POLICY AND PROCEDURES

OFFICE OF EXECUTIVE PROGRAMS

Guide to the Orientation Program in the Center for Drug Evaluation and Research

Table of Contents

PURPOSE

This MAPP establishes policies, responsibilities, and procedures for the new employee Orientation Mentoring Program within the Center for Drug Evaluation and Research (CDER).

BACKGROUND

CDER's overall training is designed to give each new employee the opportunity to develop and improve skills, knowledge, and abilities that will enable the Center to carry out its mission. The Orientation Program is an essential training and development initiative that uses the skills of experienced employees who have knowledge and understanding of the Center's operating procedures and can help new employees grow and learn about the way the Center operates.

POLICY

- All employees new to CDER will be assigned an Orientation Mentor for approximately 3 to 6 months at the start of their CDER employment. Because the

Office or Division can best assess the workload of an Orientation Mentor, the Office or Division Director or a designated representative has the responsibility of matching the Orientation Mentor with the new employee.

- For reviewers, the Orientation Mentor and Mentee should be matched by discipline within the Office or Division (e.g., chemist with a chemist).

- The Office or Division should identify the Orientation Mentor before the new employee's start date. The Orientation Mentor should be experienced and willing to serve as a mentor.

RESPONSIBILITIES

The Orientation Mentoring Program ensures that orientation meets the specific training needs of the new employee and is integrated with the new employee's overall CDER training. This program assists new employees in the development of necessary knowledge, skills, and abilities so that they will be able to perform their jobs.

The following sections outline the responsibilities of the Orientation Mentor, Mentee, Office or Division, and CDER.

- **The Orientation Mentor will:**

  1. Develop knowledge of mentoring.

  2. Facilitate Mentee understanding of CDER organization structure, culture, and regulatory history.

  3. Increase the competence and confidence of Mentee by providing constructive feedback, guidance, and advice.

- **With regard to orientation, the Orientation Mentor will:**

  1. Discuss and advise the Mentee on the Orientation Checklist (OC), customizing the OC to meet the new employee's needs.

  2. Assist the new employee with researching appropriate assignments, training courses, projects, and other activities.

  3. Hold regularly scheduled meetings and informal meetings with the Mentee to discuss work assignments, processes, and procedures.

- **The new employee or Mentee will:**

  1. Acknowledge the efforts of the Orientation Mentor and accept constructive feedback.

  2. Actively participate in the New Employee Orientation Course.

  3. Discuss the OC with the Orientation Mentor.

  4. Identify potential learning opportunities that will help meet the job's requirements.

  5. If the Mentor is a reviewer or regulatory project manager, become familiar with the administrative, logistical, technical, legal, and ethical aspects of regulatory science at CDER.

  6. Actively participate in additional training, development, and formal didactic programs (e.g., interpersonal skills and information technology) suggested by the Orientation Mentor.

  7. Be open to advice and feedback from the Orientation Mentor.

  8. Seek help (e.g., conflict resolution) and advice from the Orientation Mentor, appropriate Center staff, and other subject-matter experts as necessary.

  9. Complete orientation activities in a timely and professional manner.

  10. Provide feedback and suggestions to the Orientation Mentor, Supervisor, and appropriate Center staff to improve the Orientation Mentoring Program.

- **The Office or Division (Director, Supervisor, or Team Leader) will:**

  1. Prospectively identify an Orientation Mentor for each new employee recruited for the Office or Division. The selection should be made before the new employee arrives so that the Mentor can help the new employee with the initial adjustment to the workplace. Whenever possible, efforts should be made to provide a peer mentor in addition to the Supervisor or Team Leader.

  2. Recognize Orientation Mentoring as an assigned duty of the Orientation Mentor.

  3. Provide guidance regarding operation of the Office or Division (e.g., interacting with sponsors, writing reviews, scheduling meetings, interacting with other Divisions).

  4. Ensure that the new employee has time to work with the Orientation Mentor.

In choosing the prospective Orientation Mentor, the Office or Division will consider the Orientation Mentor's:

1. Desire to serve as the Orientation Mentor and willingness to participate in the Orientation Mentoring Program.

2. Experience (at least 1 year at workplace).

3. Knowledge of mentoring concepts.

4. Interpersonal skills.

5. Communication skills (oral and written).

6. Time and work management skills.

7. Familiarity with the Center's organization.

8. Prior training or teaching experience (although not a prerequisite).

CDER will:

1. Develop overall guidelines and goals.

2. Support standards for incentive and/or award mechanisms for Orientation Mentor participants.

3. Provide training for Orientation Mentors, both initial and continuing.

4. Evaluate the program on a continuous basis through regular meetings and assessment from Orientation Mentors, Mentees, and Supervisors.

