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
  o What are the standards of evidence
  o What are the standards of review
  o Will submission go to panel
  o How much will it cost
  o How long will it take to get approval

10:00 – 10:45 am Development of a PMA Submission Strategy
FDA (Invited)
• 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

Important Notice
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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

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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

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5:00 – 6:00 pm  Networking Reception

Oct 11, 2019

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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