

**MEDICAL DEVICE CLUSTER
REGULATORY COMPLIANCE COMMITTEE
Meeting Minutes Report**

MEETING DATE: June 28, 2007
TIME: 10:00 am
LOCATION: Roche Diagnostics, Ponce PR
FACILITATOR: Nidia Acevedo
ATTENDEES: Augusto Rodríguez, Betsy Rosario, Gloria E. Rodríguez, Heriberto Díaz, José A. Lamboy, Juan O. Pérez, Leo Rivera, Lismarie Álamo, Magda Céspedes, Miguel Centeno, Miguel O. Beltrán, Nelson Perea, Rafael Berly, Ramón Cayuela, Ramón Ruperto and Sigfredo Peña.

I. Welcome – Miguel Centeno

Miguel Centeno welcomed all the participants of the Regulatory Compliance (RC) Committee. He mentioned that this committee was developed as a result of the establishment of key strategies that the Medical Device (MD) Cluster will be implementing.

II. Introduction – Nelson Perea

Nelson Perea introduced the concept of the MD Cluster as well as the RC Committee. He also mentioned that the cluster is composed of other three committees: Education, Supply Chain and Benchmarking.

III. Presentation of Agenda – Nidia Acevedo

A. Selection of Committee Members

As agreed during the meeting the RC Committee will be composed as follows:

Role	Member
Chairperson	Nidia Acevedo
Co-Chairperson	Betsy Rosario
Communication Officer	Lismarie Alamo
Project Leader I	Heriberto Díaz
Project Leader II	Ramón Ruperto

B. Selection of Conference Theme or Topics

An open discussion of the themes that could be presented for the next meeting was held. It was agreed that next forum will be dedicated to share best practices and lessons learned from own previous experiences. The following is the list of topics presented:

1. Validations
2. CAPA
3. Non-Conforming Material Management
4. Trending of RC
 - a. PR vs. US (The standard applied to PR operations and Upcoming changes of FDA –San Juan District Office)
 - b. Global Competency
5. FDA Lessons Learned
6. Combination Products (Regulatory Perspective)
7. Supplier Management
8. Complaints Management
9. International Regulatory Regulations applicable to MD
10. Computerized Systems

In order to prioritize and decide three (3) topics, a voting system was used. The following themes were selected:

1st Trending of RC

2nd CAPA

3rd Combination Products

C. Meeting Schedule and Frequency

A tentative timeframe for next meeting was set as mid-September (10-21 September 2007). It was mentioned that the best speaker for the Trending of RC topic is an FDA Representative. Nidia Acevedo will be performing the communication with an FDA to confirm the date for the next meeting. Once date and location be confirmed it will be communicated.

D. Presentation of Main Event (Regulatory Conference)

The idea of the Main Event of Regulatory Compliance was presented. It was mentioned that the next meeting will be set as a success criteria of the Main Event.

The meeting was adjourned at 12:10 pm