POLICY AND PROCEDURES

OFFICE OF EXECUTIVE PROGRAMS

CDER Federated Training Model

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PURPOSE

This MAPP describes the roles and responsibilities for the Division of Training and Development (DTD) and the Office Training Liaisons, office directors, division directors, supervisors, team leaders, and staff within the Center for Drug Evaluation and Research (CDER). The MAPP establishes a "Federated Training Model" for planning, developing, delivering, facilitating, and managing training activities throughout the Center.

BACKGROUND

Since the early 1980s, the Center's training programs have focused on providing science-based education, mission-specific training, and long-term development. Along with the increasing number of CDER staff, the scope of training continues to expand both in science and non-science areas. Until recently, this effort has been constrained, as have all Center functions, by a lack of consistent resource availability, including both staff and funding. These inconsistent resources have resulted in ad hoc, "first come first serve" training support to CDER program areas, as well as limited availability of discipline- and office-specific training activities.

A recent CDER-wide-initiative to update professional competencies and plan for future training across Offices has underlined the need to adjust our approach for how training is accomplished in the Center.

DTD can provide CDER-wide training functions that apply to all disciplines and program areas effectively; however, some of the scientific and specialized technical training, especially discipline- and office-specific training, is best planned for and managed at the Office and/or Division levels. This MAPP articulates a new direction for how training will be planned and delivered in the future.

The Federated Training Model will help ensure that every employee in CDER has a set of competencies required for his or her job, and has a plan in place for developing and/or maintaining the knowledge and skills necessary to do the job.

To that end, the Federated Training Model will also facilitate collaboration between DTD and the Offices to ensure that CDER provides appropriate and timely training experiences for everyone to develop and enhance their knowledge and skills to meet mandates in each CDER Office.

This MAPP supersedes CDER MAPP 4550.3 rev 1, signed 3/13/98 and 4550.3 rev 2, signed 5/4/10.

POLICY

Division of Training Development (DTD) is accountable for all aspects of the CDER Federated Training Model. DTD is also responsible for the overall planning, development, and implementation of Center-wide training, as well as oversight of evaluation of all training within CDER. The responsibility for evaluation will include periodic assessments of the CDER Federated Training Model to identify opportunities for improvement and to ensure that CDER staff are receiving the training they need to be successful in their jobs.

Each office in CDER is responsible for its own office- and discipline-specific training, including development of Individual Development Plans (IDPs) for each member of the staff in the office; planning, development, and implementation of office- and discipline-specific training; and collection of training data, including course content, key registration and cost information, and evaluation data.

All aspects of training, including programs, services, information, and data will be 508 Compliant, as described in the Americans with Disability Act. All programs, services, information, and data offered will be provided with full access to employees with disabilities equal to the level of access provided to employees without disabilities. Section 508 requires Federal agencies to purchase electronic and information technologies (E&IT) that meet specific accessibility standards.

Individuals with disabilities, who need reasonable accommodation to participate in any CDER-wide training, are requested to submit a description of the necessary accommodation in writing, by close of the course registration period, to DTDinfo@fda.hhs.gov. Requests for accommodation for a discipline-specific training should contact the listed Office Training Liaison or program manager. Sign language interpreting services should be directed via email to interpreting.services@oc.fda.gov.

CDER courses are open to all qualified CDER employees. There is no cost to CDER employees for attending a CDER course. Fellows who work within CDER, Fellows who work elsewhere in FDA, and Federal employees of other FDA components and DHHS are admitted on a space-available basis. These employees should contact the Director, DTD, regarding the course(s) of interest. FDA employees external to CDER who are interested in attending a CDER-wide training activity will be put on the waiting list when course registration has reached the maximum number of participants. Employees interested in a discipline-specific activity should contact the Office Training Liaison. CDER does not discriminate admission on the basis of race, color, sex, age, handicap, religion, nationality, or ethnic origin.

