AdvaMed
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Events & Education

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?**
Jayna Wiebel, FDA
- 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**
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**

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1:55 pm – 2:30 pm **Regulatory Compliance During Study Conduct**
Jaap Laufer, Emergo by UL
- 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**
Albert Rodriguez, 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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12:00 pm – 1:15 pm **Applied Learning and Discussion**

- Hypothetical Case Study Review
- Facilitated Breakout Group Deep Dive
- Key Takeaways
- Final Program Q&A