AdvaMed
Advanced Medical Technology Association

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

Crowne Plaza Irvine
17941 Von Karman Ave
Irvine, CA

March 15 – 16, 2007

Thursday, March 15

8:30 – 9:00 CONTINENTAL BREAKFAST

9:00 – 9:10 Welcome
Alonza Cruse, LA District Director
Thomas Maeder, Executive Director, MTLI, AdvaMed

9:10 – 9:50 Organizational Structure of FDA
Alonza Cruse, LA District Director
- 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 – 10:20 Doing Business in a Regulated Industry
William Sutton, Deputy Director, DSMICA
- The history of FDA regulation of medical devices
- Classes of medical devices
- Premarket approval – PMAs and 510(k)s
- Postmarket interactions with the agency

10:20 – 10:40 BREAK

10:40 – 11:10 Overview of the Quality System Regulation
Joseph Puleo, Supervisory Consumer Safety Officer, CDRH, DSMICA

11:10 – 11:30 Management Responsibility
Mizanu Kebede, Vice President, WW Quality Assurance, Regulatory Affairs & PEx, Advanced Sterilization Products, a Johnson & Johnson company

11:30 – 12:00 Design Control
Kimberly Trautman, Quality System Expert, CDRH, Office of Compliance

12:00 – 1:30 LUNCH

1:30 – 2:00 **Human Factors**
Ron Kay, Public Health Advisor, CDRH, DUPSA

2:00 – 2:30 **Documents, Records and Change Control**
Joseph Puleo, Supervisory Consumer Safety Officer, CDRH, DSMICA

2:30 – 3:00 **Purchasing Controls and Acceptance Activities**
Kimberly Trautman, Quality System Expert, CDRH, Office of Compliance

3:00 – 3:20 **BREAK**

3:20 – 3:50 **Production and Process Control**
Dan Kiser, Director, Quality Systems, Advanced Sterilization Products a Johnson & Johnson company

3:50 – 4:30 **Corrective and Preventive Actions**
Vickie Anderson, Supervisory Consumer Safety Officer, LA District

4:30 – 5:00 **Complaint Handling, MDR and Servicing**
Katherine Jacobitz, Supervisory Consumer Safety Officer, LA District

5:00 – 5:30 **Question & Answer Session**

5:30 – 6:30 **RECEPTION**

Friday, March 16

8:30 – 9:00 **CONTINENTAL BREAKFAST**

9:00 – 9:30 **FDA Inspections**
Vickie Anderson, Supervisory Consumer Safety Officer, LA District

9:30 – 10:00 **Compliance Issues**
Pamela Schweikert, Director, Compliance Branch, LA District
- 483s
- Warning Letters and untitled letters
- The agency review process
- How to respond to a 483

10:00 – 10:30 **Training and Audits**
Industry Representative

10:30 – 10:45 **BREAK**

10:45 – 11:15 **Manufacturers and Suppliers – the Chain of Regulatory Responsibility**
Dan Kiser, Director, Quality Systems, Advanced Sterilization Products a Johnson & Johnson company
- Contractual relationships and responsibilities
- A checklist of regulatory issues

11:15- 11:45 Interacting with FDA – where do you go for assistance?
William Sutton, Deputy Director, DSMICA
- Small Business Representative
- DSMICA
- CDRH Ombudsman
- Internet/Device Advice

11:45 – 12:00 Morning Question & Answer Session

12:00 – 1:30 LUNCH

1:30 – 2:15 Reimbursement and Medical Technology
Mary Syiek, Vice President, Sales Operations, Reimbursement, & Compliance, Endocare
- Reimbursement for medical devices
- Reimbursement and strategic planning
- Reimbursement issues to consider throughout the product life cycle

2:15 – 3:30 Fraud and Abuse
R. Michael Scarano Jr., Partner, Foley & Lardner 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
R. Michael Scarano Jr., Partner, Foley & Lardner LLP
- 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