



Investigational Device Exemption (IDE) Submission Workshop

The Westin Casuarina Hotel
Las Vegas, NV
February 24, 2010

Wednesday, February 24th

- 8:30 – 9:00** **REGISTRATION AND CONTINENTAL BREAKFAST**
- 9:00 – 9:05** **Welcome**
Thomas Maeder, Executive Director, MTLI, AdvaMed
- 9:05 – 9:45** **What Is an IDE**
Lynn Henley, Public Health Analyst, FDA/CDRH
- The purpose of an IDE exemption
 - Different types of IDEs
 - What an IDE does (and does not) permit
 - When should manufacturers or physicians seek an IDE
 - Roles of IRBs, investigators, and sponsors
- 9:45 – 10:45** **Developing an IDE Strategy**
Anthony Blank, VP Cardiovascular Regulatory Affairs, Boston Scientific
- What to consider and when
 - Preclinical testing before human studies
 - Making the best use of pre-IDE meetings
 - Using foreign data in a US submission
 - What makes an IDE submission successful
- 10:45 – 11:00** **BREAK**
- 11:00 – 12:00** **Mechanics of an IDE Application**
Anthony Blank, VP Cardiovascular Regulatory Affairs, Boston Scientific
- The elements of an IDE
 - Avoiding common errors and deficiencies
 - Key elements of the study protocol
 - The role of risk analysis in an IDE
 - Managing planned or unplanned device or study changes

- Reimbursement for clinical studies
- Pre-IDE meetings

12:00 – 1:15

LUNCH

1:15 – 2:00

Regulatory Requirements During Trial Conduct

Michael Morton, Senior Director, Regulatory Affairs, Medtronic

- Monitoring
- Consenting of patients
- Enrollment requirements
- Adverse event reporting
- Sponsor records and reports
- Investigator records and reports
- Protocol deviations

2:00 – 3:00

BIMO Audits

Linda Godfrey, Chief, Program Enforcement Branch A, Division of Bioresearch Monitoring, FDA/CDRH

- 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

3:00 – 3:15

BREAK

3:15 – 4:00

Reporting Results

Michael Morton, Senior Director, Regulatory Affairs, Medtronic

- Clinical study reports (interim and final)
- Dissemination to the medical community and to regulators
- Incorporation into pre-market submissions
- Assessment of impact to product labeling

4:00 – 5:00

Best Practices

All FDA and Industry Faculty

5:00

ADJOURNMENT

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the

information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.