



**AdvaMed**

Advanced Medical Technology Association  
Events & Education



## **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



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**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 Internal 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



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**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**