AdvaMed
Advanced Medical Technology Association
Events & Education

Premarket Approval (PMA) Submissions Workshop

Courtyard Irvine Spectrum | Irvine, CA
March 1-2, 2018

March 1, 2018

8:00 – 8:30 am **Registration Check-In and Continental Breakfast**

8:30 – 8:35 am **Welcome and Introductions**

8:35 – 9:30 am **Beginning at the Beginning**

- 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

9:30 – 10:15 am **Development of a PMA Submission Strategy**

- Product definition
- Development of testing requirements and strategy
- Desired patient population
- Desired claims
- Early interactions with FDA
- Planning for product iterations

10:15 – 10:30 am **Break**

10:30 – 11:30 am **Mechanics of PMA Quality System Submission Development and Review**
Bleta Vuniq, CDRH, FDA

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

11:30 – 12:15 pm **During Submission Review**

- Interactions with the FDA
- When/How to expect questions
- Types of letters
- Timelines
- Day 100 meetings

- Labeling review

12:15 – 1:15 pm **Lunch**

1:15 – 2:00 pm **CDRH Ombudsman's Office – Roles & Responsibilities and the Appeals Process**
Abiy Desta, CDRH, FDA

2:00 – 2:45 pm **Preparation for Advisory Panels**
Rachael Roehrig, 3D Communications

- 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

2:45 – 3:00 pm **Break**

3:00 – 3:45 pm **BIMO Audits**
Sheena Green, CDRH, 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

3:45 – 4:30 pm **Inspectional Activity**
Bleta Vuniq, CDRH, FDA

- Pre-approval inspections
- How to prepare for an inspection

4:30 – 5:30 pm **Networking Reception**

March 2, 2018

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

9:00 – 9:45 am **Conditions of Approval Studies**

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

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9:45 – 10:45 am **Dealing with the Unexpected**
Quynh Hoang, King & Spaulding
- Clinical outcomes
- Animal test results
- Adverse panel recommendation

10:45 – 11:00 am **Break**

11:00 – 11:30 am **The Care and Feeding of Approved PMAs**
- Periodic ("Annual") Reports
- Supplemental Submissions

11:30 – 12:00 pm **Real World Case Studies**

12:00 pm **Adjournment**