

# Premarket Approval (PMA) Submissions Workshop

Virtual Event  
May 23- 25, 2023

*\*Schedule Reflected in Eastern Time*

## May 23, 2023

**11:00 am – 11:05 am      Welcome and Introductions**

**11:05 am – 12:00 pm      Beginning at the Beginning**  
*Quynh Hoang, King & Spalding*

- When is a De Novo or PMA required
- PMA: what to expect
  - What are the standards of evidence
  - What are the standards of review
  - Will submission go to panel
  - How much will it cost
  - How long will it take to get approval

**12:00 pm – 12:45 pm      Development of a PMA Submission Strategy**  
*Stacy Monza, FDA*

- Product definition
- Development of testing requirements and strategy
- Desired patient population
- Desired claims
- Early interactions with FDA
- Planning for product iterations

**12:45 pm – 1:00 pm      Group Q&A**

**1:00 pm – 1:15 pm      Break**

**1:15 pm – 1:55 pm      Mechanics of PMA Quality System Submission Development and Review**  
*Jhumur Banik, FDA*

- Defining data requirements
- Required elements
- Presentation of information with clarity
- Expectations during review
- Best practices
- Manufacturing & Quality Systems
- Case for Quality

### **Important Notice**

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.

**1:55 pm – 2:40 pm**

**During Submission Review**

*Jennifer Bolton, Boston Scientific*

- Interactions with the FDA
- When/How to expect questions
- Types of letters
- Timelines
- Day 100 meetings
- Labeling review

**2:40 pm – 2:55 pm**

**Group Q&A**

**2:55 pm – 3:10 pm**

**Break**

**3:10 pm – 3:55 pm**

**Conditions of Approval Studies**

*Jennifer Bolton, Boston Scientific*

- Criteria and objectives
- Early collaboration with FDA
- Reaching agreement
- Reporting outcomes
- 522 Studies

**3:55 pm – 4:40 pm**

**Preparation for Advisory Panels**

*Jessica Ringel, King & Spalding*

- When?
- Who are the panel members?
- Why have a panel meeting?
- Preparation for a panel meeting
- What to expect before, during, and after
- Best practices

**4:40 pm – 4:55 pm**

**Group Q&A**

**Close Day 1 of Program**

**May 24, 2023**

**11:00 am – 11:45 am**

**Inspection Activity**

*Jacob Dyer, FDA*

- Pre-approval inspections

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- How to prepare for an inspection

**11:45 am – 12:45 pm      Dealing with the Unexpected**  
*Tony Blank, AtriCure*

- Clinical outcomes
- Animal test results
- Adverse panel recommendation

**12:45 pm – 1:00 pm      Group Q&A**

**1:00 pm – 1:15 pm      Break**

**1:15 pm – 2:00 pm      The Care and Feeding of Approved PMAs**  
*Monica Montanez, NAMSA*

- Periodic (“Annual”) Reports
- Supplemental Submissions
- 30-day notices

**2:00 pm – 2:30 pm      CDRH Ombudsman’s Office**  
*Ken Skodacek, FDA*

- Roles & Responsibilities
- The Appeals Process

**2:30 pm– 2:45 pm      Group Q&A**

**2:45 pm      Closing Remarks and Adjourn**

## May 25, 2023

**12:00 pm – 1:15 pm      Applied Learning and Breakout Discussions**  
*Jennifer Bolton, Boston Scientific*  
*Quynh Hoang, King & Spalding*  
*Angela Mallery, NAMSA*

- PMA Recap
- Facilitated Breakout Group Deep Dive
  - Hypothetical Case Studies
  - Key Takeaways
- Regroup for Final Program Q&A

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