Late cycle deficiencies and Industry perspective

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Disclaimer

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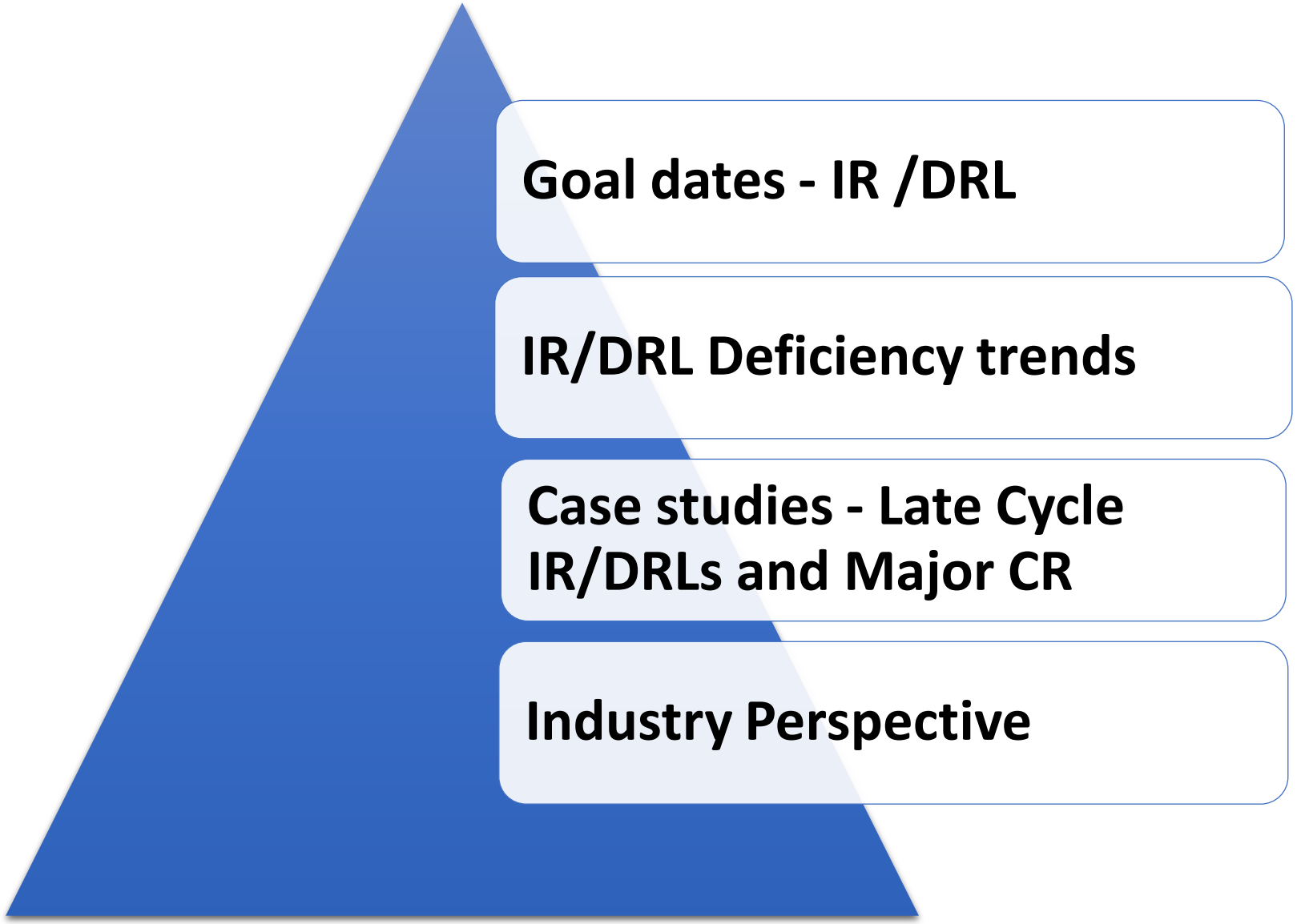
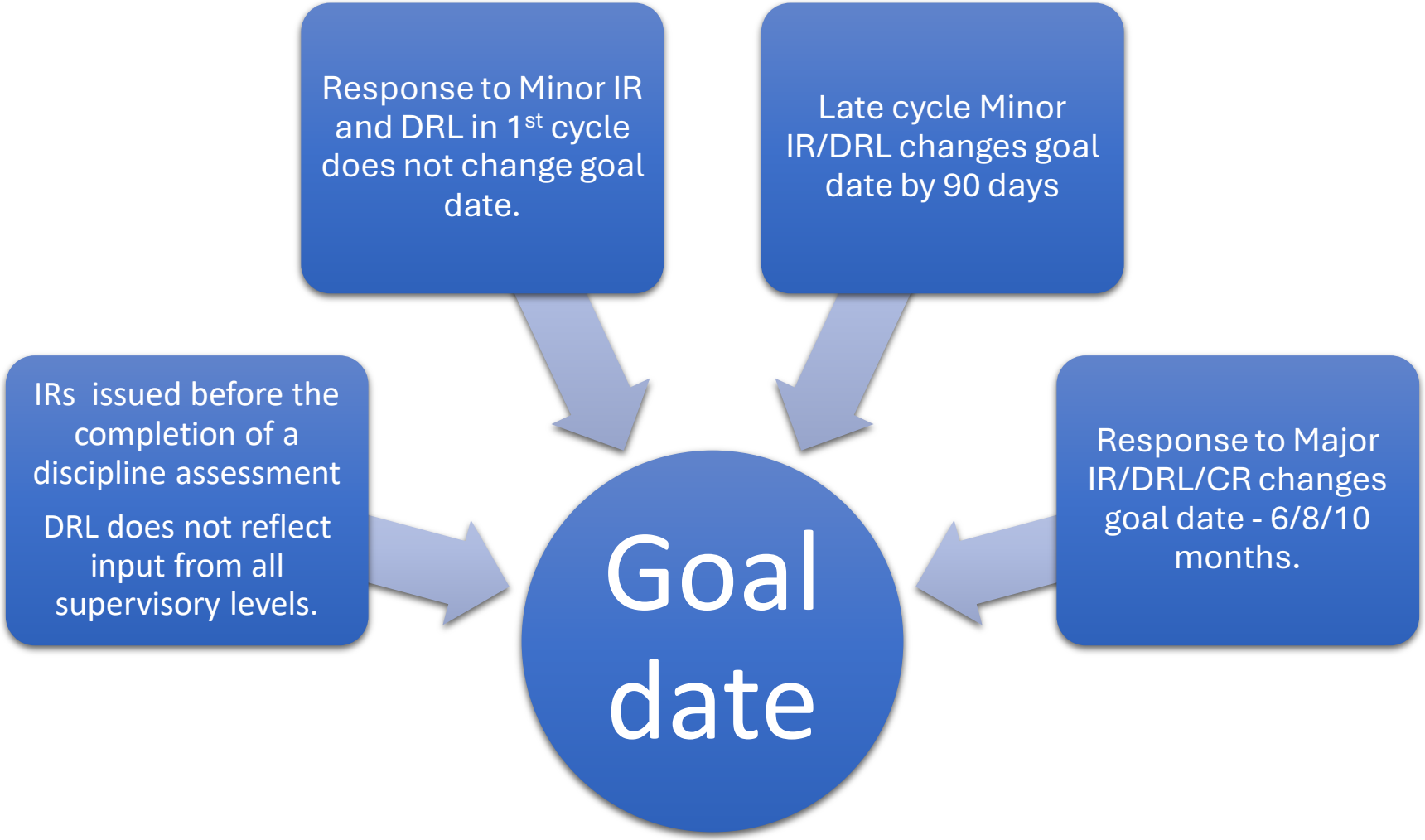
Agenda

