AdvaMed/Porzio 2022
MedTech Compliance 101 – THE BOOT CAMP

DAY ONE – Wednesday, September 14th

Program Section	Start Time	Duration	Topic/Details *All Sessions Will Be Interactive Throughout*
	8:00 am	30 min.	**Breakfast**
One	8:30 am	30 min.	**Introduction (AdvaMed & Porzio)** • Faculty Bios • Program Overview • Attendees' Goals for This Program/Polling • AdvaMed Intro – Chris White
Two	9:00 am	45 min.	**The Amorphous Power of Culture (Porzio)** • Impact of Culture on Compliance • Pressure Points that Can Affect (and Change?) Culture
Three	9:45 am	45 min.	**The Foundation of Your Compliance Program (Porzio)** • Converting the Required Elements of an Effective Compliance Program into a Structure • The Tools and an Environment to Manage Risk • Motivating Senior Management and Educating the Board
	10:30 am	15 min.	*Break*
Four	10:45 am	60 min.	**What Interests The Government These Days (Porzio)** • Recent Government Enforcement Actions & Areas of Focus • Lessons Learned and Their Relevance to Your Business • New Developments: Privacy, FDA Initiatives, and COVID-19, Telehealth SFA, Medical Education
Five	11:45 am	60 min.	**Identifying & Mitigating Your Major Compliance Risk Areas (Porzio)** • Critical Areas to Assess and Address Including: Interactions with HCPs and Other Health Care Entities; Managing Third-Party Distributors; Data Privacy; Other Compliance Challenges • Practical Methods to Address Risk
	12:45 pm	45 min.	*Lunch*
Five (Continued)	1:30 pm	60 min.	**Identifying & Mitigating Your Major Compliance Risk Areas (Porzio)** • Critical Areas to Assess and Address Including: Interactions with HCPs and Other Health Care Entities; Managing Third-Party Distributors; Data Privacy; Other Compliance Challenges • Practical Methods to Address Risk

	2:30 pm	60 min.	**The 2022 AdvaMed Code** (AdvaMed) (AdvaMed) – **Pat Fogarty speaker & panel, Terry Chang** • Goals of the Code • Recent Updates to the 2022 Code (e.g. alcohol at Speaker Programs) • AdvaMed Code Tools & Resources (VBH, Benchmarking, HealthStream Training Course, Certification) • Attendees' Questions
Six			
Seven	3:30 pm	60 min.	**Interactive Break Out Session** (Porzio) • Present hypothetical scenarios and consider application of the AdvaMed Code and other compliance considerations • Conducting a compliance risk assessment
	4:30 pm	15 min.	*Break*
Seven (continued)	4:45 pm	60 min.	**Interactive Break Out Session** (Porzio) • Present hypothetical scenarios and consider application of the AdvaMed Code and other compliance considerations • Conducting a compliance risk assessment
Eight	5:45 pm	15 min.	**Review of Day One/Plan for Day Two**
	6:00 pm	15 min.	**Adjourn Day One**
	6:15 pm	120 min.	**Program Reception - The Henri – 1301 Pennsylvania Avenue. N.W., Washington, DC**

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DAY TWO – Thursday, September 15th

Program Section	Start Time	Duration	Topic/Details *All Sessions Will Be Interactive Throughout*
	8:00 am	30 min.	**Breakfast**
Nine	8:30 am	60 min.	**Managing Promotional, Medical, Corporate & Investor Communications (including Social Media): What You Can/Should/Shouldn't Say to Whom** (Porzio) • Regulatory Requirements for Promotion • Recent Developments: FDA and FTC Enforcement • Key Considerations for Scientific Exchange, Disease Awareness and Corporate Communications • Social Media and Considerations with Use of "Influencers"
Ten	9:30 am	90 min	**Industry Panel – Healthcare Compliance and All Its Glory in the Medical Device Business** **Moderator: Michelle Axelrod, Senior Vice President, Porzio Life Sciences** **Speakers:**

			• **Chris White, Chief Operating Officer, General Counsel, AdvaMed** • **Daniel Spicehandler, Vice President, Compliance – Commercial Divisions, Stryker** • **Marc Began, Executive Vice President, General Counsel and Secretary, ABIOMED** • **Kathryn Stager, Compliance Officer and Vice President of Regulatory Affairs and Quality Systems, SPR Therapeutics** • *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.*
Eleven	11:00 am	45 min	***OUS- Focused Panel on Foreign Corrupt Practices Act, Global Compliance, Distributor Compliance, AdvaMed Tools & Resources* (AdvaMed)**
	11:45 am	10 min.	*Break*
Twelve	11:55 am	50 min.	**Spend Transparency Developments: Inside and Outside of the U.S. (Porzio)** • The Last Federal Reporting Period – A Top Line Review • Recent US State Activities • OUS Developments
Thirteen	12:45 pm	15 mins	**Closing Discussion, Q&A and Wrap-up (AdvaMed and Porzio)** • Any Remaining (Burning) Questions • So What Are You Going to Do When You Get Back to Work?
	1:00 pm	-	**Adjourn Day Two**