



New Validation Technology BootCamp

MONTREAL

February 13-17 , 2012

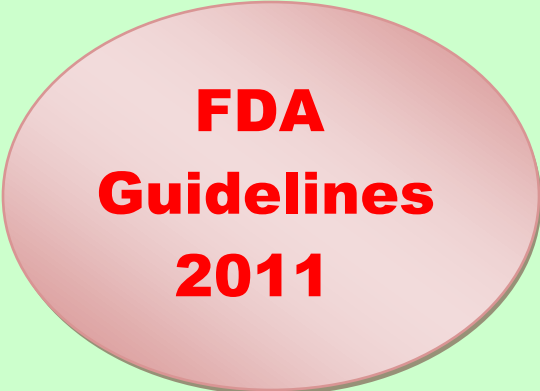
Holiday Inn - Pointe-Claire

Features

- **NEW Modern Process Validation**
- **Modern cleaning Validation**
- **Facility and equipment qualification?**
- **Risk analysis**
- **Advanced Topics**
- **Protocols and SOPs**
- **3 workshops**



Science and Risk Based
Process Validation



**FDA
Guidelines
2011**

Day 1

8:00 Registration- Continental Breakfast

8:30 Course Starts

Introduction

Current regulatory requirements for process validation for pharmaceuticals and biopharmaceuticals as per HPFB, and **New FDA and EMEA.**

New Process Considerations

- Process design
- Process qualification
- Continued Process Verification
- Process variables ,how to control your process?
- How about grandfather product validation ?

Validation Essentials

- New Validation Basics and Regulatory Requirements
- Definitions ;Validation Support Programs ,Documentation , SOPs
- PPQ Protocols, The Validation Life Cycle ; Change Control and Validation
- How Much is Enough!

Case study

- How to avoid serious mistakes ? Examples

4:30 **End of day one**

Day 2

8:00 Continental Breakfast

8:30 Course Starts

Validation Master Plan

- What are the important elements in the validation master plan Protocol and Report Format ?

Process Critical Parameters for nonsterile products

- Critical Parameters to be considered for tablet manufacturing;
- process optimization and troubleshooting.
- What are the critical considerations for product and process scale-up ?

Role of Blend Uniformity and process validation

- Importance of Raw Material Characterization
- Sample Size and Procedures
 - Acceptance Criteria and analytical procedures
- Blend Uniformity Analysis Recommendations for Simple Dosage Forms
- Blend Uniformity Analysis Recommendations for Complex Dosage Forms and Complex Processes

How to Organize an efficient Validation file

- Style and format for validation file
- How to write a validation protocol?
- Presenting Validation Data
- How to make the validation file a working document?

Workshop 1

- Validation Master Plan

4:30 End of Day 2

Day 3

Advanced Topics

8:00 Continental Breakfast

8:30 Course Starts

Statistical Tools in Validation

- Why Statistical Tools ?
- The Basic application of different tools and their use in Process Validation.
- How to design experiments effectively for Process validation?
- Process Capability Studies

Establishing the minimum process capability for a pharmaceutical manufacturing process

- Establishing valid sampling and testing specifications
- Establishing valid Release specification
- How to correct process mean and process variability for their uncertainty
- Examples

Process Analytical Technology (PAT)- changing the validation Paradigm

Techniques of Risk analysis and process validation

- The new ICH Q9
- Application of risk assessment in Validation
- Examples

Cleaning Validation

Fundamentals of Cleaning Validation

- History and evolution of cleaning validation
- Key components of a cleaning validation
- Cleaning validation lifecycle

II. Regulatory Requirements for Cleaning Validation

- GMPs as related to cleaning validation
- HPFB,FDA and EU requirements and industry standards
- Inspection guidelines related to cleaning
- Recent regulatory trends and issues
- How to establish “worst case” condition for shared equipment and products?

Workshop 2

- Validation of nonsterile product
- This work shop will include group participation in solving two case problems.

4:30 End of day 3

Day 4

8:00 Continental Breakfast

8:30 Course Starts

Residue sampling and Assessments

- Sources of contamination or residues
- Development of suitable analytical methods
- Calculation of residue limits, scientifically justifiable
- Maximum allowable carryover (MACO) and minimum allowable detection limit (MADL)
- HPLC, TOC and other analytical methods
- “Visually clean” as criteria
- Determine “how clean is clean”

Risk Analysis of Cleaning Validation

- Risk-based approach to cleaning validation
- FDA’s risk-based approach to cleaning validation activities
- Using risk management principles when choosing validation targets
- Equipment grouping and residue grouping
- ‘Dirty ‘ hold times vs. ‘Clean’ hold times)

Cleaning Validation Protocol

- Parameters and criteria for cleaning validation protocols
- Limits and other acceptance criteria
- Using Statistics and quality tools in cleaning validation studies

Workshop 3

Course participants will be teamed to resolve a cleaning validation problem.

Including writing up of a protocol.

4:30 End of day 4

Day 5

8:00 Continental Breakfast

8:30 Course Starts

Facility and Equipment Qualification

Qualification Master plan

- Equipment and Facility Master Plan model:
 - Structure
 - Areas of emphasis:
 - Infrastructure and Facilities
 - Equipment

DQ, IQ, OQ and PQ

- Design Qualification
 - Risk analysis
 - Documentation Required
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Facility Validation

- Specification Phase
- Planning
- FATs and PDI
- Commissioning
- What are the 20 tools of Facility validation?

Validation of Utilities:

- Gas systems for sterile operations
- Steam systems
- Vacuum systems
- Electrical systems

4:30 End of Course

Registration

New Validation Technology BootCamp

Please check the date of interest:

Montreal February 13-17, 2012

Please return the completed registration form to:

By Mail: **By Fax:** (514) 697- 4355 **By Phone:** (514) 695-8622

proGamma Science Corporation

6600 TransCanada, Suite 452,

Pointe Claire Quebec, Canada H9R 4S2

Please Register the :

Name: _____ CAD \$ 1450

Delegate (1): _____ 5days

Delegate (2): _____ 5days

Delegate (3): _____ 5 days

Delegate (4): _____ 5 days

Delegate (5): _____ **FREE**

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Conference Venue : Holiday Inn Pointe-Claire

Registration fee: CAD\$ 1450 includes the presentation material, lunch and refreshments, for the registered delegate for the complete 5days. Individual days are allowed for \$450 per day

Group discount: For every 4 delegate the fifth is **FREE**, delegates from the same company must register at the same time .

Cancellation / Substitutions: You must notify us in writing (fax) **10** business days before the conference date to cancel to receive a refund. No cancellation will be accepted after that date. Notify us by Fax for any substitutions. ASAP, 3 business days before the conference.

Accommodation Information: Registered delegates will have a corporate rate available through proGamma science Corporation at the Holiday Inn,Pointe-Claire. To reserve a room and take advantage of this special rate call and ask for the proGamma Science Corp. discount.