

**AdvaMed/Porzio 2022**  
**MedTech Compliance 101 – THE BOOT CAMP**

**DAY ONE – Wednesday, September 14th**

<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>One</b>	8:30 am	30 min.	<b>Introduction (AdvaMed &amp; Porzio)</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 – Chris White</li> </ul>
<b>Two</b>	9:00 am	45 min.	<b>The Amorphous Power of Culture (Porzio)</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	45 min.	<b>The Foundation of Your Compliance Program (Porzio)</b> <ul style="list-style-type: none"> <li>• Converting the Required Elements of an Effective Compliance Program into a Structure</li> <li>• The Tools and an Environment to Manage Risk</li> <li>• Motivating Senior Management and Educating the Board</li> </ul>
	10:30 am	15 min.	<b>Break</b>
<b>Four</b>	10:45 am	60 min.	<b>What Interests The Government These Days (Porzio)</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: Privacy, FDA Initiatives, and COVID-19, Telehealth SFA, Medical Education</li> </ul>
<b>Five</b>	11:45 am	60 min.	<b>Identifying &amp; Mitigating Your Major Compliance Risk Areas (Porzio)</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>
	12:45 pm	45 min.	<b>Lunch</b>
<b>Five (Continued)</b>	1:30 pm	60 min.	<b>Identifying &amp; Mitigating Your Major Compliance Risk Areas (Porzio)</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> </ul>

			<ul style="list-style-type: none"> <li>Practical Methods to Address Risk</li> </ul>
<b>Six</b>	2:30 pm	60 min.	<b>The 2022 AdvaMed Code (AdvaMed) – Pat Fogarty speaker &amp; panel, Terry Chang &amp; Ethan Gumpert</b> <ul style="list-style-type: none"> <li>Goals of the Code</li> <li>Recent Updates to the 2022 Code (e.g. alcohol at Speaker Programs)</li> <li>AdvaMed Code Tools &amp; Resources (VBH, Benchmarking, HealthStream Training Course, Certification)</li> <li>Attendees' Questions</li> </ul>
<b>Seven</b>	3:30 pm	60 min.	<b>Interactive Break Out Session (Porzio)</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>
	4:30 pm	15 min.	<b>Break</b>
<b>Seven (continued)</b>	4:45 pm	60 min.	<b>Interactive Break Out Session (Porzio)</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>Eight</b>	5:45 pm	15 min.	<b>Review of Day One/Plan for Day Two</b>
	6:00 pm	15 min.	<b>Adjourn Day One</b>
	6:15 pm	120 min.	<b>Program Reception – AdvaMed Rooftop</b>

## **MedTech Compliance 101 – THE BOOT CAMP**

### **DAY TWO – Thursday, September 15<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	60 min.	<b>Managing Promotional, Medical, Corporate &amp; Investor Communications (including Social Media): What You Can/Should/Shouldn't Say to Whom (Porzio)</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>Ten</b>	9:30 am	90 min	<b>Industry Panel – Healthcare Compliance and All Its Glory in the Medical Device Business (AdvaMed &amp; Porzio)</b> <ul style="list-style-type: none"> <li>• This session will involve current in-house Compliance Officers and the AdvaMed Senior Executive Vice President and General Counsel and Chief Policy Officer who will discuss the multifaceted considerations associated with managing and mitigating health care compliance risks in today’s medical device industry.</li> </ul>
	11:00 am	45 min	<b>OUS- Focused Panel on Foreign Corrupt Practices Act, Global Compliance, Distributor Compliance, AdvaMed Tools &amp; Resources (AdvaMed)</b>
	11:45 am	15 min.	<i>Break</i>
<b>Eleven</b>	12:00 am	30 min.	<b>Spend Transparency Developments: Inside and Outside of the U.S. (Porzio)</b> <ul style="list-style-type: none"> <li>• The Last Federal Reporting Period – A Top Line Review</li> <li>• Recent US State Activities</li> <li>• OUS Developments</li> </ul>
<b>Twelve</b>	12:30 pm	30 mins	<b>Closing Discussion, Q&amp;A and Wrap-up (Chris White, AdvaMed and Porzio)</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>
	1:00 pm	-	<b>Adjourn Day Two</b>