hiring process you might have experienced as a candidate. Please rank your satisfaction with these elements." "Don't Know or not Applicable" responses were excluded from analysis. Response patterns are similar across organizational units, but CDER new hires have somewhat higher satisfaction rates than CBER new hires during the ethics and security background screening, FDA NEO, and Center NEO that ranges 12-18% more.

Table C-19. Qualitative data on pre-employment onboarding from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OCHM	OEI / OSPO	Others	Within FDA Control
Working Well												
Ethics pre-clearance processes and definitions (standardized, documented)		•	•						•		•	•
eArrive for initiating security process		•	•		•				•	•	•	•
Challenges												
Lengthy security or ethics clearance process		•					•	•				
Confusion about security or ethics clearance process		•					•	•	•			•
Ethics pre-clearance initiated too early or too late					•						•	
Insufficient stages in eArrive to clearly and accurately convey status											•	
Lack of position-specific information prior to EOD							•	•				
In some Centers, decentralized processes lead to errors and inefficiencies			•								•	•

*Survey open responses, interviews, and focus groups.

Retention

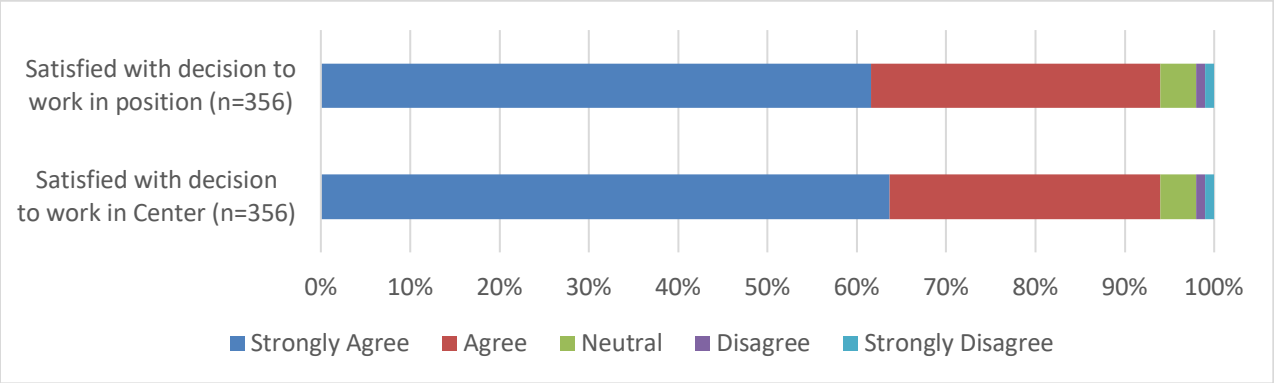
The final phase of the talent lifecycle involves the retention of staff who have been brought on to the Agency, which is supported by use of benefits and incentives. To develop data for our assessment of retention, ERG analyzed data on retention and attrition and conducted interviews, focus groups, and surveys of staff involved in or impacted by retention initiatives.

In this section, ERG presents the following results:

- New hire satisfaction with decision to work at FDA (Figure C-28).
- Influence of FDA programs on CDER and CBER staff retention (Figure C-29).
- FDA, CDER, and CBER attrition rates by fiscal year (Figure C-30) and losses by type and fiscal year (Figure C-31).
- Reasons why CDER and CBER staff would consider leaving their Center (Figure C-32) and destinations they would consider (Figure C-33).
- Opinions about retention processes among OHCM staff (Figure C-34) and Center HR/HC staff (Figure C-35).
- HR/HC staff opinions on HR/HC culture at FDA (Figure C-36).
- Key themes and feedback about retention from all sources (Table C-20).

These data provide evidence that retention at FDA (including CDER and CBER) is strong. New staff are generally satisfied with their decision to join their Center, FDA's mission contributes to staff of all tenures decision to remain at the Agency, and attrition rates are low. HR/HC staff identify additional opportunities for improving workplace culture as well.

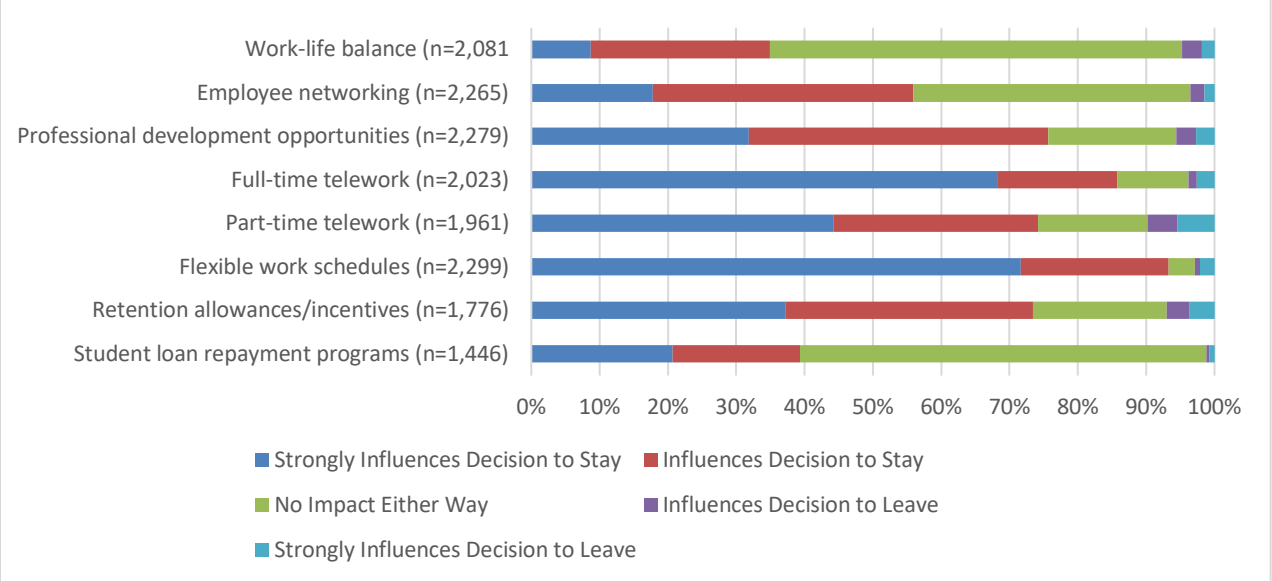
Figure C-28. CDER and CBER new hire satisfaction with their decision to work at FDA*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Rate your level of agreement with the following statements related to your experience with FDA's hiring and pre-employment onboarding process." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across CDER and CBER new hires.

