Application Communications: Quality Assessment Perspective

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Pharmaceutical Quality

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A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

assuring *every* dose is safe and effective, free of contamination and defects.

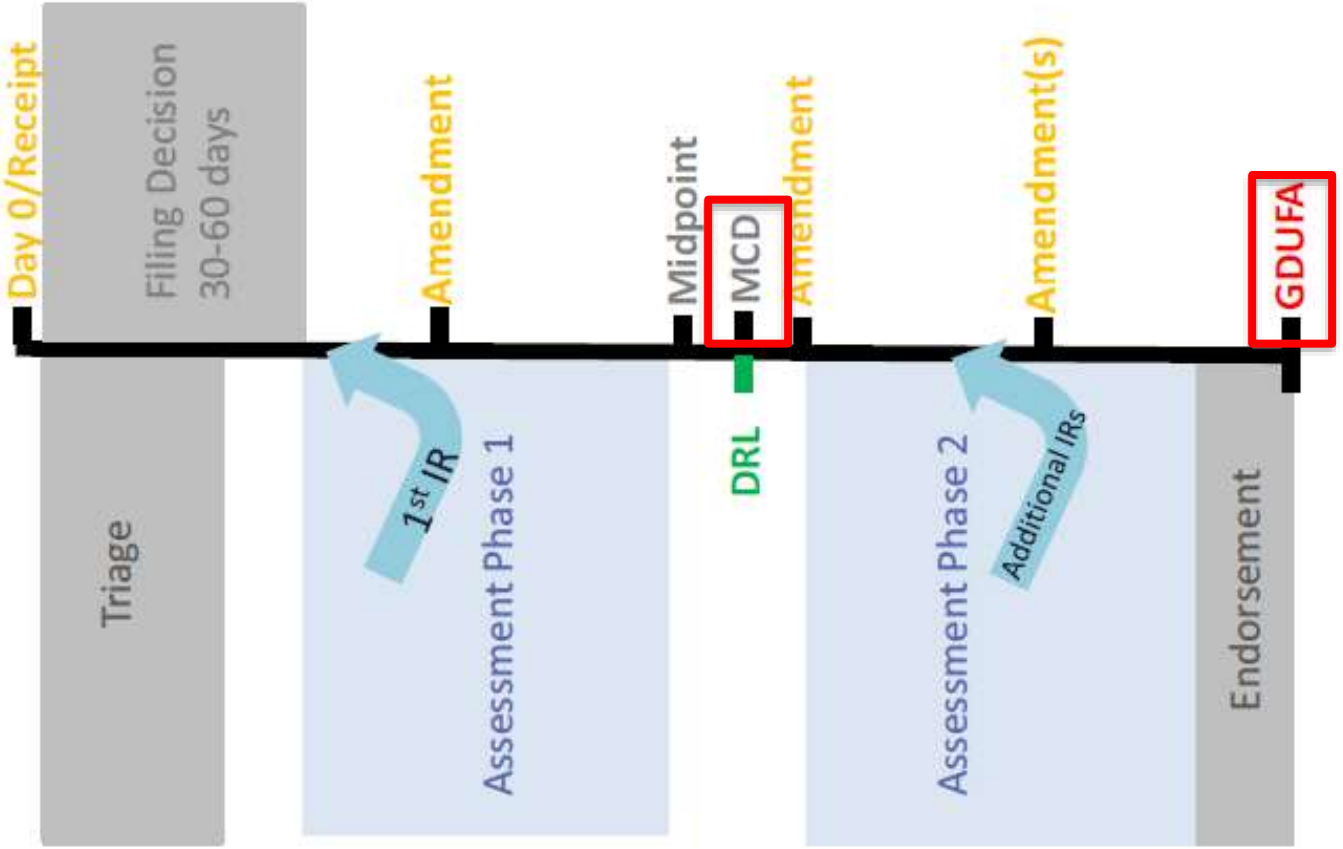

FDA
It is what gives patients confidence
in their *next* dose of medicine.

