



## The Essentials of Medical Device Regulations: A Primer for Manufacturers and Suppliers

Sheraton Dallas Hotel  
Dallas, Texas  
September 14-15, 2010

### Tuesday, Sept. 14

- 8:30 – 9:00**                    **REGISTRATION AND CONTINENTAL BREAKFAST**
- 9:00 – 9:10**                    **Welcome**  
*Reynaldo (Ricky) R. Rodriguez, Jr., Dallas District Director, FDA*  
*Frank Wilton, Senior Vice President, Membership & Marketing, AdvaMed*
- 9:10 – 9:50**                    **Organizational Structure of FDA**  
*Reynaldo (Ricky) R. Rodriguez, Jr., Dallas District Director, FDA*
- Organizational structure of FDA: CDRH and the field
  - Organizational structure of the region and district – who's who
  - Typical interactions with the District Office
- 9:50 – 10:45**                **Doing Business in a Regulated Industry**  
*William M. Sutton, Deputy Director, DSMICA, FDA/CDRH*
- Definition of a medical device
  - Medical Device Classification
  - Registration and Listing
  - Premarket review - 510(k)/PMA
  - Postmarket activities
- 10:45 – 11:00**                **BREAK**
- 11:00 – 11:30**                **Overview of the Quality System Regulation**  
*FDA Speaker – Dallas District*
- 11:30 – 12:00**                **Management Responsibility**  
*FDA Speaker – Dallas District*

<b>12:00 – 12:30</b>	<b>Design Control</b> <i>FDA Speaker – Dallas District</i>
<b>12:30 – 1:30</b>	<b>LUNCH</b>
<b>1:30 – 2:15</b>	<b>Import Operations (Medical Devices)</b> <i>FDA Speaker – Dallas District</i>
<b>2:15 – 3:00</b>	<b>Purchasing Controls and Acceptance Activities</b> <i>FDA Speaker – Dallas District</i>
<b>3:00 – 3:20</b>	<b>BREAK</b>
<b>3:20 – 3:50</b>	<b>Production and Process Control</b> <i>FDA Speaker – Dallas District</i>
<b>3:50– 4:30</b>	<b>Corrective And Preventive Actions</b> <i>FDA Speaker – Dallas District</i>
<b>4:30 – 5:00</b>	<b>Complaint Handling, MDR and Servicing</b> <i>FDA Speaker – Dallas District</i>
<b>5:00 – 5:30</b>	<b>Question &amp; Answer Session</b>
<b>5:30 – 6:30</b>	<b>RECEPTION</b>

**Wednesday, Sept. 15**

<b>8:30 – 9:00</b>	<b>CONTINENTAL BREAKFAST</b>
<b>9:00 – 9:30</b>	<b>FDA Inspections</b> <i>FDA Speaker – Dallas District</i>
<b>9:30 – 10:00</b>	<b>Compliance Issues</b> <i>FDA Speaker – Dallas District</i> <ul style="list-style-type: none"><li>• 483s</li><li>• Warning letters and untitled letters</li><li>• The agency review process</li><li>• How to respond to a 483</li></ul>
<b>10:00 – 10:30</b>	<b>Training and Audits</b> <i>Nicole Petty, Senior Manager, Learning &amp; Development, Stryker Instruments</i>
<b>10:30 – 10:45</b>	<b>BREAK</b>
<b>10:45 – 11:15</b>	<b>Manufacturers and Suppliers – The Chain of Regulatory Responsibility</b> <i>Industry Speaker</i> <ul style="list-style-type: none"><li>• Contractual relationships and responsibilities</li><li>• A checklist of regulatory issues</li></ul>

- 11:15 – 11:45**                    **Interacting with FDA – Where Do You Go for Assistance?**  
*David Arvelo, Small Business Representative (SBR), FDA Southwest Region*  
*William Sutton, Deputy Director, DSMICA, FDA/CDRH*
- Small Business Representative
  - DSMICA
  - Internet/Device Advice/CDRH Learn
- 11:45 – 12:00**                    **Morning Question & Answer Session**
- 12:00 – 1:30**                    **LUNCH**
- 1:30 – 2:15**                    **Reimbursement and Medical Technology**  
*Demetrios Kouzoukas, Of Counsel, Covington and Burling LLP*
- Reimbursement for medical devices
  - Reimbursement and strategic planning
  - Reimbursement issues to consider throughout the product life cycle
- 2:15 – 3:30**                    **Fraud and Abuse**  
*Demetrios Kouzoukas, Of Counsel, Covington and Burling LLP*
- The boundaries of legitimate promotion
  - Off-label promotion and anti-kickback laws
  - Safe harbors
- 3:30 – 3:50**                    **BREAK**
- 3:50 – 4:20**                    **The AdvaMed Code of Ethics**  
*Jason Cone, Senior Vice President, Chief Compliance Officer, Kinetic Concepts, Inc.*
- The changing landscape of medical marketing
  - Effective marketing/ethical marketing
  - Educating your sales force and your customers
- 4:20 – 5:00**                    **Afternoon Question & Answer Session**
- 5:00**                                **ADJOURNMENT**

***Important Notice***

*The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.*