Investigational Device Exemption (IDE) Submissions Workshop
Virtual Event
February 24, 2021
*Schedule Reflected in Eastern Time

Feb 24, 2021
11:00 – 11:05 am Welcome and Introductions

11:05 – 11:45 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

11:45 am – 1:00 pm Preparing the Technical & Functional Aspects of an IDE
Pam Weagraff, IQVIA
- 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

1:00 – 1:05 pm Break

1:05 – 1:45 pm Regulatory Compliance During Study Conduct
Vinny Podichetty, JenaValve Technology, Inc.
- Monitoring
- Consenting of patients
- Enrollment requirements
- Adverse event reporting
- Sponsor records and reports
- Investigator records and reports
- Protocol deviations

1:45 – 2:25 pm Reporting Results
Pam Weagraff, IQVIA
- 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

2:25 – 2:35 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.
2:35 – 3:15 pm  Optimizing the Pre-PMA Meeting  
Anisa Mohanty, McDermott Will & Emery LLP  
Vernessa Pollard, McDermott Will & Emery LLP  
- Purpose and value of the meeting  
- Requesting a Pre-PMA meeting  
- Identifying discussion questions  
- Team preparation and rehearsals

3:15 – 3:55 pm  Developing an IDE Strategy  
Tony Blank, Infinity Biomedical Group  
- 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

3:55 – 4:00 pm  Break

4:00 – 4:30 pm  BIMO Audits  
Christopher Gioffre, 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

4:30 pm  Closing Remarks and Adjourn

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