The Q-Submission Program: What it is & Best Practices

FDA Small Business Regulatory Education for Industry (REdI)

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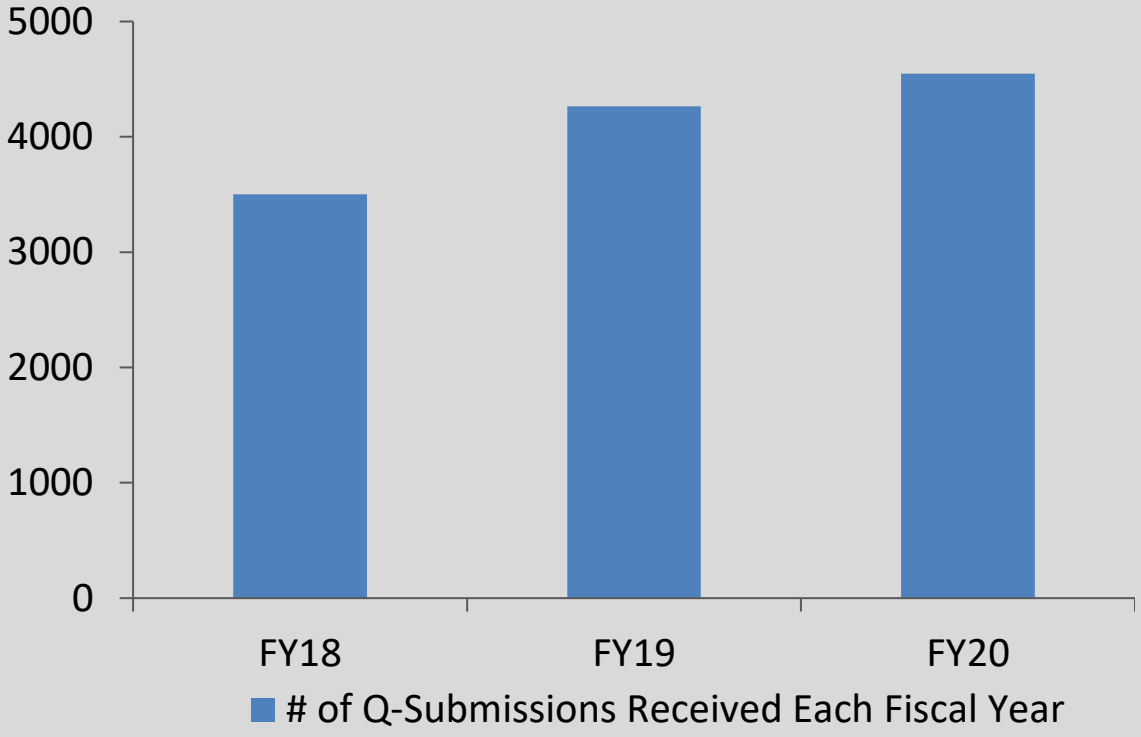
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Over 4500 Q-Submissions



Learning Objectives

- Introduce the Q-Submission Program
- Describe Common Q-Submission Types
- Identify useful Q-Submission practices

Q-Submission Program Overview

Q-Submission Program Evolution

1995 — Pre-IDE Program
- Mechanism to obtain FDA feedback on future IDE's

2013 — Pre-Submission (Pre-Sub) Program
- Requests for feedback on Pre-IDE's, Pre-PMA's, Pre-510(k)'s

2019 — Q-Submission (Q-Sub) Program
- Requests for feedback and meetings for medical device submissions
- Pre-Submissions + other requests for FDA interaction

Q-Submission Program

The Q-Submission Program provides a mechanism to request interactions with the FDA related to medical device submissions

