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

**Feb 5, 2025**

**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?**
*Tony Blank, Senior Director of Regulatory Affairs, AtriCure*

- 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**
*Blake Wilson, 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**

**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.

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

*Blake Wilson, Partner, Global Regulatory, Hogan Lovells*

- 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*

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**4:00 – 4:45 pm** **BIMO Inspections**

*Blake Wilson, Partner, Global Regulatory, Hogan Lovells*

- 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**

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