PROCEDURES

During the first few days on the job, the Orientation Mentor will welcome the new employee and encourage questions. Using the OC (see Attachment A), the Orientation Mentor will facilitate the new employee's training and development. The OC will identify competencies for the new employee. The Orientation Mentor, together with the new employee, will review and identify training opportunities that will develop the competencies (see the list of recommended competencies located on the Intranet at http://cdernet.cder.fda.gov/dtd/index.htm).

- **The Office or Division will provide the new employee with the following:**

  1. Introduction to all personnel within the Office or Division.

  2. Introduction to additional staff (e.g., co-locates).

  3. Orientation to Office or Division facilities (e.g., mailboxes, message center, copier, fax, color printer).

  4. Tour of Office or Division supplies and information on how to request additional items.

  5. Introduction to the timekeeper.

  6. Discussion about attendance policy and procedures (e.g., timekeeping, time cards, leave slips, leave approval, lunch schedules, flexitime, alternate work schedule, flexiplace).

  7. Explanation about other policies and practices (e.g., inclement weather, tardiness, overtime, credit time, telephone use, mail service).

  8. Explanation about what the new employee can or cannot expect from secretaries and other Office or Division staff.

  9. Discussion about regularly scheduled meetings and seminars that the new employee is expected to attend (or can attend if interested).

  10. Discussion about when CDER's orientation sessions are held and when new employees are expected to attend the sessions.

  11. Overview of CDER's computer system, introduction to the Office or Division's computer resource person, and explanation about how to reach CDER Help Desk.

  12. Tour of building and discussion of other CDER facilities.

  13. Discussion about resources (e.g., libraries, cafeteria, bank machines, personnel office, conference rooms, parking office, credit union, health unit).

  14. Discussion about building security (e.g., fire drills).

  15. Discussion about parking at all Center facilities and availability of shuttle buses.

  16. If the Mentor is a reviewer or regulatory project manager, explanations about the Document Room (e.g., DFS, COMIS).

  17. Discussion about document handling and document flow.

18. Discussion about the roles of the Orientation Mentor and the Supervisor.

19. Regularly scheduled meetings for the Orientation Mentor and Mentee.

- During the first few weeks, the Orientation Mentor will ensure that the new employee participates in the following activities:

    1. Discussion about any areas of concern.

    2. Review of Office or Division policies and procedures, as well as references (e.g., guides, instruction manuals) that are available in the work area.

    3. Identification of staff with certain areas of expertise.

    4. Discussion about articles, documents (e.g., MAPPs, guidances), and Web sites related to the job.

    5. Positive feedback and suggestions that will help the new employee learn the job and fit in with the group.

    6. Discussion about books, work products, and journals available within the Office or the Division.

    7. Discussion about continuing education credits for seminars and/or courses if appropriate.

    8. Discussion about scheduling meetings with the Office or the Division staff (e.g., Office or Division Director, Supervisor, Team Leader, other reviewers).

    9. Identification of the person or persons the new employee can contact for information if the supervisor is absent.

    10. If the Mentor is a reviewer or regulatory project manager, discussion about the new reviewer's place in the Center organization and interaction with other disciplines.

    11. Discussion about the outside request-to-work form and the ethics and disclosure form.

When the orientation period is complete, the Orientation Mentor will provide an update to the Team Leader or Supervisor about the Mentee's status. The Mentor should provide feedback to the Supervisor occasionally throughout the orientation period.

The Team Leader, Supervisor, or designee will then use the Individual Development Plan (IDP) (Attachment B) to continue working with the employee in his or her training and development.

REFERENCES

1. FDA Staff Manual Guide 3120.1, *FDA Training and Staff Development Policy (General)*. This guide establishes the general policy of the Food and Drug Administration (FDA) in the area of training and career development and lists the corollary documents from Public Law, Executive Order, Office of Personnel Management Regulations, and Department of Health and Human Services (DHHS) Instruction, 410-1, Management of Training.

2. CDER MAPP 4400.3, *CDER Federated Training Model*. This MAPP establishes policies and assigns responsibilities for CDER training programs.

3. CDER Training Catalog, Division of Training and Development, Office of Training and Communications, Center for Drug Evaluation and Research

4. Bell, C.R. (1998), *Managers as Mentors. Building Partnerships for Learning*, San Francisco, CA: Berrett-Koehler

DEFINITIONS

Orientation mentoring: A partnership between an experienced employee and a new employee that prepares the new employee to perform the job with understanding and competence.

Orientation mentor: An experienced employee who could be a team leader, supervisor, or another office or division staff member.

Mentee: The new employee.

