# Best Communication Practices with FDA

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# Industry Communication with FDA

- In the Office of Pharmaceutical Quality (OPQ), the Regulatory Business Process Manager (RBPM) is the main point of contact for all quality-related submissions.
- The first official communication regarding the submission will indicate the RBPM that will be the point of contact.
- Each quality-related submission type will have a different RBPM assigned, as RBPMs are not assigned to specific products.
- The RBPM is also the main point of contact for the Center for Devices and Radiological Health (CDRH) and the Office of Therapeutic Biologics and Biosimilars (OTBB) for all quality-related inquiries.

# Industry Communication with FDA

Topics about a specific submission that may be addressed informally include:

- General inquiries
- Questions regarding timelines
- Administrative questions

Preferred communication via email

# Industry Communication with FDA

A formal meeting request ensures the request is routed to the appropriate review team to ensure a thorough and timely review, and provides an official record

Topics may include:

- Questions regarding specific regulations
- Post-action questions
- Manufacturing questions
- Emerging Technology Program
- Questions specific to upcoming supplement submissions, including:
  - Appropriate category
  - Sufficient or appropriate data to include

# Formal Industry Communication with FDA

Meeting requests:

- Meeting packages must provide sufficient background information
- Please review FDA guidance on meeting requests to ensure the correct type of meeting is requested
  - Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products
- When referring to the guidance, please note the appropriate number and nature of questions that are permitted per meeting type
- When questions are more complex, please limit the number of questions

# Important Information For Submissions

Supplements with CMC information:

- Cleary state the proposed changes in the cover letter
- Provide manufacturing schedules during review cycle for additions of new manufacturing sites
- 356h forms should include all relevant manufacturing sites related to the proposed changes
- If the change contains Established Conditions, please include in the cover letter
- Clearly state on the cover letter if the change applies to a group of approved products, and list all applicable products
  - A cover letter and module 3 information should be submitted to each supplement within the group
  - For reference, see MAPP 5015.6: Review of Grouped Supplements (2022)

# Important Information For Submissions

## Emerging Technology Communication

- Industry representatives who meet the qualifications for the Emerging Technology Program should submit a written request to participate in the program along with a five-page proposal.
- The five-page proposal must include:
  - A brief description of the proposed emerging technology
  - A brief explanation why the proposed emerging technology is substantially novel and unique and should be considered under this program
  - A description of how the proposed emerging technology could potentially improve product safety, identity, strength, quality, or purity
  - A summary of the development plan and any perceived roadblocks to implementation (e.g., technical or regulatory)
  - A timeline for a submission
- Requests and proposals may be sent by email to: CDER-ETT@fda.hhs.gov

# End of Presentation