



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

San Juan Marriott Resort
San Juan, PR
August 12 – 13, 2009

Wednesday, August 12th

8:30 – 9:00

REGISTRATION AND CONTINENTAL BREAKFAST

9:00

Welcome

Maridalia Torres, District Director, San Juan District, San Juan, PR
Thomas Maeder, Executive Director, MTLI, AdvaMed

9:15 – 10:00

Organizational Structure of FDA

Virginia Meeks, Director of Investigations Branch, San Juan, PR

- Organizational structure of FDA: CDRH and the field
- Organizational structure of the region and district – who's who
- Typical interactions with the District Office

10:00 – 11:00

Doing Business in a Regulated Industry

Joseph Tartal, Branch Chief, Technical Assistance Branch, DSMICA/CDRH, Silver Spring, MD

- Definition of a medical device
- Medical Device Classification
- Premarket review - 510(k)/PMA
- Postmarket activities
- FDA Amendments of 2007

11:00 – 11:15

BREAK

11:15 – 11:45

Import Procedures for Medical Devices

Nancy Rosado, Import Program Manager, SJN-DO, San Juan, PR

- Role of the Filer/Broker/Importer
- Importation of Device Components

- 11:45 – 1:00** **Compliance Operations and Medical Devices**
Rafael Nevarez, Compliance Officer, SJN-DO, San Juan, PR
- Importation of Devices
 - Importation of Device Components
 - Detention/DWPE/Import Alerts
 - 766/Reconditioning
 - Refusal/Redelivery/Liquidated Damages
 - Import for Export
- 1:00 – 2:00** **LUNCH**
- 2:00 – 2:45** **Filer Audits: Product Codes/FURLS/Disclaims**
Nancy Rosado, Import Program Manager, SJN-DO, San Juan, PR
- 2:45 – 3:30** **Overview of the Quality System Regulation**
Aileen Velez Cabassa, Consumer Safety Officer, DSMICA/CDRH, Silver Spring, MD
- 3:30 – 3:45** **BREAK**
- 3:45 – 4:30** **Management Responsibility**
Noreen Muniz, Investigator, SJN-DO, San Juan, PR
- 4:30 – 5:15** **Design Control**
Joseph Tartal, Branch Chief, Technical Assistance Branch, DSMICA/CDRH, Silver Spring, MD
- 5:15 – 6:00** **QUESTION & ANSWER SESSION**
- ADJOURNMENT**
- 6:00 – 7:00** **RECEPTION**

Thursday, August 13th

- 8:30 – 9:00** **REGISTRATION AND CONTINENTAL BREAKFAST**
- 9:00 – 10:00** **Interacting with FDA – Where Do You Go for Assistance?**
Joseph Tartal, Branch Chief, Technical Assistance Branch, DSMICA/CDRH, Silver Spring, MD
- Small Business Representative (SBR)
 - DSMICA
 - CDRH Learn
- 10:00 – 10:30** **Purchasing Controls and Acceptance Activities**
Aileen Velez Cabassa, Consumer Safety Officer, DSMICA/CDRH, Silver Spring, MD

10:30 – 10:45	BREAK
10:45 – 11:15	Production and Process Control <i>Wanda Torres, Medical Device Specialists, SJN-DO, San Juan, PR</i>
11:15 – 12:00	Corrective and Preventive Actions <i>Joseph Tartal, Branch Chief, Technical Assistance Branch, DSMICA/CDRH, Silver Spring, MD</i>
12:00 – 12:30	Morning Question & Answer Session
12:30 – 1:30	LUNCH
1:30 – 2:00	Complaint Handling, MDR and Servicing <i>Karl Hezel, Investigator, SJN-DO, San Juan, PR</i>
2:00 – 2:45	FDA Inspections <i>Jose Pedro, Supervisor, SNJ-DO, San Juan, PR</i>
2:45 – 3:30	Compliance Issues <i>Margarita Santiago, Consumer Safety Officer, San Juan District, San Juan, PR</i>
3:30 – 3:45	BREAK
3:45 – 4:30	Training and Audits <i>Judith Meritz, Partner, Baker Donelson</i>
4:30 – 5:15	Manufacturers and Suppliers – The Chain of Regulatory Responsibility <i>Judith Meritz, Partner, Baker Donelson</i> <ul style="list-style-type: none">• Contractual relationships and responsibilities• A checklist of regulatory issues
5:15 – 6:00	Afternoon Question & Answer Session
6:00	ADJOURNMENT

Important Notice

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