AdvaMed
Advanced Medical Technology Association
Events & Education

Premarket Approval (PMA) Submissions Workshop

Virtual Event
March 1-3, 2022
**Schedule Reflected in Eastern Time*

March 1, 2022

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**
Dharmesh Patel, 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

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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**
Gerry Prud'homme, Hogan Lovells
- 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**

March 2, 2022

11:00 am – 11:45 am **Inspection Activity**
Kenneth Chen, FDA
- Pre-approval inspections
- How to prepare for an inspection

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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**
Gerry Prud'homme, Hogan Lovells
- 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**

March 3, 2022

12:00 pm – 1:15 pm **Applied Learning and Discussion**
- Hypothetical Case Study Review
- Facilitated Breakout Group Deep Dive
- Key Takeaways
- Final Program Q&A