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   Can a New Sales Compensation Plan Fix the Commercial and Compliance Issues at This Hypothetical Company?
  • Attendee Teams Will Develop Sales Compensation Plans to Address the Business and Compliance Issues at a Hypothetical Company
  • Intended and Unintended Consequences Resulting from Changes to Sales Compensation Will Be Discussed

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