POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

Procedures for CDER Medical Officer Conversion to Career-Conditional

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PURPOSE

This MAPP describes the policies and procedures for qualification and application for medical officers in the Center for Drug Evaluation and Research (CDER) to convert from level 1, associate reviewer, to level 2, reviewer. This MAPP also includes the general expectations for formal training and work assignments to be completed by the medical officer during the first years of employment for successful conversion from the temporary appointment of level 1, associate reviewer, to the career conditional appointment of level 2, reviewer.

BACKGROUND

- CDER hires medical officers on temporary appointments because distinct differences exist between the work required by a CDER medical officer and the training and experience of many physicians before coming to CDER. Although a medical officer's clinical training, experience, and expertise are key components

to be a successful reviewer, due to the uniqueness of the clinical review process, most new reviewers require additional experience and training. Although the extent of this varies depending on the new reviewer's previous training and experience, in general the initial years of work at CDER are considered to be the equivalent of a fellowship in drug development and drug regulation.

- A medical officer is considered a candidate for conversion to career conditional appointment when he or she has successfully completed the formal training requirements outlined in this MAPP and the work accomplishments as established by the team leader/supervisor.

POLICY

- No time requirement is imposed for conversion from a Level 1 associate reviewer to a level 2 reviewer. Conversion to level 2 is achieved by meeting the defined criteria set forth in this MAPP. Generally, a reviewer should be able to move from level 1 to level 2 within 2-3 years. Work performance and work products will be reviewed for accuracy, completeness, and overall quality and factored in when considering a candidate's eligibility for conversion.

- Supervisors remain responsible for the performance evaluation of reviewers. Performance evaluations should rate individual reviewers at their existing level, not at a level they are working to achieve.

RESPONSIBILITIES

The Candidate will:

- At the request of the team leader/supervisor, meet with their team leader, supervisor, and division director to discuss expected training and work assignments.
- If applicable, initiate discussions requesting course credit in lieu of coursework with the team leader and, if advised, prepare a memorandum of request for review by the supervisor.
- Meet with the team leader, supervisor, and division director to discuss requirements and eligibility for conversion to level 2.
- Prepare a written summary of accomplishments in support of conversion to level 2 for team leader/supervisor review.
- Provide a complete conversion package (with cover sheet and checklist (Attachment C)) to the team leader and/or supervisor.

The Team Leader and/or Supervisor of the Candidate will:

- Meet with the candidate for frank and open discussions of the candidate's training and assignment scheduling.
- Clearly communicate to the candidate his or her progress and map out required work accomplishments to qualify for conversion.
- If applicable, the team leader will make an initial assessment regarding credit in lieu of coursework, and following a discussion with the candidate make the final approval or disapproval decision on the written request.
- Maintain documentation of candidate's work and assignments to be used in support of conversion, including material that documents that the candidate applies and follows appropriate policies, laws, and regulations in completion of his or her work, follows appropriate guidances and MAPPs in completing assignments (e.g., the safety review guidance, the Clinical Review Template), and that the work product is generally accepted as complete and adequate by his or her team leader/supervisor without need for extensive revisions or corrections.
- Meet with the candidate and division director to review the candidate's summary of accomplishments and Training Log to assess the candidate's eligibility for conversion.
- Communicate to the candidate whether to proceed with preparation of the conversion package.
- Provide guidance in preparing and review of the candidate's conversion package.
- Forward recommendations for conversion to the division director.
- Conduct regularly scheduled performance evaluations.

The Division Director will:

- Meet with the candidate, team leader, and/or supervisor to review the candidate's summary of accomplishments and Training Log, and make recommendation as to whether the candidate should proceed with the conversion package.
- Review the conversion package for accuracy and completeness and ensure that it fully demonstrates the candidate's qualification for conversion.
- If applicable, write a memorandum recommending conversion and forward with the conversion package to the office director.
- Meet with the office director to discuss the candidate's eligibility and review their conversion package.
- If applicable, initiate personnel action for conversion once the package is returned with the office director's concurrence.
- Notify the candidate of the decision.

