OFFICE OF PHARMACEUTICAL SCIENCE

Office of Pharmaceutical Science Coordinating Committee (OPS CC)

CONTENTS

PURPOSE

- This document describes the organization, membership, responsibilities, and procedures of the Office of Pharmaceutical Science Coordinating Committee (OPS CC) in the Center for Drug Evaluation and Research (CDER). OPS CC serves as a forum for identifying and discussing scientific, technical and regulatory issues that may require OPS to develop and implement applicable policy.

BACKGROUND

- Since the Office of Pharmaceutical Science was established, its staff has used forums such as the division directors and office directors meetings to identify, develop, and implement science policy within the organization. In addition, coordinating committees such as the Chemistry, Manufacturing, and Controls Coordinating Committee (CMC CC), the Complex Drug Substances Coordinating Committee (CDS CC), and the Biopharmaceutics Coordinating Committee (BCC) have served as forums for CDER scientists and policy development staff to discuss current scientific, technical, and regulatory issues and to manage the guidance development process. The coordinating committees formed technical committees and working groups, composed of staff having expertise and/or interest in specific topics, to address important scientific, technical, or regulatory issues and to develop guidances that describe the latest thinking by FDA on these issues. The OPS CC will assume the roles and responsibilities of the CMC CC, CDS CC, and BCC and serve as a forum for cross-cutting scientific, technical, and regulatory issues arising in OPS. In addition, OPS CC will assume the responsibilities for the management of working groups to address such issues.

REFERENCES

- MAPP 7200.1 – Management of the Chemistry, Manufacturing, and Controls Coordinating Committee
- MAPP 7210.3 – Management of the Complex Drug Substances Coordinating Committee

ORGANIZATION

- The following are general descriptions and explanations about the organization of the OPS CC. Organization of the committee may be adjusted due to changes in membership and/or workload.

OPS CC

1. **Oversight:** The OPS Office Director and Deputy Office Director manage the OPS CC.

2. **Chair**: The OPS CC is chaired or co-chaired by a senior staff member(s) from OPS, who will be selected by the OPS director. The chair(s) will serve a two-year term. A chair may designate an acting chair if she/he is unable to attend a meeting.

3. **Membership**: The size of the OPS CC is approximately 11 members to provide an efficient forum for meeting the committee's objectives. In addition to the chair or co-chairs, OPS CC membership includes designees from the Office of New Drug Chemistry (ONDC), the Office of Generic Drugs (OGD), the Office of Biotechnology Products (OBP), the Office of Testing and Research (OTR) and the Associate Director for Microbiology.

4. **Management Leads:** Members of the OPS CC may be asked to serve as management leads to the ad hoc working groups.

5. **Project Manager/Executive Secretary**: One or more persons, designated by the chair or co-chairs, serve as project manager and/or executive secretary to the coordinating committee.

6. **Observers**: Invited staff from OPS, CDER and other Agency offices may attend OPS CC meetings as observers, when appropriate, based on their expertise or interest in a topic.

AD HOC WORKING GROUPS

- Working groups may be used to facilitate the initiatives of the OPS CC. A working group is a small, short-term ad hoc group that is formed to address specific issues of concern and to communicate the findings to OPS and the coordinating committee. The groups will develop recommendations for resolution of issues and decide on appropriate mechanisms or forums

for communicating scientific, technical, or regulatory information (i.e., internal training, stakeholder workshops, and guidances).

1. **Chair :** The OPS CC will select a chair for each working group, taking into account individual expertise, interest in the subject matter, and workload. As appropriate, the chair or co-chairs may lead a working group. The chair of the working group is expected to serve until completion of the project. If it is necessary to appoint a new chair before the project is completed, the OPS CC will select a replacement chair.

2. **Membership:** The working groups will include four to six members. Members will be chosen to serve on a working group based on their qualifications, expertise, and interest in the subject matter. Members are expected to serve until completion of a particular project. In the event that a working group needs extended time to complete its assignment, the OPS CC may identify new members to rotate into the working group.

3. **Observers:** When appropriate, and with OPS CC approval, individuals from Agency organizations may serve as observers of the working groups.

- **RESPONSIBILITIES**

  - **OPS CC is responsible for:**

    1. Developing and implementing guidances, policies, and procedures for quality product review for pharmaceuticals to facilitate consistent practices for submissions and reviews.

    2. Serving as a forum to discuss scientific, technical, and regulatory issues that may arise among CDER staff.

    3. Coordinating, facilitating, and monitoring the OPS CC ad hoc working groups, including:

       - Choosing management leads for working groups
       - Having responsibility for structure, function, and membership
       - Assigning projects
       - Reviewing and approving final work products (e.g., guidances, presentations) before sending to CDER management for clearance and approval
       - Serving as facilitators or resource staff for advice or problem solving as necessary
       - Reviewing the list of working groups at least once a year

    4. Promoting and coordinating discussion groups and other extramural activities related to OPS objectives and initiatives.

    5. Promoting internal research projects related to pharmaceutical quality activities at the office and center level.

    6. Establishing ad hoc working groups to address specific issues.

7. Providing scientific and technical information and recommendations to CDER staff, the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Devices and Radiological Health (CDRH), and others as necessary.

8. Providing recommendations for and collaborating with the Advisory Committee for Pharmaceutical Science and other CDER and/or Agency advisory committees on scientific and technical issues, as appropriate.

9. Serving as a forum for dispute resolution for science and regulatory issues (e.g., chemistry, bioequivalence, 505(j), and 505(b)(2)) that arise within the organization.

10. Assessing the need for and providing recommendations on the development of guidance documents, including guidances for industry, policy and/or procedure documents, concept papers, and topics for international and compendial harmonization.

