



FY2020 OTED ANNUAL REPORT



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FROM THE DIRECTOR OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT (OTED)



OTED's charge is helping people realize their full potential through our training initiatives including training, education, career development and voluntary program specific certification programs. Our stakeholder population includes FDA, ORA, State, local, tribal, territorial regulators who conduct inspections, compliance and laboratory activities, and management and support of FDA's public health initiatives.

The Office of Training Education and Development (OTED) developed our internal Website: <https://fda.sharepoint.com/sites/insideFDA-ORA-OTED/> as a location for our FDA and ORA students, staff and stakeholders to learn more about our organization. Please take some time to familiarize yourself with this website to help you have a great training, education, and development experience.

We developed an external website, for our State, local, tribal, and territorial partners to assist in understanding our organization. This website also assists in understanding the collaborative relationship between OTED and the FDA ORA Office of Partnership. <https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted>

We value our students and stakeholders and want to thank you for the hard work you do every day to protect public health. Thank you for all you do each day.

Patricia L. Alcock

Executive Summary

This is our inaugural FY2020 OTED Annual Report. It was specifically developed to provide recognition of the tremendous accomplishments OTED has made in meeting our mission of training FDA, ORA, State, Local, tribal, and territorial regulatory staff. The Annual Report also provides an overview of many of the completed and/or ongoing priorities and initiatives we have developed in support of continuous improvement and provides a high-level overview of our organization.

During FY20, we too were met with many challenges and changes because of COVID-19. One of the positive outcomes of the pandemic, was that it allowed us to become more flexible and innovative with virtual learning tools and learning tools. For example, in our third and fourth quarters of FY20 we transitioned thirty (30) instructor led classroom courses to virtual instructor led courses for delivery in FY20 and during first quarter of FY21. There were 2379 people trained in a total of 115 courses in FY2020. This work would not have been accomplished without the dedication and resiliency of OTED Training Officers, Instructional System Specialists, Instructors, Subject Matter Experts, and our contract partners.

OTED Mission

OTED's mission is to provide high quality learning opportunities through timely, cost-effective learning products that support the Food and Drug Administration's (FDA) mission and strategic goals and meets current training and development needs of ORA personnel, state and local regulatory officials, and other stakeholders.

OTED Vision

Developing and delivering collaborative FDA training products by leveraging our staff strengths to assist public health regulatory officials in excelling in their job performances and improving public health safety for all.

OTED Responsibilities

ORA's Office of Training Education and Development (OTED) is responsible for the training and development of a 5,000 member staff located in ORA's field and headquarters offices throughout the United States and Puerto Rico. In addition, OTED is responsible for providing training to state, local, tribal, and territorial regulatory partners involved in the regulation of human and animal food products regulated by FDA.

OTED FY20 Priorities

FY20 was the third year the OTEd Director established priorities in addition to our routine training and certification delivery schedule. The establishment of Office wide priorities allows for clear and transparent identification of highest priority work assignments and projects. In addition, the priorities allow OTEd staff to relate their work efforts to HHS, FDA and/or ORA strategic plans. The establishment of OTEd Priorities in any given FY allow OTEd leadership and staff to assess workload capacity management.

The following is a high-level summary of some of the FY20 OTEd Priorities.

1. Implement OTEd Training & Certification Delivery in FY20

Our primary responsibility to ORA, and our State, local, tribal, and territorial partners is the delivery of training to personnel. We also continue to offer personnel certification programs to ORA inspection personnel.

Training Courses

The COVID-19 pandemic, which started in March 2020 did require OTEd, our instructors and students to pivot from the traditional classroom training to different training delivery platforms to continue to train. Our delivery of training courses in FY20 started with in person classroom courses from October 2019 through early March 2020. Our in-person classroom course deliveries were stopped in mid-March 2020 through approximately May 2020 due to COVID-19. We were able to pivot, with the assistance of our experienced staff and instructors to transition our in-person classroom courses to virtual instructor led courses for delivery in FY20 and FY21. A total of 115 courses were accomplished in FY20 using either the in-person classroom model (63 courses), blended learning (25 courses) or live webinars (27 courses).

Certification Exams and Programs in FY20

During FY20, OTEd was able to administer certification exams to 37 ORA Investigators representing seven (7) commodity-based programs during our in-person examination delivery. We were forced to cancel the Spring 2020 session due to COVID-19. Other aspects of certification exams (job analysis, item test question writing) were able to be conducted using virtual meeting platforms.