The Office Director will:

- Meet with the division director to discuss the candidate's eligibility and review the conversion package.
- Check the conversion package for accuracy and completeness and ensure that it demonstrates the candidate's qualification for conversion.
- If a waiver or credit in lieu of coursework is requested, the office director will be the final approving official.
- Sign the conversion recommendation memorandum as either approved or disapproved and return to the division director. If disapproved, detail in writing why the candidate is not qualified at this time and what steps are needed for the candidate to qualify.

PROCEDURES

1. Once required training requirements and work assignments have been met, the candidate, team leader, supervisor, and division director will discuss level 2 qualifications and reach verbal agreement that the candidate is eligible for conversion.
2. The candidate will maintain a summary of accomplishments and a Training Log (Attachment A) to be used in support of conversion and forward to the team leader and/or supervisor for consideration.
3. If applicable, credit in lieu of coursework will be determined by the following:
    a. The candidate will initiate discussions with their team leader to evaluate prior experience, previous course work, or on-the-job training to be considered for credit in lieu of coursework. The candidate must be able to demonstrate both alternative training and mastery of the specific course content.
    b. The team leader will assess the verbal request for credit in lieu of coursework and advise the candidate to submit a memorandum of request to the supervisor if applicable.
    c. The candidate will prepare the memorandum providing a thorough justification requesting credit in lieu of coursework and route the memorandum through the team leader to the supervisor.
    d. The supervisor will review the memorandum requesting credit in lieu of coursework and approve or disapprove as appropriate. If the request is disapproved then the supervisor will meet with the team leader and candidate to explain the decision.
    e. Approved credit in lieu of coursework will be noted on the Training Log (Attachment A) by the candidate and the signed memorandum(s) will be submitted as part of the final conversion package.
4. The team leader and/or supervisor will forward the recommendation for conversion, the Training Log, and the conversion package to the division director for consideration.

5. The division director will review all documentation, sign concurrence of the recommendation memorandum as appropriate, and forward to the office director.
6. The office director will meet with the division director, discuss the candidate's qualifications, and review the conversion package.
7. The office director will sign the recommendation memorandum as appropriate either approved or disapproved. If disapproved, the office director will outline the reasons for disapproval in writing and the necessary steps to complete the qualification process. The office director will return the memorandum and conversion package to the division director.
8. If approved, the division director initiates the personnel action for conversion and notifies the candidate.

REFERENCES

1. FDA, Staff Manual Guide 3120.1, FDA Training and Staff Development Policy.
2. CDER, Office of Executive Programs, Division of Learning and Organizational Development (inside.FDA).
3. CDER, Office of Executive Programs, Division of Learning and Organizational Development, Catalog & Programs (inside.FDA).
4. CDER, Office of Executive Programs, Division of Learning and Organizational Development, CDER Competencies, Position- Specific Competencies, Office of New Drugs, OND Clinical Reviewer (inside.FDA).
5. CDER, Office of Executive Programs, Division of Learning and Organizational Development, Catalog & Programs, New Reviewers Blended Learning Program (inside.FDA).

DEFINITIONS

- **Conversion Package.** The conversion package is the description and examples of a candidate's knowledge, skills, and abilities that demonstrate satisfactory completion of the qualification guidelines for a level 2 reviewer. The package includes:
  1) Written summary of the candidate's accomplishments
  2) Candidate's completed Training Log (Attachment A)
  3) Approved memorandums for credit in lieu of coursework (if applicable)
  4) Conversion memorandum from the division director to the office director recommending the candidate for conversion (Attachment B is a sample)

- **Level 1 Associate Reviewer.** A new reviewer, generally on his or her first appointment with CDER. Associate reviewers work with their team leaders and mentors (if applicable) to learn the review process and actively pursue the scientific/regulatory knowledge necessary to work at the full performance

level. Typically, an associate reviewer's position is at the general schedule (GS) grade 14 level.

