

AdvaMed MedTech Compliance Workshop

DAY ONE – Wednesday, September 16th

Program Section	Start Time	Duration	Topic/Details <i>All Sessions Will Be Interactive Throughout</i>
	8:00 am	30 min.	Breakfast
One	8:30 am	30 min.	Introduction • Faculty Bios • Program Overview • Attendees’ Goals for This Program/Polling • AdvaMed Intro
Two	9:00 am	45 min.	The Power of Culture: Building and Sustaining a Compliance-Oriented Organization Explores how to establish and maintain a culture of integrity and ethical decision-making across an organization. Attendees will discuss strategies for embedding compliance into daily operations and facilitating meaningful organizational impact. The session will include real-world examples and interactive discussion on leading a culture of compliance, overcoming resistance, and measuring cultural progress.
Three	9:45 am	60 min.	Enforcement Update: Key Trends, Emerging Risks, and Lessons Learned Provides an overview of recent federal and state enforcement actions affecting the medical technology industry and executive leadership, including developments under the Anti-Kickback Statute, False Claims Act, and Foreign Corrupt Practices Act. Speakers will analyze notable settlements and emerging enforcement priorities, with discussion of practical takeaways.
	10:45 am	15 min.	Break
Four	11:00 am	60 min.	Key Compliance Risks: Navigating a Complex Landscape Explores key legal and compliance risk areas relevant to medical technology companies operating in the U.S. and globally. Topics discussed will include: • Compliance considerations related to Interactions and Engagements with HCPs and Other Individuals/Entities • Grants, Sponsorships and Donations • Reimbursement Communications/Support Activities • Managing Compliance in a Global Environment, including Third Party Distributors Attendees will also have an opportunity to raise additional challenges, unique risk areas, and questions.
	12:00 pm	60 min.	Lunch

Four (cont'd)	1:00 pm	60 min.	Session Continued: Key Compliance Risks: Navigating a Complex Landscape Explores key legal and compliance risk areas relevant to medical technology companies operating in the U.S. and globally. Topics discussed will include: • Compliance considerations related to Interactions and Engagements with HCPs and Other Individuals/Entities • Grants, Sponsorships and Donations • Reimbursement Communications/Support Activities • Managing Compliance in a Global Environment, including Third Party Distributors Attendees will also have an opportunity to raise additional challenges, unique risk areas, and questions.
Five	2:00 pm	60 min.	Privacy and AI in Medtech: Navigating an Evolving Regulatory Landscape Attendees will examine key privacy and data protection considerations for medical technology companies, including state health data privacy laws, cross-border data transfer mechanisms, and compliance implications of AI and machine learning technologies. The session will address AI governance frameworks, FDA guidance on AI/ML-enabled technologies, and practical strategies for managing these emerging issues.
	3:00 pm	15 min.	Break
Six	3:15 pm	60 min.	Interactive Discussion: Test Your Knowledge and Confirm Your Approach This session will present hypothetical questions and scenarios and consider application of the AdvaMed Code and other applicable industry codes, and current legal and compliance risks.
Seven	4:15 pm	75 min.	The Importance of Risk Assessments and Break-Out Session: This interactive break-out session will guide attendees through best practices for conducting enterprise-wide compliance risk assessments. Participants will review hypothetical scenarios involving different business and compliance organization models and work together to identify risk factors, prioritize areas of concern, and develop mitigation strategies. The session will also address how to document risk assessments and communicate findings to leadership.
	5:30 pm	-	Adjourn Day One
	6:00 pm	120 min.	Program Reception – Succotash Prime, 915 F Street, N.W. Washington, DC 20004

DAY TWO – Thursday, September 17th

Program Section	Start Time	Duration	Topic/Details <i>All Sessions Will Be Interactive Throughout</i>
	8:00 am	30 min.	Breakfast
	8:30 am	30 min.	Recap of Day 1 and Interactive Q&A
Nine	9:00am	45 min.	AdvaMed Update: Advocacy and Policy Priorities - Pat Fogarty, Deputy General Counsel and SVP, Legal, AdvaMed - Ida Nassar, VP, Assistant General Counsel, Head of Global Ethics & Compliance Policy, AdvaMed This session provides an overview of AdvaMed’s advocacy and legal and compliance policy priorities as the leading voice for the medical technology industry, including its focus on advancing innovation, patient access to the best care for them, and a predictable regulatory environment. Key topics include the foundational role of the AdvaMed Code of Ethics in guiding ethical interactions and effective compliance programs and its role in AdvaMed’s broader advocacy.
Ten	9:45am	90 min	Industry Panel: Perspectives from Legal and Compliance Leaders • Alex Abbott, Chief People & Compliance Officer, Arthrex • Ida Nassar, Vice President, Assistant General Counsel, Head of Global Ethics & Compliance Policy, AdvaMed • Terri C. Segura, Vice President, Compliance Officer, Zimmer Biomet • Kathryn Stager, Regulatory Affairs, Quality Assurance, and Compliance, SPR Therapeutics A panel of experienced in-house legal and compliance professionals will share insights on managing complex compliance challenges in the medical technology industry. Topics will include benchmarking approaches, resource allocation, board and leadership communication, and emerging trends. Attendees will have the opportunity to pose questions and engage in open discussion.
	11:15am	15 min	BREAK
Eleven	11:30am	60 min.	External Communications: Promotional, Scientific, and Digital Considerations Explores compliance considerations related to external communications, including promotional claims, scientific exchange, social media, including the use of influencers, and direct-to-patient communications.
	12:30	60 min.	Lunch
Twelve	1:30 pm	60 min.	Interactive Session on Digital Communications and Social Media This session will present hypothetical scenarios to address challenges with communicating product information, disease state, and corporate developments to consumers/general public, HCPs and key stakeholders.
Thirteen	2:30pm	45 min.	Legal vs. Compliance The distinct but complementary roles of Legal and Compliance have never been more important – or more challenging to

			navigate. This session will explore the overlap of these two important disciplines in organizations of various sizes, their dynamic interplay, opportunities for collaboration, and potential areas of tension.
	3:15pm	15 min.	Open Q&A; Workshop Wrap-Up, Closing Discussion
	3:30pm	-	Adjourn Day Two