Registration is required for most CDER courses unless noted in the Calendar of Training Events. In line with DHHS policy, all training must be managed through the HHS Learning Portal, the Department's Learning Management System (LMS), located at http://inside.fda.gov:9003/EmployeeResources/Training/TrainingCDER/ucm011461.html

For the majority of CDER training activities, course materials and handouts will be distributed electronically. Each participant will be responsible for printing and bringing materials to CDER training activities.

For a course to be added as completed on an individual's transcript in the HHS Learning Portal, that individual must have attended a minimum of 80% of the activity, verified by a sign-in sheet or on-line signature, in addition to completing all of the required learning activities. The requirements to receive a Statement of Credit for continuing medical, pharmacy, or nursing education are (1) attendance verified by a sign-in sheet, (2) completion of lecture and final evaluation forms, and (3) participation in the learning activity.

FDA/CDER is a provider of continuing medical, pharmacy and nursing education credit. Activities are designed to provide instruction in the regulatory review of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation as well as leadership and other topics necessary to accomplish the mission of the FDA while adhering to the guidelines outlined by the Accreditation Council on Continuing Medical Education, the Accreditation Council for Pharmacy Education and the Maryland Nurses Association.

Goals

The goals of the CDER Federated Training Model are to:

- Enable CDER to tailor its training programs to address the competencies required CDER-wide, as well as for each of its scientific disciplines; technical and regulatory areas; and administrative, managerial, and leadership requirements.
- Establish and maintain up-to-date competencies and curriculum schedules for each of CDER's scientific disciplines; technical, regulatory, and administrative staff; and managerial and leadership positions.
- Position DTD to create standards and efficiencies across CDER and to focus on designing and delivering center-wide training.
- Create an opportunity for the CDER offices to build capabilities for planning, managing, and implementing their own office-specific training, with expert guidance from DTD.

Scope

The scope of the activities included in the Federated Training Model includes:

- Assurance that all employees have the opportunity to develop their foundational knowledge and skills, particular to and necessary for a successful career within CDER, as outlined in the CDER Core Competencies.
- Provision for all CDER scientific disciplines, technical and/or regulatory staff to have appropriate opportunities to develop the knowledge and skills necessary to conduct high quality and rigorous evaluations of drugs and drug products, and provide oversight of post marketed drugs. This includes scientific, technical, and regulatory/policy related training opportunities. Whenever possible, these activities will be available for continuing medical education (CME), continuing nursing education (CNE), and/or continuing pharmacy education (CPE) credit.
- Provision for all other staff in administrative, managerial, and leadership positions to have appropriate opportunities to develop the knowledge and skills necessary to perform their jobs with quality, efficiency, and effectiveness.

Delivery methods include traditional live instructor led activities, live sessions available via streaming video and live sessions recorded and available for play back later, as well as other computer and web-based instructional formats.

RESPONSIBILITIES

1. The Director of DTD will oversee all activities related to CDER's Federated Training Model, including:
   a. Serve as the CDER Training Officer
   b. Serve as the Chair of the CDER Training Coordinating Committee
   c. Serve as a member of the OMT Subcommittee on Training

d. Develop and maintain CDER-wide and discipline-specific competencies, in conjunction with the appropriate subject matter experts and Office Training Liaisons
e. Prepare annual "Call for Training" to go out to the Office Training Liaisons to anticipate training needs for the upcoming fiscal year, based on requirements of the OMT Subcommittee on Training
f. Work with Office Training Liaisons and others as appropriate to develop consolidated assessment of CDER's training needs annually
g. Work with CDER senior managers to develop annual budget for training to include Center-wide training operations costs, as well as funding for special training initiatives, based on consolidated assessment of CDER's training needs
h. Develop and update training related MAPPS
i. Develop and update instructional and design standards/methods
j. Provide guidance as needed on all aspects of training design, development, and implementation, including:
    i. Analyze training need and plan for training activities to leverage individual development plans
    ii. Design and develop training activities, including oversight of Continuing Education requirements, development of training objectives related to competency models, selection of training media, use of learning activities appropriate to activity content, etc.
    iii. Coordinate with DTD training staff, CDER committees and faculty, and vendors
    iv. Use the HHS-mandated learning management system (the HHS Learning Portal) for registration and maintenance of transcripts
    v. Use off-the-shelf and customized training purchase orders and contracts
    vi. Evaluate individual training activities through standard on-line evaluation service provided by DTD
    vii. Evaluate overall program by target audience (Center-wide, Management/leadership, Office-specific, Discipline-specific)
k. Maintain catalog of CDER-wide training available.
l. Maintain a listing of training vendors used in CDER and their course offerings, with related contract information, costs, and evaluation ratings
m. Serve as the primary interface between CDER-wide training programs and external participants, such as staff from other Centers.

