
COMPLIANCE

MANAGEMENT OF CDER COMPLIANCE COORDINATING COMMITTEE

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PURPOSE This MAPP describes:

- The roles and responsibilities of the Compliance Coordinating Committee (CCC);
 - The procedures to be used for establishing compliance-related committees in the Center for Drug Evaluation and Research (CDER);
 - The structure and function of the various committees;
 - The procedures to be used in designating members to serve on such committees; and
 - The responsibilities of those designated to serve on such committees.
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BACKGROUND

CDER has formed many committees and working groups to address various compliance issues. These committees perform most effectively if the objectives of the committee and the responsibilities of its members are clearly defined. The work of each

committee should also be effectively communicated both within and outside of CDER. Coordination of the functions of these committees is desirable to ensure effective use of staff resources and to establish and maintain consistent policy in the Center. To achieve these various objectives with regard to compliance issues, CDER has established the CCC.

ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There will be some fluctuation in implementation as necessary given membership and workload demands.

- **CCC**
 1. **Chair** - The Compliance Coordinating Committee is presently chaired by the Director, Office of Compliance, or a designated representative.
 2. **Executive Secretary** - The Chairperson may act as Executive Secretary, or appoint either a full-time or part-time Executive Secretary to the Compliance Coordinating Committee.
 3. **Members** - Members of the Compliance Coordinating Committee include the Chair, the CDER Director, the CDER Associate Director for Policy, and representatives from the Office of Compliance (OC), Office of Pharmaceutical Science (OPS), Office of Review Management (ORM), and Office of Regional Operations (ORA/ORO). Membership should include Office/Division level personnel. There will be no term limits.
 4. **Other Participants** - With the concurrence of the CCC Chair, observers and consultants from other Offices, Divisions, Centers, or Federal government organizations may be included in the activities of the CCC to facilitate cross Center and/or Agency interactions.
- **Subcommittees**
 1. **Chairs and Vice-Chairs** - The Compliance Coordinating Committee will select a chairperson and, when desired, a vice-chair for each subcommittee, taking into account expertise and interest in the subject matter of the committee.

2. **Advisors** - Functional managers serve in an advisory capacity to subcommittees. These managers shall be capable of providing subcommittees expert advice to facilitate the subcommittee in meeting its objectives.
3. **Membership** - Members should be chosen to serve on committees based upon their qualifications, expertise and interest in the subject matter of the committee.

Invitations for representation should be offered to OC, each of the ODEs, OGD and other interested CDER Offices or FDA Centers as appropriate to the committee goals and expertise desired. Membership should be kept small (5 to 7 members on core subcommittees; generally no more than two from the same Division). To facilitate productivity of the committees, the use of smaller ad hoc working groups to address specific issues should be encouraged.

RESPONSIBILITIES

- **CCC**
 1. Facilitates communication between the Office of Compliance and other units within CDER.
 2. Develops policy on compliance issues in CDER and makes policy recommendations to higher agency management.
 3. Coordinates, facilitates and monitors the efforts of the subcommittees including: establishing committee structure, function and membership; assigning topics; reviewing and approving final committee products before transmission to CDER management for clearance.
 4. Coordinates resolution of compliance issues in CDER.
- **The Executive Secretary**
 1. Arranges and organizes meetings. Issues to be brought before the CCC should be directed to the attention of the Executive Secretary who will schedule them in consultation with the Chair of the CCC.
 2. Prepares summary minutes of each CCC meeting. Meeting minutes will

be made available to all CDER employees. The minutes will be filed electronically on the CDER common shared drive in the appropriate subdirectory.

3. Maintains files of committee activities.

- **Subcommittees**

1. Serve as a source of advice and assistance to CCC in responding to CDER staff on matters pertaining to compliance issues;
2. Develop, as needed, policies and procedures. New policies and procedures developed by the subcommittees should be circulated for comment widely in the Center to obtain the input of all who may be affected by them, and CCC concurrence shall be obtained before the policies and procedures are submitted to management for final signature; and
3. Establish working groups, with approval from CCC, on specific issues bringing in additional expertise as necessary.

- **The Chair of Each Subcommittee**

1. Schedules and conducts meetings of the committee as required to fulfill the committee's objectives. To implement this responsibility, the chair shall prepare an agenda and distribute it to the committee members in advance of each committee meeting. The vice-chair shall call and run meetings in the absence of the chairperson.
2. Prepares brief minutes of each meeting, distributes the draft for comment, finalizes the minutes, and notifies the members and chair of the CCC of their existence. Minutes are filed on the X: drive under the appropriate subdirectory. For those subcommittee chairs who do not yet have access to the X: drive, minutes should be provided to the Executive Secretary on diskette for filing on the CDER common drive.
3. Ensures that copies of all records of committee meetings and other deliberations of the committee are placed in a file for that specific committee to be maintained by the Executive Secretary for the CCC, and ensure that copies of all records of committee meetings and other deliberations of the committee are placed in that file,

4. Creates and maintains, with the assistance of the committee members, a task list for the committee describing major tasks the committee is undertaking, projected milestones and completion dates, and the current status of each project. The chair serves as, or appoints a committee member to serve as the, project manager for the subcommittee.
5. Reports to the CCC on the activities of the committee as needed. In preparation for each report, the chair should provide to the CCC, at least a week in advance of the meeting, an updated task list, a summary of achievements since the last report to the CCC, a projection of activities for the next six months, and a list of issues for which CCC input is needed.

