



FY2021 OTED Annual Report

U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Training Education and Development (OTED)



U.S. Food and Drug Administration/ORA/OTED

11919 Rockville Pike
Rockville, MD 20852

Phone: 301-796-4550

Phone: 301-827-8708

Email: oted@fda.hhs.gov

Intranet Website: [Office of Training, Education and Development - Home \(sharepoint.com\)](#)

Internet Website: [Office of Training Education and Development \(OTED\) | FDA](#)

Table Of Contents

<u>Introduction by OTED Director</u>	3
<u>OTED Mission, Vision & Responsibilities</u>	4
<u>Goals and Objectives</u>	4
<u>OTED FY2021 Strategic Priorities</u>	5
<u>OTED Training & Certification FY2021 Routine Workplan</u>	6
<u>Accomplishments by Division:</u>	
• Division of Instructional Systems and Technology (DIST)	8
• Division of Multi-Program Leadership and Management Training (DMPLMT)	10
• Division of Programmatic Training (DPT)	12
• Division of Test, Measurement and Certification (DTMC)	14
<u>FY21 Data and Charts</u>	16



Introduction by OTED Director, Patricia Alcock

Welcome to our FY2021 OTED Annual Report!

The Office of Training Education and Development (OTED) provides training, education, and development opportunities to our ORA colleagues and to our Human and Animal Food state, local, tribal, and territorial regulatory partners. We provide mandatory and voluntary personnel certification programs to ORA inspectional employees. OTED's mission is to help people realize their full potential through timely, cost-effective learning products that support the FDA mission. FY2021 required OTED, our instructors, students, and contractors to continue to show flexibility, resilience and innovation during the ongoing COVID-19 pandemic.

OTED, like many other organizations, had attrition due to promotions and/or retirements of OTED staff members. Many of our staff responded to Department of Health and Human Services (HHS) and Public Health Service (PHS) deployments including the Unaccompanied Minors Program and COVID19 vaccination clinics. Through all of the challenges we encountered in FY2021, we remained true to our mission and continued to deliver critical training and developed new approaches to expand our reach. This included completing more work with less staff when compared to FY2020! I am extremely proud of the work accomplished through our critical and collaborative relationships between OTED staff, contractors, cooperative grantees, and FDA Center and ORA experts, who provide their expertise, knowledge, and time to support our public health workforce.

I hope you find our FY2021 OTED Annual Report helpful in seeing all we accomplished in FY2021 by OTED and our collaborative relationships with dedicated public health professionals!

Patricia L. Alcock
Patricia L. Alcock

OTED Mission

OTED's mission is to provide high quality learning opportunities through timely, cost-effective teaching 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 the Commonwealth of Puerto Rico and the US Virgin Islands. 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.

Goals and Objectives

OTED's primary function is to deliver training, education, development and certification products to ORA and our State, local, tribal and territorial partners. This requirement is critical to our success and includes making sure our course content is accurate; OTED staff have the tools, procedures and resources to do our jobs; we demonstrate how our work products support and enhance FDA's public health mission; and utilize the various data sources supporting our mission. The recent and ongoing pandemic has required OTED to deliver our courses via virtual Instructor Led Training (vILT) and continue to modernize our approaches with virtual delivery platforms.

OTED's routine work products and priority initiatives are well aligned with the ORA Strategic Priorities.

As a reminder, the ORA Strategic Priorities are:

- Manage a world class workforce and promote a culture of excellence;
- Improve ORA's core business processes;
- Leverage and expand ORA's Public Health Partnerships;
- Improve ORA's Administrative Processes, Facilities and IT Infrastructure.

OTED FY21 Strategic Priorities

FY2021 was the fourth 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 several of OTED's FY2021 Strategic Priorities completed in FY2021 across OTED. Our priorities were focused on continuous improvement for our stakeholders as well as internally at OTED. Each of the OTED priorities align under the ORA priorities and has been noted as such with a bolded parentheses following each statement.