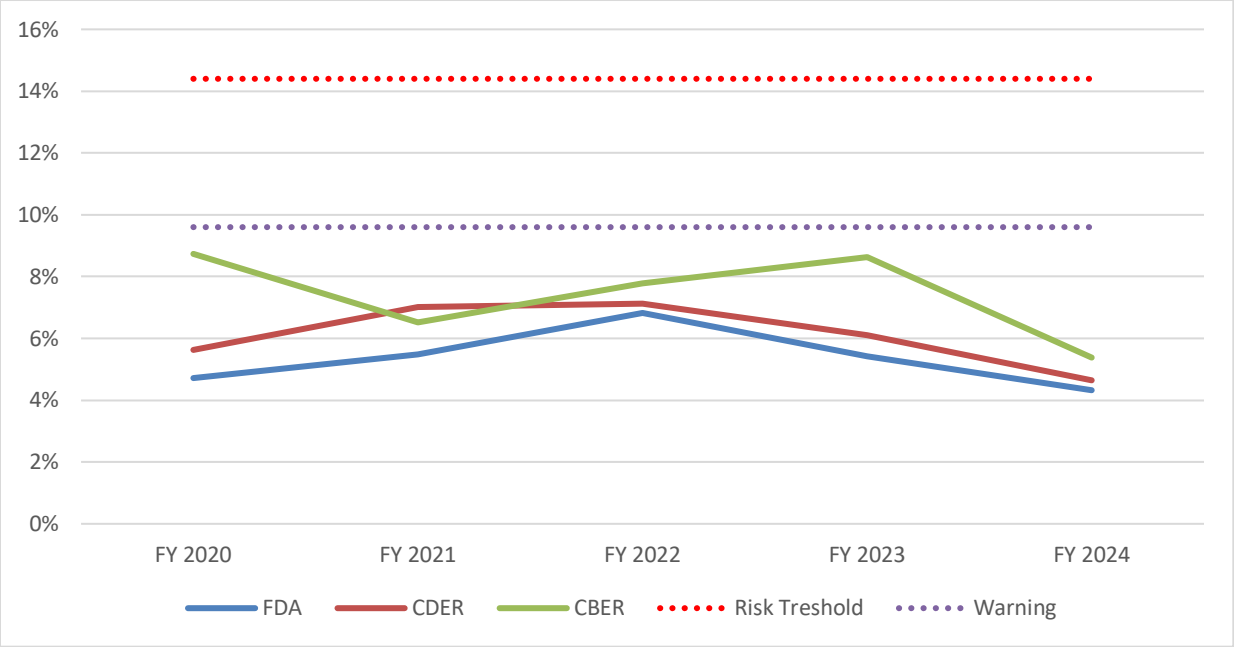
Figure C-29. Influence of FDA programs on CDER and CBER staff retention*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Rate the impact that each of the following programs has on your decision to stay with or leave [CDER/CBER]." Response patterns are similar across CDER and CBER staff. "Don't Know/Applicable" responses were excluded from analysis.

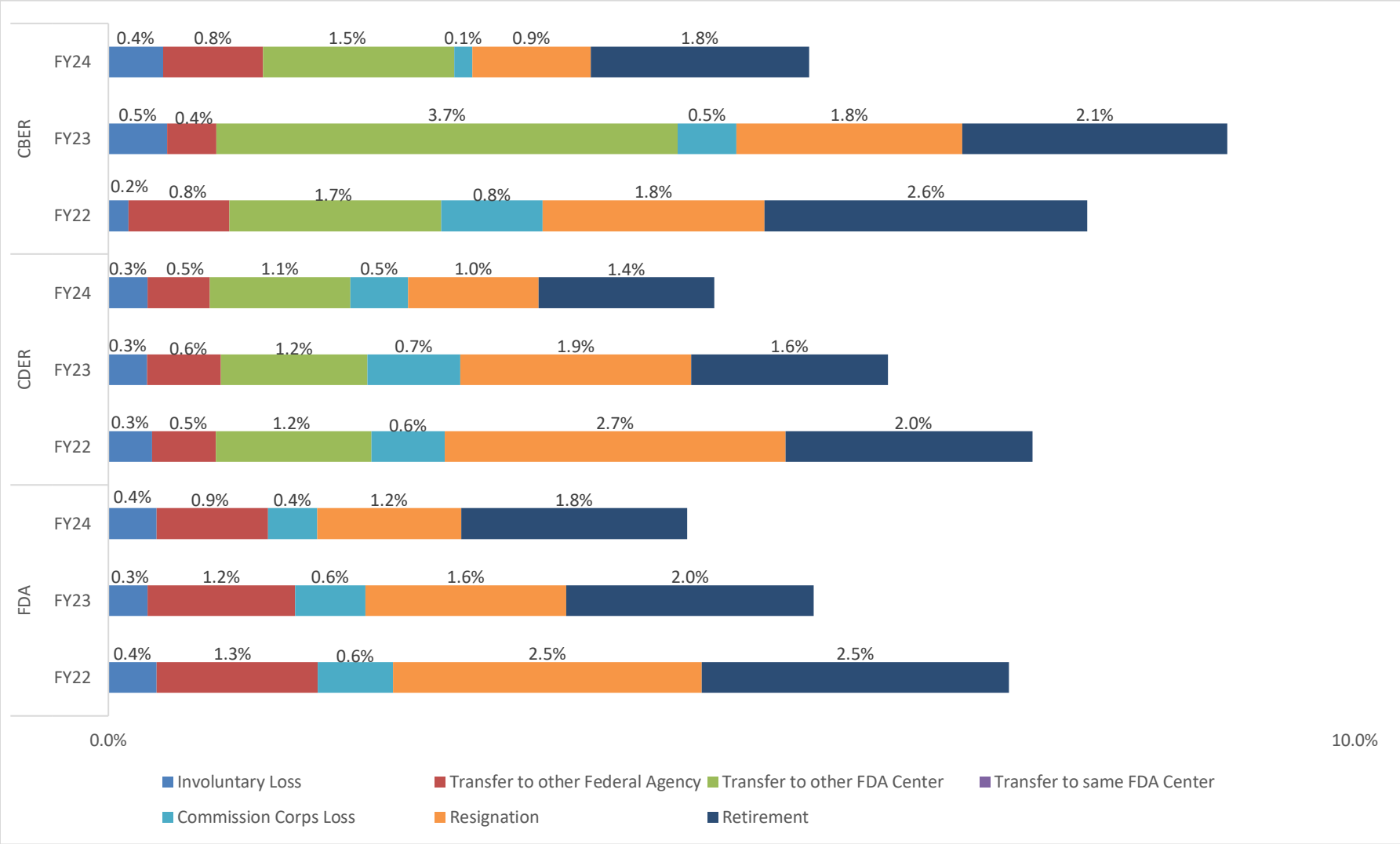
Figure C-30. Attrition rate by fiscal year, FY2020 to FY2024



Sources: FDA Human Capital Reporting and Analysis Portal: WAPOR, data updated as of 01/23/2025; retrieved 02/03/2025. FDA Workforce Hiring and Attrition Trends (WHAT) Report, data updated 01/21/2025, retrieved 02/04/2025.