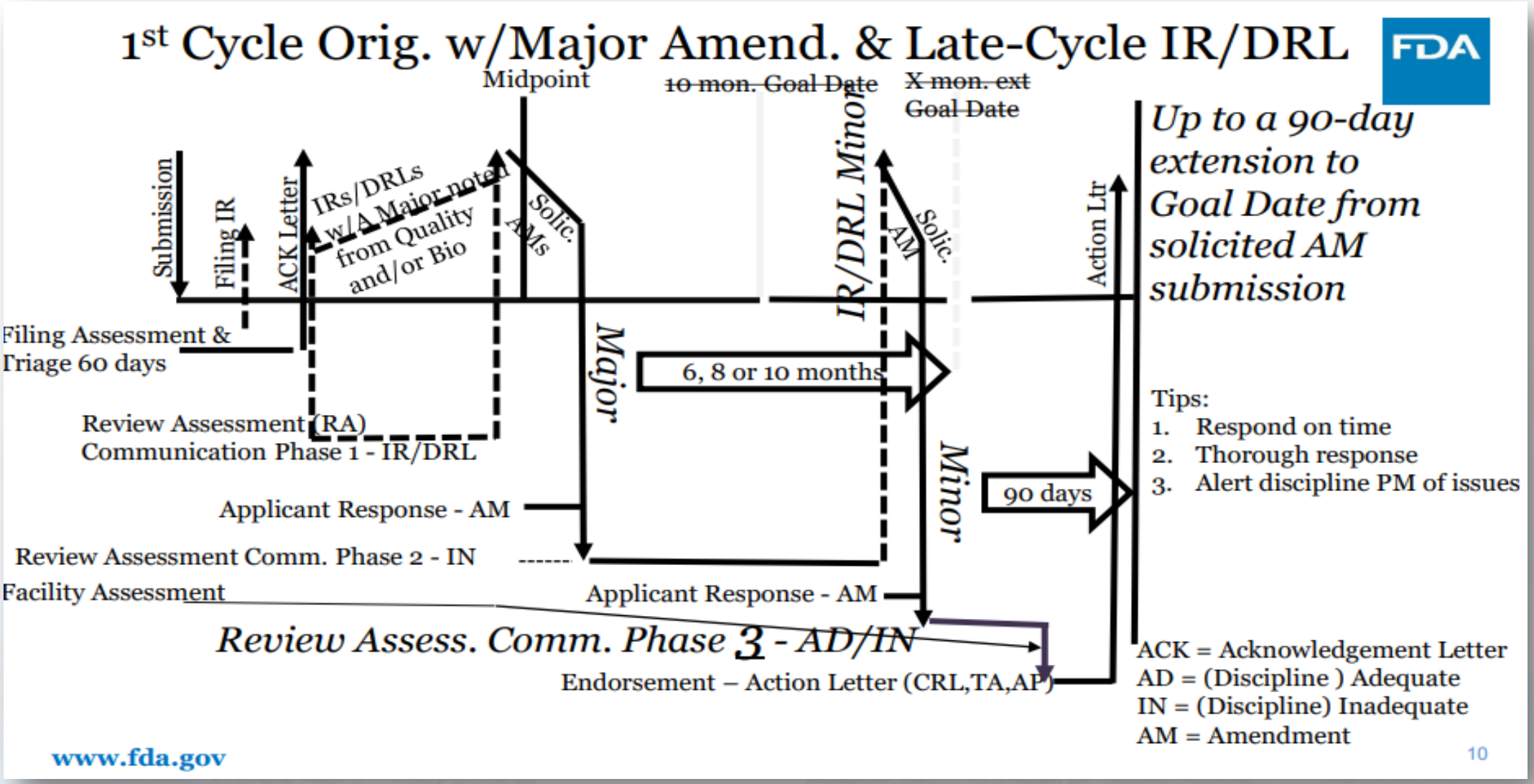

Goal dates - IR /DRL
IR/DRL Deficiency trends
Case studies - Late Cycle IR/DRLs and Major CR
Industry Perspective

IR/DRL and Goal Dates



FDA Guidance - Information Requests and Discipline Review Letters Under GDUFA Guidance for Industry – Oct 2022
MAPP - Issuance of Information Requests and/or Discipline Review Letters for Abbreviated

