AdvaMed
Advanced Medical Technology Association
Events & Education

Investigational Device Exemption (IDE) Submissions Workshop

Virtual
February 17, 2027

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9:00 – 9:05 am **Welcome and Introductions**

9:05 – 10:00 am **What Is an IDE?**
Anne Talley, Chemical Engineer, FDA
- Regulatory Context
- When is an IDE needed?
- Roles of sponsors, investigators and IRBs
- The IDE Application and Helpful Tips

10:00 – 11:00 am **Developing an IDE Strategy**
Tony Blank, Senior Director of Regulatory Affairs, AtriCure
- What to consider and when
- Preclinical testing before human studies
- Making the best use of pre-submission meetings
- Using foreign data in a US submission
- Characteristics of a successful IDE submission

11:00 – 11:15 am **Break**

11:15 am – 12:30 pm **Preparing the Technical & Functional Aspects of an IDE**
Speaker TBA
- Elements of an IDE: Intro/Background, Manufacturing/Device, Labeling, Reference/Other
- Avoiding common errors and deficiencies
- The role of risk analysis in an IDE
- Managing planned or unplanned device or study changes

12:30 – 1:30 pm **Lunch Break**

1:30 – 2:15 pm **Regulatory Compliance During Study Conduct**
Tony Blank, Senior Director of Regulatory Affairs, AtriCure
- Monitoring
- Consenting of patients
- Enrollment requirements
- Adverse event reporting
- Sponsor records and reports

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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.

- Investigator records and reports
- Protocol deviations

2:15 – 3:00 pm **Reporting Results**
Speaker TBA

- 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
- Requirements for registering trials on CT.gov

3:00 – 3:15 pm **Break**

3:15 – 4:00 pm **Optimizing the Pre-Submission Meeting**
Tony Blank, Senior Director of Regulatory Affairs, AtriCure

- Purpose and value of the meeting
- Requesting a pre-sub meeting
- Identifying discussion questions
- Team preparation and rehearsals

4:00 – 4:45 pm **BIMO Inspections**
Amrin Chowdhury, Health Scientist, 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

4:45 – 5:15 pm **Q&A**

5:15 pm **Adjournment**

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