



Investigational Device Exemption (IDE) Submission Workshop

Washington, DC
October 28, 2009

Wednesday, October 28th

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**
Sheila Brown, RN, Nurse Consultant, 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**
Christine Brauer, Consultant, Brauer Device Consultants

- 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

Christine Brauer, Consultant, Brauer Device Consultants

- 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

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