POLICY AND PROCEDURES

OFFICE OF PHARMACEUTICAL QUALITY

Process for Evaluating Emerging Technologies Related to Quality

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PURPOSE

This MAPP describes the policies and procedures to be followed by the Office of Pharmaceutical Quality (OPQ) and the Emerging Technology Team (ETT)[1] in the Center for Drug Evaluation and Research (CDER) either for reviewing a prospective applicant's request[2] to participate in the Emerging Technology Program (ETP)[3] or for providing input on an emerging technology identified in a regulatory submission. This MAPP also broadly describes the role of the ETT in providing quality assessments of the emerging technology-related components of the chemistry, manufacturing, and controls (CMC) portion of an applicant's or prospective applicant's regulatory submission (e.g., an investigational new drug application (IND), a new drug application (NDA), a biologics license application (BLA), an abbreviated new drug application (ANDA), a CMC supplement or amendment to an application, or an application-related drug master file submission).

This MAPP is intended to enhance the interoffice communications of the Food and Drug Administration (FDA), FDA's evaluation of presubmission information or data, collaboration between CDER offices and the Office of Regulatory Affairs about FDA's quality assessment of an application, coordination within FDA on facility

[1] The ETT comprises relevant representatives from all Food and Drug Administration pharmaceutical quality and inspection offices.

[2] In this document, the term *request* refers to a request for Agency input on an emerging technology made by a prospective applicant prior to any regulatory submission.

[3] The ETP allows a prospective applicant to submit questions or proposals to the ETT about the use of a specific emerging technology (i.e., a proposed novel technology that may be used by the pharmaceutical and related industries) prior to that prospective applicant's regulatory submission.

visits and inspectional activities, and FDA's documentation of regulatory activities pertaining to emerging technologies.

This MAPP does not replace existing policies and procedures related to the review of regulatory submissions; however, this MAPP does supplement those policies and procedures by describing the ETP's policies and procedures for providing prospective applicants with expertise-based input and recommendations on emerging technologies within planned regulatory submissions.

BACKGROUND

On December 23, 2015, FDA published a draft guidance for industry titled *Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base.* This draft guidance describes the ETP, which OPQ developed to assist prospective applicants that intend to identify an emerging technology in the CMC portion of their regulatory submission. Also, this draft guidance explains that this program encourages prospective applicants to interact with FDA on matters related to new technology development and implementation before they submit an application for CDER to review. This draft guidance further explains that interested applicants may submit, in advance of their application submission, requests to participate in the program and, if accepted, obtain input from FDA on the proposed technology. Early engagement with the Agency on emerging technologies is strongly encouraged. However, emerging technologies will also be identified within submitted applications during the course of the integrated quality assessment.

POLICY

1. General

- The ETT will serve as OPQ's primary contact for prospective applicants that are interested in implementing an emerging technology.

2. Participation in the ETP Prior to a Regulatory Submission

- The ETT will manage and evaluate all requests for consideration by prospective applicants, which are made and received through the CDER-ETT@fda.hhs.gov email account, to participate in the ETP.

- The ETT will make the final determination on the acceptance of a request to participate in the ETP.

- If a request is deemed acceptable (per established criteria), the ETT will collaborate with relevant FDA offices (e.g., the OPQ suboffices or the Office

of Regulatory Affairs) as needed to provide scientific and regulatory advice to the prospective applicant (i.e., before that applicant files a regulatory submission that identifies an emerging technology), following the procedures outlined in this document.

3. Assessment of an Emerging Technology Identified in a Regulatory Submission

- If an emerging technology is identified in a filed or received regulatory submission by OPQ staff (e.g., Branch Chiefs or reviewers from the relevant OPQ office) or at the request of an applicant, the responsible office/division will consult the ETT, and the ETT chair will determine whether an ETT member (or ETT members) should participate in the quality assessment of the regulatory submission (per the procedures outlined in this MAPP).

- If an emerging technology is identified in a filed or received regulatory submission and was assessed by the ETT prior to submission, the ETT member who completed the original consult will participate, as appropriate, in the review of the submission, including participating on the OPQ integrated quality assessment team[4] for the NDA, ANDA, or BLA. The OPQ integrated quality assessment process would then remain the same.

