

IFPAC/INDUNIV PAT/QbD Summit 2011

Tuesday, 21 June, 2011

Quadrant I – Regulatory – QbD / Interaction with the FDA

DAY ONE –AM Session Chair: Dr. Carlos Tollinche, INDUNIV

- 9:00a.m. **Introduction and Opening Remarks**
Dr. Carlos Tollinche, INDUNIV
- 9:10a.m. **A View of This Year's Conference**
Rodolfo Romañach, Ph.D., UPR, Mayaguez, PR
- 9:30a.m. **Transforming QC & QA in Light of QbD & PAT**
Eric Sanchez, Janssen-Ortho, Global Technical Services-Solids Platform
- 10:10a.m. **Break**
- 10:35a.m. **Manufacturing Perspective on the Implementation of a QbD/PAT New Product
Regulatory Submission**
Frances Montes, Euripides Guillen, Angel Vega, Carmen Lopez, Bristol-Myers Squibb
Manufacturing, Humacao, PR
- 11:15a.m. **QbD/PAT: Update and Regulatory Perspective**
Vibhakar Shah, Ph.D., FDA, CDER, DMPQ, Silver Springs, MD
- 12:00p.m. **Lunch**
- 1:30p.m. **Implementation of Process Analytical Technology in a Bulk API Process in Merck,
Barceloneta, PR**
Dr. K. Ganeshwar Prasad, Dr. Zhihao Lin, Dr. George Zhou, Dr. Tseng-En Hu, Dr. John
Higgins and Paul Fernandez, Merck Sharp & Dohme PR, Inc., Barceloneta, PR

IFPAC/INDUNIV PAT/QbD Summit 2011

Tuesday, 21 June, 2011 – Continued

Quadrant II: The Business Case for PAT & QbD

Chair: Manuel Hormaza, IBS Caribe

2:30p.m. **Elements to Building a Tangible Business Case for PAT & QbD**
Jose Montenegro, Pfizer, Vega Baja, PR

3:00p.m. **The Financial Returns on Investments in PAT and Lean Manufacturing: Benchmarks and Case Study**
Manuel Hormaza, IBS Caribe

3:30p.m. **Break**

4:00p.m. **The Business Case for Real Time Release**
Carlos Conde-Reyes, Ph.D.

4:30p.m. **The Business Case for PAT & QbD Panel Discussion**
Manuel Hormaza, IBS Caribe, Carlos Conde-Reyes,
Eric Sanchez, Janssen-Ortho, Nelson Rivera, J&J and
Jose Montenegro, Pfizer

5:15p.m. **Close/Reception**

Exhibit – 10:00a.m. –6:00p.m.

Setup – 7:00a.m. – 10:00a.m.

IFPAC/INDUNIV PAT/QbD Summit 2011

Wednesday, 22 June, 2011

Quadrant III – QbD/PAT in Pharmaceutical Manufacturing

DAY TWO - AM Session Chair: Rodolfo Romañach, Ph.D., UPR, Mayaguez, PR

- 9:00a.m. **Raman PAT Application for Monitoring Cell Culture Seed Expansion and Production Processes**
Danais Carrion, Amgen Manufacturing, Juncos, PR
- 9:45a.m. **Enhanced Process Understanding using QbD Approaches during Earlier Stages of Biopharmaceutical Process Development**
Antonio Moreira, Ph.D., Vice Provost for Academic Affairs, UMBC, Baltimore, MD
- 10:30a.m. **Break**
- 11:00a.m. **Multivariate Batch Analysis for Process Characterization, Monitoring and Optimization**
Chris McCready, Umetrics
- 11:30a.m. **Better Process Understanding with Combined Spectral Information from PAT Analyzers Based on Molecular Spectroscopy**
Yan Wang, Ph.D. and John Richmond, Ph.D., Bruker Optics, Inc., Billerica, MA
- 12:00p.m. **Lunch**

IFPAC/INDUNIV PAT/QbD Summit 2011

Wednesday, 22 June, 2011 – Continued

Quadrant IV: Continuous Manufacturing-Pharmaceutical Engineering & Control for PAT and QbD

PM Session Chair: Carlos Conde-Reyes, Ph.D.

- 1:30p.m. **NIR Monitoring of Continuous Blending Process**
Yieana Colon, UPR, Mayagüez, PR
- 2:00p.m. **Mastering Continuous Manufacturing: Current Technology and the Regulatory Environment**
Rebecca Vangenechten, Siemens AG, Antwerp, Belgium
- 2:30p.m. **Understanding Continuous (Open) Processes: Control Advantages**
Carlos Velazquez, Ph.D., UPR, Mayagüez, PR
- 3:00p.m. **Break**
- 3:30p.m. **Continuous Manufacturing of Polymeric Gel Strips for Pharmaceutical Formulations**
Lucas Sievens Figueroa, Ph.D., NSF-ERC Structure Organic Particulate Systems, Rutgers/NJIT
- 4:00p.m. **Near Infrared Analysis of Polymeric Gel Strips**
Rodolfo Romañach, Ph.D., UPR, Mayagüez, PR
- 4:30p.m. **Operational Excellence Panel Discussion**
Details include: QbD/PAT initiatives being worked on from an operational excellence perspective. Specific projects to be discussed include: PR PAT Forum coordination towards optimizing processes, reducing variability and overall process control.
- 5:00p.m. **Session Wrap-up**
- 5:15p.m. **Close/Reception**

Exhibit – 10:00a.m. – 4:00p.m.

Tear down – 4:00p.m. – 6:00p.m.