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, Partner, 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**
11:00 – 12:00 pm	**Mechanics of PMA Quality System Submission Development and Review** *Jhumur Banik, Team Lead, Biomedical Engineer; PMA, HDE, Q-Submission and Device Tracking Lifecyle (PHQ) Team, Division of Submission Support (DRP1), Office of Regulatory Programs (ORP), CDRH, FDA* • Defining data requirements • Required elements • Presentation of information with clarity • Expectations during review • Best practices • Manufacturing & Quality Systems • Case for Quality

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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 Affair, 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 Affair, 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**