PAT Certification

Process Analytical Technology

Moving from QbD to Real Time Release Testing

9th Edition
Starts May 22nd, 2012

May

June

Five Modules

1. PAT & QbD Regulatory Trajectories
   (*Case Studies Included*)
2. Process Design and Understanding
3. Process Measurement and Analysis
4. Design Space, MVDA and DoE Applications
5. RTRT Roadmap, Lifecycle Approach

Certification

•WHAT•

A hybrid distance learning & hands-on PAT Certification program designed with the Pharma, Bioscience and Medical Device industries needs in mind.

•WHEN•

A 44 hours program beginning in May 22nd with five multi disciplinary modules including two hands-on lab sessions, of two days each.

•WHO's Teaching•

Instructor mix from various backgrounds including local and foreign academic institutions, suppliers, and industry such as:

Principal Faculty

Rodolfo Romañach, PhD – UPR-M

Supporting Faculty

David Gonzalez, PhD - UPR-M
Carlos Velazquez, PhD-UPR-M
Manuel Hormaza, PE - IBS Caribe
and other PAT subject matter experts.

•WHO should attend•

This certification is intended for pharmaceutical, biotechnology and Medical Devices professionals, scientists and engineers from various backgrounds who need a convenient way to learn and apply PAT and QbD with a goal of eventual 'Realtime Release'

•How•

Sessions of 3 hours will be offered once a week in the late afternoon. Participants will log in remotely via the web.

Two Hands-on lab sessions on four full days are scheduled to complement learning process.

Sponsored by the Center for Professional Education & Training of the Polytechnic University and IBS Caribe, Inc., a PAT Solutions Provider from Puerto Rico

IBS Caribe, Inc.
Innovations in Biosciences

Universidad Politécnica Puerto Rico

PAT Process Analytical Technology Certification

Module Abstracts

1

PAT & QbD Regulatory Trajectories

The first module of the PAT certification curriculum focuses on the Regulatory events that have led the Pharmaceutical and Biotech industries to embrace the initiatives that the FDA called Process Analytical Technology (PAT) and Quality by Design (QbD). The Module starts with how PAT & QbD may offset some of the challenges facing the Industry today by increasing quality and reducing costs and waste. Furthermore it points forward Realtime Release and Continuous Manufacturing.

A review of the FDA Critical Path Initiative, ICH Q8, Q9 & Q10 and PAT guidance leads to increase process understanding and move towards the *desired state*. This module will provide a foundation for the following topics by briefly describing the multiple disciplines and specialization areas required for a successful QbD/PAT implementation, which will subsequently be covered in detail. As defined by the FDA, this PAT certification will emphasize on the necessary systems for design, measurement, analysis, and control of manufacturing processes.

2

Process Design & Understanding

PAT & QbD State of the Technology in PR and abroad; a review of the current global trends in industry in RTRT. PAT local Case Studies in Dry Solids and Biotech (Cell Culture). QbD based preapproval inspection (PAI) readiness, CTD overview and discussion.

Real Time Release Testing (RTRT) & Continuous Manufacturing. Current developments (these topics will complement the hands-on section at UPR-M).

3

Process Measurements and Analysis – Hands-On Lab of two days

A Hands-on, intensive, practice workshop with a variety of optical analyzers applied to modern pharmaceutical formulations. Analyzers (FT-NIR, NIR, Raman) parts and functions, calibration and operation allowing participants to interrogate prepared samples and to observe special effects in the spectral graphs produced. Use of different softwares to acquire and process spectra.

Chemometric Model Development. Identify NIR and Raman advantages and limitations for process understanding. Review Diffuse Reflectance and FT-NIR functionalities and applications from RMID to Content Uniformity and extrusion. Transmission applications: solvent recovery, crystallizations, Fermentation, etc.

Discussion of particle size effects and other physical characteristics on NIR spectra. Also discussed are: Outlier Detection, Number of Factors selection, Model Error Evaluation and Validation.

4

Design Space, MVDA & DoE Applications – Hands-On Lab of two days

This two days lab uses software installed in computers to study Design of Experiments (DoE). This involves Design Space concepts to optimize experiments and to describe the Experimentation Space, Design Space and Control Space of a multivariable system and the relationship between the variables. Umetrics SIMCA-P+ software will be use to teach Multivariate Analysis for process monitoring and control through PLS and PCA. The session ends with what differentiates Multivariate Analysis in Chemometric applications and process data analysis using a spectral data set and SIMCA-P+.

5

The Real Time Release Roadmap

Using as the basis IBS's Roadmap to RealTime Release™ (2004), this module overviews the Lifecycle approach to PAT processes, from feasibility to system maintenance; including updated ASTM standards covering Verification of PAT systems. PAT projects must have a disciplined strategic approach that improves the bottom line as demonstrated with ROI calculations with benefits like improved cycle times, inventories, reduced non value added activities, reduced plant footprint, energy savings, etc. These factors are analyzed in PAT applications.

For a more detailed PAT Certification Abstract please go to http://www.ibscaribe.com/wp-content/uploads/2012/04/ABS.pdf
For Itinerary go to http://www.ibscaribe.com/wp-content/uploads/2012/04/Itinerary.pdf

- After a successful 2011 with the 8th edition course in PAT Certification, participants responded with 93% satisfaction.

Prices and Registration

- 2011 Prices: First participant is $3,500 the second or more is $3,000/ea before May/4/2012; after May/4/2012 the registration fees are $3,900 and $3,500, respectively'. Prior payment is required to complete the registration. Please visit our online pre-registration form at http://www.ibscaribe.com/?page_id=1653 for more details.
- Participants will log in remote by webinar (industry leading Cisco, Webex). Remote participants will need a broadband internet connection for live presentations and audio (VoIP)
- Certification diploma criteria, requires attendance as well as hands-on proficiency and/ or tests.

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