***AdvaMed/Porzio 2023***

***MedTech Compliance Bootcamp***

 **DAY ONE – Wednesday, September 13th**

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| **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*** Faculty Bios
* Program Overview
* Attendees’ Goals for This Program/Polling
* AdvaMed Intro
 |
| ***Two*** | 9:00 am | 45 min. | **The Amorphous Power of Culture** * 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*** Converting the Required Elements of an Effective Compliance Program into a Structure
* The Tools and 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*** Recent Government Enforcement Actions & Areas of Focus
* Lessons Learned and Their Relevance to Your Business
* New Developments
 |
| ***Five*** | 11:45 am | 60 min. | **Identifying & Mitigating Your Major Compliance Risk Areas** * 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** * 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
 |
| ***Six*** | 2:30 pm | 45 min. | **The AdvaMed Code** – **30th Anniversary*** Goals of the Code
* AdvaMed Code Tools & Resources (VBH, Benchmarking, HealthStream Training Course, Certification)
* Attendees’ Questions
 |
| ***Seven*** | 3:15 pm | 60 min.  | **Interactive Break Out Session** * Present hypothetical scenarios and consider application of the AdvaMed Code and other compliance considerations
* Conducting a compliance risk assessment
 |
|  | 4:15 pm | 15 min. | ***Break*** |
| ***Seven*** ***(continued)*** | 4:30 pm | 60 min. | **Interactive Break Out Session*** Present hypothetical scenarios and consider application of the AdvaMed Code and other compliance considerations
* Conducting a compliance risk assessment
 |
| ***Eight*** | 5:30 pm | 15 min. | **Review of Day One/Plan for Day Two** |
|  | 5:45 pm | 15 min. | **Adjourn Day One** |
|  | 6:00 pm | 120 min. | **Program Reception - The Henri – 1301 Pennsylvania Avenue. N.W., Washington, DC**  |

 **DAY TWO** **– Thursday, September 14th**

|  |  |  |  |
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| **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** * 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"
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| ***Ten*** | 9:30 am | 90 min. | **Industry Panel – Healthcare Compliance and All Its Glory in the Medical Device Business** * Hear from a panel of industry leaders in compliance who will discuss the multifaceted considerations associated with managing health care compliance risks in today’s medical device industry
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| ***Eleven***  | 11:00 am | 45 min. | **OUS- Focused Panel on AdvaMed’s Global Compliance Priorities**  |
|  | 11:45 am  | 15 min.  | *Break* |
| ***Twelve***  | 12:00 pm | 45 min. | **Hot Topics and Related Guidance** * Highlight Current Compliance Issues and Trends and Impact on Medtech Industry
 |
| ***Thirteen*** | 12:45 pm | 15 min.  | **Closing Discussion, Q&A and Wrap-up*** Any Remaining (Burning) Questions
* So What Are You Going to Do When You Get Back to Work?
 |
|  | 1:00 pm | - | **Adjourn Day Two** |