Learning Objectives

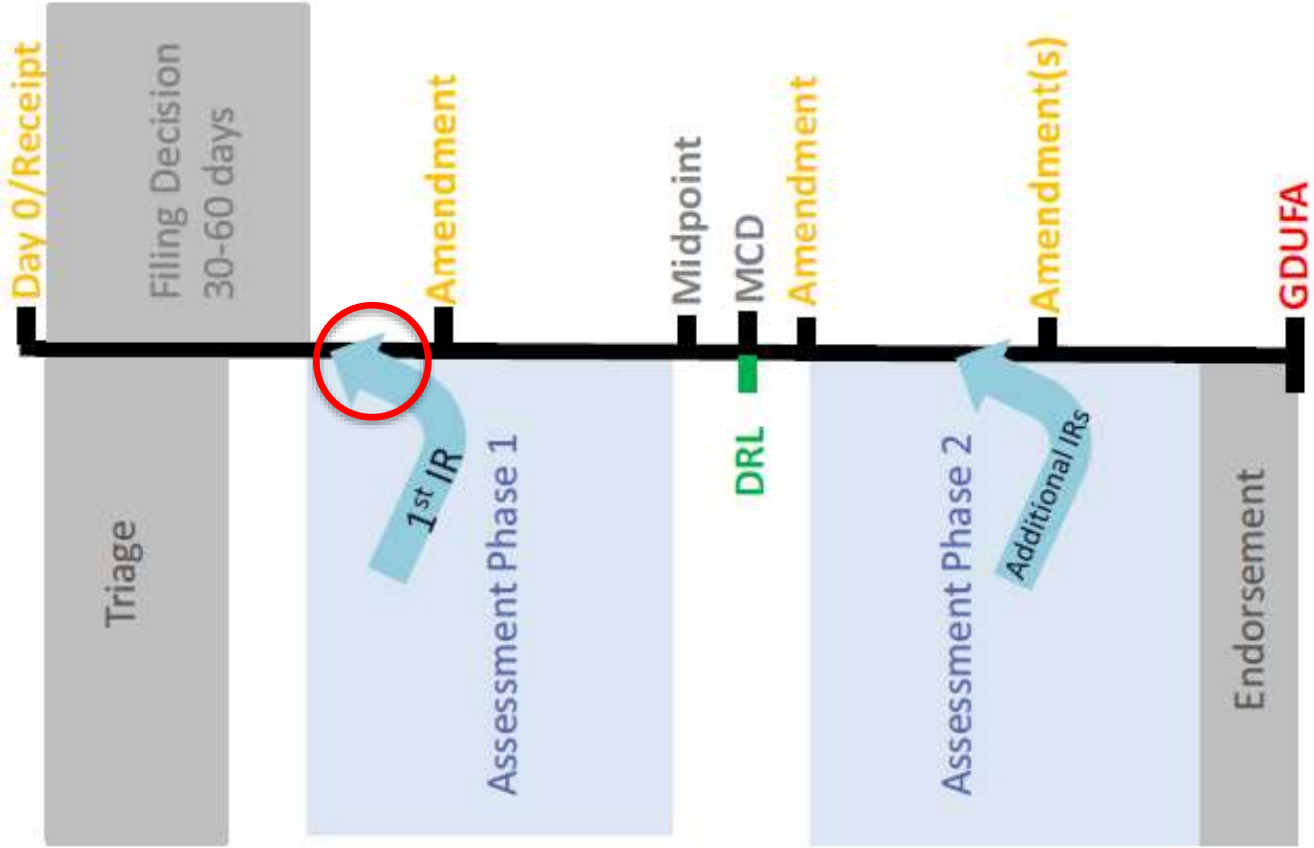
- Know the ANDA assessment timeline and identify OPQ communication timepoints
- Describe typical OPQ communications during ANDA assessment cycle
- Review Best Practices
- Review Frequently Asked Questions and Answers