1. Develop and issue an FY2021 OTED Annual Report that summarizes our accomplishments in training, education, development and certification. Report will also summarize our critical accomplished projects and initiatives. **(#1 Manage a world class workforce and promote a culture of excellence)**
2. Implement OTED's FY2021 Annual Quality Audit Plan and management reviews including any corrective action measures. **(#2 Improve ORA's core business processes)**
3. Identify and implement the FY2021 Federal Employee Viewpoint Survey improvements. This includes hosting an OTED wide Focus Group in FY2021 following the FY2020 OTED EVS Survey results and developing 1-2 areas for improvement in FY2021. **(#1 Manage a world class workforce and promote a culture of excellence & #2 Improve ORA's core business processes)**

-
4. Align Independent Course Delivery, Instructor Qualification, and Train the Trainer programs with OTED procedures, forms, and practices for implementation in FY2021/FY2022. This new Train the Trainer program will allow OTED to have State personnel deliver specific and required ORA training programs, on their own behalf, allowing OTED and ORA to leverage training resources and meet the needs of our state partners. **(# 3 Leverage and Expand ORA's Public Health Partnerships)**
 5. Implement OTED's Records Management Plan by having FY2019 and FY2020 training records copied and moved to the appropriate location. This will allow OTED to have a central repository for all training records, including course materials, for Freedom of Information Act (FOIA) requests, GAO/OIG requests, National Archives and Records Administration (NARA) requirements, and for future OTED Training Officers/Training Specialists. **(#4 Improve ORA's Administrative Processes, Facilitates and IT Infrastructure)**
 6. Procure a new Learning Management System for integration and implementation in FY2022. **(#4 Improve ORA's Administrative Processes, Facilitates and IT Infrastructure, #3 Leverage and Expand Public Health Partnerships)**

OTED Training & Certification FY2021 Routine Workplan

OTED's routine work includes the design, development and delivery of training and certification in support of our stakeholder's needs. For FY2021, due to the ongoing COVID-19 pandemic, our work products were delivered virtually. Using a variety of virtual delivery platforms (Adobe Connect, Zoom.gov, WebEx) required our staff, students, and instructors to learn new delivery platforms. This prompted OTED to provide additional training on these tools to all involved including our students, instructors and contractors, where necessary. In FY2021, we continued to convert instructor led training materials to virtual instructor led materials for delivery in FY2021 and beyond. This work was completed by OTED staff as well as contractors and cooperative agreement partners and reviewed by subject matter experts.

Our work products and deliverables, whether it is training courses, job aids, certification exams or development programs, are accomplished by collaboration within OTED's Divisions and with our ORA and FDA Center Subject Matter Experts.

A high-level summary of our routine work is provided:

1. Delivered 354 individual learning events (e.g., courses, webinars, facilitated group conversations, panel discussions, leadership program culminations, etc.) in 50+ regulatory commodity areas (i.e., Human and Animal Foods, Medical Devices, Emergency Response, Biologics, Bioresearch Monitoring Operations (BIMO), Pharma and Cooperative programs [retail, milk and shellfish] areas). Thanks to our exceptional partnerships and contracts, approximately 16% of these courses were delivered through partnerships with the following three (3) cooperative agreement grantees and three (3) academic institutions:
 - A. Association of Food and Drug Officials (AFDO)
 - B. National Environmental Health Association (NEHA)
 - C. International Food Protection Training Institute (IFPTI)
 - D. Purdue University
 - E. Ohio State University
 - F. North Carolina State University
2. Converted 55 courses from Instructor Led Training (ILT) to Virtual Instructor-Led Training (vILT) for delivery in FY2021 and beyond. This includes:
 - A. 41 course conversions in the Division of Programmatic Training (DPT)
 - B. 14 course conversions in the Division of Multi-Program, Leadership, and Management Training (DMPLMT)
3. Collaborated and streamlined across OTED to revise and update 18 documents in total for the Course Announcement Policy, Templates, and Samples. The streamlined templates removed the redundant information and provided succinct information students need to know to attend the training course.
4. Nine Public Health Service (PHS) Officers on staff in OTED served on deployments supporting the HHS Unaccompanied Minors Mission and/or provided COVID-19 vaccine administrations, nursing and pharmacy support. Additionally, several OTED civilian staff members assisted with the HHS Unaccompanied Minors Mission.

In addition to the above-mentioned accomplishments, we are providing additional accomplishments for FY2021 under each OTED Division heading in this Annual Report.

Specific FY2021 Accomplishments by OTED Division

Division of Instructional Systems and Technology (DIST)



What is DIST responsible for in OTED?

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 of the Rehabilitation Act, where our staff verifies that our training, education, development and certification deliverables are accessible to people with disabilities.

