Investigational Device Exemption (IDE) Submissions Workshop
Virtual Event
May 18 – 19, 2023
Schedule Reflected in Eastern Time
**Agenda as of February 8, 2023*

May 18, 2023

11:00 am – 11:05 am   **Welcome and Introductions**

11:05 am – 11:40 am   **What Is an IDE?**

- Regulatory Context
- When is an IDE needed?
- Roles of sponsors, investigators and IRBs
- The IDE Application and Helpful Tips

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   **Group 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

2:30 pm – 3:05 pm   Reporting Results

- 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

- 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

- 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

May 19, 2023

12:00 pm – 1:15 pm   Applied Learning and Breakout Discussions
- IDE Recap
- Facilitated Breakout Group Deep Dive
  - Hypothetical Case Studies
  - Key Takeaways

Important Notice

- Regroup for Final Program Q&A