AdvaMed
Advanced Medical Technology Association
Events & Education

Premarket Approval (PMA) Submissions Workshop

Virtual Event
February 25 – 26, 2021
**Schedule Reflected in Eastern Time*

Feb 25, 2021

11:00 – 11:05 am **Welcome and Introductions**

11:05 am – 12:00 pm **Beginning at the Beginning**
Michael Morton, Michael C. Morton Regulatory Consulting

- 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 – 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 – 12:50 pm **Break**

12:50 – 1:30 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

1:30 – 2:15 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

2:15 – 2:25 pm **Break**

2:25 – 3:10 pm **Conditions of Approval Studies**

Jennifer Bolton, Boston Scientific

- Criteria and objectives
- Early collaboration with FDA
- Reaching agreement
- Reporting outcomes
- 522 Studies

3:10 – 3:55 pm **Preparation for Advisory Panels**

Michael Morton, Michael C. Morton Regulatory Consulting

- 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

3:55 – 4:00 pm **Break**

4:00 – 4:30 pm **BIMO Audits**

Christopher Gioffre, FDA

- The purpose of a BIMO inspection
- When and how a BIMO inspection occurs
- Preventing findings and responding to findings
- Typical and atypical observations – cautionary tales from the field

AdvaMed
Advanced Medical Technology Association
Events & Education

Feb 26, 2021

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

11:45 am – 12:45 pm **Dealing with the Unexpected**
Quynh Hoang, King & Spalding
- Clinical outcomes
- Animal test results
- Adverse panel recommendation

12:45 – 12:55 pm **Break**

12:55 – 1:40 pm **The Care and Feeding of Approved PMAs**
Linda Wang, Dexcom
Kiley Hubert, Dexcom
- Periodic ("Annual") Reports
- Supplemental Submissions
- 30-day notices

1:40 – 2:25 pm **CDRH Ombudsman's Office – Roles & Responsibilities and the Appeals Process**
Ken Skodacek, FDA

2:25 – 2:30 pm **Break**

2:30 – 3:00 pm **Real World Case Studies**
Quynh Hoang, King & Spalding

3:00 pm **Closing Remarks and Adjourn**