2. Launch Telepresence technology for one FDA ORA food training course.

We were able to successfully pilot one food course using newly installed virtual technology at ORA Human and Animal Food (HAF) Division offices. This approach allowed OTED to host training in Rockville and have students participate from multiple HAF Divisions at their office location. The new to FDA technology was piloted in February 2020 and was found to be successful to OTED training personnel, the instructors, and the students. Further use of the technology was stopped in FY2020 as FDA was unable to access FDA offices and gathering of more than ten (10) employees in one location was not allowed due to CDC COVID-19 recommendations. The information learned from the pilot, combined with lessons learned via virtual instructor led training will assist OTED in the future for the Telepresence technology.

3. Develop and Implement OTED Student Handbook.

The purpose of the Student Handbook is to provide information on OTED, our registration process, course announcement process, inclement weather and expected conduct during our courses. Introductory videos were also created as part of the communication strategy and are readily available on the same intranet and internet links. The handbooks are available at the following links:

Internal to FDA: <https://fda.sharepoint.com/sites/insideFDA-ORA-OTED/>

External to FDA: <https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/oted-student-handbook>

4. Maintain Pilot Independent Course Delivery and Train the Trainer Program and identified needed process flow diagrams, approach, and procedures for internal OTED usage with contractor.

OTED continued to collaborate with associations such as the Association of Food and Drug Officials (AFDO) and the National Association for State Department of Agriculture (NASDA) and with two State partners (CA, NY) in piloting a Train the Trainer program for two FDA ORA training courses. OTED also contracted with a small business to help develop internal processes, workflow diagrams and procedures to assist in this change in OTED's business model.

5. Develop, issue and complete FY20 OTED EVS Action Plan based on FY19 OTED Employee Viewpoint Survey results. The plan specifically addressed providing increased communication; transparency on accomplishments within and across the Office; assessing OTED staff's training needs and reevaluating the internal OTED awards programs.

6. Develop and implement OTED Diversity and Inclusion activities including providing listening sessions to all OTED staff following racial unrest in our country following the deaths of African Americans in the US. Our listening session approach was used as a model for other ORA Programs and Offices in FY2020. OTED also provided "Unconscious Bias" training session for any employee wanting to learn more about unconscious bias.

OTED FY20 Accomplishments

Immediate Office

Budget, Contracts, Grants and Facility Accomplishments:

- Managed OTED's multi-million budget with over 491 individual budget line items including courses, meetings, and contracts.
- Awarded 11 Contracts/IAA's/Grants/Cooperative Agreements which was 71.3% of the total budget
- Developed and submitted two (2) contract modifications which were awarded in response to virtual learning requirements
- Shipped virtual instructor led training course supplies to 948 virtual learners. This was a change in FY20 operations where course supplies had to be delivered to every student versus a specific training room or location.
- Restructured the OTED Fulfillment Center to maximize storage and efficiency of training and certification supplies

Quality and Records Management

FY '20 was a transition year for OTED's Quality Team as the Office decided to discontinue its accreditation under the International Association of Continuing Education and Training (IACET). Although the accreditation provided a convenient quality standard to look to for training quality metrics, some of the requirements impacted the Office's ability to advance critical initiatives like the emerging Independent Course Delivery and Train-the Trainer programs. Therefore, in May 2020 the Office formally announced that it would discontinue its IACET accreditation. As OTED sunset its IACET accreditation, the Quality Team initiated an evaluation of all 83 standing policies and procedures and redesigned a quality standard for OTED training courses. This transition is expected to drive the majority of FY '21 work and result in new expectations (standards) for training courses and an overall reduction of the number of policies and procedures that the office will maintain as some policies and procedures were driven by compliance with IACET's accreditation standard.

Similar to the Quality Team, the Records Management Team experienced a significant amount of transition as the Office implemented more efficient and effective training course record control methods and measures. Although implementing these expectations resulted in implementing a formal corrective and preventive action plan (CAPA) due to observations of non-compliance with Federal Records Act of 1950 and FDA SMG 3291.1 – FDA Records Management Policy, the Office has made tremendous strides with applying key records management functions to training course records by identify, naming, and retaining mission-critical training course records with an expectation that during FY '21 100% of FY '20 records are identified and retained consistent with records management policies.

As alluded to above, in FY '20 records management policies started emerging so that the Office would have a better system of identifying, naming, using, tracking, and controlling, retaining (saving), and dispositioning records. A draft Records Management Program Manual that was delivered to management is expected to be finalized in FY '21 and implemented soon after.

The Team's overall accomplishments are highlighted in the table below. All accomplishments are outlined in OTED's 2020 Management Review available at this [link](#).