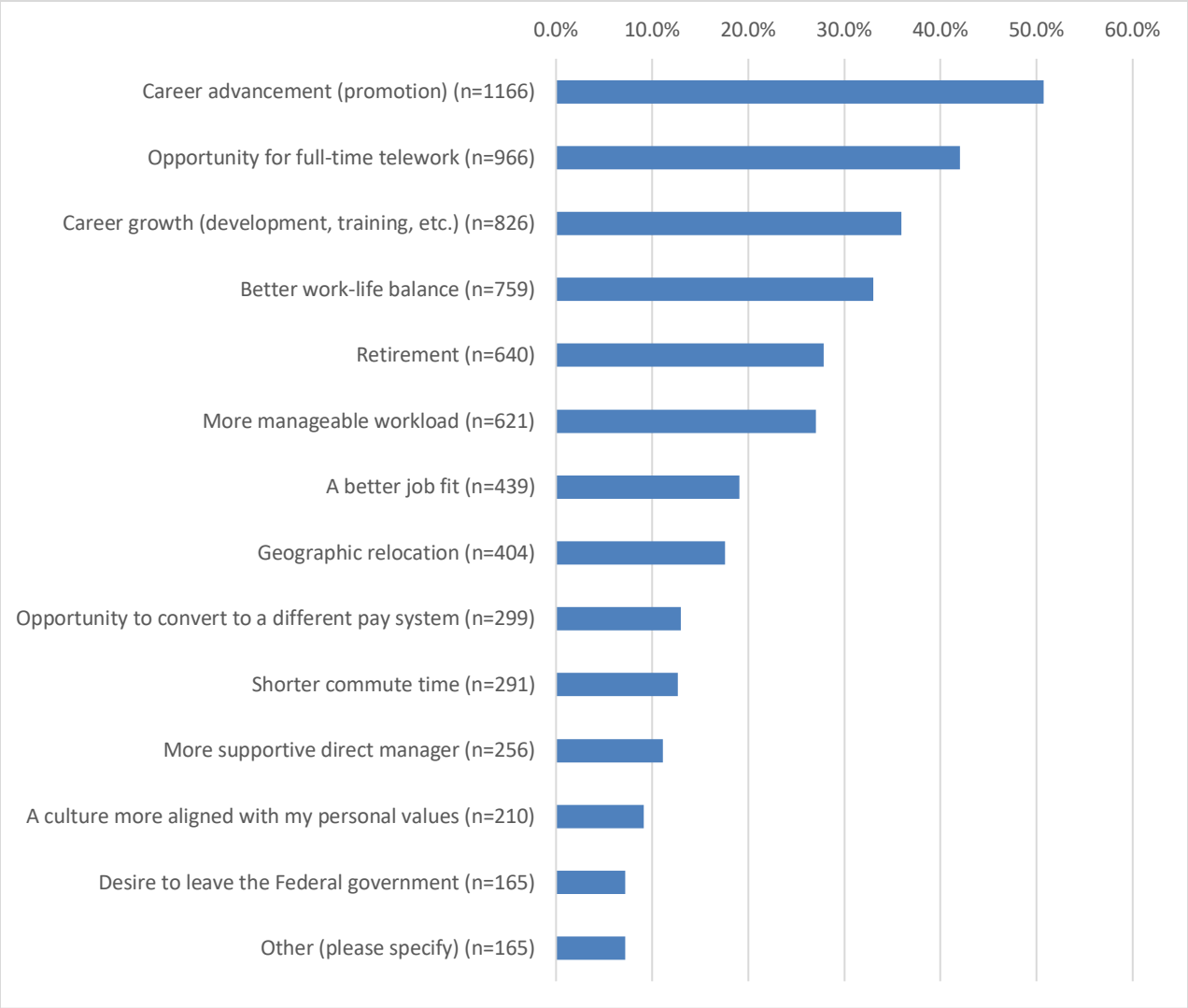
Attrition risk threshold, 14.4%, and attrition warning threshold, 9.6% (adapted from FDA WHAT report). FDA defines attrition risk as the highest rate of attrition before attrition outpaces hiring, and FDA also includes an attrition warning threshold.

Figure C-31. FDA, CDER, and CBER workforce losses as a percentage of total workforce by type for FY2022, FY2023, and FY2024



Source: WAPOR, data updated as of 01/23/2025; retrieved 02/03/2025. Note: FDA-level data do not include Center-level transfers.

