AdvaMed
Advanced Medical Technology Association
Events & Education

Investigational Device Exemption (IDE) Submissions Workshop

AdvaMed Office
1301 Pennsylvania Ave. N.W. Suite 400 Washington, D.C.
February 5, 2025

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8:30 – 9:00 am	**Registration Check-In and Continental Breakfast**
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** *Kristin Zielinski Duggan, Partner, Global Regulatory, Hogan Lovells* • Monitoring • Consenting of patients • Enrollment requirements • Adverse event reporting • Sponsor records and reports • Investigator records and reports • Protocol deviations
12:30 – 1:30 pm	**Networking Lunch**
1:30 – 2:15 pm	**Regulatory Compliance During Study Conduct** *Tony Blank, Senior Director of Regulatory Affairs, AtriCure*

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- 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

2:15 – 3:00 pm **Reporting Results**

Kristin Zielinski Duggan, Partner, Global Regulatory, Hogan Lovells

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3:00 – 3:15 pm **Break**

3:15 – 4:00 pm **Optimizing the Pre-Submission Meeting**

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

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 **Speaker Q&A**

5:15 pm **Adjournment**