Quality and Records Management Accomplishments	
Assignment	Accomplishments
Form Index Project	Created a list of proposed forms used at OTED to further cross reference P/Ps that support the OTED form.
OTED Course Evaluation P&P	Created a new policy & procedure (P&P) for course evaluations.
OTED Course Evaluation – Analysis Follow-up Report	Prepared Office course evaluation summary report.
Informal Audit of Courses	Conducted informal audit of perspective courses to be used in the IACET Reaccreditation.
Program Effectiveness Measurement	Trained and implemented a process to measure effectiveness of our development, administration, delivery, and support of education/training.

Quality and Records Management Accomplishments	
Assignment	Accomplishments
Learning Objective Updates	Initiated draft policy that learning objectives are specific and measurable, achievable, realistic, and time-based. Also, OTED policy has changed to require the use of three-part objectives for the TLOs.
Course Content Review Checklist	Created a policy and job aid for reviewing course content for quality, currency, effectiveness, and applicability.
Biography Template	Created a template to document individuals' professional development for those who are involved in the design, development, and delivery of learning events (Biography template)
Management Review	Reviewed and evaluated the effectiveness of OTED's Quality Management System to determine its continued suitability and adequacy.
Handbooks	Implemented the Training Officer Handbook.
Internal Audit	Evaluated OTED's compliance with the requirements of the Quality Management System and the ANSI/IACET (American National Standards Institute/International Association of Continuing Education and Training) 1-2018 Standard.
Records Management Program Manual	Provided a draft manual for the overall Records Management Program for OTED staff that will provide the policies/procedures and expectations for OTED staff pertaining to records management.
Records Management Audit	Conducted FY '20 audit of Record Management System.

Division of Instructional Systems and Technology (DIST)

DIST is responsible to contributing to the design and development of training and supporting and enriching learning technologies with multimedia. This Division is also responsible for Section 508 reviews for OTED materials. In addition, this Division will manage the learning content management system (LCMS) which is primarily used to create, store, and deliver e-learning content, as well as organize, store, and deliver older versions of courses.

- Converted 47 additional training courses to Virtual Instructor Led Training in collaboration with OTED's Division of Programmatic Training and Division of Multi-Program Leadership and Management Training and instructors.
- Designed and developed new and or existing ORA training courses:

Six Pharmaceutical courses Developed/Updated

DG220J100	Non-Sterile CGMP Pharmaceutical Surveillance Inspections On-the-Job Training (OJT)
DG220	Non-Sterile CGMP Pharmaceutical Surveillance Inspections
DG221	Non-Sterile CGMP Pharmaceutical Surveillance Inspections Site Visit
DG222J100	Non-Sterile Active Pharmaceutical Inspections OJT
DG222	Non-Sterile Active Pharmaceutical Inspections
DG430	Human Drug Compounding Inspections

Two Biologics/BIMO courses Developed

BR226	Inspections of Bioavailability and Bioequivalence
BR227	PADE Reporting Inspections and REMS Reporting Inspections

One Imports course Updated

IM201	Advanced Import Operations
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- Assisted OTED grants and associations in conducting a gap analysis of the Integrated Food Safety System National Curriculum Standard (NCS). The Animal Food Gap Analysis project group developed a gap analysis protocol to reveal and measure the status of OTED training course objectives against the NCS standardized competencies based on scientific and regulatory guidelines. This task was to ensure all aspects of training are relevant, current, and sustainable for professional success. In addition, the analysis also identified and addressed gaps within a commodity training area.
- Created OTED internal job aids and training to assist Training Officers, Instructional Designers, Instructors and ORA Program Training Officers with how to use the various virtual training platforms for virtual training
- Designed, developed, and created Videos for use in OTED training courses and OTED communication tools, including:
 - Support for course development and to transition course content to video content as requested
 - Continued ‘Spotlight on’ series across OTED Divisions
 - Supported ORA initiatives as requested such as ONEORA Spotlight Series

Division of Programmatic Training (DPT)

The Division of Programmatic Training's primary responsibility is designing, developing, and delivering training and educational programs for the Office of Regulatory Affairs (ORA) staff and other regulatory partners in the program areas of Human and Animal Food, Pharmaceutical Quality, Biologics, Bioresearch Monitoring, Medical Device and Radiological Health, and Tobacco.