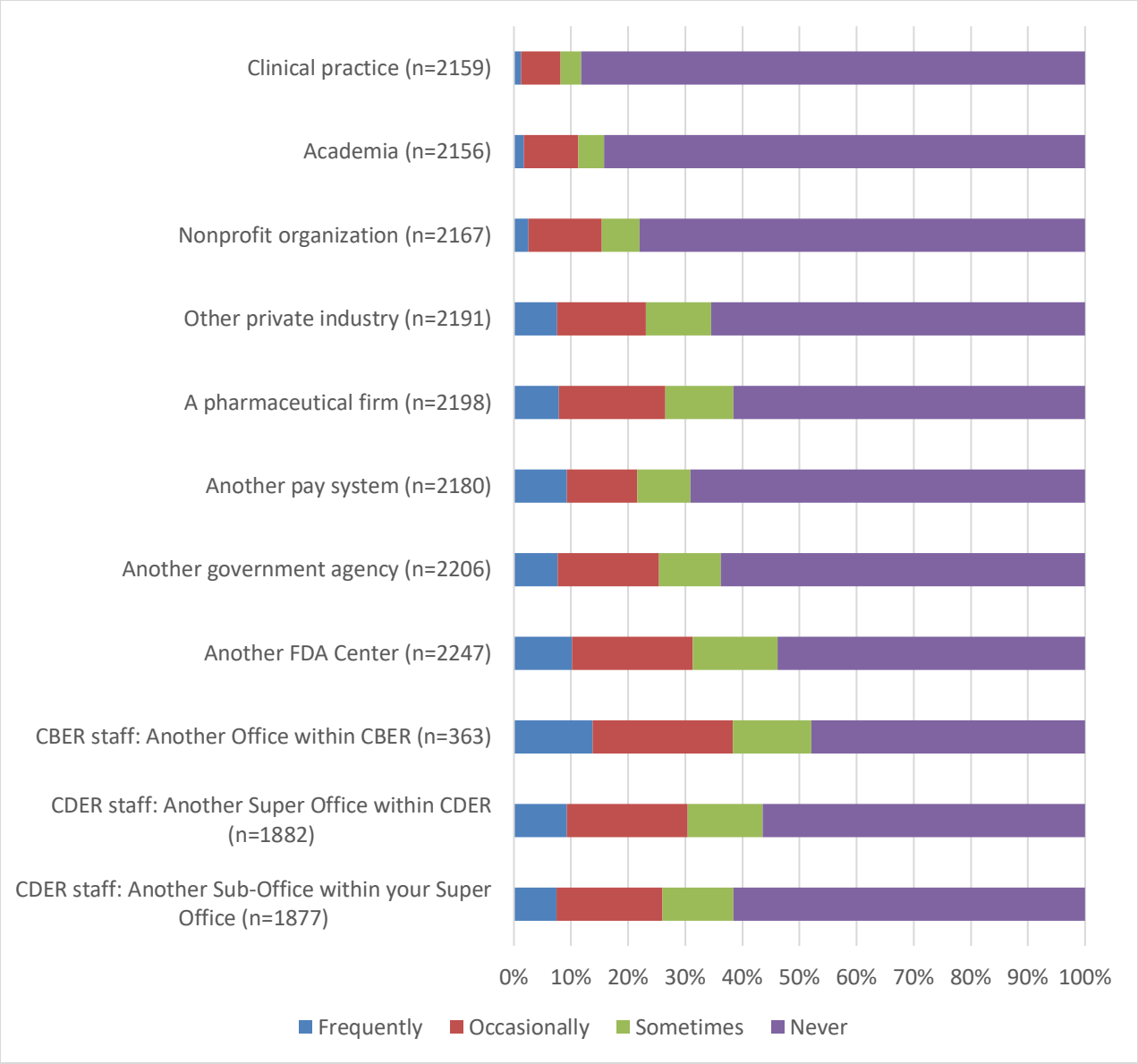
Figure C-32. Reasons CDER/CBER staff would consider leaving current Center (n=2,299)



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "For which of the following reasons would you consider leaving your current Center?"

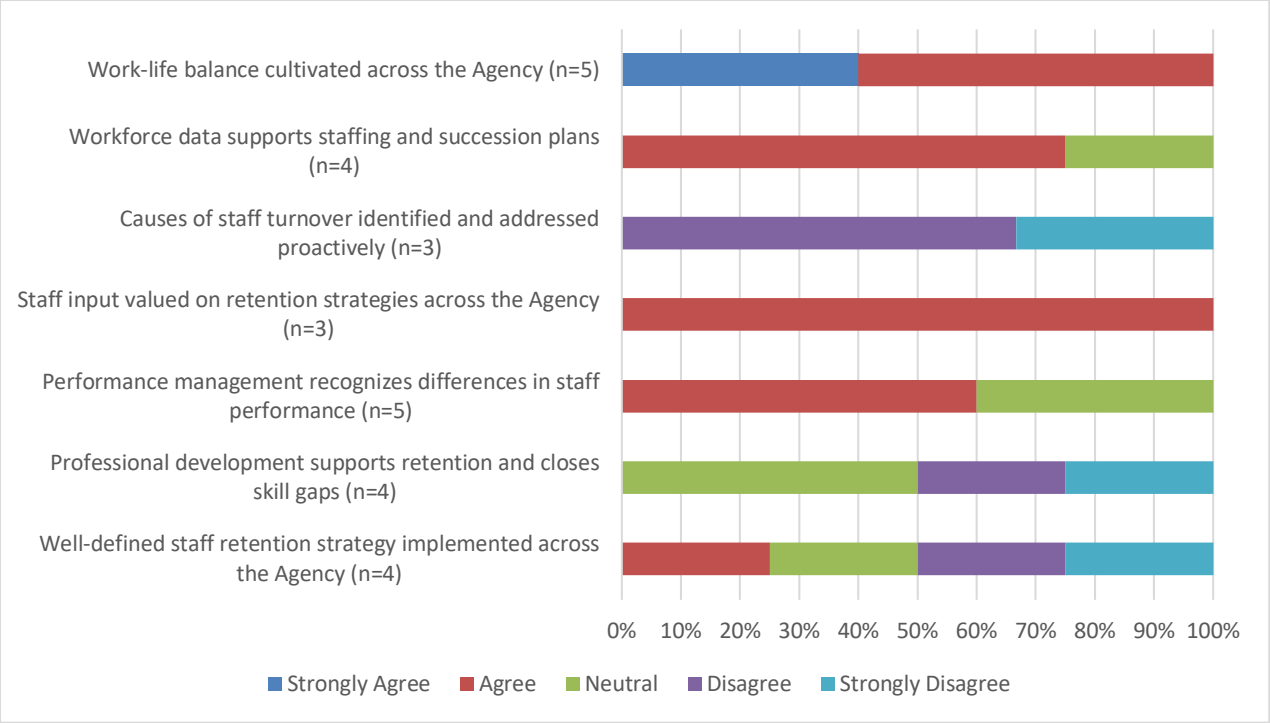
Figure C-33. Potential destinations for CDER and CBER staff if they were to leave current position*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "In the past six months, how often, either passively or actively, have you considered looking for another position in:" "Not Applicable" responses were excluded from analysis. Response patterns are similar across CDER and CBER staff.