2. The Deputy Director of DTD will work with the Director, DTD, to facilitate the successful completion of DTD's responsibilities, as detailed above. In addition, he or she will oversee all activities related to Continuing Education credit, including:
    a. Serve as the CE Administrator for the FDA/CDER Continuing Education Program, with final decision-making authority for matters related to CE
    b. Provide expert consulting on continuing education credit, including continuing medical education (CME), continuing nursing education (CNE), and continuing pharmacy education (CPE)
    c. Serve as the primary interface between CDER's CE program and organizations outside of DTD, such as other Staff Colleges in FDA.

3. DTD Points of Contact (POCs) will be the DTD interface with CDER Offices. They will:
   a. Provide expert consulting on instructional design and training program management to Office Training Liaisons
   b. Provide expert consulting on continuing education credit, including continuing medical education (CME), continuing nursing education (CNE), and continuing pharmacy education (CPE)
   c. Work with Office Training Liaisons to coordinate training evaluation program and ensure appropriate use of CDER evaluation tools
   d. Recommend the best approach for using vendors in training design and delivery for office specific-training requirements
   e. Provide guidance to the offices on accessing the roster of vendors and the offices' responsibilities for managing the contract agreement
   f. Facilitate sharing of information among offices and DTD.

4. CDER Office Directors will oversee the Office's responsibilities of the Federated Training Model and will identify the Office Training Liaison to work with DTD.

5. The Office Training Liaisons will oversee the discipline- and office-specific training for their office and respective disciplines. They will:
   a. Take responsibility for working with the Office leadership and disciplines to develop an IDP for each individual as appropriate to the specific Office, based on CDER and discipline specific competencies and templates, provided by DTD
   b. Take responsibility for working with the Office leadership and disciplines to develop office-wide training needs and respond to annual "Call for Training"
   c. Work with DTD and appropriate subject matter experts to maintain CDER-wide and discipline-specific competencies.
   d. Use CDER standard training templates and documents to plan and implement office and discipline specific training
   e. Work with DTD POCs to ensure appropriate use of CDER evaluation tools for training evaluation program
   f. Communicate with office staff about training opportunities at office-specific level, Center-wide level, and outside of CDER
   g. Serve as a member of the CDER Training Coordinating Committee
   h. Share information with other offices and DTD through the Training Coordinating Committee, such as plans, issues and challenges, barriers, and best practices
   i. Provide advice and guidance to their respective office director in preparation for meetings on the OMT Subcommittee on Training
   j. Prepare and manage training budgets for their respective offices as directed by their office management
   k. Complete other duties as assigned at the office level.

PROCEDURES

The Model includes five major activities:

I. Define CDER Training Needs
II. Develop CDER Training Strategy
III. Execute CDER Training Strategy
IV. Evaluate CDER Training Strategy
V. Support Individual Learning and Development.

I. Define CDER Training Needs

1. Identify Offices' Training Needs**:** Annually, the Office Training Liaisons will:
   a. Work with the team leaders/supervisors in each of their disciplines to identify training needs in their Office, based on the "Call for Training" from DTD
   b. Consolidate training needs for their Office and have them reviewed and approved by the Office Director
   c. Send their Office's training needs to their DTD POC, as specified in the "Call for Training"

