FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Welcome to today's FDA/CDRH Webinar

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Q-Submission Program for Medical Device Submissions

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June 11, 2019

Agenda

- Objectives
- Background
- Q-Submission Program and Scope of Guidance
- Types of Q-Submissions
- Significant Changes in Q-Submission Guidance
- Resources and Questions

Definitions

- ***Q-Submission:*** Mechanism to request different types of interactions with the FDA
- ***Premarket Approval Application (PMA):*** Mechanism to request approval for a class III medical device
- ***Investigational Device Exemption (IDE):*** Mechanism to request approval for a significant risk clinical study of an unapproved device or unapproved use of a device
- ***Investigational New Drug (IND):*** Mechanism to request a drug or biological drug be used in a clinical investigation

Objectives

- Provide an overview of the scope of the Q-Submission Program described in the FDA's Guidance Document *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program* published May 7, 2019

- Provide an overview of the different mechanisms available to request feedback from or interactions with the FDA

- Review significant changes made in this Guidance Document

Background

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

2013 — Pre-Submission Program
- Pre-IDE submissions + feedback requests prior to other marketing submissions (e.g. Pre-PMAs, Pre-510(k)s)

2019 — Q-Submission Program
- 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

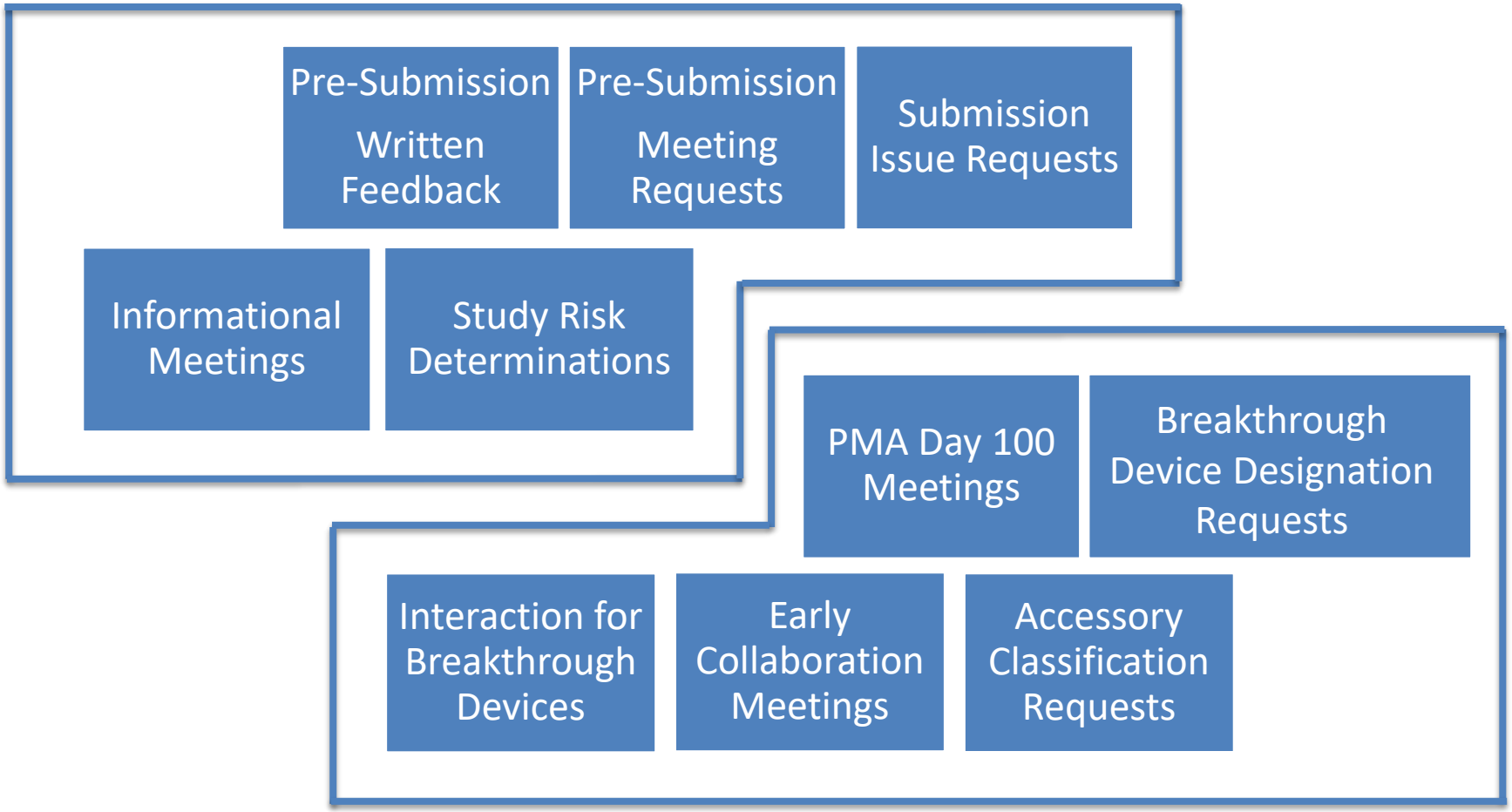
- Different topics for interactions
- Different types of feedback

