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Reviewers' Advice to Emerging Companies and First-Time Filers

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10:15 AM – 11:45 AM

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Avoid “Rookie Mistakes”

- Failure to Meet with FDA or Use Meetings Wisely
- Failure to Respond to Concerns
- Premature Submission
- Failure to Submit a Complete Application

Failure to Use Meetings Wisely

- Follow the guidance
  - Guidance for Industry, Formal Meetings with Sponsors and Applicants for PDUFA Products
- End-of-Phase 2 meetings are the most important
  - Pre-submission meetings are too late to fix big problems
- Pay attention to what is being said
  - Be aware of “regulatory speak”
  - Understand and consider FDA perspective

Failure to Respond to Concerns

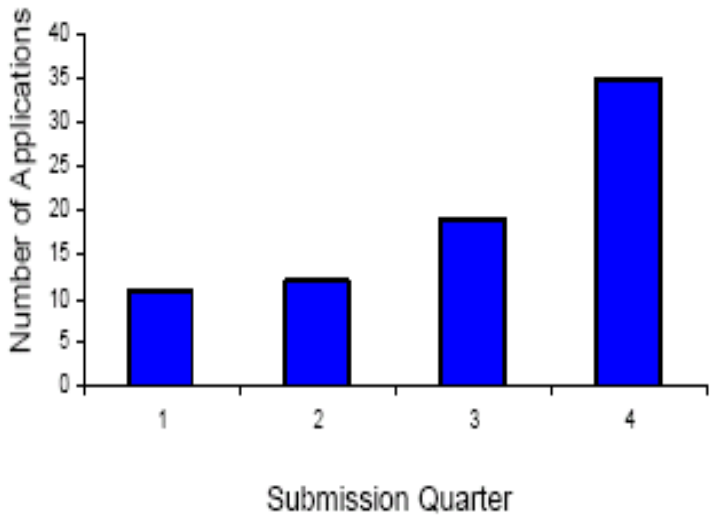
- 71% of major deficiencies are identified at a pre-submission meeting but not resolved by first action
  - Alternative pathways are a possibility!
  - Need early and open discussions on acceptable resolution pathways
- Persisting disagreements over issue resolution delays → approval delays

Premature Submission

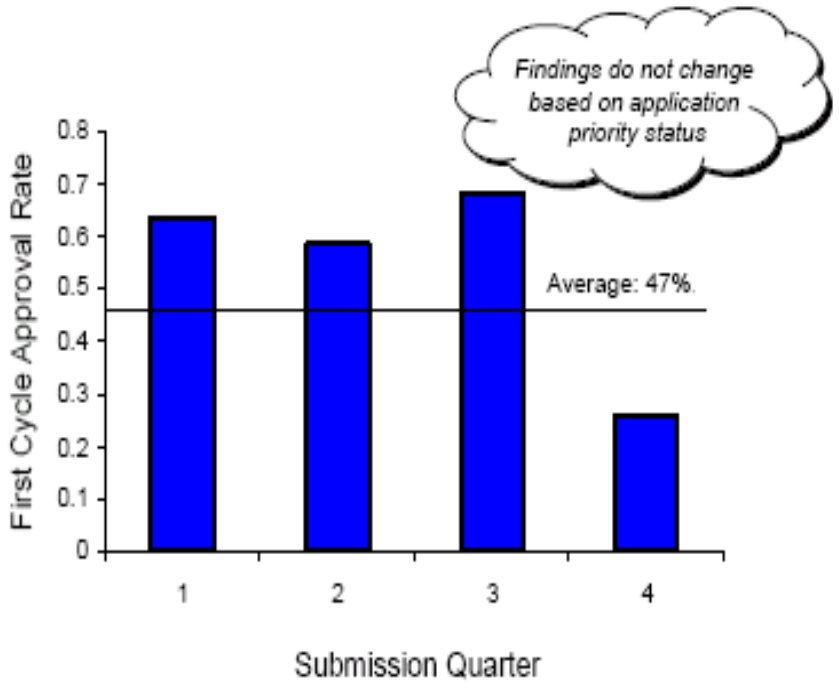
- Don’t submit your application before it’s ready
  - 4th quarter submissions are 2-3x those in any other quarter in a calendar year
  - 4th quarter applications have the lowest rate of first-cycle approval
- Multiple review cycles are NOT faster

Submission Timing vs. Number of Submissions or First-Cycle Approval Rates

a. Number of Submissions by Quarter (aggregate 2001-2004*)



b. Approval Rate by Quarter Submitted



(*): Similar findings observed for individual years

Failure To Submit A Complete Application

- If you have to ask “Can we submit the [fill in the blank] section of the application [fill in the length of time] after we submit the application?” you are not ready
- Is your electronic submission ready?

What Reviewers are Saying:

- Do your homework
- Successful applicants have planned well and taken advantage of every opportunity to receive Agency feedback *on everything*
- Hire consultants if you do not have in-house expertise -
  - do not ask FDA to develop your program
- Foundation is established in INDs especially for biologics - plan accordingly
- Science, not marketing, should drive your program

Recommended Reading

Booz Allen Hamilton
"Independent Evaluation of
FDA's First Cycle Review Performance –
Retrospective Analysis Final Report"
January 2006

http://www.fda.gov/ope/pdufa/PDUFA1stCycle/pdufa1stcycle.pdf