AdvaMed
Advanced Medical Technology Association
Events & Education

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

AdvaMed
Advanced Medical Technology Association
Events & Education

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

- 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