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
FDA (Invited)
- 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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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

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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

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