In FY2020 DPT:

- Identified new and novel approaches to interact and train learners virtually. Each virtual training session adapted use of WebEx and Adobe Connect learning platforms and deployed innovative tactics to simulate on-site inspection simulations and provide participants hands on experience during training.
- Collaborated with existing Academic contractors to deliver 8 sessions of the FD152 Food Processing and Technology course via Ohio State and Purdue Universities.
- Implemented new 5-year Cooperative Agreements for projects with the Association of Food and Drug Officials (AFDO), Association of Public Health Laboratories (APHL); the International Food Protection Training Institute (IFPTI), the National Environmental Health Association (NEHA) and the University of Tennessee- Kentucky (UTK).
 - Major project highlights are course redevelopment/virtual conversion to virtual training support during COVID 19 crisis.
 - Assistance with the development and operation of the Integrated Food Safety System (IFSS) National Curriculum Standard Development
- Continued to focus on course development of course content in high priority FDA ORA regulatory areas including: Human and Animal Food, Biologics, Bioresearch Monitoring (BIMO) and Radiological Health with a focus on redesigning programs.
- Continued to refine approach to developing a 2-year training schedule based on existing FDA, ORA, and State contract data in collaboration with ORA's Planning Staff. This collaboration allowed OTED to compare existing ORA

Program specific training data to that of planned FY21 inspection work to determine gap in training needs.

- Developed the first Training Pathway for Human and Animal Foods training to assist the learner (ORA and State partners) and their management in understanding sequence of training courses. Other FDA regulated program areas are expected in FY21 and beyond.
- Collaborated and coordinated with ORA's Office of Cooperative Programs on the Retail Food Specialist and Retail Food training programs and assisted in streamlining and aligning under FDA's New Era for Smarter Food Safety initiative.

Division of Multi-Program Leadership and Management Training: (DMPLMT)

DMPLMT is responsible for designing, developing, and implementing training and educational programs, professional development, and career growth opportunities for ORA investigators, analysts, compliance officers, support staff, managers, supervisors, and the Food Emergency Response Network (FERN). These programs include a variety of classroom, virtual, and online trainings and skill-building tools and resources in the areas of compliance, imports, laboratory, ORA information technology systems, administration, leadership, management, and basic investigator programs.

In FY20, DMPLMT offered 23 courses. In response to the COVID-19 pandemic, OTED collaborated with grant partners and contractors to complete conversions of fifteen courses from instructor-led training (ILT) to virtual instructor-led training (vILT). This required significant effort to adapt course content, exercises, and facility tours to virtual formats, while engaging the same level of interactivity in virtual vs in-person courses. Starting with the rapid conversion of the MP101 Basic Investigator Law Course, which was converted from a 5-day (8 hours per day) face-to-face course to a 10-day (4 hours per day) vILT course within the first two weeks of travel limitations, DMPLMT was able to apply lessons learned and move to converting additional courses. At the same time, Division staff completed training and became proficient in multiple virtual training platforms to support the conversion to vILT. DMPLMT began delivery of the redesigned vILT courses in April 2020.

This includes the rapid conversion from ILT to vILT:

- In 6 weeks for Basic New Hire/Investigator Training: MP102 Evidence Development, training 45 staff across 2 offerings.
- In 3 weeks for Basic New Hire/Investigator Training: MP118 Interviewing Skills and Personal Safety, training 45 staff across 2 offerings.
- In 6 weeks for CS153 ORADSS Imports, training 13 staff.

Other notable FY20 accomplishments include:

- The 3rd cohort of the award-winning FDA Alumni Advisory Program (FDAAAP) was announced and launched in partnership with the Office of Personnel Management (OPM) and the FDA Alumni Association (FDAAA). Seven ORA managers and supervisors were mentored.
- 40 applicants were selected to participate in the Potential Supervisor Program's (PSP) 4th cohort, which runs for 12 months. Since its inception, approximately 160 ORA staff have participated in PSP.
- 33 participants completed the Resilient Leadership Program's (RL) 9th cohort, which ran for 8 months. Since its inception, approximately 553 ORA managers and supervisors have participated in RL.
- 20 participants completed MG314 Making the LEAP from Management, the two-week kick-off course for the Leadership Excellence Advancement Program's (LEAP) 2nd cohort. Since its inception, approximately 40 ORA managers and supervisors have participated in LEAP.
- The Basic New Hire/Investigator Training Program was redesigned to be in alignment with agency programmatic goals. This curriculum update included restructuring 80 hours of course content.
- In partnership with the Office of Personnel Management (OPM), began a competency modeling study on ORA first-line supervisor and mid-level manager positions to update the Management and Leadership Development Program (MLDP) competency model.

