



PMA Submissions Workshop

Hilton Alexandria Old Town
Alexandria, VA
October 29 - 30, 2009

Thursday, October 29th

8:30 – 9:00

REGISTRATION & CONTINENTAL BREAKFAST

9:00 – 9:05

Welcome

Thomas Maeder, Executive Director, MTLI, AdvaMed

9:05 – 9:45

Beginning at the Beginning

Anthony Blank, Vice President Cardiovascular Regulatory Affairs, Boston Scientific

Commentators: Nicole Wolanski, Director, Premarket Approval Section, ODE, CDRH

Laura Byrd, PMA Staff, ODE, CDRH

Angela Smith, Scientific Reviewer, Division of Cardiology Devices, FDA/ODE

- When is a PMA required
- 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

9:45 – 10:45

Development of a PMA Submission Strategy

Ashley Boam, Interventional Cardiology Devices Branch, ODE, CDRH

Commentators: Anthony Blank, Vice President Cardiovascular Regulatory Affairs, Boston Scientific

Elizabeth Hillebrenner, Scientific Reviewer, Division of Cardiovascular Devices, ODE, CDRH

- 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** **BREAK**
- 11:00 – 11:30** **Development of a PMA Submission Strategy (continued)**
- 11:30 – 12:15** **Meetings with the FDA**
Les Weinstein, Ombudsman, FDA/CDRH
Commentator: Angela Smith, Scientific Reviewer, Division of Cardiology Devices, FDA/ODE
- When
 - With whom
 - Processes
 - Best practices
- 12:15 – 1:30** **LUNCH**
- 1:30 – 2:30** **Mechanics of PMA Submission Development and Submission**
Christine Brauer, Regulatory Affairs Consultant
Commentators: Anastacia M. Bilek, Branch Chief, OPMD Division of Enforcement B.
Laura Byrd, PMA Staff, ODE, CDRH
Brian Novak, Director, Regulatory Affairs, Interventional Cardiology, Boston Scientific
Elizabeth Hillebrenner, Scientific Reviewer, Division of Cardiovascular Devices, ODE, CDRH
- Traditional or Modular
 - Defining data requirements
 - Required elements
 - Presentation of information with clarity
 - Expectations during review
 - Best practices
 - Manufacturing & Quality Systems
- 2:30 – 3:15** **During Submission Review**
Angela Smith, Scientific Reviewer, Division of Cardiology Devices, FDA/ODE
Commentators: Elizabeth Hillebrenner, Scientific Reviewer, Division of Cardiovascular Devices, ODE, CDRH
Industry Faculty
- Interactions with the FDA
 - When/How to expect questions
 - Types of letters
 - Timelines
 - Day 100 meetings
 - Labeling review
- 3:15 – 3:30** **BREAK**
- 3:30 – 5:00** **Inspectional Activity**

Linda Godfrey, Chief, Program Enforcement Branch A, Division of Bioresearch Monitoring, FDA/CDRH
D. Laurie Bernato, M.N., R.N., CCRP Senior Regulatory Operations Officer, FDA/CDRH
Anastacia M. Bilek, Branch Chief, OPMD Division of Enforcement B.

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

5:00 ADJOURNMENT

Friday, October 30th

8:00 – 8:30 CONTINENTAL BREAKFAST

8:30 – 9:30 Advisory Panels

Geretta Wood, Advisory Panel Coordinator, ODE, CDRH
Michael Morton, Senior Director, Regulatory Affairs, Medtronic
Commentators: Elizabeth Hillebrenner, Scientific Reviewer, Division of Cardiovascular Devices, ODE, CDRH

- 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

9:30 – 10:15 Conditions of Approval Studies

Anthony Blank, VP Cardiovascular Regulatory Affairs, Boston Scientific
Danica Marinac-Dabic, Chief, Epidemiology Branch, FDA/CDRH

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

10:15 – 10:30 BREAK

10:30 – 11:30 Dealing with the Unexpected

Brian Novak, Director, Regulatory Affairs, Interventional Cardiology, Boston Scientific
Les Weinstein, Ombudsman, FDA/CDRH
Commentator: Angela Smith, Scientific Reviewer, Division of Cardiology Devices, FDA/ODE

- Clinical outcomes
- Animal test results
- Adverse panel recommendation

- Dispute resolution
- Role of Ombudsman

11:30 – 12:30

The Care and Feeding of Approved PMAs

Laura Byrd, Laura Byrd, PMA Staff, ODE, CDRH

Commentator: Industry Faculty

- Periodic (“Annual”) Reports
- Supplemental Submissions

12:30 – 1:30

LUNCH

1:30 – 3:30

Real World Case Studies

*Anthony Blank, Vice President, Cardiovascular Regulatory Affairs,
Boston Scientific*

Michael Morton, Senior Director, Regulatory Affairs, Medtronic

3:30

ADJOURNMENT

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