



PMA Submissions Workshop

The Westin Casuarina Hotel
Las Vegas, NV
February 25 – 26, 2010

Thursday, February 25th

8:00 – 8:30 **REGISTRATION AND CONTINENTAL BREAKFAST**

8:30 – 8:35 **Welcome**
Thomas Maeder, Executive Director, MTLI, AdvaMed

8:35 – 9:00 **Beginning at the Beginning**
Anthony Blank, Vice President Cardiovascular Regulatory Affairs, Boston Scientific

- 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

9:00 – 10:00 **Development of a PMA Submission Strategy**
Laura Byrd, PMA Staff, ODE, FDA/CDRH

- Product definition
- Development of testing requirements and strategy
- Desired patient population
- Desired claims
- Early interactions with FDA
- Planning for product iterations

10:00 – 10:15 **BREAK**

10:15 – 11:30

Mechanics of PMA Submission Development and Submission

Anastacia M. Bilek, Branch Chief, FDA/OPMD Division of Enforcement
Helen Lavin, Regulatory Affairs Manager, Boston Scientific

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

11:30 – 12:30

During Submission Review

Laura Byrd, PMA Staff, ODE, FDA/CDRH

- Interactions with the FDA
- When/How to expect questions
- Types of letters
- Timelines
- Day 100 meetings
- Labeling review

12:30 – 1:45

LUNCH PRESENTATION - MEETINGS with the FDA

Les Weinstein, Ombudsman, FDA/CDRH

- When
- With whom
- Processes
- Best practices

1:45 – 2:45

Advisory Panels

Michael Morton, Senior Director, Regulatory Affairs, Medtronic

Anastacia M. Bilek, Branch Chief, FDA/OPMD Division of Enforcement

Laura Byrd, PMA Staff, ODE, FDA/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

2:45 – 3:00

BREAK

3:00 – 4:00

Conditions of Approval Studies

Michael Morton, Senior Director, Regulatory Affairs, Medtronic

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

ADJOURNMENT

4:00 – 5:00 **RECEPTION**

Friday, February 26th

8:15 – 8:45 **REGISTRATION AND CONTINENTAL BREAKFAST**

8:45 – 10:15 **Inspectional Activity**

Anastacia M. Bilek, Branch Chief, FDA/OPMD Division of Enforcement

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

10:15 – 10:30 **BREAK**

10:30 – 11:30 **Dealing with the Unexpected**

Anthony Blank, Vice President Cardiovascular Regulatory Affairs, Boston Scientific

- Clinical outcomes
- Animal test results
- Adverse panel recommendation

11:30 – 12:30 **The Care and Feeding of Approved PMAs**

Laura Byrd, PMA Staff, ODE, FDA/CDRH

- Periodic (“Annual”) Reports
- Supplemental Submissions

11:30 – 12:30 **LUNCH**

1:30 – 3:00 **Real World Case Studies**

ADJOURNMENT

Important Notice

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