→ Many different types of Q-Submissions

Scope of Guidance Document

- Identifies and describes different Q-Submission types
- Identifies submission types covered in other guidance documents and tracked as Q-Submissions
- Identifies submission types outside the scope of the Q-Submission Program
- Outlines Q-Submission Processes

Q-Submission Types



Pre-Submissions

Requests for feedback from the FDA regarding future premarket submissions, Accessory Classification Requests, or CLIA Waivers

Pre-Submission Meeting

Pre-Submission Written Feedback

- Specific questions
- Recommend 3-4 substantial topics
- Help guide product development, develop protocols, prepare premarket applications

Pre-Submission MDUFA IV Commitments

Pre-Submissions are the only Q-Submission with MDUFA IV commitments and goals

- MDUFA IV commitments included in Guidance Document:
  - Goal feedback timelines
  - Applicants responsible for draft minutes
  - New Pre-Submission Acceptance Checklist (RTA)
  - Example questions leading to productive interactions
    - Appendix 2 (page 27)
  - Consistency in provided feedback

Submission Issue Requests

Requests 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 in formal response
- Help move project forward

Study Risk Determinations

Requests for a risk determination for proposed clinical study

- FDA provide final decision in writing
- Risk determination for proposed clinical study defined in CFR 812
- 4 possible final determinations:

Significant Risk | Non-Significant Risk | Exempt | Basic Physiological Research

Informational Meetings

Meeting intended to share information with the FDA

- No official feedback
- Interactive dialogue
- Topics can include:
  - Device development
  - New technologies
  - Topics outside the scope of other Q-Submissions

Other Q-Submission Types

- Interactions tracked as Q-Submissions that have specific policy and procedures described in other FDA Guidance Documents:
  - PMA Day 100 Meetings
  - Breakthrough Device Requests and Interactions
  - Early Collaboration Meetings
  - Accessory Requests
- Lower volume of requests

Significant Changes from Pre-Submission Guidance

Included MDUFA IV Commitments for Pre-Submissions:

- RTA timeframe
- Meeting scheduling logistics
- Written feedback timing

To support these goals we have developed 2 type of Pre-Submissions:

	RTA	Meeting Scheduled	Written Feedback Due	Performance Goal
Pre-Submission Meeting	By Day 15	By Day 30	5 Days before meeting or Day 70 – whichever is sooner	• Meeting Set Date • Written Feedback Date
Pre-Submission Written Feedback	By Day 15	N/A	Day 70	• Written Feedback Date

Significant Changes from Pre-Submission Guidance

Acceptance Review (RTA):

- Pre-Submission RTA streamlined
- Submission Issue Request & Informational Meeting RTA removed

Submission Issues Requests

- Naming:
  - Submission Issue Meetings → Submission Issue Requests
- Requested Feedback:
  - Written Feedback **OR** Meeting
- 2 Tiered Review Timeline:

	Time between when associated letter was sent and Submission Issue Request was received	Goal Review Time
i.	≤ 60 days	21 Days
ii.	> 60 days	70 Days

Summary

- Many Q-Submission types all providing a mechanism to request FDA interaction
  - Each has its own review process and timelines
- New FDA Guidance Document:
  - Describes Q-Submission types and timelines
  - Provides resources for the Q-Submission types with policy and procedures described in other FDA Guidance Documents
- All Q-Submissions follow the same general processes regarding:
  - Formal submissions to the Document Control Center (DCC)
  - eCopy (electronic copy) requirements
  - Tracking with original Q-Submissions, supplements, & amendments
  - Meeting formats and submission of meeting minutes

Resources

- Q-Submission Program Final Guidance
- Breakthrough Device Program 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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Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn: Under the “How to Study and Market Your Device” section; Subsection: “Pre-Submissions”