



proGamma Science Corporation
Seeking and Providing Excellence in Training and Consulting
Since 1985

Computer Systems Validation Boot Camp

Computer
and Software system
Boot Camp

CSV
Boot Camp

Montreal

Features

- **21 CFR Part 11**
- **Industry Standards: GAMP, RISK and GERM**
- **System Development Life cycles**
- **GAP analysis**
- **Advanced Topics: strategies for: LIMS, ERP and Legacy**
- **Corporate Computer Systems Network Validation**
- **Protocols and SOPs**
- **3 workshops**

Day 1

8:00 Registration- Continental Breakfast

8:30 Course Starts

▪ **Computer and Software Validation Fundamentals**

- Introduction
- Validation Principles
- Definition of Computerized Systems
- Elements of Validation
- Principles of Validation
- Regulators and Regulations ,TPD, FDA,EU

▪ **21 CFR Part 11**

- Rules for ER,ES
- Value of regulation
- Hybrid records
- Open and close control systems
- Audit trail

▪ **Standards – IEEE, GAMP, GERM**

- Why standards
- IEEE important related documents
- GAMP 4 and 5
- GERM

▪ **System Development Lifecycle (SDLC)**

- What is SDLC
- Types of SDLC
- V- life cycle and validation life cycle

▪ **Validation Master Plan**

- Why is important
- What is in a typical master plan
- What is in MP for CS
- Benefits of MP and when is needed
- Examples

▪ **Design Qualification (DQ)**

- auditing vendors
- System, design, definition and implementation
- System testing

Case study 1 Validation of the OFF the shelf Software

Case study 2 Validation of LIMS

Day 2

8:00 Continental Breakfast

8:30 Course Starts

Qualifications

- IQ, OQ, PQ

Validation Tools:

- Document Based (DM, T- Matrix, 2D process charts)
- Automatic Script Development

CSV SOPs and Vendor audits

- Establish an understanding of the CSV SOPs
Show the importance of vendor audit
- Early vendor assessment

CSV strategies

- Custom Build Systems
- Configurable Systems
- Shop Floor Equipment
- Off the Shelf Systems

VP strategies

- Manufacturing Resource Planning (MRP II)
- Programmable Logic Controller (PLC)

Workshop 1

- Installation qualification-VP. Protocol, SOP and Qualification forms

4:30 End of day 2

Day 3

Advanced Topics

8:00 Continental Breakfast

8:30 Course Starts

CSV Strategies

- Custom Build Systems
- Configurable Systems
- Shop Floor Equipment
- Off the Shelf Systems

GAMP 5

- Principals and Framework
- Procedure and guides
- Good Practice Guidance
- Concepts: Validation and Planning, –Risk and Impact Assessment, User and Supplier Partnership, Treacibility,
- Examples

21CFR part 11- validation

- What Does Part 11 Require?
- Key Principles
- Special Considerations
- Effects on CS
- How to act proactively?

CSV for ERP systems

- SAP example
- Validation –Where to start?
 - What Modules?
 - Items to be Considered
 - Role of the Teams
 - Deliverables
- Regulatory Check

Workshop 2

- Operational Qualification–OQ–CL,Protocol, and SOP

4:30 **End of day 3**

Day 4

8:00 Continental Breakfast

8:30 Course Starts

CSV for LIMS

- LIMS Overview
- Validation –Where to start?
 - Test Scripts Items to be Considered
 - Role of the Teams
 - Approach
- Regulatory Check

CSV for Legacy systems

- Legacy System Overview
- Retrospective Evaluation
- Retrospective Validation
 - IQ, OQ and PQ
 - FDA Trigger Points
- Integration with new Systems
 - Time Capsule Approach
 - Migration Approach

Corporate Computer Systems Network Validation

Regulatory Requirements for Networks

- TPD
- FDA
- EU

Network Definitions

- Local Area Network (LAN)
- Wide Area Network (WAN)
- Network Application (LIMS vs. ERP)

Network Components

- Protocols
- Ethernet
- Media and Topologies
- Transceivers
- Repeaters
- Bridges and Routers
- Terminal and Print Servers

4:30 End of day 4

Day 5

8:00 Continental Breakfast

8:30 Course Starts

Validation Strategy for Networks

- Relationship between Validation and System Life Cycle
- Validation Activities for a Network
- Relationship between Network Specifications and Testing
- Documentation in the Life Cycle

Workshop 3

- Retrospective Validation of a Laboratory LAN
- Sample Test protocol for network qualification

Specifications and Security of Networks

- The LAN Design Specifications
- The WAN Design Specifications
- Security

Recent FDA Warning Letters on Networks

4:30 End of Course

Registration Form

CSV BootCamp

Please check the date of interest:

Montreal Date Scheduled _____

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 :

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Conference Venue : Holiday InnPointe Claire

Registration fee: \$ 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 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, Montreal. To reserve a room and take advantage of this special rate call and ask for the proGamma Science Corp. discount.