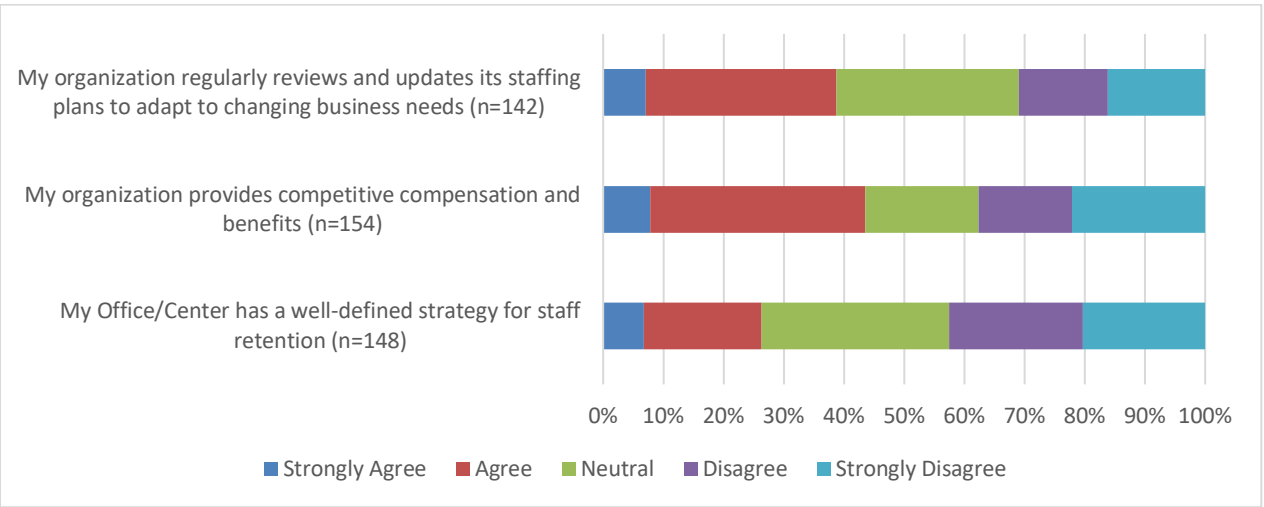
Figure C-34. Opinions on retention effectiveness by OHCM staff*



Source: OHCM HR/HC Staff Survey conducted by ERG (September 2024) for this assessment.

*Survey item: "Please rate your level of agreement with the following statements regarding retention." "Don't Know or Not Applicable" responses were excluded from analysis.

Figure C-35. Opinions about retention processes by CDER and CBER staff involved in HR/HC processes*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Please rate your level of agreement with the following statements regarding FDA's recruiting, hiring, pre-employment onboarding, and retention activities. Select 'Don't Know or N/A' for the activities that you don't actively support as a primary function of your job." "Don't Know or Not Applicable" responses were excluded from analysis. Results shown are based on CDER and CBER HR/HC who indicated at least 25% involvement in retention activities. Response patterns are similar across CDER HR/HC staff and CBER HR/HC staff, however CDER HR/HC staff generally have higher rates of agreement than CDER HR/HC staff that range 14%-16% higher.

Figure C-36. Opinions on HR/HC culture by staff involved in HR/HC processes*

Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey item: "Based on activities you are involved with, please rate your level of agreement with the following statements regarding FDA's HR/HC culture." "Don't Know or Not Applicable" responses were excluded from analysis.

Table C-20. Qualitative data on retention from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others	Within FDA Control
Working Well												
Positive work environment and culture, including work-life programs		●	●		●		●	●	●			●
Recognition by incentive awards							●	●				
Belief in the Agency mission and/or public health work			●		●		●	●				●
Positive working relationships with colleagues and team		●	●				●	●	●			●
Having flexible schedules and telework increases work-life balance		●			●		●	●				
Good employee engagement (e.g., FEVS)		●			●				●			●
Challenges												
Pay not competitive with industry or commensurate with work performed		●	●		●		●	●				
Lack of promotion pathways		●	●	●			●	●				●
Overwhelming workload, sometimes linked to slow hiring processes and understaffing		●			●		●	●	●			●
Need more time for career growth and experiential learning opportunities, as well as refresher courses on processes, that should be available across all positions and organizations		●			●		●	●	●			●

*Survey open responses, interviews, and focus groups.

C.3 FDA Hiring Process Transparency

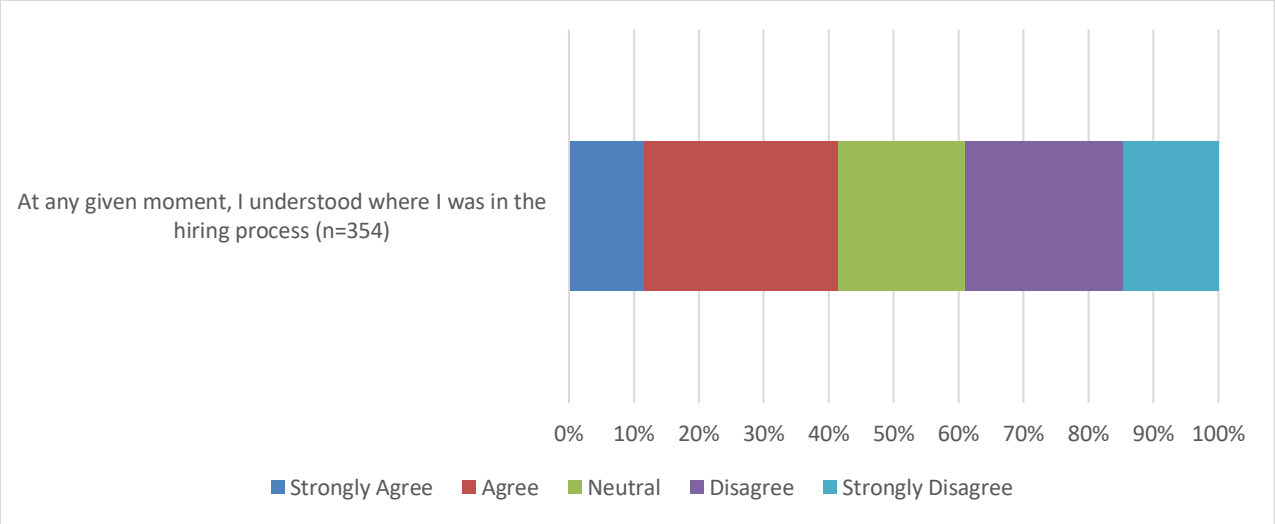
This section provides results related to the transparency of the hiring process from the perspectives of interested parties: new hires, HR/HC staff, and other staff involved in the hiring process (hiring managers, leadership, and review staff). To develop data for our assessment of hiring process transparency, ERG conducted interviews, focus groups, and surveys with these parties.

