



## **MedTech Compliance 101**

**October 22-23, 2019**

**The Westin Crystal City**

**1800 Richmond Highway, Arlington, Virginia 22202**

### **Tuesday, October 22, 2019**

**8:00 am – 8:30 am**

**Breakfast**

**8:30 am – 9:00 am**

**Introduction**

- Faculty Bios
- Attendees' Goals for This Program
- Compliance Survey Results: What Your US Compliance Colleagues Think About Today's Hot Issues

**9:00 am – 9:45 am**

**The Amorphous Power of Culture**

- Impact of Culture on Compliance
- Pressure Points that Can Affect (and Change?) Culture

**9:45 am – 10:25 am**

**The Foundation of Your Compliance Program**

- Converting the 7 (or 8) Elements of an Effective Compliance Program into a Structure
- The Tools and an Environment to Manage Risk

**10:25 am – 11:10 am**

**What Interests the Government These Days**

- Recent Government Enforcement Actions & Areas of Focus
- Lessons Learned and Their Relevance to Your Business

**11:10 am – 11:25 am**

**Break**



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<b>11:25 am – 12:45 pm</b>	<b>Identifying &amp; Mitigating Your Major Compliance Risk Areas</b> <ul style="list-style-type: none"><li>• Critical Areas to Assess and Address Including: Interactions with HCPs and Other Health Care Entities; Managing Third-Party Distributors; Data Privacy; Other Compliance Challenges</li><li>• Practical Methods to Address Risk</li></ul>
<b>12:45 pm – 1:30 pm</b>	<b>Lunch</b>
<b>1:30 pm – 2:00 pm</b>	<b>The 2020 AdvaMed Code</b> <ul style="list-style-type: none"><li>• New Elements of the 2020 Code</li><li>• Attendees' Questions</li></ul>
<b>2:15 pm – 3:05 pm</b>	<b>Interactive Case Study</b> <ul style="list-style-type: none"><li>• All attendees will be given the same hypothetical case study.</li><li>• Attendees will split into 3 groups. Each group will focus on specific areas of the company and the associated issues.</li><li>• Together we will discuss each group's conclusions in the session to follow.</li></ul>
<b>3:05 pm – 3:20 pm</b>	<b>Break</b>
<b>3:20 pm – 4:30 pm</b>	<b>Each Breakout Group's Presentation: Fixing Issues in the Case Study</b> <ul style="list-style-type: none"><li>• Group #1</li><li>• Group #2</li><li>• Group #3</li></ul>
<b>4:30 pm – 4:45 pm</b>	<b>Review of Day One/Plan for Day Two</b>
<b>4:45 pm – 5:00 pm</b>	<b>Adjourn Day One/Walk to Nearby Off-site Program Reception</b>
<b>5:00 pm</b>	<b>Program Reception</b>
<b><u>Wednesday, October 23, 2019</u></b>	
<b>8:00 am – 8:30 am</b>	<b>Breakfast</b>



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**8:30 am – 9:15 am**

**Managing Promotional, Medical & Investor Communications: What You Can/Should/Shouldn't Say to Whom**

- The Rules, the Processes, the People
- The Difficulties/The Resolutions
- Hypothetical Communications: Attendees Review and Discuss Good & Not-So-Good Communications

**9:15 am – 10:55 am**

**Industry Panel – Health Care Compliance and All Its Glory in the Medical Device Business**

- This session will involve current in-house Compliance Officers and the AdvaMed Senior Executive Vice President and General Counsel who will discuss the multifaceted considerations associated with managing and mitigating health care compliance risks in today's medical device industry.
- Throughout the discussion, attendees will be able to ask questions.

**10:55 am – 11:10 am**

**Break**

**11:10 am – 11:30 am**

**Sunshine Act Reporting So Far and Transparency Developments at the State Level & Outside the US**

- The Last Federal Reporting Period – A Top Line Review
- Recent US State Activities
- OUS Developments

**11:30 am – 12:00 pm**

**Closing Discussion, Q&A and Wrap-up**

- Any Remaining (Burning) Questions
- So What Are You Going to Do When You Get Back to Work on Tuesday?

**12:00 pm**

**Adjourn Day Two**