Moving Goal Dates



FDA presentation on GDUFA 3 goal date illustrations

Common Trends- Late Cycle IR/DRLs

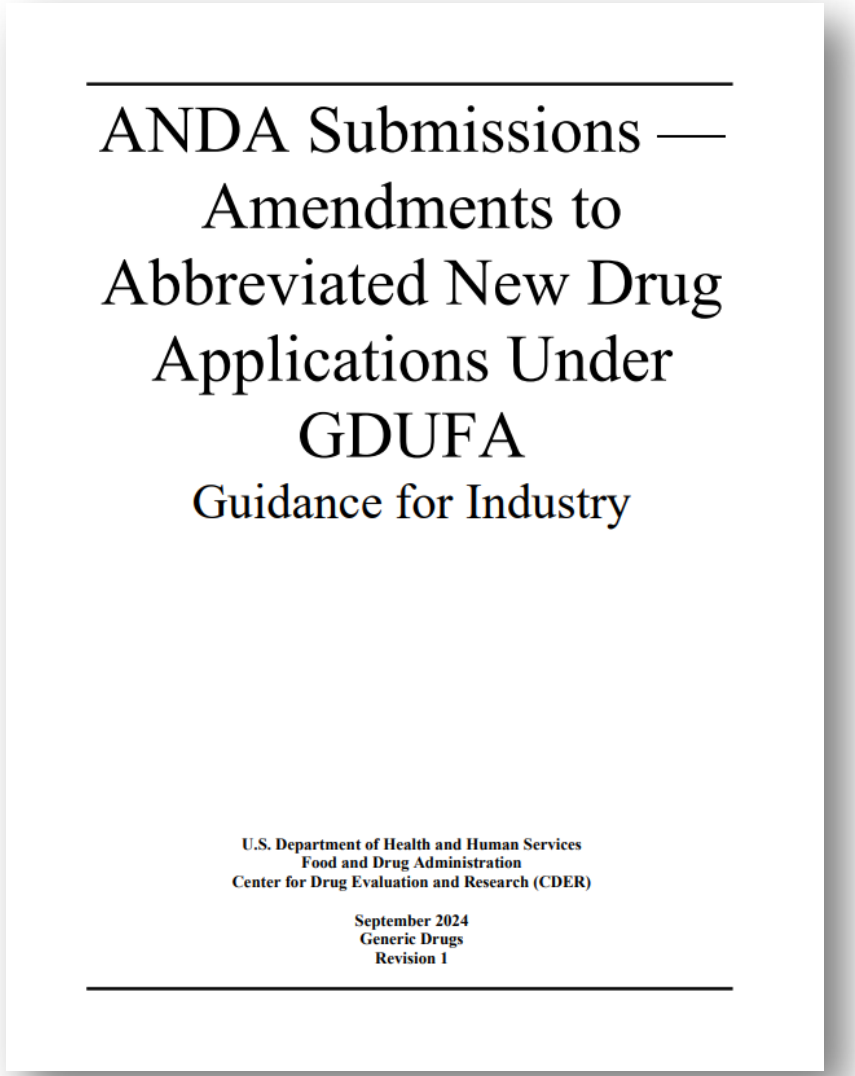
Anticipated/Known

- Labeling
  - RLD updates
  - Editorial issues
- REMS
  - REMS material
  - Website
- Administrative
  - Later listed patents and exclusivities

Unpredicted

- Stability data/ Tighten impurity specs
- DMF deficient/Amendment
- Nitrosamines & Methods
- Dissolution/Discriminating methods
- Retest periods
- Bioequivalence Invitro bio study related, Solubility Studies
- Justify/tighten process control parameters
- USP Compliance/updates
- Hidden Facilities

