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**POLICY AND PROCEDURES**

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**OFFICE OF THE CENTER DIRECTOR**

**Collaboration in Managing the CDER Drug Quality Oversight Program**

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**PURPOSE**

The purpose of this MAPP is to promote communication, collaboration, and operational transparency between the Office of Pharmaceutical Science (OPS) and Office of Compliance (OC) in managing CDER’s drug quality oversight program.

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**BACKGROUND**

FDA’s drug quality oversight program was established to ensure that the knowledge, controls, and decision-making processes needed to maintain a high-quality drug supply are in place throughout the pharmaceutical sector. In support of that program, OPS and OC serve as equal partners in managing CDER’s drug quality oversight program, and they are expected to work collaboratively to produce the optimum public health outcome. Each office has different, critical roles and responsibilities that are frequently interdependent, so collaboration and coordination are essential.

In response to that need, this MAPP was developed to document the overarching principles and processes for supporting communication and collaboration between OPS and OC and encouraging operational transparency. It is important that these collaborations be based on modern and sound scientific principles to facilitate the overall regulation of product quality.

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**POLICY**

OPS and OC will follow the procedures set forth in this MAPP to ensure collaboration. Each office will implement detailed procedures for these activities—along with other interactive processes and standards—through each office’s quality management system.

Policy and procedures that affect both offices and the joint quality oversight program will be developed through interdisciplinary teams or directly through CDER’s Quality Coordinating Committee (QCC). Policy and procedures that affect a single office will be developed independently but shared with the other office. Policy and procedures will be documented within each office’s quality management system.

To ensure that staff in both OPS and OC are focused on the (1) need for significant interaction to ensure drug product quality and (2) appropriate processes and policies that govern these interactions, OPS and OC will support integration of their quality management systems. These systems will be documented and, where applicable, coordinated with the Office of Regulatory Affairs’ quality system. As processes and policies are revised, OPS and OC will work together to ensure changes effectively meet each office’s internal requirements.

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**RESPONSIBILITIES****Office of Compliance**

- OC is the lead organization for evaluating the adequacy of drug manufacturing practices and quality systems at facilities, based primarily on inspections, and for establishing policy for good manufacturing practice (GMP) standards and quality systems.

**Office of Pharmaceutical Science**

- OPS is the lead organization for reviewing the Chemistry, Manufacturing, and Controls (CMC) section of drug applications and for establishing policy and standards for CMC submissions.

**Quality Coordinating Committee**

- QCC, which reports to FDA’s Council on Pharmaceutical Quality (CPQ), serves as a forum for cross-cutting scientific and technical issues that arise regarding quality regulation in both review and inspection. QCC promotes innovation and ensures that regulatory decisions and standards are based on sound science.
- QCC will serve the following purposes for both OC and OPS:
  - As necessary, QCC will develop policy and standards to incorporate into quality systems and communicate with stakeholders.

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- QCC will discuss identified industry practices and procedures to confirm that a practice or process is an innovative technology and organize a working group to develop and implement any needed regulatory policy.
  - As necessary and according to a process to be documented in the Committee charter, QCC will resolve disputes between OC and OPS offices or individuals when differences cannot be resolved at lower management levels.
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## PROCEDURES

- A. In interacting on issues and developing policies and procedures that affect the regulation of drug product quality, OPS and OC will:
- Collaborate and coordinate on issues under the drug quality oversight system throughout the drug product lifecycle.
  - Ensure that policies, procedures, standards, and decisions are science- and risk-based and incorporate modern and sound scientific principles and new technologies.
  - Ensure an integrated quality systems approach.
  - Ensure good communication between OPS and OC regarding the drug quality oversight system, including appropriate information sharing.
  - Resolve issues in a timely manner through appropriate collaborative mechanisms as documented in each office's quality management system.
  - Follow the tenets of the Equal Voice Initiative (see MAPPs 4151.1 R.1, *Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain*; 4151.2 R.1, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director*; and 4151.8, *Equal Voice: Discipline and Organizational Component Collaboration in Scientific and/or Regulatory Decisions*).
- B. Provided below are procedures that OPS and OC will follow throughout the drug product life cycle. (Attachment 1 shows how these activities intersect throughout the life cycle.)
1. *New Drug Application (NDA)/Abbreviated New Drug Application (ANDA) Preapproval Inspections*
- a. **Identify all establishments involved.** During OPS's initial review of a submission, it is important for OPS to identify all establishments involved in the manufacture of drug products (e.g., facilities that manufacture, process, label, pack, hold, or perform testing and quality control) and share its findings with OC in a timely manner.

- b. Maintain communication during the review timeframe.** OPS and OC will maintain communication during this time to ensure that appropriate establishments are inspected and field inspectors are aware of any specific product quality or compliance issues.
- c. Share establishment evaluation outcomes.** OC will share evaluation and inspection outcomes with OPS in a timely manner to support the final recommendations related to the application.

## 2. *NDA/ANDA Postapproval Changes*

- a. Identify all establishments involved.**
  - During OPS's review of supplements, it is important for OPS to identify any new establishments involved in the manufacture of drug products (e.g., facilities that manufacture, process, label, pack, hold, or perform testing and quality control) and major manufacturing changes and share its findings with OC in a timely manner.
  - OPS and OC will use discussion to resolve any ambiguities, as well as identify any medically necessary products that might be involved.
- b. Maintain communication during the review timeframe.** OPS and OC will maintain communication during the review timeframe to ensure that appropriate establishments are inspected and that field inspectors are aware of any specific product quality or compliance issues.
- c. Share establishment evaluation outcomes.** OC will share evaluation and inspection outcomes with OPS in a timely manner to support the final recommendations related to the submission.

## 3. *Biologics Licensing Application (BLA) Prelicensing Inspections*

- a. Determine need for establishment inspections.** During the review of a BLA, OPS and OC will collaboratively evaluate the establishments used in the manufacture of the product and determine the need for inspections.
- b. Conduct collaborative inspections.** OPS and OC will hold pre-inspection planning meetings. An OC-led team will conduct the inspections and prepare the inspection report.

## 4. *BLA Postlicensing Supplements*

- a. Determine need for establishment inspections.** During the review of a BLA supplement, OPS and OC will collaboratively determine which office will lead

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the review based on the content of the supplement and whether an establishment inspection is necessary.

- b. Conduct collaborative inspections.** An OC-led team will conduct the inspections and prepare the inspection report. The lead office will document the review results with the inspection team's involvement.

5. *Ongoing Collaborative Evaluation of Defects and Incidents*

- a. Share notification of potential defect or incident.** Whether OC is notified of a potential defect or OPS identifies a potential manufacturing defect during a quality review, communication between offices will occur in a timely manner to ensure collaboration during FDA's evaluation of the potential defect.
- b. Develop collaborative response.** OPS and OC reviewers and OC compliance officers will maintain close coordination, as well as discuss issues such as the potential for drug shortages or other disruptions to the drug supply, to arrive at appropriate compliance actions and recommendations.

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**REFERENCES**

1. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.1 Rev. 1: Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain.
2. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2 Rev. 1: Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director.
3. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component.

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**EFFECTIVE DATE**

This MAPP is effective 2/1/2013.

ATTACHMENT 1: Collaboration throughout the Pharmaceutical Product Life Cycle