Overview of ANDA Assessment Timeline and OPQ Communication Timepoints

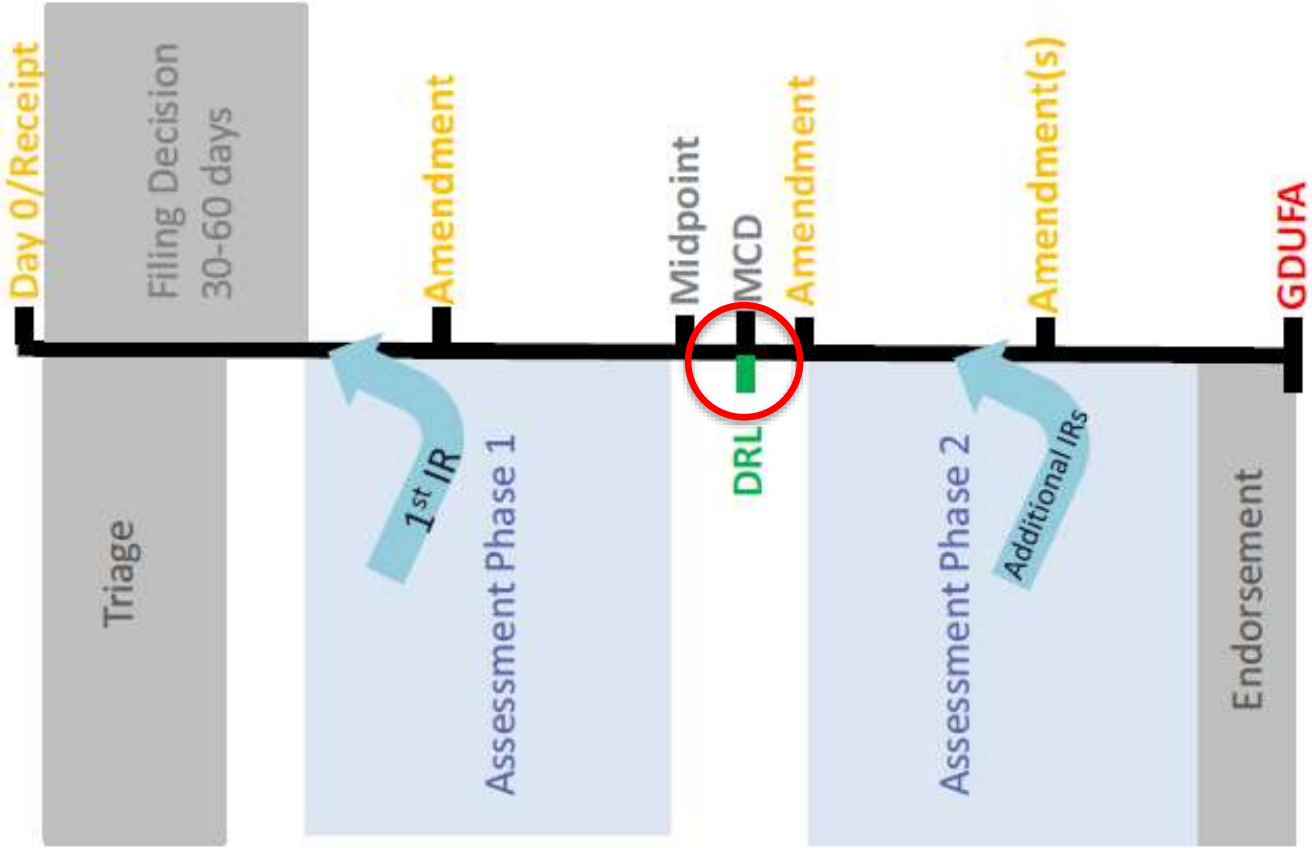
ANDA Assessment Timeline



OPQ Communication Timepoints



OPQ Communication Timepoints