FY2021 DIST Accomplishments

1. Conducted a comprehensive analysis of the ORA Basic Investigator Training Curriculum, including classroom, pre-requisites, e-learning modules, and supporting materials. Developed recommendation for consideration in redesigning the training program to determine path forward for new curriculum design.
2. Collaborated with FDA, ORA and OTED internal and external stakeholder to create multiple video production projects. Highlights include:
 - A. ORA Consumer Safety Officer New Hire Fundamentals Program
 - B. Orientation to International Inspections training
 - C. Food GMPs and Evidence Development training
 - D. Managing a Newly Hired Consumer Safety Officer training
 - E. ORA All Hands Meeting Videos including:
 - i. ACRA Senior Executive Team's Thank You Message
 - ii. ORA All Hands Introduction Video
 - iii. ORA Honor Award Ceremony

-
- iv. Combined Federal Campaign Finish Strong Message
 - F. ORA ACRA Messages for regulatory associations, including:
 - i. Parental Drug Association
 - ii. Conference for Food Protection
 - G. CDER requested videos to assist in the NBC4 and Telemundo 44 Health and Fitness Expo by providing three (3) informational videos on Sickle Cell Anemia.
 - 3. Designed, developed and delivered Adobe Connect training to OTED staff and ORA Program Training Officers (PTOs) to assist in learning Adobe Connect platform for training courses and meetings.
 - 4. Maintenance and update of OTED's intranet and internet web pages. Updates included coordination with OTED personnel to improve, update and redesign OTED's internet page, following FDA's decision to migrate all intranet pages to SharePoint. Webmaster and OTED staff also reviewed, redesigned, remarket, rebranded OTED's internet pages as a result of continuous improvement and information sharing with external stakeholders.
 - 5. Provided training to DIST staff to increase skill sets with variety of online training tools including but not limited to: Adobe Connect, Lectora and Captivate.
 - 6. Instructional System Specialists were responsible for the development and monitoring of contract agreements and verification that work products were developed by contractors met OTED's needs. Contract work managed at DIST included:
 - A. Web module development for ORA Pharmaceutical and Biologics training
 - B. Adobe Connect Audio package which was required as part of Adobe Connect training utilized by OTED
 - C. Foreign Language Contract for ORA Operational staff to use to assist on foreign inspections.
 - 7. Collaboration with OTED Divisions and Quality Team, including:
 - A. In-Service Training of OTED staff on Needs Analysis Reports
 - B. In-Service Training of OTED staff on Curriculum Design Documents
 - C. Development and finalization of using SMART Objectives for OTED learning objectives
-

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



What is DMPLMT responsible for in OTED?

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.

FY2021 DMPLMT Accomplishments

1. Delivered 79 individual learning events (courses, webinars, facilitated group conversations, panel discussions, leadership program culmination sessions) in FY2021
2. Launched three cohorts of our FY2021 ORA's Leadership Development programs concluded, in support of developing future and existing leaders in ORA. This includes the completion of three developmental programs including:
 - A. Potential Supervisors Program Cohort 4: 36 ORA participants
 - B. Leadership Excellence Advancement Program (LEAP) Cohort 2: 19 ORA participants
 - C. Resilient Leadership Program Cohort 10: 30 ORA participants
3. Collaborated with ORA's Office of Management to revise and update the ORA New Supervisor Checklist and job aid for inclusion in the ORA Supervisory Toolkit for Onboarding, Acculturation, and Offboarding ORA Employees
4. To accommodate ORA's onboarding and training of recently hired Consumer Safety Officers in ORA Programs, OTED increased class size for Basic New Hire

Program from 30 to 60 people per virtual class offering.

5. Updated the existing ORA Basic Analyst Training Control Document, working in collaboration with ORS and OTED peers to address improvements and changing needs.
6. Reviewed and updated 15 online Microbiological Control Module courses in ComplianceWire for newly hire analysts, in collaboration with ORS. Update was necessary based on changes in science, technology and ORS needs.
7. Converted a total of 17 OTED Instructor Led Training courses to virtual Instructor Lead courses for delivery in FY2021. Specific courses included:
 - A. Using Online Reporting Analysis Decision Support (ORADDS) – Domestic (CS154)
 - B. Using ORADDS – Laboratory (CS156)
 - C. Advanced ORADDS (CS159)
 - D. Import Operations (IM101)
 - E. Advanced Import Operations (IM201)
 - F. Regulatory Science (LB236)
 - G. Introduction to Fundamentals of Regulatory Chemistry (LB237B)
 - H. Overview of BSL-2 and BSL-3 Principles (LB313B)
 - I. Personnel Practices for New Supervisors (MG106)
 - J. Soft Skills for Supervisors (MG130)
 - K. Soft Skills for Professionals (MG132)
 - L. Resilient Leadership (MG301)
 - M. Personnel Practices for ORA Supervisors and Managers (MG308)
 - N. Leadership Excellence Advancement Program (LEAP)(MG314)
 - O. Computer Aided Inspections (MP143)
 - P. Introduction to FDA Fundamentals (OD108)
 - Q. Leading with Impact (OD201)
8. Collaboration in progress with OPM to rescope the ORA Management and Leadership Development Program (MLDP) and update management competencies for training programs.

