

## MedTech Compliance Bootcamp (Draft)

DAY ONE – Tuesday, September 10th

Program Section	Start Time	Duration	Topic/Details <i>All Sessions Will Be Interactive Throughout</i>
	8:00 am	30 min.	<b>Breakfast</b>
<b>One</b>	8:30 am	30 min.	<b>Introduction</b> <ul style="list-style-type: none"> <li>Faculty Bios</li> <li>Program Overview</li> <li>Attendees' Goals for This Program/Polling</li> <li>AdvaMed Intro</li> </ul>
<b>Two</b>	9:00 am	45 min.	<b>The Amorphous Power of Culture</b> <ul style="list-style-type: none"> <li>Impact of Culture on Compliance</li> <li>Pressure Points that Can Affect (and Change?) Culture</li> </ul>
<b>Three</b>	9:45 am	60 min.	<b>The Foundation of Your Compliance Program</b> <ul style="list-style-type: none"> <li>Relevant Laws, Rules and Guidance</li> <li>Converting the Required Elements of an Effective Compliance Program into a Structure</li> <li>The Tools and Environment to Manage Risk</li> <li>Motivating Senior Management and Educating the Board</li> </ul>
	10:45 am	15 min.	<b>Break</b>
<b>Four</b>	11:00 am	60 min.	<b>What Interests The Government These Days</b> <ul style="list-style-type: none"> <li>Recent Government Enforcement Actions &amp; Areas of Focus</li> <li>Lessons Learned and Their Relevance to Your Business</li> <li>New Developments</li> </ul>
	12:00 pm	60 min.	<b>Lunch</b>
<b>Five</b>	1:00 pm	120 min.	<b>Compliance Deep Dive: Identifying and Mitigating Ongoing and Emerging Risk Areas Inside and Outside the United States</b> <ul style="list-style-type: none"> <li>Identifying High Risk Areas</li> <li>Addressing and Mitigating Risks Locally and Globally</li> </ul> <p>Considerations related to Interactions with HCPs and Other Health Care Entities; Managing Third-Party Distributors; Data Privacy; Other Compliance Challenges</p>
	3:00 pm	15 min.	<b>Break</b>
<b>Six</b>	3:15 pm	120 min.	<b>Interactive Break Out Session</b> <ul style="list-style-type: none"> <li>Present hypothetical scenarios and consider application of the AdvaMed Code and other compliance considerations</li> <li>Conducting a compliance risk assessment</li> </ul>
<b>Seven</b>	5:15 pm	15 min.	<b>Review of Day One/Plan for Day Two</b>
	5:30 pm	15 min.	<b>Adjourn Day One</b>
	6:30 pm	120 min.	<b>Program Reception - The Henri – 1301 Pennsylvania Avenue. N.W., Washington, DC</b>

**DAY TWO – Wednesday, September 11<sup>th</sup>**

<b>Program Section</b>	<b>Start Time</b>	<b>Duration</b>	<b>Topic/Details</b> <i>All Sessions Will Be Interactive Throughout</i>
	8:00 am	30 min.	<b>Breakfast</b>
<b>Nine</b>	8:30 am	30 min.	<b>Recap of Day 1 and Interactive Q&amp;A</b>
<b>Ten</b>	9:00 am	60 min.	<b>Managing Promotional, Medical, Corporate &amp; Investor Communications (including Social Media): What You Can/Should/Shouldn't Say to Whom</b> <ul style="list-style-type: none"> <li>• Regulatory Requirements for Promotion</li> <li>• Recent Developments: FDA and FTC Enforcement</li> <li>• Key Considerations for Scientific Exchange, Disease Awareness and Corporate Communications</li> <li>• Social Media and Considerations with Use of "Influencers"</li> </ul>
<b>Eleven</b>	10:00 am	90 min.	<b>Industry Panel – Healthcare Compliance and All Its Glory in the Medical Device Business</b> <p><i>This session will involve current in-house Compliance Officers and AdvaMed compliance leaders who will discuss the multifaceted considerations associated with managing and mitigating health care compliance risks in today's medical device industry.</i></p>
<b>Twelve</b>	11:30 am	45 min.	<b>AdvaMed Session (TBD)</b> <ul style="list-style-type: none"> <li>• Patrick Fogarty, Deputy General Counsel and Senior Vice President, Legal, AdvaMed</li> <li>• Ida Nassar, Vice President, Assistant General Counsel, Compliance &amp; Ethics, Legal, AdvaMed</li> </ul>
	12:15 pm	45 min.	<i>Lunch Break</i>
<b>Thirteen</b>	12:45 pm	60 min.	<b>Hot Topics</b>
<b>Fourteen</b>	1:45 pm	15 min.	<b>Closing Discussion, Q&amp;A and Wrap-up</b> <ul style="list-style-type: none"> <li>• Any Remaining (Burning) Questions</li> <li>• So What Are You Going to Do When You Get Back to Work?</li> </ul>
	2:00 pm	-	<b>Adjourn Day Two</b>