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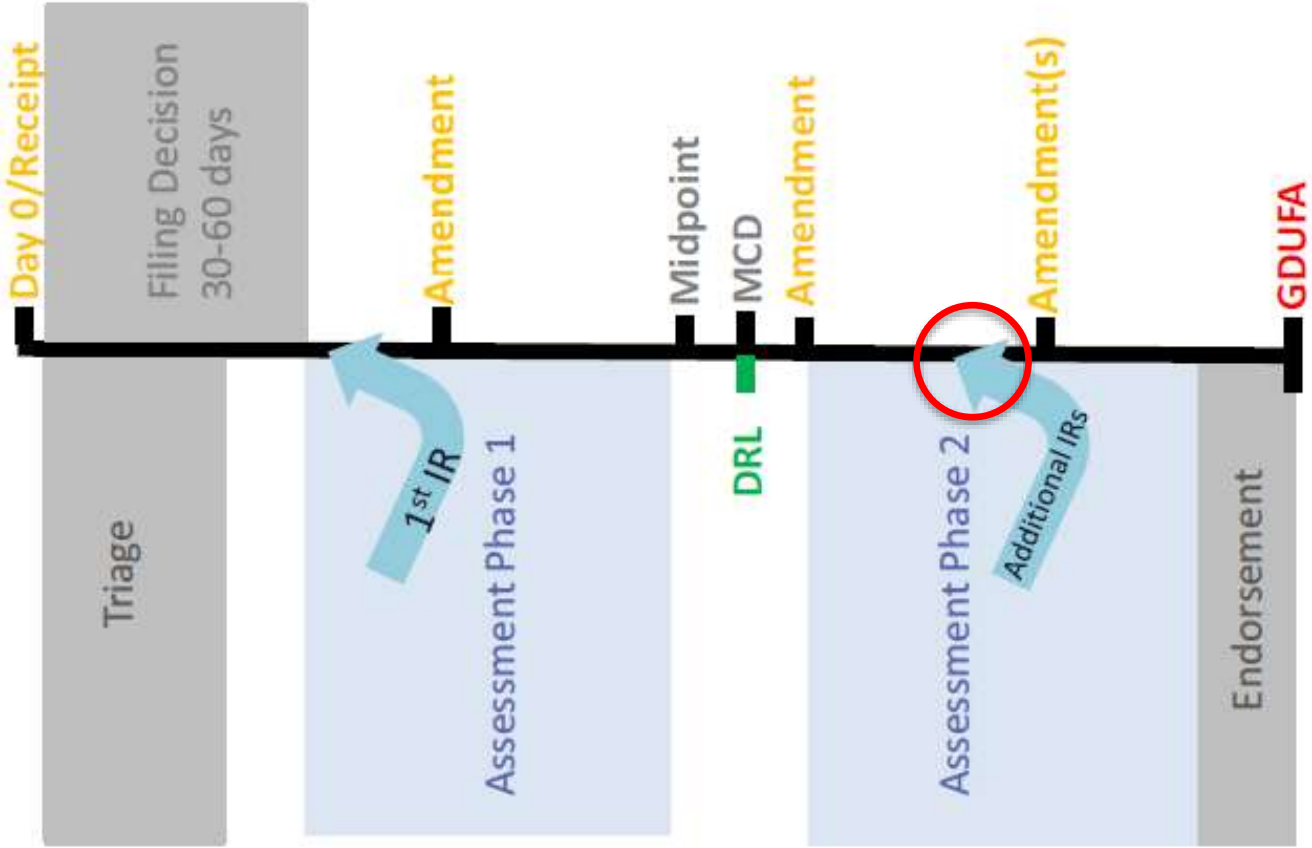

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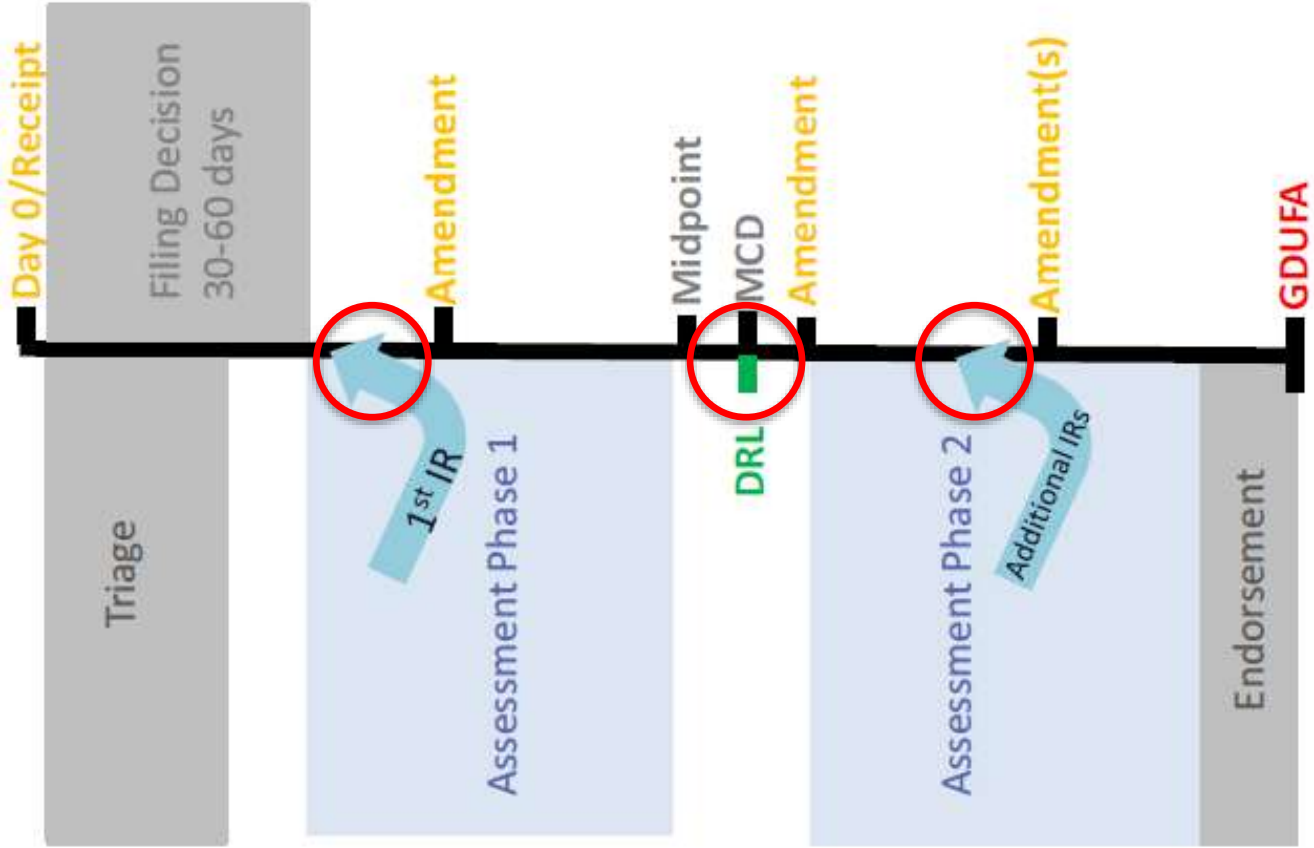

