Welcome to today’s FDA/CDRH Webinar

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Q-Submission Program for Medical Device Submissions

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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
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
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-Submission Written Feedback
- Pre-Submission Meeting Requests
- Submission Issue Requests
- Informational Meetings
- Study Risk Determinations
- PMA Day 100 Meetings
- Breakthrough Device Designation Requests
- Interaction for Breakthrough Devices
- Early Collaboration Meetings
- Accessory Classification Requests
Pre-Submissions

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

- 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:

<table>
<thead>
<tr>
<th></th>
<th>RTA</th>
<th>Meeting Scheduled</th>
<th>Written Feedback Due</th>
<th>Performance Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Submission Meeting</td>
<td>By Day 15</td>
<td>By Day 30</td>
<td>5 Days before meeting or Day 70 – whichever is sooner</td>
<td>• Meeting Set Date</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Written Feedback Date</td>
</tr>
<tr>
<td>Pre-Submission Written Feedback</td>
<td>By Day 15</td>
<td>N/A</td>
<td>Day 70</td>
<td>• Written Feedback Date</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Time between when associated letter was sent and Submission Issue Request was received</th>
<th>Goal Review Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. ≤ 60 days</td>
<td>21 Days</td>
</tr>
<tr>
<td>ii. &gt; 60 days</td>
<td>70 Days</td>
</tr>
</tbody>
</table>
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”