In this section, ERG presents the following results:

- New hire opinions about hiring process transparency (Figure C-37).
- Opinions about clarity of roles (Figure C-38) and adequacy of training and documentation (Figure C-39) among staff involved in hiring processes.
- Opinions about communication and collaboration among HR/HC staff (Figure C-40) and hiring managers (Figure C-41).
- Key themes and feedback about hiring process transparency from all sources (Table C-21).

These data provide evidence that some aspects of the hiring process are transparent, with most staff feeling that their roles are clear and processes within their control are transparent. Communication and collaboration remain a challenge, especially for hiring managers and other Center staff who require information about processes that are shared with or occur within OTS or OHCM. New hires expressed mixed opinions about hiring transparency, in part because of periods of time with little or no communication or redundant or conflicting communications from staff from different organizational units at FDA.

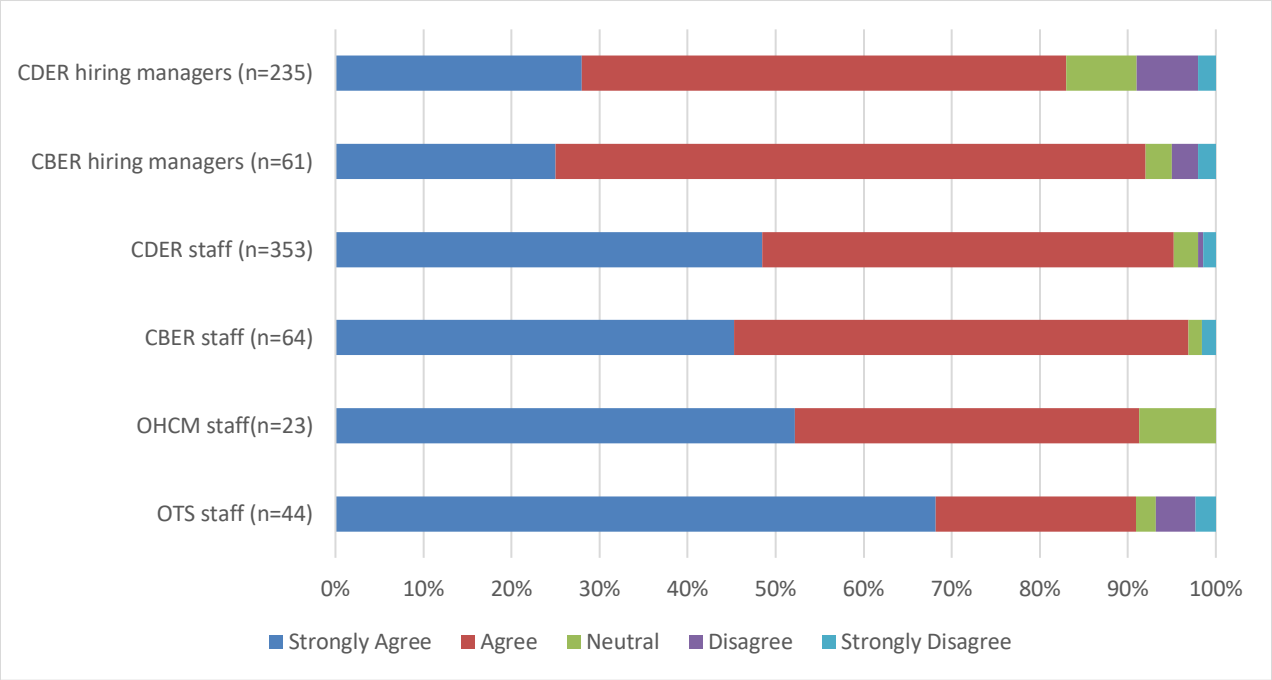
Figure C-37. Opinions about hiring process transparency among CDER and CBER new hires*



Source: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey items: "Rate your level of agreement with the following statements related to your experience with FDA's hiring and pre-employment onboarding process: At any given moment, I understood where I was in the hiring process." "Don't Know or Not Applicable" responses were excluded from analysis. Response patterns are similar across CDER and CBER. New hires in MCO/SJF positions across these Centers (n=259) had an agreement rate of 38%, which is lower than those in other positions (n=95) who had an agreement rate of 48%.

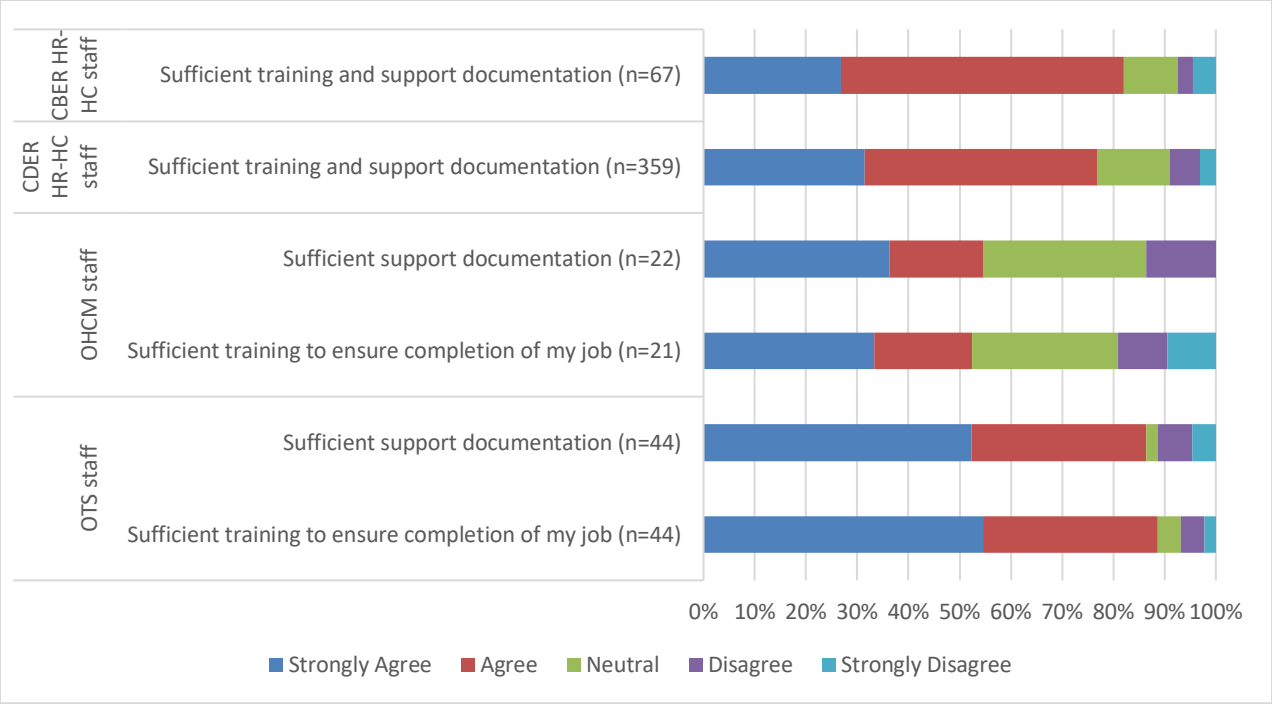
Figure C-38. Opinions about hiring process transparency among staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: CDER and CBER hiring managers: "Please rate your level of agreement with the following statements regarding the clarity of your role: I understand the expectations of my role as a hiring manager;" CDER and CBER HR/HC staff, OTS staff, and OHCM staff: "I understand the daily expectations of my job." "Don't Know or Not Applicable" responses were excluded from analysis.

