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) for reviewing a prospective applicant's request[2] to participate in the Emerging Technology Program (ETP)[3], or 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. These submissions include investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), CMC supplements or amendments to an application, or application-related drug master file submissions.

This MAPP is intended to enhance the interoffice communications of the Food and Drug Administration (FDA), the FDA's evaluation of presubmission information or data, collaboration between CDER offices and the Office of Inspections and Investigations (OII) regarding the FDA's quality assessment of an application,

[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 in the pharmaceutical and related industries) prior to that prospective applicant's regulatory submission.

coordination within the FDA on facility visits and inspectional activities, and the FDA's documentation of regulatory activities pertaining to emerging technologies.

This MAPP does not replace existing policies and procedures related to the assessment of regulatory submissions. However, it does supplement those policies and procedures by describing the ETP's policies and procedures for offering prospective applicants recommendations regarding emerging technologies within planned regulatory submissions.

BACKGROUND

In September, 2017, the FDA published a final guidance for industry titled *"Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization"*. This guidance describes the ETP, which OPQ developed to assist prospective applicants that intend to include and identify an emerging technology within the CMC portion of their regulatory submission, explains that this program encourages prospective applicants to interact with the FDA on matters related to new technology development and implementation before submitting an application for CDER to assess, further explains that interested applicants may submit requests to participate in the program in advance of their application submission. If accepted, applicants can obtain input from the FDA on the proposed technology. The guidance strongly encourages early engagement with the Agency on emerging technologies. However, emerging technologies may 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 interested in implementing an emerging technology.

2. Participation in the ETP Prior to a Regulatory Submission

- The ETT will manage and evaluate all requests from prospective applicants to participate in the ETP. These requests should be submitted through the CDER-ETT@fda.hhs.gov email account.

- The ETT will make the final determination on the acceptance of requests 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 OII) as

needed, provide scientific and regulatory advice to the prospective applicant before they file a regulatory submission that identifies an emerging technology, and follow 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., Supervisors or assessors from the relevant OPQ suboffices) or at the request of an applicant, the responsible office/division will consult the ETT, and the ETT chair will determine whether ETT member(s) should participate in the quality assessment of the regulatory submission (per the procedures outlined in this MAPP).

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

    - The ETT member will focus on the application assessment 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.

    - 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.

[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 developing part of the integrated quality assessment 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 the ETT.

- 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, as appropriate.

- Identify and address any emerging technology policy issues.

2. **OPQ** will follow established internal procedures related to the application assessment and the inspection of 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 whether the request by the prospective applicant includes sufficient justification for inclusion in the program, based on the criteria for acceptance into the program as described in the FDA guidance.

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 andits 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 for participation 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 IND assessment 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 including the Offices of Product Quality Assessment I, II, III as well as the Office of Pharmaceutical Manufacturing Assessment.

c. The roles and responsibilities of the following staff in managing emerging technology-related regulatory submissions will remain the same: Office of Program and Regulatory Operations Regulatory Business Process Manager, the OGD Regulatory Project Manager, and the OND Regulatory Project Manager. The only change is that the ETT member will participate on the OPQ assessment team.

REFERENCE

- FDA guidance for industry, *Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization* (2017)

EFFECTIVE DATE

This MAPP is effective upon publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/19/2017	Initial	N/A
5/1/2020	N/A	Administrative edit: office name change from the Office of Process and Facilities to the Office of Pharmaceutical Manufacturing Assessment
12/1/2022	N/A	Recertified: no changes
6/11/2025	N/A	Administrative edit: office name change from the Office of Regulatory Affairs to the Office of Inspections and Investigations.