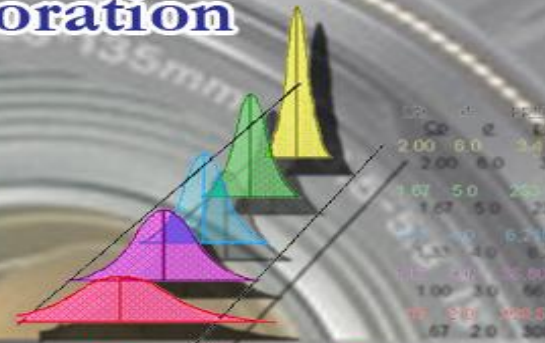




**proGamma Science Corporation**



## **New Validation Technology BootCamp**

### **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:

Date Scheduled \_\_\_\_\_ City \_\_\_\_\_

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**

SUBTOTAL \$ \_\_\_\_\_

GST \$ \_\_\_\_\_

\* Only for Quebec residence PST\* \$ \_\_\_\_\_

Total: \$ \_\_\_\_\_

Name: \_\_\_\_\_

Company : \_\_\_\_\_

Address : \_\_\_\_\_



City: \_\_\_\_\_ State / Province: \_\_\_\_\_ Postal code / Zip : \_\_\_\_\_

Telephone : ( ) \_\_\_\_\_ Fax : ( ) \_\_\_\_\_ E-mail: \_\_\_\_\_

Signature: \_\_\_\_\_

### Method of Payment:

Please charge my credit card: **Please Fax this form if you are paying with credit card**

Card Number : \_\_\_\_\_ Expiry Date : \_\_\_\_\_

Name ( as shown on card ) : \_\_\_\_\_

Signature ( required ) : \_\_\_\_\_

Authorization # Date:
--------------------------

**Conference Venue :** Depending On-City

**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.