Division of Programmatic Training (DPT)



What is DPT responsible for in OTED?

The Division of Programmatic Training's primary responsibility is designing, developing, and delivering training and educational programs for the 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.

DPT collaborates with regulatory associations and OTED funded cooperative grantees to design the Human and Animal Food Integrated Food Safety System (IFSS) National Curriculum Standard (NCS).

DPT actively participates with internal and external workgroups, delivers conference presentations, represents OTED on program Steering Committees, collaborates with boards and committees and guides the development of commodity specific program standards.

FY2021 DPT Accomplishments

1. Delivered 275 individual learning events (e.g., courses, webinars, facilitated group conversations, etc.) in regulatory commodity areas (i.e., Human and Animal Foods, Medical Devices, Emergency Response, Biologics, BIMO, Pharma and Cooperative programs [retail, milk and shellfish] areas). Thanks to our exceptional partnerships and contracts, approximately 16% of these courses were delivered through partnerships with the following three (3) cooperative agreement grantees and three (3) academic institutions:
 - A. Association of Food and Drug Officials (AFDO)
 - B. National Environmental Health Association (NEHA)
 - C. International Food Protection Training Institute (IFPTI)
 - D. Purdue University
 - E. Ohio State University
 - F. North Carolina State University

-
2. Finalized and delivered new Medical Product Training Courses in Pharmaceutical Quality and Bioresearch Monitoring. Specifically,
 - A. Non-Sterile cGMP Pharmaceutical Surveillance Inspection Site Visit (DG221)
 - B. Non-Sterile Active Pharmaceutical Ingredient Inspection Course (DG222)
 - C. Post marketing Adverse Drug Experience (PADE) Reporting Inspections / Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections (BR227)
 3. Participated in FDA Agency Workgroups to include New Era for Smarter Food Safety Core Elements 2 and 3
 4. Participated in various cross-operational FDA teams, work groups and committees in support of training. Examples include:
 - A. Retail Food Executive Leadership Assessment Team (ELAT) for retail program,
 - B. National Retail Food Team workgroups,
 - C. Milk and Dairy Programs Steering Committees
 - D. Shellfish Steering Committees and Workgroups
 5. Participated in regulatory association work group meetings and conferences including:
 - A. Conference for Food Protection (CFP) parliamentarian team
 - B. Partnership for Food Protection (PFP) Training and Certification Work Group
 6. Continued to manage and collaborate with OTED's 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).
 - A. Major project highlights are course redevelopment/virtual conversion to virtual training support during COVID 19 crisis.
 - B. Assistance with the development and operation of the Integrated Food Safety System (IFSS) National Curriculum Standard Development
 7. Collaborated with OSCP and regulatory partners to streamline the State, Local, Tribal, Territorial registration process to increase local agencies availability. The
-

new approach of prioritizing attendees from agencies allowed for an increase in new local agencies having access to FDA training.

Division of Testing, Measurement and Certification (DTMC)



What is DTMC responsible for in OTED?

The Division of Testing, Measurement, and Certification (DTMC) is responsible for maintaining the ongoing quality of ORA personnel certification programs, including Level 1 Investigator and Level 1 Analyst 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.

FY2021 DTMC Accomplishments

1. Implemented the FY21 Certification and Job Task Analysis Schedule. Specific accomplishments include:
 - A. Conducted and completed 11 Job Task Analyses (JTAs) (full and updates) in the following areas aligned by ORA Office: OHAFO (6), OMPTO (3), ORS (1), Compliance (1).
 - B. Completed assessment development or review work for 8 courses (of 15 requested). This included the establishment of test blueprint, test questions that are defensible, and a clear interpretation of what the test means to the student regarding his/her learning at the training course.