Common trends of Major CRs


ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

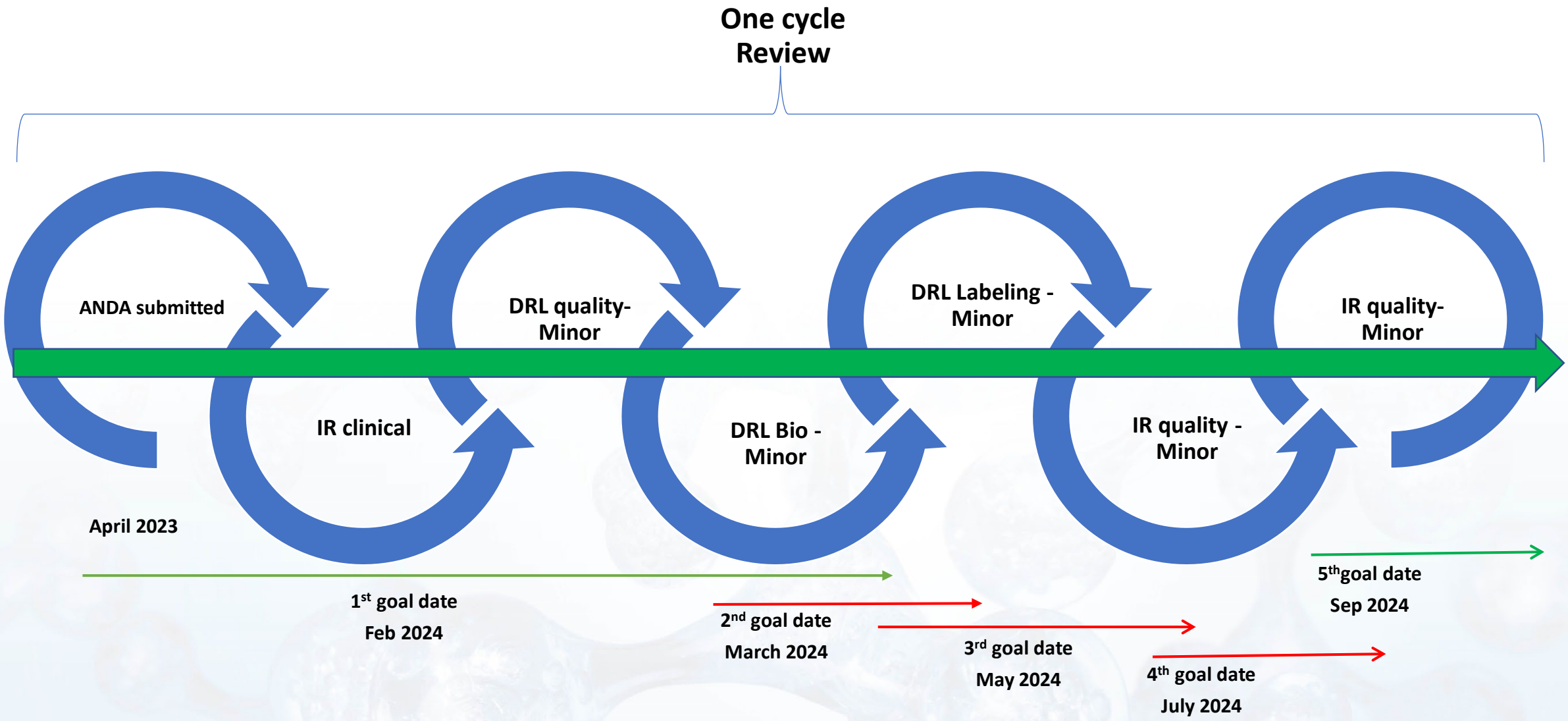
September 2024
Generic Drugs
Revision 1

Describes Amendment Classifications and how amendment classifications impacts the goal date

Non exhaustive list of deficiency categorized as Major

ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA

Case Study 1 - IR/ DRL



Case Study 2 - Major

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Scenario	Action	Outcome
Initial IRs responded	Complex regulatory issue identified but not notified	No CR, past goal date
Applicant unaware of Complex regulatory issue	No action by FDA, No DRLs issued	More than X months past goal date
Complex Regulatory issue, Legal issue, Technical consult Facility inspection identified	Time needed to develop methods and test Facility inspection needed	Goal date moves, delayed approval

Industry Perspective

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Know your product

- Risk assessment and deficiency tracking
- Deficiency trend analysis
- Awareness to changing requirements

Understand the Review Cycle

- Important to understand where the DMF reviews are in relation to the ANDA review cycle
- Work with RPM to understand discipline review status and work within GDUFA III framework
- Utilize the imminent approval pathway when possible

Industry Perspective

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Continuous Communication with DMF holders

- Ensuring amendments do not impact ANDA review timelines
- Identification of hidden facilities
- Alignment on deficiency responses

Complex Regulatory Issues

- FDA may be limited in the information that can be provided to applicants based on complex regulatory issues related to the drug product or class of products
- Communication with FDA is key to stay informed on the status of the application

Key takeaways

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Proactive Approach

- DMF Prior Assessments, PFCs, and Priority Review Requests.
- Pre ANDA/Development meetings and TCON
- Pre/Post PSG meetings
- Controlled Correspondance

Post-ANDA

- Post CR clarifications & Controlled Correspondence
- Build quality resubmissions
- MRCM/EMRCM meeting
- Open and Clear
- Communications with external and internal stake holders

FDA & Industry events

- Participate in SBIA Industry Assistance events
- Follow FDA public communications (Generic Drug Updates and more)
- Monitor FDA guidance update

Thank you!

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