- Different stages of product development
- Different types of feedback

→ Many different types of Q-Submissions

Q-Submission Types

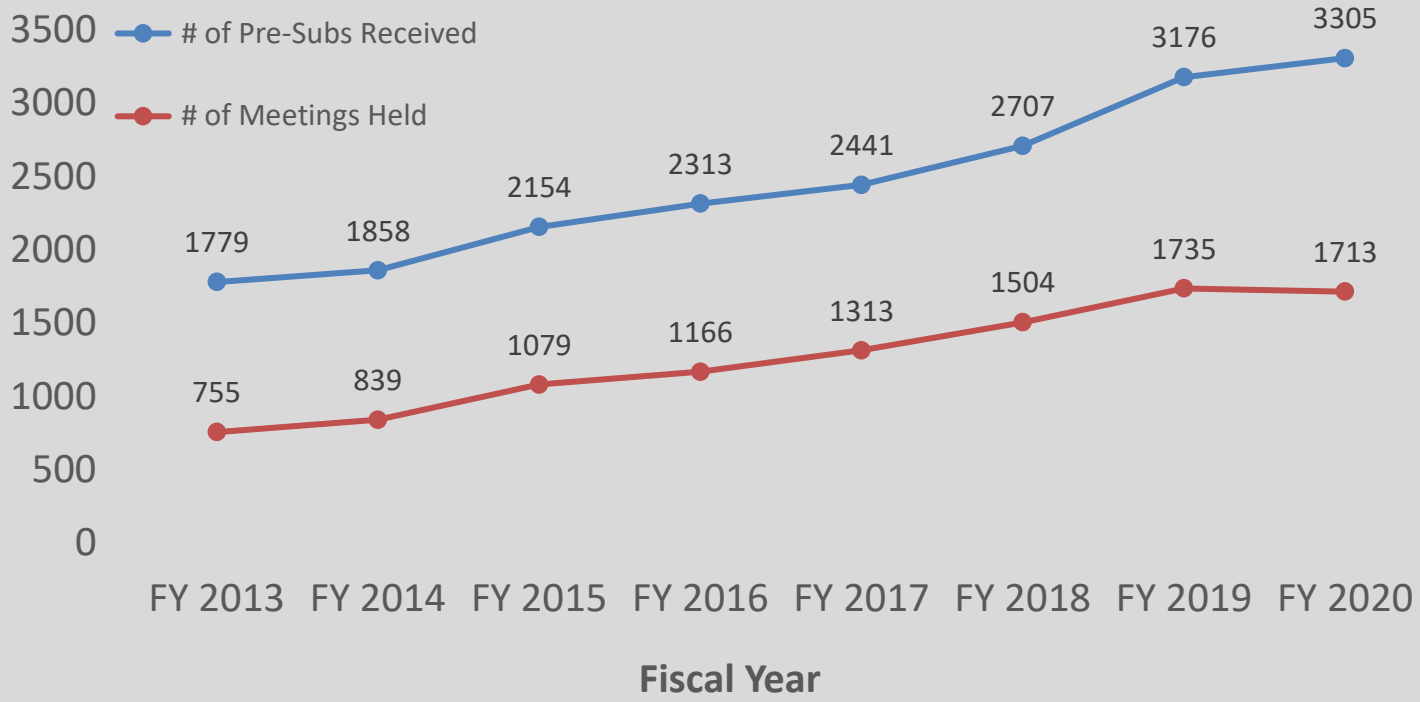
Pre-Subs	Submission Issue Request	Informational Meeting
Study Risk Determination	Breakthrough Request & Interaction	STeP Request & Interaction
PMA Day-100 Meeting	Accessory Request	Early Collaboration

Q-Submission Types

- Pre-Subs
- Submission Issue Request
- Informational Meeting

Common Types of Q-Submissions

Pre-Subs Received



Pre-Subs

A formal request for written feedback on a future IDE or marketing submission

Pre-Submission Meeting

Pre-Submission Written Feedback

- Feedback is provided in writing and a meeting is held, if one is requested
- Can support future premarket submission, IDE, Accessory Classification Request or CLIA Waiver
- One type of Q-Submission