-
2. In support of ORA's Retail Food Specialist Program, OTED, working collaboratively with Office of State Cooperative Programs (OSCP) to develop updated training and certification standards for the ORA Retail Food Specialist position. This initiative will assist ORA and OSCP in developing specific training framework to effectively train, certify and qualify Retail Food Specialists. The following work was accomplished in support of the training and certification program for ORA Retail Food Specialists:
 - A. Completed Retail Specialist Job Task Analysis (JTA) report outlining the knowledge, skills, abilities, and behaviors required for the ORA position
 - B. Completed Gap Analysis report of the JTA versus the current Retail Food Specialist training curriculum and provided recommendations.
 - C. Developed and received approval by OSCP leadership for a two-year project plan for the training and certification program development.
 - D. Established joint OTED/OSCP development team to develop and implement recommendations for training and certification program for ORA Retail Specialists.

 3. Conducting comprehensive evaluations of OTED training course evaluations, including for:
 - A. National New Hire Course FY2012-2021, for:
 - i. Food and Drug Law Course (MP101)
 - ii. Evidence and Development (MP102)
 - iii. Personal Safety & Interviewing (MP118)
 - B. FDA Alumni Advisor Program (FDAAAP) summary evaluation and program close out report
 - C. FY2020 Course Evaluation Roll-up review for both Instructor Led and Virtual Instructor Led training courses.

 4. Collaborated with OTED peers in cross-operational assignments impacting OTED including:
 - A. ORA Basic Analyst Training Control Document updates
 - B. Course Announcement Policy, Templates and sample documents

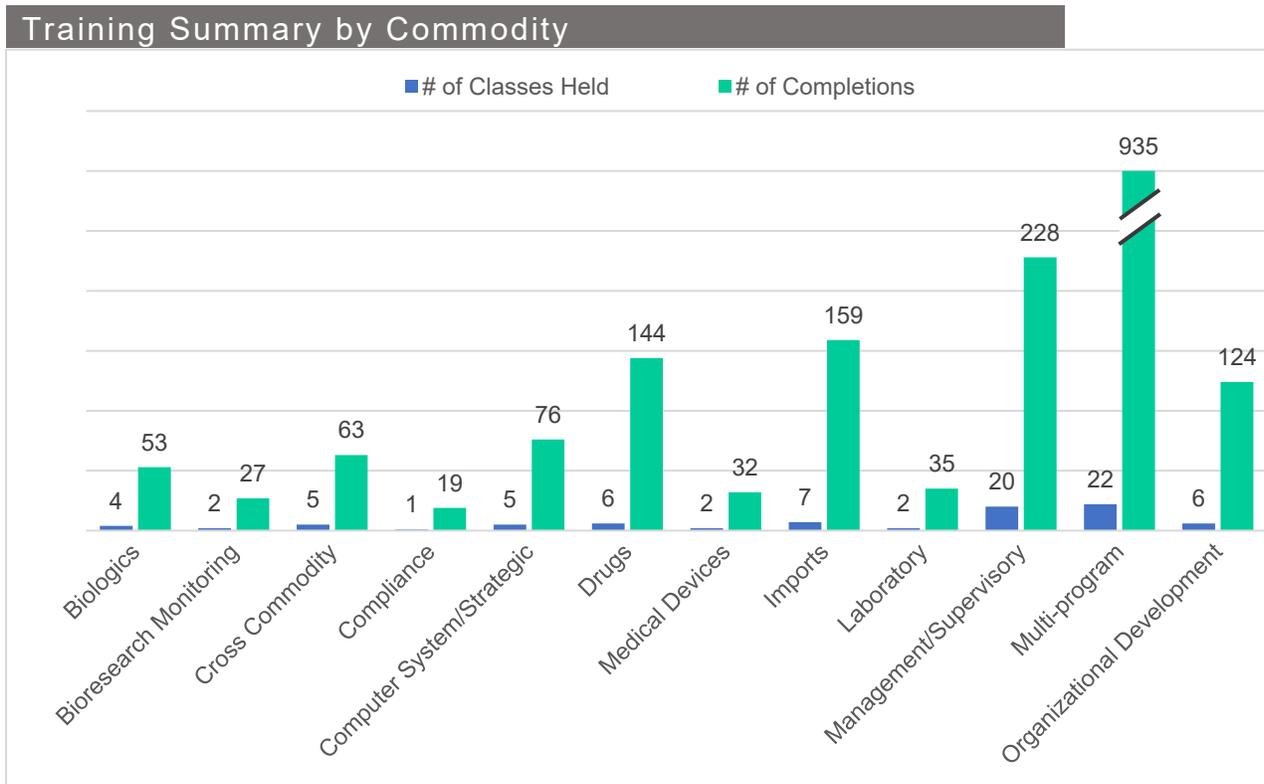
 5. Designed and facilitated FY2021 OTED Listening Session following the OTED FY2020 Federal Employee Viewpoint Survey results. Provided OTED leadership with recommendations to consider for implementation based on analysis and feedback.
-