- **Advisors of Subcommittees**

1. As functional managers familiar with departmental operations, advisors are responsible for assisting members of the subcommittees in identifying project objectives.
2. Provide expert guidance and advise to subcommittees as needed.
3. Conduct periodic reviews of the subcommittee to assess its progress in accomplishing project objectives.

- **Members of Subcommittees**

1. Represent their division's/office's views on issues considered by the subcommittees that pertain to their areas of responsibility;
 2. Communicate with their division\office management about the deliberations of the subcommittees.
 3. Regularly attend the meetings of the subcommittees for which they are the designated representatives. If a member cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the chair.
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PROCEDURES

- **Meetings** - Meetings of the CCC are held monthly or as needed.

- **Reports** - All CCC meetings will result in reports documenting issues presented to the CCC membership, announcing committee decisions and the rationale for each decision. Copies of the reports will be distributed to CCC members and the original reports will remain with the committee chair and/or the Executive Secretary. Recommendations made by the CCC will be delivered to the person or organization that sponsored the discussion for their disposition and action.
- **Creation of New Subcommittees or Working Groups** - Suggestions for the creation of new subcommittees, including ad hoc working groups that may report to CCC directly or to a subcommittee, should be made in writing to the CCC.

Each suggestion should be accompanied by a brief statement of the proposed objectives of the subcommittee, the names of persons who might serve on the subcommittee as members, advisors, or chairs and vice-chair, the expected frequency of meetings, and the subcommittee's expected life (e.g., three months, on-going).

The CCC will determine whether the subcommittee should be established and will notify affected CDER staff of the creation of a new compliance-related subcommittee. A list of current subcommittee members will be maintained by CCC.

Changes in the membership or objectives of a subcommittee should be submitted to the CCC for concurrence.

- **Disbandment of Subcommittees or Working Groups** - A subcommittee shall be disbanded when:
 1. It reaches the end of its scheduled lifetime;
 2. It has fulfilled its objectives; or
 3. The CCC determines the subcommittee is not fulfilling a necessary function in the Center.

Every six months, the CCC shall review the list of subcommittees to determine whether any of the subcommittees on the list should be disbanded or the membership or chair changed. If, after discussions with the chair of the subcommittee, it appears that a subcommittee no longer performs a useful function, the CCC shall issue a notice recommending that the subcommittee be

disbanded. A copy of this notice will be filed in the appropriate subdirectory on the X: drive with the title "FINAL."

- **Dispute Resolution** - One of the primary functions of the CCC is to serve as a forum for dispute resolution for compliance issues that arise in the Center. The chair of the CCC is responsible for bringing upper management perspective to resolution of disputes involving compliance issues. If the CCC cannot reach agreement on a particular issue, the issue should be brought to the attention of Center management for resolution.

 - **Communications with CCC Members and Management**
 1. The activities of the CCC will be communicated to the staff in CDER through distribution and electronic filing of the minutes of the CCC and subcommittee meetings.
 2. A monthly meeting of the CCC members will serve as the mechanism for facilitating communications between the CCC members and CDER staff.
 3. CDER staff may raise issues to the CCC by bringing them to the attention of:
 - a. The appropriate CCC representatives;
 - b. The Executive Secretary of the CCC;
 - c. Any CCC member; or
 - d. A subcommittee chair.
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EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A

**COMPLIANCE COORDINATING COMMITTEE
WORKING GROUPS****1. Active Pharmaceutical Ingredients Working Group**

Objectives: To develop guidance for the proper manufacture and handling of active pharmaceutical ingredients.

2. Pharmacy Compounding Working Group

Objectives: To identify the issues related to pharmacy compounding and suggest recommendations or solutions.

3. Evaluating Test Results Working Group

Objectives: To create guidance for the proper handling of out of specification analytical test results.

4. Pre-Approval Inspections Working Group

Objectives: To develop alternative criteria used for determining when a pre-approval inspection is needed in an effort to more efficiently use application review and inspectional resources.

5. Plant Readiness Working Group

Objectives: To identify the issues related to industry readiness and recommend processes to efficiently handle ANDA/NDA application submissions.

6. CDER AIP Working Group

Objectives: To draft a general MAPP that will capture the AIP procedures.

Attachment B

RECOMMENDATION FOR THE CREATION OF A CDER CCC SUBCOMMITTEE OR WORKING GROUP

1. Name of Committee:

2. Objectives:

3. Composition:

Chair:

Vice Chair:

Advisors:

Membership:

4. Meeting Frequency:

5. Completion Date:

Concur: _____ **Non-concur:** _____

Chair, CCC

Date