

Investigational Device Exemption (IDE) Submissions Workshop

Virtual Event

February 15-16, 2022

**Schedule Reflected in Eastern Time*

February 15, 2022

- 11:00 am – 11:05 am** **Welcome and Introductions**
- 11:05 am – 11:40 am** **What Is an IDE?**
- The purpose of an IDE exemption
 - What an IDE does (and does not) permit
 - When manufacturers or physicians should seek an IDE
 - Roles of IRBs, investigators, and sponsors
- 11:40 am – 12:15 pm** **Developing an IDE Strategy**
- 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**
- 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** **Q&A**
- 1:40 pm – 1:55 pm** **Break**
- 1:55 pm – 2:30 pm** **Regulatory Compliance During Study Conduct**
- Monitoring
 - Consenting of patients
 - Enrollment requirements
 - Adverse event reporting
 - Sponsor records and reports
 - Investigator records and reports
 - Protocol deviations

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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2:30 pm – 3:05 pm	Reporting Results <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Purpose and value of the meeting• Requesting a Pre-sub meeting• Identifying discussion questions• Team preparation and rehearsals
3:40 pm – 3:55 pm	Q&A
3:55 pm – 4:10 pm	Break
4:10 pm – 4:40 pm	BIMO Inspections <ul style="list-style-type: none">• 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

February 16, 2022

12:00 pm – 1:15 pm	Applied Learning and Discussion <ul style="list-style-type: none">• Hypothetical Case Study Review• Facilitated Breakout Group Deep Dive• Key Takeaways• Final Program Q&A
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