

# Investigational Device Exemption (IDE) Submissions Workshop

Virtual Event

May 18 – 19, 2023

*\*Schedule Reflected in Eastern Time*

## May 18, 2023

- 11:00 am – 11:05 am**     **Welcome and Introductions**
- 11:05 am – 11:40 am**     **What Is an IDE?**  
*Christina Savisaar, FDA*
- Regulatory Context
  - When is an IDE needed?
  - Roles of sponsors, investigators and IRBs
  - The IDE Application and Helpful Tips
- 11:40 am – 12:15 pm**     **Developing an IDE Strategy**  
*Tony Blank, 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
- 12:15 pm – 12:20 pm**     **Break**
- 12:20 pm – 1:25 pm**     **Preparing the Technical & Functional Aspects of an IDE**  
*Kristin Zielinski Duggan, Hogan Lovells*
- 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
- 1:25 pm – 1:40 pm**     **Group Q&A**
- 1:40 pm – 1:55 pm**     **Break**

### **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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- 1:55 pm – 2:30 pm**      **Regulatory Compliance During Study Conduct**  
*Tony Blank, AtriCure*
- Monitoring
  - Consenting of patients
  - Enrollment requirements
  - Adverse event reporting
  - Sponsor records and reports
  - Investigator records and reports
  - Protocol deviations
- 2:30 pm – 3:05 pm**      **Reporting Results**  
*Kristin Zielinski Duggan, 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
- 3:05 pm – 3:40 pm**      **Optimizing the Pre-Submission Meeting**  
*Tony Blank, AtriCure*
- Purpose and value of the meeting
  - Requesting a Pre-sub meeting
  - Identifying discussion questions
  - Team preparation and rehearsals
- 3:40 pm – 3:55 pm**      **Group Q&A**
- 3:55 pm – 4:10 pm**      **Break**
- 4:10 pm – 4:40 pm**      **BIMO Inspections**  
*Irfan Khan, 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
- 4:40 pm**      **Closing Remarks and Adjourn**

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**May 19, 2023**

**12:00 pm – 1:15 pm**

**Applied Learning and Breakout Discussions**

- IDE Recap
- Facilitated Breakout Group Deep Dive
  - Hypothetical Case Studies
  - Key Takeaways
- Regroup for Final Program Q&A

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