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
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
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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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