

## MedTech Compliance Bootcamp (Draft)

DAY ONE – Tuesday, September 10th

| Program Section | Start Time | Duration | Topic/Details<br><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><br><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>   |