11. Managing international activities, including the International Conference on Harmonisation (ICH) process, and establishing OPS roles and responsibilities.

12. Establishing liaisons and interactions with other CDER and FDA coordinating committees and task groups.

- **OPS CC chair or co-chairs are responsible for**:

1. Bringing the OPS, CDER, and Agency perspective to the guidances, policies, and procedures under development and to the resolution of scientific, technical, and regulatory issues.

2. Managing the OPS CC decision-making process.

3. Facilitating meetings, including developing and/or approving meeting agendas, assigning action items, defining responsibilities, and approving timelines.

4. Approving OPS CC derived documents as part of the CDER clearance process.

5. Approving the ad hoc working groups that are established by OPS CC to address specific issues.

6. Resolving differences among OPS CC participants on issues brought before the committee.

- **OPS CC members are responsible for:**

1. Establishing ad hoc working groups to address specific issues.

2. Providing input on issues before the OPS CC and participating in the decision-making process.

3. Acting as technical reviewers for OPS CC related documents before the documents start through the CDER clearance process.

- **The management lead is responsible for:**

1. Managing the ad hoc working group to which he/she has been assigned.

2. Working with OPS CC to identify potential members for the group.

3. Attending working group meetings.

4. Reviewing and sharing periodic reports from the group chair(s).

5. Serving as facilitator, resource, and advisor to the group.

6. Continuing as point person for specific project topic and any pending issues after disbandment of working group.

- **The executive secretary/project manager is responsible for**:

1. Scheduling regular OPS CC meetings and meetings related to specific issues in consultation with the OPS CC chair or co-chairs.

2. Preparing the agenda and summary minutes for each OPS CC meeting and making them available, as appropriate. The meeting minutes will be filed on the shared drive (R:\\fda\cder\ops\opscc).

3. Maintaining the current membership list and organizational information.

4. Providing project management support for the OPS CC and, as necessary, for the ad hoc working groups. Responsibilities include maintaining data on projected milestones, completion dates, and current status of each project.

5. Ensuring that significant issues are brought to the attention of appropriate OPS management for resolution.

6. Maintaining archival records.

7. Assisting the ad hoc working groups in clearance procedures for release of information.

- **The observers are responsible for:**

1. Providing input on topics for OPS CC meetings and for meetings of ad hoc working groups, as requested.

2. Clearing attendance with their respective management teams and informing the executive secretary of their attendance prior to the OPS CC meeting.

- **The ad hoc working groups are responsible for:**

  1. Identifying concerns and proposing recommendations on technical documents, policies, and procedures to OPS CC.

  2. Sharing the resulting work products with other parts of the center to obtain their input, as appropriate.

  3. Serving as a source of advice and assistance to the OPS CC on various scientific, technical, and regulatory issues.

  4. Aiding in the development of responses to public inquiries and applying appropriate clearance procedures for the release of information.

  5. Tracking milestones and providing updates to the OPS CC on respective project assignments.

  6. Communicating with colleagues within CDER and other Agency offices when issues have the potential to impact multiple groups in the Agency.

  7. Obtaining public input on technical issues in accordance with good guidance practices (GGPs).

  8. Sending periodic reports from the group chair to the appropriate OPS CC management lead for review and providing a copy to the executive secretary/project manager.

PROCEDURES

- **Communications with OPS CC members and other OPS staff:** Activities of the OPS CC will be communicated to appropriate staff members through the distribution and electronic filing of meeting minutes.

- **Mechanism for bringing issues before OPS CC:** FDA staff may submit topics to the OPS CC by: (1) raising the topic at routine team or division meetings, or (2) taking the topic to the chair of the appropriate ad hoc working group, to the OPS CC chair/co-chairs or project manager/executive secretary.

- **Technical documents:** When an ad hoc working group determines that a technical document (e.g., guidance, concept paper) should be developed, the chair will bring the recommendation before the OPS CC. The OPS CC will decide whether the document is appropriate and, if so, who should be responsible for writing the document. Guidance documents are to be developed in accordance with GGPs.

- **Establishment of new ad hoc working groups:** New working groups may be established as follows:

1. The OPS CC may establish a new working group because a scientific, technical, and/or regulatory issue needs to be addressed. Interested members of the OPS CC may identify and contact potential members for the new working group. The OPS CC will also identify the management lead from current membership of the OPS CC.

2. Agency staff may suggest the formation of a working group to address a scientific, technical, or regulatory issue by completing the form, "Recommendation for Establishing an Ad Hoc Working Group Under the Office of Pharmaceutical Science Coordinating Committee (OPS CC**)**" (see Attachment 1). The proposal should include a statement of the proposed objectives for the group, suggestions for membership, chair/co-chair, and the expected timeframe for completion of the project.

- **Disbandment of ad hoc working groups:** OPS CC will disband an ad hoc working group when: (1) it fulfills its objectives or (2) OPS CC determines that the group is no longer necessary.

  The group's management lead will continue as point person for the specific project topic and/or pending issues.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

ATTACHMENT A

RECOMMENDATION FOR ESTABLISHING AN AD HOC WORKING GROUP UNDER THE OFFICE OF PHARMACEUTICAL SCIENCE COORDINATING COMMITTEE (OPS CC)

Proposed Name for the Committee:

Objectives for the Proposed Committee:

Composition (If you have suggestions for the following positions, please include them below.):

- **Chair:**
- **Vice-chair:**
- **Membership:**

Projected Meeting Frequency:

Target Completion Date:

Submitted by:

☐ **OPS CC Concurrence** ☐ **OPS CC Non-concurrence**

_____ _____

Chair/Co-chair OPS CC **Date**

_____ _____

Chair/Co-chair OPS CC **Date**

Comments: