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

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**Important Notice**
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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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