Orientation: The period of time, usually 3 to 6 months, depending on the new employee learning progress.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

MAPP Number	Revision Number	Effective Date	Revisions
4550.7	Initial	8/4/03	n/a
4550.7	Rev. 1	6/1/07	Changes to Responsibilities section.
4400.1	Initial	7/15/11	Changed MAPP number to reflect change of responsibilities from OCOMM to OCD / DTD. Reformatted MAPP into new template.

ATTACHMENT 1 -- Orientation Checklist

Name _____

Competencies	Activities	Learning and Training Opportunities	Mentor or Designee's Initials and Date Completed
CDER Core Competencies • CDER Organization • Communication • Computer Skills • Critical Thinking • Drug Development Process • Team Work • Time Management • Regulations	• Introduction to all personnel within the Office or Division.		
	• Introduction to additional staff (e.g., co-locates).		
	• Orientation of new employee to Office or Division facilities (e.g., mailboxes, message center, copier, fax, color printer).		
	• Tour of Office or Division supplies and information on how to request additional items.		
	• Introduction of new employee to the timekeeper.		
	• Discussion about attendance policy (e.g., timekeeping, time cards, leave slips, leave approval, lunch schedules, flexitime, alternate work schedule, flexiplace).		
	• Explanation about Office or Division policies and practices regarding issues such as inclement weather, tardiness, overtime, credit time, telephone use, mail service.		
	• Explanation about what the new employee can or cannot expect from secretaries and other Office or Division staff.		
	• Discussion about regularly scheduled meetings and seminars the new employee is expected to attend (or can attend if interested).		
	• Discussion about when CDER's orientation sessions are held and informing the new employee that he or she is expected to attend.		
	• Overview of CDER's computer system, introduction to the Office or Division's computer resource person, and explanation about how to reach CDER Help Desk.		
	• Tour of building and discussion of other CDER facilities.		

Competencies	Activities	Learning and Training Opportunities	Mentor or Designee's Initials and Date Completed
	• Discussion about resources (e.g., libraries, cafeteria, bank machines, personnel office, conference rooms, parking office, credit union, health unit).		
	• Discussion about building security (e.g., fire drills).		
	• Discussion about parking at all Center facilities and availability of shuttle buses.		
	• If the Mentor is a reviewer or regulatory project manager, explanation about the document room (e.g., DFS, COMIS).		
	• Discussion about document handling and document flow.		
	• Discussion about the roles of the Orientation Mentor and Supervisor.		
	• Regular meeting schedule between Orientation Mentor and Mentee.		
	• Discussion about any areas of concern.		
	• Discussion about scheduling meetings with office or division staff (e.g., Office or Division Director, Supervisor, Team Leader, other reviewers).		
	• Discussion about the outside request-to-work form and the ethics and disclosure form.		
Specific Discipline or Job Competencies	• Review of policies and procedures for the Office or the Division, as well as references such as guides and instruction manuals that are available in the work area.		
	• Identification of staff with certain areas of expertise.		
	• Discussion about articles, documents (e.g., MAPPs, guidances), and Web sites related to the job.		
	• Positive feedback and suggestions that will help the new employee learn the job and fit in with the group.		
	• Discussion about books, work products, and journals available within the Office or the Division.		
	• Discussion about continuing education credits for seminars and/or courses if appropriate.		

Competencies	Activities	Learning and Training Opportunities	Mentor or Designee's Initials and Date Completed
	• Identification of person or persons the new employee can contact for information if the Supervisor is absent.		
	• If the Mentor is a reviewer or a regulatory project manager, discussion about the new reviewer's place in the Center organization and interaction with other disciplines.		

ATTACHMENT 2 -- Individual Development Plan

\

The purpose of the Individual Development Plan (IDP) is to help an employee identify training and development opportunities to address personal development needs

An IDP Includes
- Clearly defined goals
- Specific assignments, training courses, projects, and other activities
- Proposed completion dates or time frames for the activities listed

The Steps in the IDP Process are

Step 1: Assessment and Self Assessment

Outcome: Working drafts of an IDP that include competencies, goals, and possible training or developmental opportunities.

Step 2: Employee Meeting with Team Leader, Supervisor, or Designee

Outcome: A mutual commitment between the Team Leader and the employee regarding the IDP plan.

Step 3: Final IDP Plan

Outcome: Employee completes a final written plan for signatures.

Step 4: IDP Implementation

Outcome: The follow-through on an IDP commitment.

Step 5: Follow-up and Review

Outcome: Ongoing support of a career development plan for the employee.

INDIVIDUAL DEVELOPMENT PLAN

Name _____

Signature _____ Date _____

Team Leader, Supervisor, or Designee Signature _____Date _____

Competencies	Goals	Learning and Training Opportunities	Date Completed