2. Identify CDER-wide Training Needs: Based on the Office training needs received in the "Call for Training," DTD will:
   a. Consolidate training needs for all of CDER
   b. Meet with the Office Training Liaisons to classify and quantify the needs by the following, as defined in the annual "Call for Training":
      i. Center-wide training needs
      ii. Anticipated new employee training needs
      iii. Office-specific training needs
      iv. Discipline-specific training needs (including administrative and professional as well as scientific disciplines)
      v. Management/leadership training needs
   c. Work with the Office Training Liaisons to evaluate identified training needs against existing/available resources
   d. Prepare comprehensive table of training needs for CDER, by classification and with appropriate resource determinations
   e. Work with CDER senior management to prioritize identified training needs
   f. Based on outcome of work with senior management, define/document prioritized training needs for the year
   g. Work with Office of Executive Programs (OEP) senior management to prepare Center-Wide training budget.

II. Develop CDER Training Strategy

1. Develop the Annual CDER Training Strategy**:** Annually, the DTD POCs will:

a. Meet with the Office Training Liaisons to identify the best approach for delivering CDER-wide training options and provide consultation on Office-specific training
b. Make final decisions on the CDER-wide training activities for the upcoming year
c. Develop a preliminary CDER-wide training schedule that will publish both CDER-wide and Office-specific training activities.

2. Develop the Annual Office-specific Training Strategy: Annually, the Office Training Liaison will:
   a. Make final decisions on the office-specific curriculum offerings for each discipline for the upcoming year
   b. Work with DTD to develop the preliminary training schedule that will publish both CDER-wide and Office-specific training activities.

3. Develop Program Evaluation Strategy for all training activities conducted within CDER: Annually, the Director, DTD, will:
   a. Develop a strategy for evaluating the training activities to be conducted within the Center, including some form of the following accepted levels of evaluation:
      i. Level 1: Reaction (participants' reaction to the training in the moment)
      ii. Level 2: Learning (assessment of what was learned in the training in the moment)
      iii. Level 3: Job behavior (assessment of what was transferred from the learning environment to the working environment)
      iv. Level 4: Organizational results (return on investment)
   b. Work with the Office Training Liaisons to provide electronic evaluation survey support to their office-specific evaluation efforts.

III. Execute CDER Training Strategy

1. Develop and Deliver CDER-wide Training: The Director of DTD will:
   a. Review the preliminary CDER-wide training schedule periodically for changes, based on changes in CDER priorities
   b. Procure the appropriate contractors or in-house staff to design and deliver the CDER-wide training
   c. Oversee the design/delivery of CDER-wide training solutions whether conducted by in-house resources or external resources, using established CDER instructional design and delivery guidance and standards
   d. Oversee use of the HHS Learning Portal for registration and tracking of completed training.

2. Develop and Deliver Office-specific Training: The Office Training Liaisons will:
   a. Work with the Office Director to determine availability of funds and select which training needs will be addressed in the Office-specific training for the year
   b. Work with DTD POCs to identify best approach to deliver Office-specific training

c. Consolidate selected training options into an Office-specific course schedule and send it to the DTD POC for them to integrate into the CDER training calendar
d. Work with discipline representatives to select and procure the appropriate contractors or in-house staff to design and deliver the selected Office-specific training
e. Oversee the design/delivery of office-specific training solutions whether conducted by in-house resources or external resources, using established CDER instructional design and delivery guidance and standards, including CE standards and guidance, if appropriate
f. Use the HHS Learning Portal for registration and tracking of completed training.

3. Publish and Market CDER-wide and Office-specific Training: The Director of DTD will:
   a. Regularly update the CDER training calendar by integrating new CDER-wide training as well as Office-specific training, when appropriate for Center-wide dissemination, submitted by the Office Training Liaisons
   b. Publish the integrated CDER training calendar and make it available to staff through a range of appropriate channels.