Division of Testing, Measurement and Certification (DTMC)

The Division of Testing, Measurement, and Certification (DTMC) is responsible for maintaining the ongoing quality of Level 1 Investigator and Level 1 Analyst certification programs, Level 2 Cooperative certification programs, and the voluntary Commodity-specific certification programs. DTMC develops, administers, and maintains certification examinations for investigators in the areas of Seafood, Low-Acid Canned Foods/Acidified Foods, Import, Blood Bank/Plasma Center, Clinical BIMO, Drug, and Medical Devices. DTMC is responsible for leading organizational measurement initiatives, survey-based information gathering, and data-driven change management. DTMC works with DPT, DMPLMT, and DIST to leverage course assessment information as a key component of OTED's training evaluation mission.

- Implemented the FY20 Certification Workplan as approved by OTED Management and as modified, as necessary based on the 2020 COVID-19 pandemic.
 - Administered certification exams to 36 investigators representing 7 commodity-based programs, during 1 session (a second scheduled session was cancelled due to COVID-19). Of the group that tested, 23 investigators became actively certified. Candidates successfully passed certification exams in the areas of Import (5), Blood Bank/Plasma Center (1), Clinical BIMO (4), Drug (10), and Medical Devices (3).
- Developed and implemented process for conducting virtual job task analyses
 - Performed 4 job task analyses (JTAs) in the areas of State Liaison, Clinical BIMO Investigator, Microbiologist, Import Compliance Officer roles
 - Conducted 1 item writing workshop (Import Investigator), 1 item review workshop (Import Compliance Officer), and 1 item rating workshop (Import Compliance Officer).
 - Performed item bank maintenance for 1 certification program exam (Clinical BIMO Investigator).

- Designed and delivered internal training for OTED employees on updated course evaluation form. Training topics included survey development and administration, evaluation results interpretation, and application to course development and revision.
- Conducted CEU utilization study for the purpose of evaluating the extent of awarded CEUs for professional development and credentialing.
- Conducted program evaluation study to determine OTED customer's perception of program effectiveness.
- Conducted annual OTED-wide course evaluation study. With the advent of COVID and the resulting impact on course delivery methods, the evaluation included comparative information on face-to-face instructor led and virtual instructor led formats.
- Initiated Test design, development, delivery, and evaluation policy to provide direction on technical considerations for test development and utilization.
- Continued to develop Kirkpatrick Level 2 Evaluation instrument that could be piloted for one course in the Human and Animal Food (HAF) Training Program area and one course in the Medical Products and Tobacco (MPT) area (Radiologic Health).
- Developed assessments (Level 2 instrument) for 3 HAF courses (Fundamentals of Interstate Travel Inspections, Produce Inspections for Regulators, and Produce and Sprout Inspections for Regulators) and consulted with DPT on 1 MPT area (Radiological Health).
- Evaluated OTED Course Evaluation Templates: Determined and documented areas of improvement and plans of action to improve, including but not limited to the tool, applicable procedures, instructions to staff. Presented results of evaluation to OTED Immediate Office (IO).

FY20 OTED TRAINING DATA

Number of Students Trained Per Commodity	
Commodity	Total
Biologics	19
Compliance	62
Computer Systems	83
Drugs	55
Emergency Response	28
Food	1547
Imports	103
Laboratory	27
Management/Supervisory	254
Multi-Programs	434
Organizational Development	17
Veterinary Medicine	110
Grand Total	2739

Number of Courses Per Commodity	
Commodity	Total
Biologics	1
Compliance	3
Computer Systems	4
Drugs	5
Emergency Response	1
Food	51
Imports	4
Laboratory	3
Management/Supervisory	20
Multi-Programs	18
Organizational Development	1
Veterinary Medicine	4
Grand Total	115

Number of Students Trained Per Course	
Course ID	Total
BI225	19
CP207	47
CP213	15
CS153	47
CS154	20
CS159	16
DG220	1
DG221	19
DG330	35
ER220	28
FD107	29
FD112	29
FD152	121
FD190	163

Number of Courses per Course Type	
Type of Course	Total
Blended Learning	25
Classroom	63
Live Webinar	27
Grand Total	115

FD202	66
FD204	63
FD207	150
FD215	99
FD218	150
FD219	40
FD226	76
FD254	174
FD312	161
FD326	25
FD340	31
FD373	42
FD374	27
FD375	43
FD577	35
IM101	28
IM201	29
IM220	46
LB302	20
LB322	7
MG106	20
MG109	37
MG121	15
MG132	91
MG301	33
MG308	33
MG314	20
MG8002L	5
MP100	157
MP101	82
MP102	98
MP118	97
OD108	17
VM102	55
VM220	55
Grand Total	2739