

Best Practices and Strategies for Communicating with FDA

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Learning Objectives

- Review OPQ communications during ANDA assessment cycle.
- Review best practices for communicating with OPQ.
- Provide resources to give additional details on the topics discussed.

OPQ Communications - POC



- Regulatory Business Process Manager (RBPM)
 - Primary point of contact (POC) for ALL OPQ-related communications internally and for industry
 - Works closely with OPQ assessment team and disciplines on your applications
 - Issues all communications related to the quality assessment during the assessment cycle

OPQ Communications - IR



- Information Request (IR) Letter
 - Further information/clarification needed to complete assessment throughout the assessment cycle
 - Single Quality sub-discipline or multiple Quality sub-disciplines
 - Requested response date
 - Communicated by letter, e-mail, or phone

OPQ Communications - DRL



- Discipline Review Letter (DRL)
 - Preliminary findings by the assessment team
 - May or may not represent management level assessment
 - Requested response date
 - Issued when Quality sub-disciplines have substantially completed assessments at around mid-point of the assessment cycle (Mid-Cycle Date)



Challenge Question #1

You've just received a Quality-related Information Request from OPQ. There is a comment that you are unclear about. Who should you contact first?

- A. Dr. Mike Kopcha – Director, OPQ
- B. Regulatory Project Manager (RPM, OGD)
- C. Regulatory Business Process Manager (RBPM, OPQ)
- D. Drug Product Assessor (OPQ)



Best Practices

Responding to IR/DRLs

- Responses to IR/DRLs should be complete and timely.
- Partial responses will not be accepted.
- Late responses may impact goal date or could be deferred until the next assessment cycle.
- Responses should only include information related to the IR/DRL. Additional/gratuitous information could impact timelines.

What if I need an extension to respond?



- Extension requests should be made as soon as possible by contacting the RBPM.
- The RBPM and assessment team will work together to determine if an extension will be granted.
- Your extension request should be done in a manner that provides you enough time to completely respond to the IR/DRL. Multiple extensions are not recommended.

Other Considerations



- Clearly outline all OPQ sub-disciplines impacted by the submission.
- Actively communicate with the Drug Master File (DMF) holder to anticipate submission timing.
- DMF submissions can impact that ANDA goal date.
- Ensure that ALL current facilities (including all relevant DMF facilities) and responsibilities are clearly listed on the 356h Form.

Other Considerations (cont.)



- Ensure that your cover letter for post-marketing submissions clearly indicate the type of change being submitted.
- For group supplements, be mindful of the implications of requesting changes to one application as it may impact all applications listed in the group.
- Ensure your e-mail is secure so communications can be timely. Request for secure e-mail can be sent to SecureEmail@fda.hhs.gov.

Challenge Question #2

Which of the following is true?

- A. Sending partial responses to IR/DRLs has no impact on goal dates.
- B. You do not need to communicate with the DMF holder after the application is acceptable for filing.
- C. Facility responsibilities don't need to be on the 356h.
- D. Having a secure email will ensure timely communication.

Summary

- Reach out to the RBPM for ALL Quality-related communications.
- Completely respond to all Quality IRs/DRLs by the requested response date.
- Be familiar with your ANDA assessment timeline and all possible communications.
- Reach out to the RBPM for ALL Quality-related communications.



Resources

- CDER Guidance Webpage: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>
- GDUFA Webpage: <https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>
- Good ANDA Submission Practices Guidance for Industry: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-anda-submission-practices-guidance-industry>
- CDER Small Business & Industry Assistance (SBIA): <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm>

Resources (cont.)

- Cover Letter Attachments for Controlled Correspondences and ANDA Submissions Draft Guidance for Industry : <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cover-letter-attachments-controlled-correspondences-and-anda-submissions-guidance-industry>
- ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/anda-submissions-amendments-and-requests-final-approval-tentatively-approved-andas>

Resources (cont.)



- Guidance for Industry: Information Requests and Discipline Review Letters Under GDUFA
 - <https://www.fda.gov/media/109915/download>
- MAPP 5220.5: Issuance of Information Request and/or Discipline Review Letters for ANDAs
 - <https://www.fda.gov/media/109649/download>
- MAPP 5015.6: Review of Grouped Product Quality Supplements
 - <https://www.fda.gov/media/72531/download>

Questions?

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