AdvaMed
Advanced Medical Technology Association
Events & Education

Premarket Approval (PMA) Submissions Workshop

Virtual
February 23 – 24, 2027

Feb 23, 2027

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

9:05 – 10:00 am **Beginning at the Beginning**
Jessica Ringel, 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**
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, FDA

- 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 **Lunch Break**

1:00 – 2:00 pm **During Submission Review**

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.

AdvaMed
Advanced Medical Technology Association
Events & Education

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

Feb. 24, 2027

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**

DRAFT

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.

AdvaMed
Advanced Medical Technology Association
Events & Education

11:15 am – 12:30 pm **The Care and Feeding of Approved PMAs**

Jeff Shapiro, Partner, FDA and Life Sciences, King & Spalding

- Periodic ("Annual") Reports
- Supplemental Submissions
- 30-day notices

12:30 – 1:30 pm **Lunch Break**

1:30 – 2:15 pm **CDRH Ombudsman Program**

Ken Skodacek, CDRH Deputy Ombudsman, FDA

- Confidential, independent, impartial resource for resolving disputes
- Formal appeals process (21 CFR 10.75)

2:30 – 3:30 pm **Open Forum Q&A with the Experts**

Led by: ***Tony Blank, Senior Director of Regulatory Affairs, AtriCure***

Attendees have the opportunity to engage directly with the available regulatory experts in a secure, open forum format. Participants are encouraged to ask detailed, real-world questions related to their own submission challenges, FDA interactions, and regulatory strategy considerations.

3:30 pm **Adjournment**

DRAFT

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.