    - For NDAs, ANDAs, and BLAs, the ETT member will focus on the application review and facility evaluation or inspection pertaining to the emerging technology. If the emerging technology affects multiple parts of the CMC section of an application, a representative from the ETT will serve as the Application Technical Lead (ATL) or co-ATL on the OPQ integrated quality assessment team for that application.

RESPONSIBILITIES

1. **The ETT** will collaborate with relevant FDA offices, when appropriate, to:

    - Respond to questions from prospective applicants related to their emerging technology to facilitate the planning of their regulatory submission.

[4] The OPQ integrated quality assessment team (1) reviews the CMC section of original applications containing emerging technologies; (2) conducts quality assessments and on-site evaluations; (3) as needed, collaborates on writing part of the integrated quality assessment review that will be incorporated into the OPQ integrated assessment; and (4) makes the final quality recommendation regarding the approval of submissions. For emerging technology-related regulatory submissions, the OPQ integrated assessment team comprises representatives from relevant OPQ suboffices and from the ETT.

- Identify, and help facilitate the quality assessment of, a new product or manufacturing technology while following existing legal and regulatory standards, guidance, and FDA policy.

- Assign an ETT member to participate in the OPQ integrated quality assessment team.

- Assign an ETT member to serve as the ATL or co-ATL on the OPQ integrated quality assessment team, when appropriate.

- Identify and address any emerging technology policy issues.

2. **OPQ** will follow established internal procedures related to (1) the application review and assessment and (2) an inspection of the facilities listed in the application, when appropriate.

PROCEDURES

1. If an Emerging Technology Is Identified in a Presubmission ETP Request

a. The ETT will determine, based on the criteria for acceptance into the program as described in the FDA draft guidance, whether the request by the prospective applicant includes a sufficient justification for inclusion in the program.

b. If the request is accepted into the ETP, the ETT will manage all subsequent emerging technology-related communications with the prospective applicant prior to the regulatory submission.

c. The ETT will form a project team that includes members from all relevant FDA offices to complete a quality assessment of all emerging technology-related information in the request and in its supporting documents.

d. If a prospective applicant requests a face-to-face meeting as part of an emerging technology consultation, the ETT will work with relevant FDA offices, following established policies and procedures, to schedule the meeting, provide a preliminary meeting response, conduct the meeting, and provide meeting minutes.

e. If a prospective applicant requests an on-site visit by FDA to view and discuss technology *in situ* as part of an emerging technology consultation, the ETT will work with relevant FDA offices, following established policies and procedures, to determine the appropriate subject-matter experts to participate in the visit, coordinate the visit, provide FDA agenda items for the on-site meeting, and perform other follow-up activities as needed.

f. The ETT will archive any correspondence (including, for example, the request, any emerging technology-related communications, and any meeting minutes)

from the above interactions and make this correspondence available either to the relevant OPQ investigational new drug review team or to the NDA, ANDA, or BLA quality assessment team for reference during the submission phase of any relevant regulatory application.

2. If an Emerging Technology Is Identified in a Regulatory Submission

a. An ETT member will participate in the review of the emerging technology-related component according to the roles and responsibilities described above.

b. The quality assessment of the regulatory application will continue to be performed by the respective OPQ suboffices (such as the Office of New Drug Products, the Office of Biotechnology Products, the Office of Pharmaceutical Manufacturing Assessment, and/or the Office of Lifecycle Drug Products).

c. The roles and responsibilities of the Office of Program and Regulatory Operations Regulatory Business Process Manager, the OGD Regulatory Project Manager, and the OND Regulatory Project Manager—in managing emerging technology-related regulatory submissions—will remain the same, except that the ETT member will participate in the OPQ review team.

REFERENCE

- FDA guidance for industry, *Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base* (2017)

EFFECTIVE DATE

This MAPP is effective on October 19, 2017.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/19/2017	Initial	N/A
5/1/2020	N/A	Administrative: office name change from Office of Process and Facilities to Office of Pharmaceutical Manufacturing Assessment
12/1/2022	N/A	Recertified: no changes