

ONLINE TRAINING SERIES

Introduction to Computer Systems Validation



Part 1:	May 9, 2011	11:30 AM-1:00 PM EDT
Part 2:	May 11, 2011	11:30 AM-1:00 PM EDT
Part 3:	May 13, 2011	11:30 AM-1:00 PM EDT
Part 4:	May 16, 2011	11:30 AM-1:00 PM EDT
Part 5:	May 18, 2011	11:30 AM-1:00 PM EDT

Gain insight into the basics of computer validation, regulations applicable to computer system validation, how to plan computer system validation for the system's lifecycle, and developing your own system vs. purchasing a system.

FEATURED TOPICS

Part 1 – Monday, May 9

What is CSV?

Computer Systems Validation

- History
- Process Validation
- Computer Systems Validation
- Quality/Quality Management

Part 2 – Wednesday, May 11

The Systems Life Cycle – More Parts of the Life Cycle

- More on the SLC
- Qualification
- Risk Management
- Regulations

Part 3 – Friday, May 13

Computer Systems Validation – Some Other Variations and Special Cases

- Purchased Systems
- Large Systems/Small Systems
- Other Special Cases
 - SAS, Excel, Instrumentation
- Prototyping
- Infrastructure/Qualification
- Outsourcing
- GAMP

Part 4 – Monday, May 16

Computer Systems Validation – Where Most of the Effort Goes

- Validation Plans
- Good User Requirements
- Testing (Mostly UAT)
- Change Control

Part 5 – Wednesday, May 18

The Role of Auditing in CSV

- The Basic Audit Process
- Standard Operating Procedures
- Part 11 – What to Look for
- Predicate Rules – Importance
- Computer Systems Validation –
the CSV Matrix

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COURSE INSTRUCTOR

RICHARD CHAMBERLAIN, PhD

President

ECS, Inc.

WHAT YOU WILL LEARN

- Basics of computer validation
- Regulations applicable to computer system validation
- How to plan computer systems validation for the system's lifecycle
- Developing your own system vs. purchasing a system
- Differences in internal vs. vendor audits

WHO SHOULD ATTEND

- Computer system users
- Auditors
- Quality assurance professionals
- Regulatory affairs professionals
- Information technology professionals

For information about this online training series, please contact Colleen Buckley at +1.215.442.6108 or Colleen.Buckley@diahome.org

See page 2 for Technical
Requirements and Continuing
Education Credit information.



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Introduction to Computer Systems Validation Event #11462

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LEARNING OBJECTIVES

At the conclusion of this online training series, participants should be able to:

- ▶ Validate a computer system
- ▶ Manage a computer systems validation project
- ▶ Use computer systems validation procedures within your organization
- ▶ Implement quality and risk procedures into computer systems used in your organization

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	Windows	Mac OS X	Linux
Operating Systems	2000, XP, 2003, 32-bit Vista, 64-bit Vista (not including Remote Access and Productivity Tools), 32-bit Windows 7, 64-bit Windows 7 (not including Remote Access and Productivity Tools)	10.4, 10.5, 10.6	"Ubuntu 9.04, Red Hat 5, Open SuSE 11.1, Fedora 11"
Minimum System Requirements			
Processor	Intel or AMD	PowerPC or Intel	Intel or AMD
JavaScript	JavaScript and cookies enabled	JavaScript and cookies enabled	JavaScript and cookies enabled
Other	Active X enabled (unblocked for IE is recommended)	Apple Java 5 or above	"Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system"
Browsers (Recommended browsers are shown in bold)			
Internet Explorer	6, 7 , 8		
Mozilla			1.7
Firefox	2/3/3.5	2/3/3.5	2/3/3.5
Safari		4-Mar	
Chrome	3		

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Online Training Series



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