PROGRAM DESCRIPTION

OFFICE OF NEW DRUGS

Regulatory Project Management Coordinating Committee

Table of Contents

PURPOSE

This MAPP describes:

- The roles and responsibilities of the Regulatory Project Management Coordinating Committee (RPMCC) in the Center for Drug Evaluation and Research (CDER)

- The procedures for establishing RPMCC subcommittees

- The structure and function of the RPMCC and its subcommittees

- The procedures for designating members to serve on the subcommittees

- The responsibilities of the members designated to serve on the subcommittees

BACKGROUND

- CDER has multiple committees and working groups that address various issues related to regulatory affairs and project management. Coordination of these committees ensures effective use of staff resources and establishes and promotes consistent project management policy throughout CDER. To achieve these objectives, the Office of New Drugs established the RPMCC, with an Executive RPMCC (ERPMCC). The RPMCC and ERPMCC were expanded in 2007 to include all CDER offices involved with the review of investigational new drug applications, new drug applications, abbreviated new drug applications, and biologics license applications.

Originating Office: Executive Regulatory Project Management Coordinating Committee
Effective Date: 2/26/96, 11/6/02, 5/6/2008, 06/13/13, 09/05/18

Page 1 of 5

RESPONSIBILITIES AND PROCEDURES

The RPMCC will:

- Meet monthly to discuss and review issues that would have a significant effect on regulatory project managers (RPMs) involved in application review, issues that require or would benefit from input from the RPMCC, and large expenditures from the RPMCC budget, as well as other review management and regulatory affairs issues.

- Propose agenda items for the monthly meeting to the person serving as the Executive Secretary of the ERPMCC/RPMCC.

- Communicate information from the monthly meeting to the RPM/consumer safety officer (CSO) staff as needed.

- Provide advice to the Center, Agency, Department, and regulated industry on project management as well as other review management and regulatory affairs issues.

- Develop strategies for accomplishing long- and short-term regulatory project management goals in CDER.

- Develop, recommend, and document policies and procedures (i.e., MAPPs) relating to project management and regulatory affairs.

- Coordinate, facilitate, and monitor the efforts of the RPMCC subcommittees. This includes helping resolve jurisdictional issues that might affect other technical committees (e.g., the Chemistry, Manufacturing, and Controls Coordinating Committee), divisions, offices, or centers.

- Promote and support professional development workshops and other intramural and extramural activities related to project management and regulatory affairs.

- Promote and support CDER's Division of Learning and Organizational Development training in project management, team building and related management approaches, and providing regulatory expertise for CDER staff.

The ERPMCC will:
- Meet monthly to address issues that come before the RPMCC. The ERPMCC meeting is usually held immediately before the RPMCC meeting.

- Establish new subcommittees as needed, generally in consultation with the full RPMCC.

- Modify or disband subcommittees when they are no longer needed.

Originating Office: Executive Regulatory Project Management Coordinating Committee
Effective Date: 2/26/96, 11/6/02, 5/6/2008, 06/13/13, 09/05/18

Page 2 of 5

- Make decisions on routine matters, including allocation of the RPMCC budget.

- Determine which issues should be brought before the full RPMCC. Such issues would normally include any issue that would have a significant effect on RPMs involved in application review, issues that require or would benefit from input from the RPMCC, large expenditures from the RPMCC budget, and other issues of interest to the committee.

- Review requests for speakers on project management and regulatory affairs subjects.

- Review presentations to be made by RPMs or CSOs on project management and regulatory affairs subjects.

- Maintain distribution lists for both the RPMCC and the ERPMCC.