- **Level 2 Reviewer.** A reviewer who has acquired general knowledge of the review process and successfully completed the individual development plan in accordance with this MAPP to meet the core competency level for his or her discipline. A level 2 reviewer understands the basic tools of regulatory drug review and is capable of producing good reviews with some supervisory guidance. He or she functions as a team player and cooperates with others involved in the drug review process. Typically, a level 2 reviewer's position is at the general schedule (GS) grade 14 level.

- **Training Log.** A checklist of all required coursework to be filled in by the candidate, including dates when the courses are successfully completed (Attachment A).

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/24/10	N/A	
5/14/15	1	Attachment A (Training Log) was revised to show recent changes in courses. Formatting changes were made to the document.
7/11/16	2	Attachment A (Training Log) was revised to show recent changes in courses. Reference and formatting changes were made to the document.
9/6/17	3	Attachment A (Training Log) was revised to show recent changes in courses. Reference and formatting changes were made to the document.

Training Log – Internal Courses
Medical Officer, Level 1, Associate Reviewer

All listed training is conducted through the CDER and CDER Offices. Every effort should be made to complete the individual courses in the time frames indicated, which are based on your start date. Variance in scheduling should be done only with advance approval from your team leader and/or supervisor. **Coursework can be completed in person (preferred) or through online resources as appropriate, with prior concurrence from the medical officer's team leader or supervisor.** The completed log should be submitted as part of the conversion package to level 2, reviewer.

Upon completion of each course, the course dates should be entered in the space before the course name.

The following courses and timeframes, in general, should be completed within the first 2 years. **In some cases, credit in lieu of coursework may be approved by the Division Director when a candidate can demonstrate both prior training or experience and mastery of the specific course material.** The policies and procedures for requesting credit in lieu of coursework are provided in this MAPP.

***In addition, some courses listed below are more appropriate for the activities of specific organizations and are designated to be taken "as appropriate".**

Software courses are recommended for the development of data analysis and computer skills and competencies. Courses are available through OIM, OBI, OCS, OTS and OND as noted. Some are available through the FDA OIM Training Center for a fee ($150) paid by the participant's division.

Links to Training Registration pages:
CDER Training Calendar & Schedule (Fall, Winter and Spring semesters)
OND Learning Calendar (Year-round, live and recorded)
OTS Training Page (Fall and Spring semesters)
OCS Training Page (Year-round, live and recorded)
OBI Training (Year-round)
FDA Library (Year-round)
OIMT Training Page (Year-round)

Updated April 2018

DATE COMPLETED	Required CDER Medical Officer Updated Course List (with proposed scheduling)
	0-6 Months
	CDER New Employee Orientation (Day One)
	CDER Equal Voice Training http://inside.fda.gov:9003/cder/officeofthecenterdirector/ucm261351.htm
	CDER New Reviewer Learning Program (online)
	CDER IND Learning Program (online)
	OND Introduction to Clinical Review
	OND Clinical Reviewer Handbook (print resource) http://inside.fda.gov:9003/downloads/CDER/OfficeofNewDrugs/ImmediateOffice/ONDLearningandCareerDevelopment/UCM554121.pdf
	CDER Introduction to Design and Conduct of Clinical Trials
	CDER Technical Writing -OR- OND Technical Writing for Reviewers
	OBI DARRTS Training (multiple modules)
	OBI eCTD Viewer (GlobalSubmit Review) Training
	FDA Library BMIS, Bioresearch Monitoring Information System
Optional/As Needed	OIMT MS Outlook Introduction
Optional/As Needed	OIMT MS Word Introduction
Optional/As Needed	OIMT MS PowerPoint Introduction
	6-9 Months
	CDER NDA/BLA Regs and Policies (classroom or online)
	CDER Review of Clinical Trials
	OND Ready, Set, Review
	OND 2017 Clinical Review Template Introduction
	OND The Road to Assessing Benefit and Risk
	CDER MaPP 6010.3 Clinical Review Template Attachment B (Safety Review, p. 36 – print resource) http://inside.fda.gov:9003/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm080121.pdf
	CDER Learn the Safety Dance
	OTS MedDRA Training – I & II
	OCS Data standards training
	OCS JMP and JMP Clinical Training (multiple modules)
	FDA Library Electronic Resources
	FDA Library Training: Introduction to PubMed/EBSCO Host/Research Tool

DATE COMPLETED	Required CDER Medical Officer Updated Course List (with proposed scheduling)
9-12 Months	
	CDER Topics in Clinical Trials
	CDER Basic Statistical Methods
	CDER Negotiating with Confidence
	CDER Epidemiology in Drug Safety (classroom or online)
	CDER Presentations Skills: Speaking to Inform and Persuade
	CDER or OND Career Development and Individual Development Planning
	Communication or Interpersonal Skills courses (8-12 hours suggested)
Optional/As Needed	OIMT MS Outlook Intermediate
Optional/As Needed	OIMT MS Word Intermediate
Optional/As Needed	OIMT MS PowerPoint Intermediate
Optional/As Needed	OIMT MS Excel Introduction
12-24 months	
	CDER Basic Drug Law
	CDER Principles of Generic Drug Regulation and Review (in development)
	CDER Chemistry for the Non-chemist (classroom or online)
	CDER Toxicology for Non-toxicologists (online)
Optional	OCS MAED Training (multiple modules – Live and Online)
Optional	OCS JReview Training (multiple modules – Live and Online)
Optional/As Needed	OIMT MS Excel Intermediate
Optional/As Needed	OIMT MS Word Advanced

Complete a broad portfolio of review assignments appropriate to the medical officer's role and Office. As an example, the list should include most, if not all of the following for typical review assignments:

_____Review of new commercial and research INDs
_____Review of phase 2/3 protocols
_____Review of a SPA for a clinical protocol
_____Review of IND annual reports
_____Review of an original NDA/BLA and/or a major efficacy supplement
_____Review of NDA/BLA annual reports, involvement in assessment of postmarketing safety issues
_____Participation in an advisory committee meeting related to review of a NDA/BLA application
_____Representation of his or her discipline at appropriate meetings with sponsor

ATTACHMENT B -- Sample Memorandum of Recommendation for Conversion

Center for Drug Evaluation and Research Food and Drug Administration

To: _____, M.D.
Director, Office of
_____

From: _____, M.D.
Director, Division of
_____

Date:

Subject: Recommendation for Conversion to Level 2, Reviewer.

This memorandum is to recommend and to justify the conversion of Dr. _____from the medical officer temporary appointment of level 1, associate reviewer, to the career conditional appointment of level 2, reviewer.

The initial recommendation for conversion was made by his or her supervisor (or team leader if director is the only supervisor)_____on _____ (date).

Dr._____joined the division on_____.

Dr._____has successfully completed all criteria necessary to be considered for this conversion as evidenced by the documentation in the conversion package which includes: summary of activities, training log, review examples, and most recent PMAP of record reflecting a rating of at least "Fully Successful" dated_____.

It is my pleasure to recommend Dr._____to you for consideration to be converted to the career conditional, level 2, reviewer.

_____, M.D.
Director, Division of _____

CC:
Supervisor
Team Leader
Management Officer
Program Specialist

file

ATTACHMENT C -- Checklist for Submitting a Level 2 Conversion Package

COMPONENTS OF THE CONVERSION PACKAGE:

- ☐ Summary of accomplishments
- ☐ Training log (Attachment A)
- ☐ Approved memorandum(s) for credit of in lieu of coursework (if applicable)
- ☐ Conversion memorandum providing recommendation for conversion from the division director to the office director (Attachment B is a sample)