IV. Evaluate CDER Training Strategy

1. Implement the evaluation strategy for the overall CDER Training Program: throughout the year, the Director, DTD and DTD POCs will:
   a. Review the preliminary evaluation strategy periodically for changes, based on changes in CDER priorities
   b. Work with Office Training Liaisons to collect necessary data for CDER's training program to evaluate effectiveness of the training program
      i. Develop appropriate electronic survey tools to collect "reaction" data from participants at the end of training,
      ii. Develop appropriate data collection tools to collect additional data from participants and their supervisors after three months, and after 6 months, if appropriate depending upon type of program
   c. Collect appropriate data using established tools
   d. Evaluate data collected by individual activity and overall program, looking for trends and pertinent anomalies in the data
   e. Share evaluation data with Office Training Liaisons as appropriate

2. Implement the evaluation strategy for the Office-specific training program: throughout the year, the Office Training Liaison will:
   a. Review the preliminary evaluation strategy periodically for changes, based on changes in CDER priorities and information communicated from DTD
   b. Share information with other Office Training Liaisons relative to the evaluation of training programs, as appropriate

c. Work with DTD POCs to collect necessary data for CDER's training program to evaluate effectiveness of the training program
   i. Use appropriate electronic survey tools provided by DTD to collect "reaction" data from participants at the end of training
   ii. Use appropriate data collection tools developed in conjunction with DTD to collect additional data from participants and their supervisors after three months, and after 6 months, if appropriate depending upon type of program
d. Receive electronic and other data from DTD
e. Working with DTD, evaluate data collected by individual activity and overall program, looking for trends and pertinent anomalies in the data
f. Share evaluation data with DTD and other Office Training Liaisons as appropriate.

V. Support Individual Learning and Development

1. Supervisors/Division Director will:
   a. Actively encourage their individual staff members to seek out the training they need to meet their development needs
   b. Allow staff the time they need to address training and development needs
   c. Meet with staff at least once per year to review their individual development plans
   d. Debrief the employee after training to discuss what the experience was like, what observations were made and how the training can be applied to the work
   e. Complete and return any training evaluation forms regarding their staff's training
   f. Contact their Office Training Liaison if they encounter any training needs that are not being met by the current CDER-wide or Office-specific training.

2. Personal Training Initiative: Individual staff members will:
   a. Take responsibility proactively to identify her/his development needs and find training to meet those needs
   b. Prepare an individual development plan (IDP) in conjunction with her/his supervisor
   c. Register for and complete the training identified in the IDP
   d. Provide feedback on the quality of training and any training needs that are not being met.

REFERENCES

1. CDER MAPP 4550.5, Accreditation – Continuing Education Issued 11/16/07
2. Office of Personnel Management, Training Policy Handbook http://www.opm.gov/hrd/lead/pubs/handbook/sitemap.asp
3. Office of Personnel Management, Training Reporting Rules http://www.opm.gov/cfr/fedregis/2006/71-051006-28547-a.pdf

4. CDER Training Registration http://inside.fda.gov:9003/EmployeeResources/Training/TrainingCDER/ucm011461.html
5. Charter for the CDER Training Coordinating Committee (in development)
6. Charter for the OMT Subcommittee on Training (in development)
7. Americans with Disabilities Act (ADA) 508 Compliance Documentation. http://inside.fda.gov:9003/it/InternetIntranet/Accessibility/default.htm
8. Staff Manual Guide 3130.1 http://inside.fda.gov:9003/PolicyProcedures/StaffManualGuide/VolumeIIIGeneralAdministration/ucm007696.html
9. General information on training in CDER http://inside.fda.gov:9003/EmployeeResources/Training/TrainingCDER/default.htm

DEFINITIONS

Activity: A single training event, such as a seminar, rounds or course.

Activity Evaluation: A systematic method for collecting, analyzing, and using information to answer basic questions about a single training event.

Calendar of Training Events: A schedule of Center-wide training activities distributed weekly.
http://inside.fda.gov:9003/EmployeeResources/Training/TrainingCDER/ucm011309.html

CDER Training Officer: The Director, Division of Training and Development, responsible for development, implementation, and evaluation of CDER's training policies, procedures, and programs at the direction of the Center Director.

Center-wide Training: Any training program whose target audience crosses Office boundaries to include: all CDER employees, or some number of staff from all CDER offices, or a critical mass of CDER offices and staff.

Certificates of Completion: A document issued by the HHS Learning Portal to a participant who has attended and successfully completed the activity in accordance with the stated requirements.