The Chair of the ERPMCC/RPMCC will:

- Provide overall direction to the RPMCC

- Coordinate with the ERPMCC on requests for speakers on project management and regulatory affairs issues by circulating them to the committee for consensus

- Set the agenda for and chair the ERPMCC and RPMCC monthly meetings

- Communicate about RPMCC activities to CDER management when appropriate or when requested

The Executive Secretary of the ERPMCC/RPMCC will:

- Communicate decisions made by the ERPMCC to staff and management as appropriate

- Prepare minutes of the RPMCC monthly meeting, distribute them via email to the CDER-RPM distribution list, and post them on the RPMCC shared drive using the established file naming convention

Subcommittees will:

- Complete projects assigned by the RPMCC within agreed-upon time frames

- Ensure that proposals for programs, policies, and procedures developed by the subcommittees are submitted to the ERPMCC for review and approval before broader circulation for comment

- Establish working groups, as necessary, to bring in additional expertise on specific issues

Originating Office: Executive Regulatory Project Management Coordinating Committee
Effective Date: 2/26/96, 11/6/02, 5/6/2008, 06/13/13, 09/05/18

Page 3 of 5

The Chairs or Co-Chairs of Subcommittees will:

- Report to the RPMCC at least annually to describe the status of all projects in which their subcommittee is engaged, and obtain RPMCC input and direction.

- Schedule and conduct meetings to fulfill the subcommittee's objectives. The Co-Chair will assume the responsibilities of Chair in his or her absence.

- Maintain appropriate files on subcommittee work.

- With assistance of the subcommittee members, create and maintain a task list for the subcommittee describing major tasks the subcommittee is undertaking, projected milestones and completion dates, and the current status of each project.

- Obtain input from the ERPMCC on documents proposing programs, policies, or procedures before distribution to individuals or groups outside CDER or to CDER staff other than the RPMCC or its subcommittees.

Members of Subcommittees will:

- Represent the views of their discipline, division, or office on issues considered by the subcommittee

- Obtain concurrence from management for their participation on the subcommittee and communicate with their discipline, division, or office management (whichever is appropriate) regarding the deliberations of the subcommittee

- Regularly attend the meetings of the subcommittees for which they are designated members, and contribute to the work of the subcommittees

ORGANIZATION

The following descriptions and explanations apply on a general basis. Workload demands may cause some fluctuation in implementation.

- **The RPMCC**

  – The RPMCC has two major components:

    1. **RPMCC** — The RPMCC consists of CDER associate directors for regulatory affairs (ADRAs) and staff in other equivalent roles, and CPMSs and staff in equivalent positions, for CDER offices involved in application review. The monthly CPMS meeting will be used to present issues to the full RPMCC.

Originating Office: Executive Regulatory Project Management Coordinating Committee
Effective Date: 2/26/96, 11/6/02, 5/6/2008, 06/13/13, 09/05/18

Page 4 of 5

2. **Executive RPMCC** — The ERPMCC consists of the ADRAs or equivalents for the CDER offices involved in application review. The ERPMCC will manage routine matters that come before the ERPMCC. At the discretion of the ERPMCC, matters that merit broader input will be brought before the full RPMCC for discussion. Matters may be referred to any ADRA or equivalent to be brought before the ERPMCC.

   – Chair — The position of Chair of the ERPMCC/RPMCC will rotate among members of the ERPMCC on a monthly basis.

   – Executive Secretary — The position of Executive Secretary of the ERPMCC/RPMCC will rotate among the members of the ERPMCC on a monthly basis.

- **Subcommittees**

   1. **Subcommittee Chairs and Vice Chairs (Co-Chairs)** — The ERPMCC will select a Chair and Co-Chair for each subcommittee, taking into account expertise and interest in the subject matter of the subcommittee, workload, and organizational and management skills. Alternatively, the ERPMCC may delegate selection of the Chair and Co-Chair to the subcommittee membership.

   2. **Membership** — Subcommittee members should be RPMs, CSOs, or other regulatory project management-related positions involved in application review, and should be chosen by the subcommittee Chair and Co-Chair with members' supervisory concurrence, taking into account their qualifications, expertise, workload, interest in the subject matter of the subcommittee, and the demands on their time caused by membership on other committees. In general, no person should serve on more than two subcommittees at one time. Membership should be distributed with the goal of achieving broad representation within affected offices, provided that the individuals selected possess adequate experience and skills to address the work of the subcommittee. Members who do not contribute to the work of the subcommittee (e.g., do not attend meetings) will be removed from the membership roster.

   To facilitate productivity of the subcommittees, use of smaller, short-term, ad hoc working groups to address specific issues is encouraged. Subcommittees may create working groups on specific issues bringing in additional expertise as necessary.

EFFECTIVE DATE

This MAPP is effective upon date of publication.