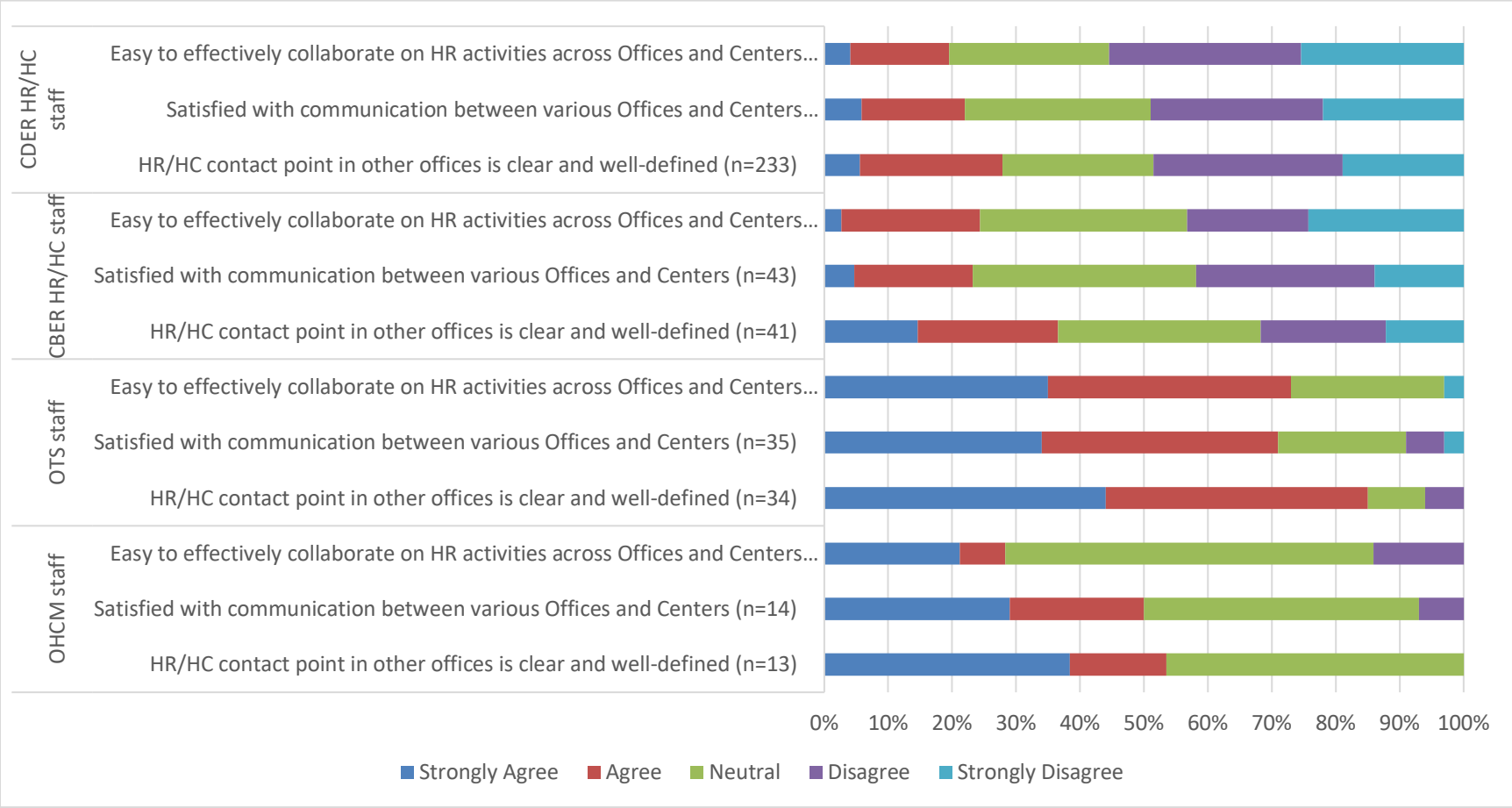
Figure C-39. Opinions about adequacy of training and documentation among staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: CDER and CBER HR/HC staff: "Please rate your level of agreement with the following statements regarding the clarity of your role: I receive sufficient training and support documentation to ensure completion of my job"; OTS and OHCM staff: "Please rate your level of agreement with the following statements regarding the clarity of your role: I receive sufficient training to ensure completion of my job; Please rate your level of agreement with the following statements regarding the clarity of your role: I receive sufficient support documentation (e.g., SOPs) to ensure completion of my job." "Don't Know or Not Applicable" responses were excluded from analysis.

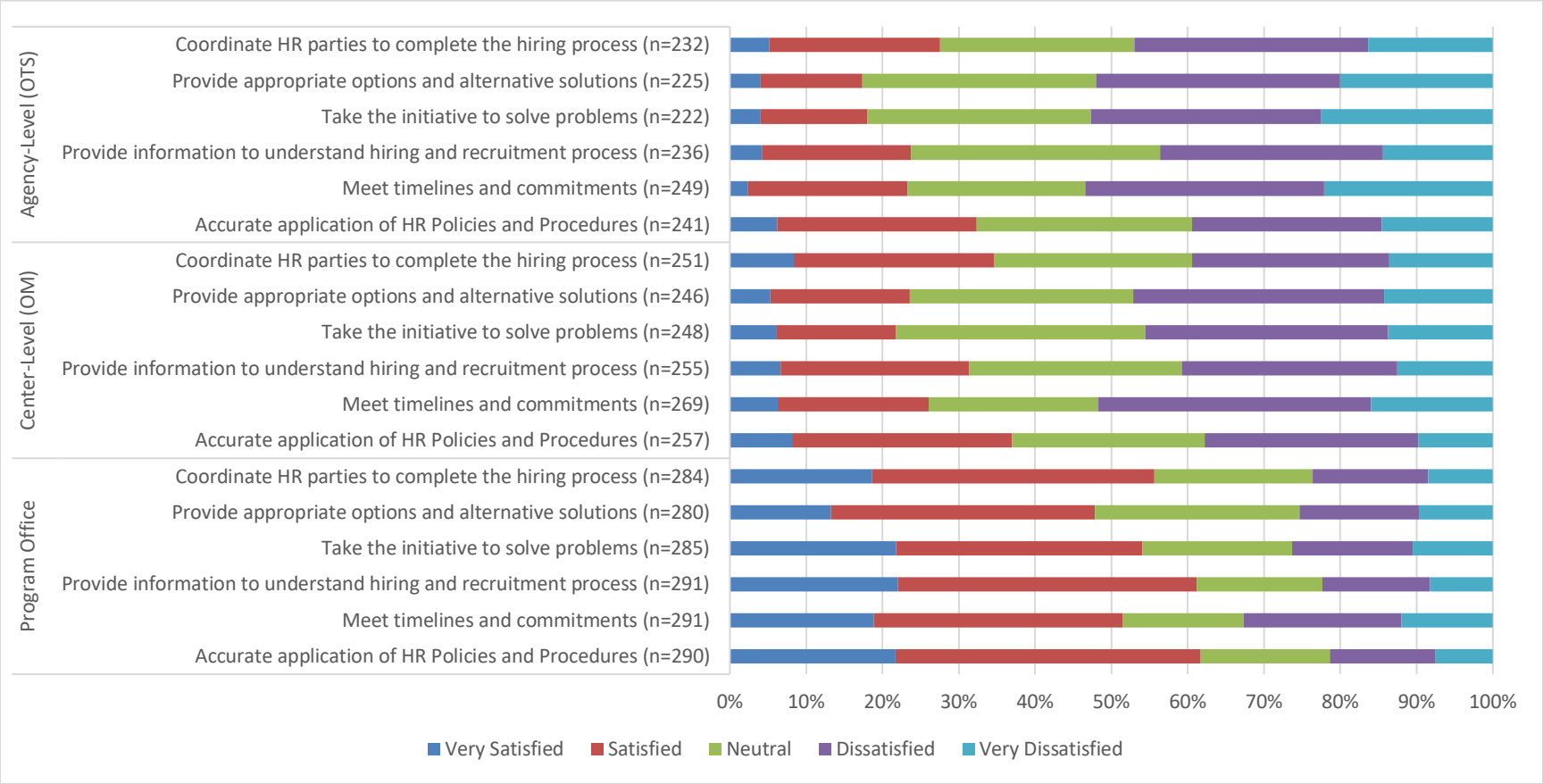
Figure C-40. Opinions about communication and collaboration across Offices and Centers by staff involved in HR/HC processes*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey (July and August 2024) and the OTS HR/HC Staff Survey and OHCM HR/HC Staff Survey (September 2024) conducted by ERG for this assessment.

*Survey items: "Based on activities you are involved with, please rate your level of agreement with the following statements regarding FDA's HR/HC communication and collaboration: My HR/HC contact point in other offices is clear and well-defined; I am satisfied with communication between various Offices and Centers; It is easy to effectively collaborate on HR activities across Offices and Centers." "Don't Know or Not Applicable" responses were excluded from analysis

Figure C-41. CDER and CBER hiring manager satisfaction with communication and collaboration with various HR staff*



Sources: CDER Staff Hiring and Retention Survey and CBER Staff Hiring and Retention Survey conducted by ERG (July and August 2024) for this assessment.

*Survey item: "Based on your experiences with hiring new employees since the start of FY23, how satisfied are you with the abilities of HR Staff in various roles within FDA, as shown in the columns below: Apply accurate knowledge of HR policies and procedures required; Meet timelines and commitments; Provide information to help me understand the hiring and recruitment process; Take the initiative to solve problems that arise; Provide appropriate options and alternative solutions, as needed; Coordinate with all HR parties necessary to complete the hiring process." "Don't Know or Not Applicable" responses were excluded from analysis. Generally, CBER hiring managers had agreement rates 15%-29% higher across survey items for Program Office and Center-level (OM) HR staff than CDER hiring managers, but both usually ranked Center-level (OM) staff survey items lower than Program Office staff. Response patterns are similar between CDER and CBER hiring managers across survey items for Agency-level staff (OTS).

Table C-21. Qualitative data on transparency from all sources*

Common Themes	All Staff	HR/HC Staff	Other Staff	New Staff	Others	All Organizations	CDER	CBER	OTS / OHCM	OEI / OSPO	Others
Working Well											
Use of HR data systems to track status and ownership of actions, with time stamps when steps are completed		•	•				•	•	•	•	
Having set meeting times for HR staff with shared processes in different Offices/Centers (e.g., OTS and CDER OM)		•	•				•		•		
Clear expectations for role		•	•				•	•	•		
Challenges											
Lack of HR data system integration and access (diminishes transparency and adds duplicative processes)		•	•				•	•	•	•	
Insufficient timeliness and communication causes lack of transparency in hiring and pre-employment onboarding processes for new hires				•			•	•			
Ineffective methods of communication and collaboration, leading to lack of transparency about timelines, statuses, and changing processes and policies in a timely manner.		•	•				•	•	•	•	
Some candidates considered other opportunities or were lost due to lack of transparency and communication during delays			•	•			•	•			
Insufficient communication and collaboration between FDA offices and staff on shared elements of the hiring process (contradictory information from HR and hiring manager, multiple identical requests for forms or information)				•			•	•			
Perception that Title 21 would be higher if employee worked in another Office or Center				•			•	•			

*Survey open responses, interviews, and focus groups