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 & 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

10:00 – 10:45 am **Development of a PMA Submission Strategy**
Tony Blank, Senior Director of Regulatory Affair, AtriCure

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

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

12:00 – 1:00 pm **Networking Lunch**

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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

4:15 – 5:15 pm **Networking Reception**

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Feb. 7, 2025

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

9:00 – 10:00 am **Inspection Activity**
Monica Montanez, Principal Strategy Consultant, NAMSA
- 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 – 3:30 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

3:30 pm **Adjournment**