Investigational Device Exemption (IDE) Submissions Workshop
AdvaMed Office
701 Pennsylvania Ave. N.W. Suite 800 Washington, D.C.
October 9, 2019

Oct 9, 2019
8:30 – 9:00 am  Registration Check-In and Continental Breakfast

9:00 – 9:05 am  Welcome and Introductions

9:05 – 9:45 am  What Is an IDE?
Douglas Dumont, FDA
- The purpose of an IDE exemption
- Different types of IDEs
- What an IDE does (and does not) permit
- When manufacturers or physicians should seek an IDE
- Roles of IRBs, investigators, and sponsors

9:45 – 10:00 am  Break

10:00 – 11:30 am  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

11:30 – 12:15 pm  Regulatory Compliance During Study Conduct
Brian Malkin, Arent Fox
- Monitoring
- Consenting of patients
- Enrollment requirements
- Adverse event reporting
- Sponsor records and reports
- Investigator records and reports
- Protocol deviations

12:15 – 1:15  Networking Lunch

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.
1:15 – 2:00 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  

2:00 – 2:30 pm  Optimizing the Pre-PMA Meeting  
*Kristin Davenport, Covington & Burling LLP*  
*Christina Kuhn, Covington & Burling LLP*  
- Purpose and value of the meeting  
- Requesting a Pre-PMA meeting  
- Identifying discussion questions  
- Team preparation and rehearsals  

2:30 – 2:45 pm  Break  

2:45 – 3:45 pm  Developing an IDE Strategy  
*Kristin Davenport, Covington & Burling LLP*  
*Christina Kuhn, Covington & Burling LLP*  
- 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  

3:45 – 4:45 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  

4:45 – 5:15 pm  Speaker Q&A  

5:15 pm  Adjournment  

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