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D. The Mid-Cycle Date (MCD) is when the first IR letter is issued

Overview of OPQ Communications during ANDA Assessment Cycle

OPQ Communications

- 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

- 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)

Best Practices

Responses to IR/DRLs

- Respond to IR/DRLs completely and promptly!
  - Partial responses will **not** be accepted
  - Late responses may impact goal date or be deferred to next assessment cycle
  - Only respond with requested information (gratuitous information may impact assessment time and goal dates)

Extension Requests

- Request extensions (if needed) as soon as possible by contacting the assigned OPQ Regulatory Business Process Manager (RBPM)
  - RBPM is POC for all Quality communications

- The RBPM and assessment team will determine whether an extension request can be granted

Responses and GDUFA Goal Dates

- The following could impact the ANDA goal date or result in the amendment being deferred:
  - Late response to IR/DRL
  - Gratuitous information submitted within IR/DRL

*DMF responses could also impact the ANDA goal date

356h Form and Cover Letter

- 356h Form: ensure all current facilities and responsibilities are clearly listed

- Cover Letter: clearly outline all OPQ sub-disciplines impacted by submission

Secure E-mail

- Ensure your e-mail is secure for timely receipt of communications

- Requests for Secure E-mail can be sent to SecureEmail@fda.hhs.gov

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D. Late responses to Quality IR/DRLs may impact the GDUFA goal date

Frequently Asked Questions

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#1: What if we cannot respond to the IR/DRL within the requested response date?

– Notify RBPM as soon as possible

Frequently Asked Questions

#2: Are multiple extensions allowed to respond to the IR/DRL?

- It is recommended when requesting an extension to request for sufficient time to completely respond to the IR/DRL instead of asking for multiple extensions

Frequently Asked Questions

#3: Who should we contact if we have questions about a Quality-related communication?

- RBPM is your POC for all OPQ communications

Frequently Asked Questions

#4: Can we respond to some of the questions and provide a commitment for the remaining questions to be submitted at a later time?

- No, commitments will not be accepted as this would constitute a partial response

Resources

- Guidance for Industry: Information Requests and Discipline Review Letters Under GDUFA
  - https://www.fda.gov/files/drugs/published/Information-Requests-and-Discipline-Review-Letters-Under-the-Generic-Drug-User-Fee-Amendments--Draft-Guidance-for-Industry.pdf

- MAPP 5220.5: Issuance of Information Requests and/or Discipline Review Letters for ANDAs
  - https://www.fda.gov/media/109649/download

Summary

- Be familiar with ANDA assessment timelines and Quality communication timepoints
- Respond to all Quality IR/DRL questions/comments completely and in a timely manner
- Reach out to OPQ RBPM for all Quality-related communications

Thank you!


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