Best Practices and Interactions with CDRH

**FDA Small Business
Regulatory Education for Industry (REdI)**
Silver Spring, MD
September 29, 2015

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Learning Objectives

- Identify foundational knowledge

- Describe the elements of a quality premarket submission

- Identify methods of communication with CDRH

- Interpret CDRH communications

Foundational Knowledge

Foundational Knowledge

- **Premarket Databases**

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

  – Identify classification/product code

  – Identify predicate devices

  – Identify performance testing

  – Identify standards and extent of FDA recognition

Foundational Knowledge

- **Device-specific Guidance**
  - Device characteristics
  - Performance testing
  - Clinical study elements
- **Program-specific guidance**
  - Content and format of premarket submission type (e.g., 510(k), PMA)

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Foundational Knowledge

- **Cross-cutting Guidance**
  - Biocompatibility
  - Sterility
  - Reprocessing
  - Benefit/risk assessment

Foundational Knowledge

- **Q-Submissions**

  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf

  – Obtain preliminary feedback

  – Non-clinical testing questions

  – Clinical study questions

  – Study risk determinations

Submission Quality

Submission Quality

- **Quality Premarket Submission**
  - Administratively complete
  - Clearly and efficiently organized
  - All required information/data included
  - Q-submission feedback addressed
  - Effectively "tells your story"

Submission Quality

- **Refuse-to-accept (RTA) Policy**
  - 510(k): **http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf**
  - PMA: **http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313368.pdf**

Submission Quality

- **Refuse-to-accept (RTA) Policy**
  - Ensures administrative completeness
  - Identifies required/expected elements
  - Address all information in the checklist
  - Provide rationale for any excluded information (not applicable to your device/submission)
  - Not a substantive review

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Submission Quality

- **Q-Submission Feedback**
  - Identify any relevant Q-submissions
  - Identify all Q-submission feedback
  - Explain how you addressed feedback
  - Identify any changes since Q-submission (e.g., device design changes, alternative testing)

Communications

Communications

- **Who should you contact?**
  - Start with Lead Reviewer, then:
  - Branch Chief
  - Division Manager
  - POS (ODE) or DPMO (OIR)

- **How often should you contact?**

Communications

- **Anticipate Questions**
  - Reviewers will have questions
  - Seeing your device for first time
  - Not intended to be a commentary on your device

Communications

- **Interactive Review**
  - Addresses questions in real-time
  - Reduces total review time
  - Minimizes questions in future correspondence
  - Important to respond within specified timeframe

Communications

- **Official Correspondence**
  - Communicates several types of decisions
  - Identifies ALL outstanding issues
  - Identifies least burdensome means of addressing outstanding issues

Communications

- **Official Correspondence**
  - Respond within stated time frame
  - Clarify any questions/requests with lead reviewer
  - Use Q-submission process for substantive issues

Communications

- **Meetings/Teleconferences**
  - Can be standalone or part of Q-submission process
  - Focus on substantive questions
  - Limit "marketing show"

Summary

- Foundational knowledge will assist in development of your premarket submission.

- High quality premarket submission promotes an efficient review.

- CDRH communications occur in multiple formats and at different points in the review process.

- CDRH communications intended to assist you in reaching a favorable decision.

Industry Education Resources
Three Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   http://www.fda.gov/Training/CDRHLearn

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm**

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D1S5