

Premarket Approval (PMA) Submissions Workshop

AdvaMed Office

701 Pennsylvania Ave. N.W. Suite 800 Washington, D.C.

October 10-11, 2019

Oct 10, 2019

8:30 – 9:00 am **Registration Check-In and Continental Breakfast**

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

9:05 – 10:00 am **Beginning at the Beginning**

Jennifer Bolton, Boston Scientific

- 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**

Joshua Nipper, 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**

Megha Reddy, FDA

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

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.



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12:00 – 1:00 pm

Networking Lunch

1:00 – 1:45 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

1:45 – 2:30 pm

Conditions of Approval Studies

Melanie Raska, Boston Scientific

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

2:30 – 2:45 pm

Break

2:45 – 3:30 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

3:30 – 4:15 pm

BIMO Audits

Albert Rodriguez, 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

4:15 – 5:00 pm

Inspection Activity

Bleta Vuniqi, FDA

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

5:00 – 6:00 pm

Networking Reception

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8:30 – 9:00 am

Continental Breakfast

9:00 – 10:00 am

Dealing with the Unexpected

Michael Morton, Michael C. Morton Regulatory Consulting

- Clinical outcomes
- Animal test results
- Adverse panel recommendation

10:00 – 10:45 am

The Care and Feeding of Approved PMAs

Carla Weise, NAMSA

- Periodic (“Annual”) Reports
- Supplemental Submissions
- 30-day notices

10:45 – 11:00 am

Break

11:00 – 11:45 am

CDRH Ombudsman’s Office – Roles & Responsibilities and the Appeals Process

Ken Skodacek, FDA

11:45 – 12:15 pm

Real World Case Studies

Carla Weise, NAMSA

12:15 pm

Adjournment

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