FY2021 OTED Data and Charts

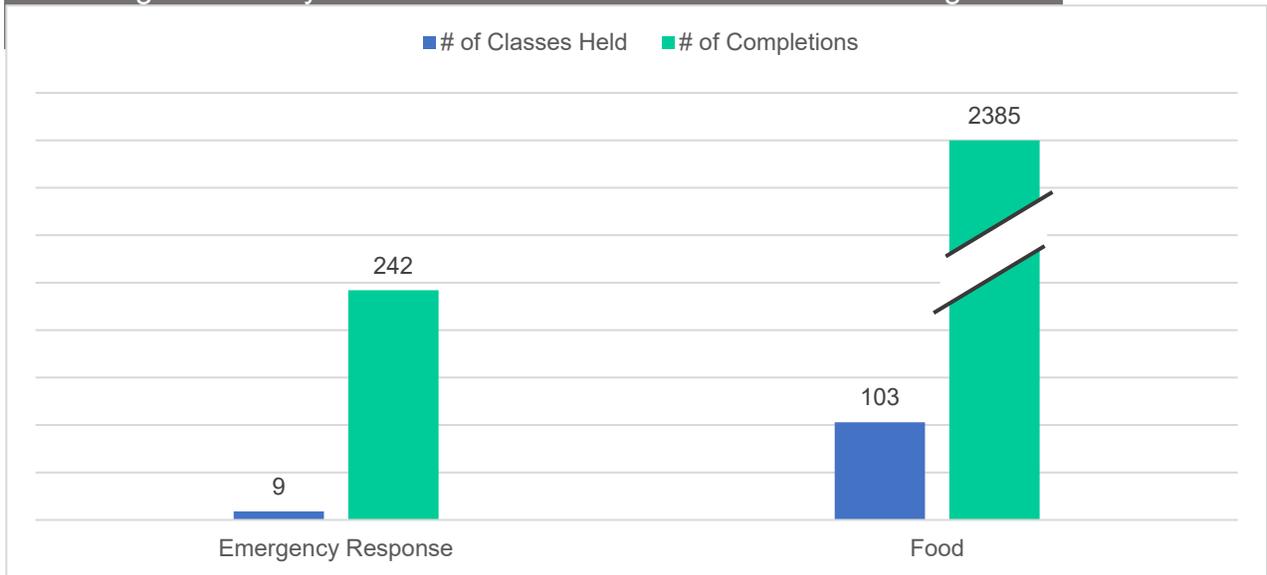
Training Summary Report

The below charts highlight the training and certification events held in FY 2021. They provide a summary of training courses by commodity, by employee type, and by delivery method.

The first two charts highlight the number of course offerings held in each program area and the number of student completions for that program. The first chart covers all program areas with the exception of Human and Animal Foods and Emergency Response, which are covered in the second chart.

