



**AdvaMed**

Advanced Medical Technology Association  
Events & Education

# Premarket Approval (PMA) Submissions Workshop

AdvaMed Office

1301 Pennsylvania Ave. N.W. Suite 400 Washington, D.C.

February 6 – 7, 2025

Feb 6, 2025

**8:30 – 9:00 am**                      **Registration Check-In and Continental Breakfast**

**9:00 – 9:05 am**                      **Welcome and Introductions**

**9:05 – 10:00 am**                      **Beginning at the Beginning**

*Elaine Tseng, Counsel, King & Spaulding*

- 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

**10:00 – 10:45 am**                      **Development of a PMA Submission Strategy**

*Nam To, Policy Analyst, FDA*

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

**10:45 – 11:00 am**                      **Break**

**Mechanics of PMA Quality System Submission Development and Review**

*Jhumur Banik, PMA Policy Analyst, HDE, Q-Submission and Device Tracking Lifecycle (PHQ) Team, Division of Submission Support (DRP1), Office of Regulatory Programs (ORP), CDRH, FDA*

**11:00 – 12:00 pm**

- 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.



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**12:00 – 1:00 pm**

**Networking Lunch**

**1:00 – 2:00 pm**

**During Submission Review**

*Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific*

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

**2:00 – 3:00 pm**

**Conditions of Approval Studies**

*Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific*

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

**3:00 – 3:15 pm**

**Break**

**3:15 – 4:15 pm**

**Preparation for Advisory Panels**

*Jessica Ringel, Partner, 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

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**Feb. 7, 2025**

**8:30 – 9:00 am**                      **Continental Breakfast**

**9:00 – 10:00 am**                      **Inspection Activity**  
*Jacob Dyer, Senior Regulatory Officer, FDA*

- Pre-approval inspections
- How to prepare for an inspection

**10:00 – 11:00 am**                      **Dealing with the Unexpected**  
*Tony Blank, Senior Director of Regulatory Affairs, AtriCure*

- Clinical outcomes
- Animal test results
- Adverse panel recommendation

**11:00 – 11:15 am**                      **Break**

**11:15 am – 12:30 pm**                      **The Care and Feeding of Approved PMAs**  
*Monica Montanez, Principal Strategy Consultant, NAMSA*

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

**12:30 – 1:30 pm**                      **Networking Lunch**

**1:30 – 2:15 pm**                      **CDRH Ombudsman’s Office**  
*Ken Skodacek, Center for Devices and Radiological Health, Deputy Ombudsman, FDA*

- Roles & Responsibilities
- The Appeals Process

**2:15 – 2:30 pm**                      **Break**

**2:30 – 4:30 pm**                      **Applied Learning and Breakout Discussions**  
*Tony Blank, Senior Director of Regulatory Affairs, AtriCure*  
*\*In person participants, only*

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

**4:30 pm**                                      **Adjournment**

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