Committee for Advanced Scientific Education (CASE)**:** The principal scientific educational advisory committee for CDER whose mission is to promote excellence in advanced scientific education. CASE also assists CDER's scientific personnel to maintain currency and a high level of competency in the advanced regulatory and scientific knowledge of drug evaluation to meet the complex challenges of evolving and innovative drug development in a global environment.

Competencies: The knowledge and skills needed by CDER's staff to support the Center's mission. A list of knowledge, skills, and abilities that can be linked to specific job tasks.

Competency Gap: The difference between the knowledge and skills staff currently possess/have, and the knowledge and skills they need now and in the near future to perform successfully.

Customized training: Tailored training program developed internally or by a company, professional association, educational institute or other source to meet identified needs of the target audience.

Discipline-specific training: Any training program whose target audience is within a specific discipline.

DTD Point of Contact: The senior DTD staff person assigned to work with the Office Training Liaison from a specific CDER Office. DTD will identify a Point of Contact (POC) for each of the super-offices within CDER.

DTD Program Manager: The DTD staff person assigned to oversee an individual training program. The DTD Program Manager (PM) will work with the appropriate planning committee or subject matter expert to develop and revise CDER-wide training activities.

Faculty: The individuals who serve as instructors for CDER's training activities, including invited guests from academia, industry or other government agencies; consultants and contractors; and internal staff.

Federated Training Model: A structured and collaborative process between DTD and all CDER Offices that leverages the best resources across CDER to plan, design, and deliver training experiences that meet specific Office, discipline, and individual training needs in a timely and appropriate manner.

HHS Learning Portal: An online learning management system utilized by HHS agencies to manage the administration, documentation, and tracking of training activities and programs.

Individual Development Plan (IDP): An individually tailored written plan/schedule developed by the supervisor and employee outlining the employee's developmental objectives and developmental activities designed to meet specific job and career objectives. The IDP is the action plan to meet CDER's competencies, improve current performance, and prepare employee for greater responsibility. An IDP template is available at:
http://inside.fda.gov:9003/EmployeeResources/Training/TrainingCDER/ucm151647.htm

Learning and Development Council: A committee made up of Training Officers (or their representatives) from each of the FDA Centers for the education and collaboration of those involved in designing training for the Centers.

Office Training Liaison: The person identified by a CDER Office to work with DTD in the Federated Training Model. The person selected for this role should be knowledgeable about the work of the office and the training required.

Office-specific training: Any training program whose target audience is within specific office boundaries.

Off-the-shelf training: Standard training program offered by a company, professional association, educational institute or other source that can be purchased by direct obligation.

OMT Subcommittee on Training: A group of senior leaders within CDER that will identify the overarching training needs of the Center and set priorities.

Program Evaluation: A systematic method for collecting, analyzing, and using information to answer basic questions or to make necessary decisions about a program.

Sign in Sheet: Provided at registration to document attendance. Signature is required to request continuing education credit and for course completion.

Statement of Credit: A document issued to a participant for continuing education credit for an activity approved to provide medical, nursing, or pharmacy continuing education credit. Requirements to receive a Statement of Credit are (1) attendance verified by a sign-in sheet, (2) completion of lecture and final evaluation forms, and (3) participation in the learning activity.

Training Coordinating Committee: A group comprised of DTD staff and Office Training Liaisons which will work closely to collaborate, leverage resources, and ensure CDER's training program (Office/Discipline specific and Center-wide) remains superior in every way.

Training Needs Assessment: The systematic method of determining if a training need exists and what training is required.

Transcripts: Participant record of registered and attended training activities, generated by the HHS Learning Portal.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

MAPP Number	Revision Number	Effective Date	Revisions
4550.3	Initial	6/23/97	n/a
4550.3	Rev. 1	3/13/98	Details added.
4550.3	Rev. 2	5/4/10	Multiple changes in Responsibilities and Procedures sections.
4400.3	Initial	7/15/11	Changed MAPP number to reflect change of responsibilities from OCOMM to OCD/ DTD. Reformatted MAPP in new template.