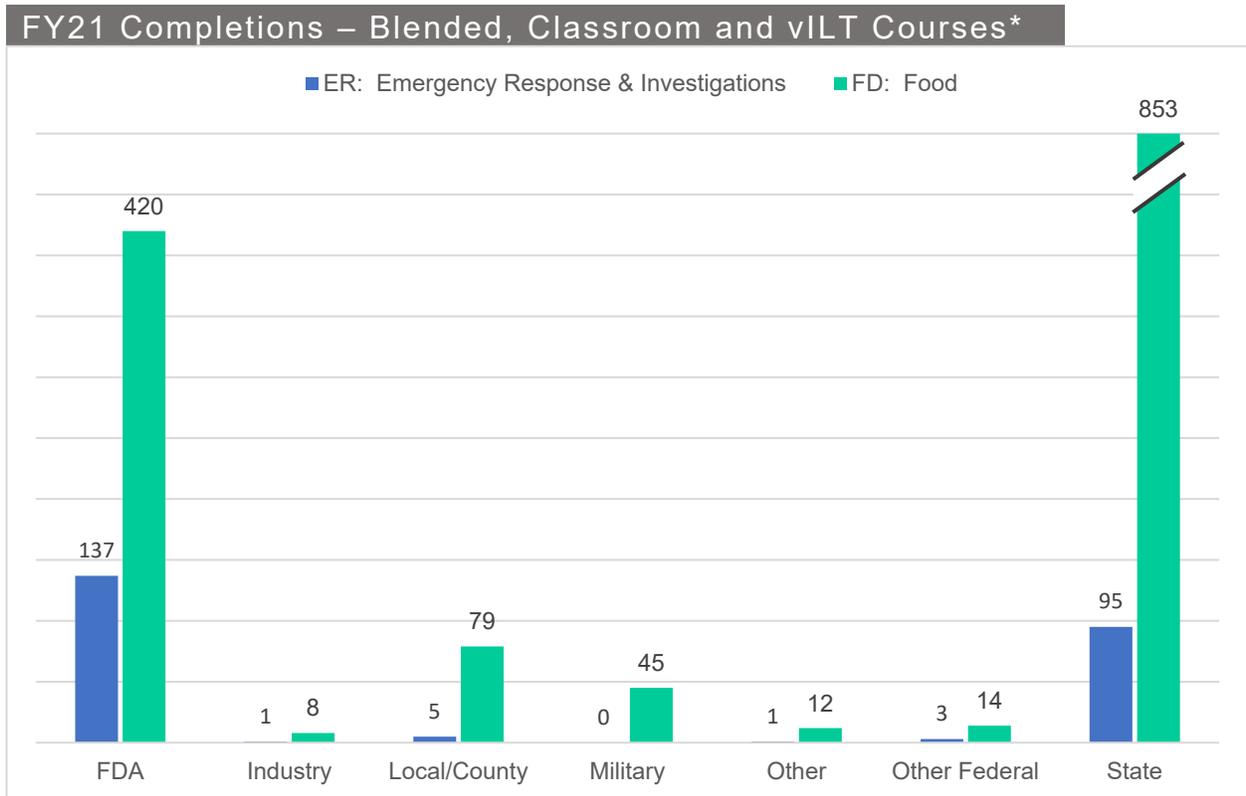


Training Summary – FDA Human and Animal Foods Program



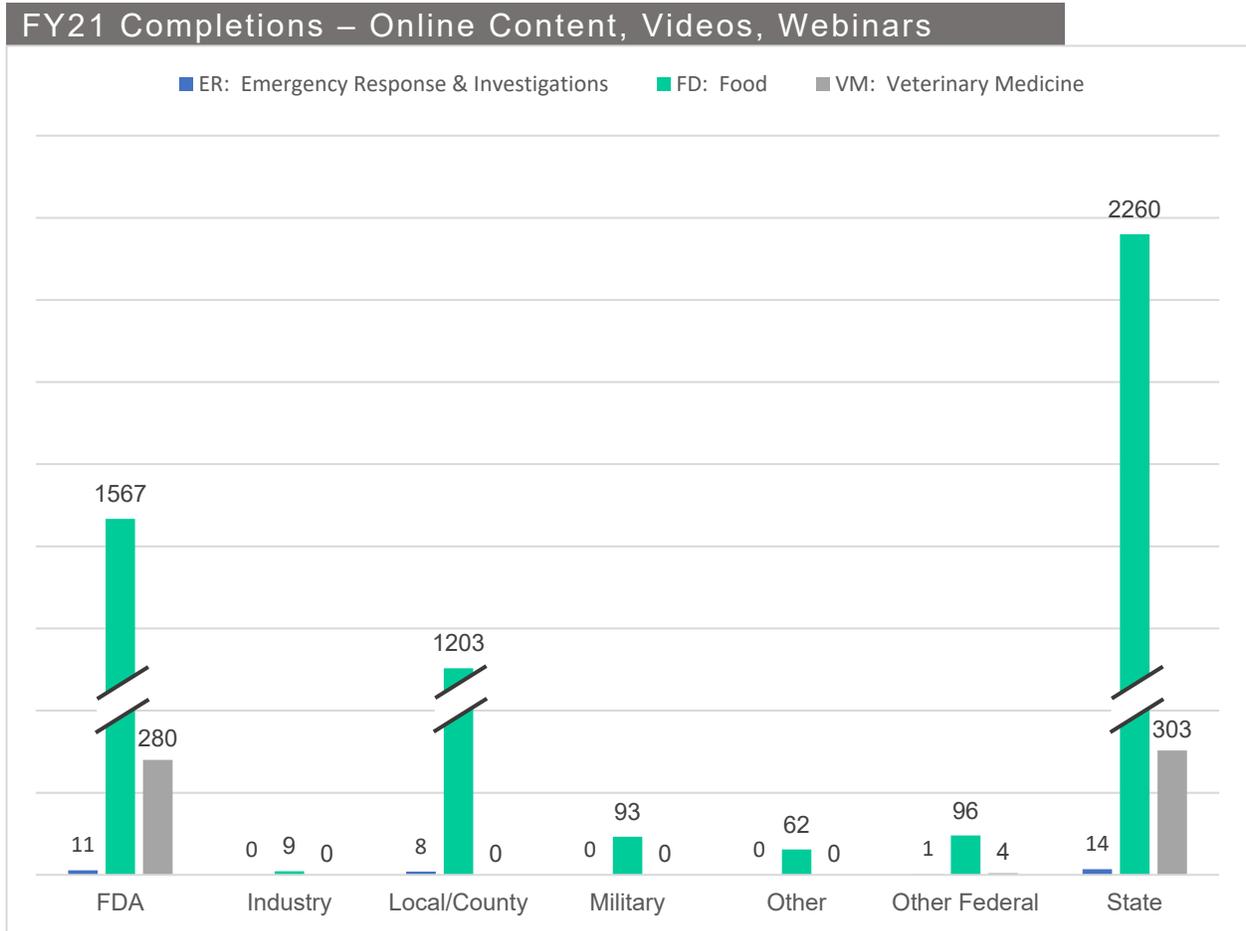
The following charts depict student completions by employee type and delivery method for Emergency Response, Human and Animal Foods, and Veterinary Medicine programs

