MedTech Compliance 201 – A Deeper Dive into Compliance Complexities
October 23-24, 2019
The Westin Crystal City
1800 Richmond Highway, Arlington, Virginia 22202

Wednesday, October 23, 2019
1:15 pm – 1:20 pm Introductions
- Welcome
- Faculty Bios
- Program Overview
- Attendees’ Goals for This Program

1:20 pm – 2:15 pm Assessing Your Company’s Compliance Risk Profile
- The Bottom Up Approach – Drawn from Those Doing the Day to Day Work in the Business
- The Top Down Approach – Drawn from the Senior Management of the Business
- Meshing the Two Approaches

2:15 pm – 3:30 pm Risk and Reason
- Attendee Teams – Representing Different Company Risk Profiles – Will Assess a variety of Scenarios and Develop Potential Responses/Actions Based on Their Team’s Risk Profile
- The Entire Group Will Discuss the Most Reasonable Approach Regardless of Assigned Risk Profile

3:30 pm – 3:45 pm Break

3:45 pm – 4:45 pm Privacy in MedTech
- Current & Emerging US State Laws & Regulations
- Considering HIPAA
- Addressing GDPR

4:45 pm – 5:20 pm Discussing Challenges and Issues Related to Value Based Arrangements

5:20 pm – 5:30 pm Review of Day One/Plan for Day Two

5:30 pm – 6:00 pm Adjourn

6:00 pm Go to Informal Dinner with Porzio/AdvaMed or Dinner on Your Own
Thursday, October 24, 2019

8:00 am – 8:30 am  Breakfast

8:30 am – 10:05 am  Communication Matters: Potential Pitfalls and Whistleblower Risk

10:05 am – 11:05 am  The Real-World Compliance Mine Fields
• Designing Programs with an Eye to Their Use
• Understanding How Things Go Away
• Programs that Should Be Thoughtfully Managed, e.g. Med Ed/Grants/Sponsorships, Co-Marketing, Reimbursement, Press Releases, International Programs

11:05 am – 11:20 am  Break

11:20 am – 12:05 pm  Conducting International Compliance Investigations
• Best Practices: Determining What Happened & Interpreting Conflicting Information
• Some “What Would You Do if During Your Investigation You Learned the Following Facts” Scenarios

12:05 pm – 12:40 pm  Motivating Your Senior Management & Board of Directors
• Obligations That Should Matter to Company Leadership
• Approaches to Gaining and Maintaining (and Inspiring?) Company Leadership’s Support for Compliance

12:40 pm – 12:45 pm  Review of The Program/Final Q&A

12:45 pm  Adjourn