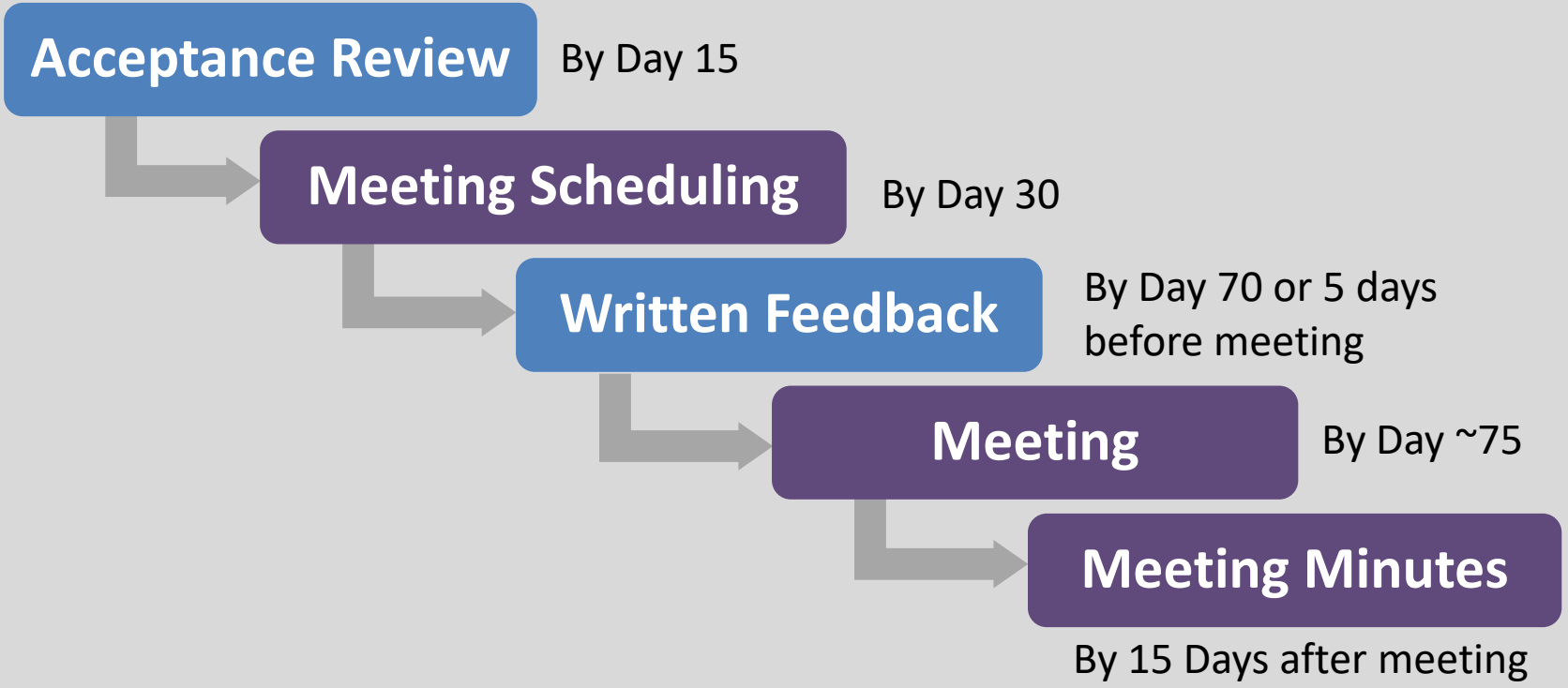
Pre-Subs Continued

- Help guide product development, develop protocols, and prepare premarket applications
- Recommend 3-4 substantial topics
- Meetings: Teleconference or In-Person
- MDUFA IV Commitments

Pre-Sub MDUFA IV Commitments

- Acceptance review (RTA) checklist
- Meeting scheduling commitments
- Written feedback timing goal:
  - Feedback by day 70 or 5 days before the meeting, whichever is sooner
- Meeting minutes submitted within 15 days

Pre-Submission Process



Pre-Sub Summary

Purpose:

Request feedback on specific questions related to a future IDE or marketing submission

FDA Action:

Provide written feedback in response to questions and hold a meeting if one is requested

Timeframe:

Written feedback is due 5 days before the meeting or Day 70

Submission Issue Requests (SIRs)

A request to discuss outstanding review issues that were provided in a marketing submission hold letter, IDE letter, or IND Clinical Hold letter

- Request written feedback **or** a meeting
- Discuss approach to address deficiencies
- Help move project forward

SIRs continued

- Specify deficiencies to discuss
- Not a pre-review of deficiency responses
- 2-Tiered Review Timeline:

SIR received **within 60 days** of FDA's letter	FDA feedback: 21 Days (as resources permit)
SIR received **more than 60 days** after FDA's letter	FDA feedback: 70 Days (as resources permit)

Informational Meetings

A meeting intended to share information with the FDA

- No official feedback
- Interactive Dialogue
- Topics can include:
  - Device development
  - New technologies
  - Topics outside scope of other Q-Subs

Q-Submissions Best Practices

What to Include in a Q-Submission

- Q-Submission type
- Type of feedback
- Specific questions
- Include information relevant to your questions
- Regulatory history (previous Q-Sub #s)
- Potential meeting dates

Preparing for a Meeting

- Use written feedback to refine agenda
- Plan which topics to discuss during the meeting
- Ensure correct people attend the meeting
- Don’t provide new information between when written feedback is sent and meeting is held

After the Meeting

- Within 15 days: submit meeting minutes
- Don’t include new discussion topics in meeting minutes
- Submit additional questions in another Q-Sub
  - Include prior Q-Sub #
- In subsequent pre-market submissions:
  - Include summary of Q-Sub discussions
  - Include how you addressed feedback

Knowledge Check

Which of the following is a type of Q-Submission?

a. Submission Meeting
b. Informational Pre-Submission
c. Pre-Submission
d. All of the above

True or False: Once I request a meeting, I cannot cancel it

a. True
b. False

Which Q-Sub type should you submit, if you have questions about deficiencies in a FDA hold letter you received?

a. Pre-Submission
b. SIR
c. Informational Meeting
d. Any of the above

Summary

- Using the Q-Submission Program, FDA provides feedback and interactions to over 4000 Q-Subs
- Each Q-Sub type has a unique purpose that depends on the stage of product development
- Including relevant information and specific questions helps FDA provide more beneficial feedback

Resources

- Q-Submission Program Final Guidance
  - Breakthrough Device Program Guidance Document
  - STeP Guidance Document
- PMA 100 Day Meeting Guidance Document
- Early Collaboration Meeting Guidance Document
- Medical Device Accessories Guidance Document
- eCopy Program for Medical Device Submissions

Questions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