This chart covers courses delivered as Virtual Instructor Led Training, traditional Classroom delivery, and blended methods (which combines independent work and pre-course work with classroom time, whether traditional or virtual).

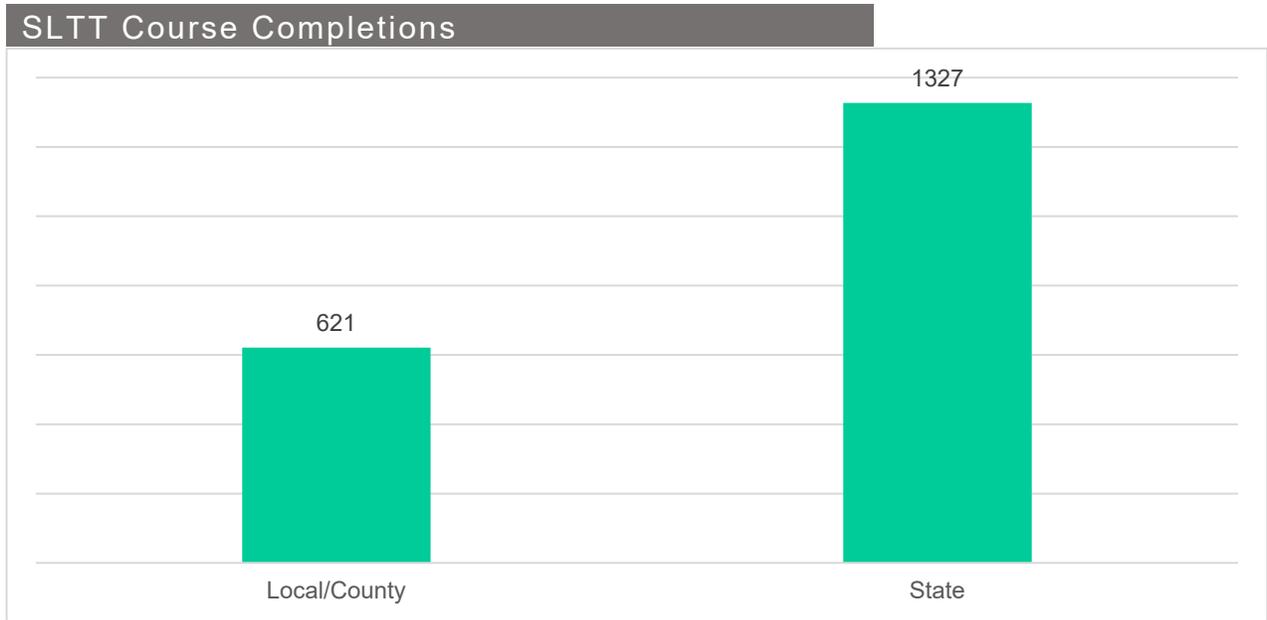


*VM: Veterinary Medicine did not deliver any FY21 Completions

The chart below depicts course completions with the three program areas from on-demand course delivery, which includes Web-Based Training modules, Video, and Webinars.



This chart shows our support for our external SLTT partners. Focused primarily on HAF courses, our SLTT partners completed the following total number of courses.



Certification Events Summary Report

The final chart compares the number of certification events held in FY2020 versus FY2021.

