COMPLIANCE & VALIDATION SERVICES

In collaboration with: INTEGRITY

Present a 3-Day Online Training Course on:

Computer System Validation

22, 23 & 24 October 2024

Online Training Course

October 2024						
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Click here to visit the web page for this course

Principal Speaker

Christopher Reid, CEO, Integrity

Chris has worked with over 60 regulated companies (small local to multinational Life Science companies). Chris has held a number positions within the ISPE, including being a member of ISPE's International Board of Directors, a member of the ISPE Foundation Board and Global Chair of the GAMP, ISPE European Forum, ISPE European Leadership Team. He has contributed to the development of GAMP 5 and many of the GAMP® Good Practice Guides.

- **Regulatory Rules & Guidance and GAMP 5 (2nd Edition)**
- **Data Management and Data Integrity**
- **Principles of Risk Based Computer System Validation**
- **Validation Planning and Methodologies**
- **Validation Activities & Information Requirements**
- **Supplier Governance**
- **Data Migration**
- **Current Trends (e.g., Computer Software Assurance)**
- **Operational Phase**
- **Infrastructure Management and Control**
- **Example IT Infrastructure Project**
- **Qualification of Packaged Systems (Equipment Control Systems)**
- **Qualification of Laboratory Systems**
- **Information / Business Systems Qualification**
- **Distributed Control System (DCS) Qualification**
- **Spreadsheet Validation**
- **Periodic Review of Computerised Systems**

Detailed content can be found on Page 3

Course Summary - Computer System Validation - 22, 23 & 24 October 2024 - Online Training Course

This course provides attendees with up-to-date and detailed information that should help them tackle the many diverse challenges of validating and operating computerised systems in a compliant and risk based way. The course aims to cover all the key areas that need to be considered when qualifying and operating computerised systems. These include: the types of computer/computerised systems and their elements; key regulations and guidance; data management and data integrity; the general principles of risk based validation; validation planning/approaches/activities; supplier governance; data migration; current trends; operational phase activities; infrastructure management; and periodic system review. It will also include an example infrastructure project and the qualification of: Packaged Systems (Equipment Control Systems); Distributed Control Systems; Laboratory Systems; Information/Business Systems and Spreadsheets. The presentations will include real life examples and the learning experience will be enhanced by using carefully structured workshops. Attendees will receive PDF file versions of all the presentations.

Presenters

Christopher Reid, CEO of Integrity: Chris has worked with over 60 regulated companies (small local to multinational Life Science companies). He has worked in life sciences industries for over 25 years, prior to which he was a computerised system development engineer and programme manager. Chris currently works with leading global organisations, defining and implementing quality/compliance solutions including quality strategies, organisation set up, quality system development, validation programme leadership, training and auditing. He has worked across pharmaceutical, biotechnology, medical device and cosmetic industries, working in many regulatory domains. Chris has held a number positions within the ISPE, including being a member of ISPE's International Board of Directors, a member of the ISPE Foundation Board and Global Chair of the GAMP, ISPE European Forum, ISPE European Leadership Team. He has contributed to the development of GAMP 5 and many of the GAMP® Good Practice Guides.

John Welbourn, Consultancy Director, Compliance & Validation Services Limited: A validation professional with over 30 years experience, John has been responsible for the management and execution of validation projects for many major pharmaceutical companies. He has broad experience in the qualification of equipment, utilities and computerised systems, and thermal mapping to support storage conditions. He has presented at conferences in the UK, Europe and the US and has authored several articles on various aspects of validation. John has contributed to The University of Manchester's, Pharmaceutical Engineering Advanced Training (PEAT) Course and Dublin Institute of Technology's (DIT) MSc. course in Pharmaceutical Process Validation.

Alison Harrington, Principal Consultant, Integrity Ltd.: Alison is a computer systems validation professional with over 28 years of experience in the pharmaceutical industry. For the past 14 years she has been providing consultancy and lead validation governance roles to a number of global IS projects, including ERP systems (SAP, Oracle and JDE) and Infrastructure. Alison also provides computer systems compliance help and support for the development and application of new products and technology, including PAT solutions. She is also very familiar with laboratory based systems (LIMS) and 21 CFR Part 11 compliance and is currently working on a laboratory data integrity remediation project. Alison's pharmaceutical career started in the laboratory as an Analytical Chemist, specialised in Process Analytical Techniques and Automation and then progressed to a Global IT Project Manager at Pfizer before moving to consultancy. She is an active participant in ISPE GAMP and has contributed to the Data Integrity Good Practice Guide.

Who Should Attend

Individuals to benefit from attending this interactive course include anyone who is involved with the compliance of computerised systems. Target disciplines include production (operation, supervision and management), quality assurance (review and approval of verification / validation documentation), validation personnel (people new to qualifying / verifying computerised systems), technical support and engineering. On leaving this course attendees will: have a better understanding of the applicable regulatory rules and guidance and other pertinent international standards / guides; have a clear understanding of the activities involved at the various stages of the system lifecycle; have many practical 'real-life' examples of how computerised system validation is actually carried out in industry; improve their individual effectiveness; and be able to look back on a valuable experience.

Online System & Course Fees

We use industry standard online meetings software platforms to run our live online training courses. Once we have received your booking, you will be contacted by email with details on how to join each day of the course. Please note that we do not record our courses.

Course fees are £1,750.00 (GBP) per attendee.

(See Page 4 for further details on fees/bookings)

Computer System Validation - Live Online Training Course - Programme:

Start Time: 08:00 London/Dublin; 09:00 Berlin/Amsterdam (CET) - Please join the course at least 5 minutes before the start.

Day 1 (Tuesday 22 October 2024)

Start: 08:00 London/Dublin; 09:00 CET

Intro: Validation of Computer Systems *[John Welbourn]:*
- The need for regulation and why we need to validate computerised systems
- A brief history of CSV
- Key regulations
- Which computers to validate
- What makes computers different
- Different types of computers
- Elements of computers

Regulatory Rules & Guidance and GAMP *[John Welbourn]:*
- 21 CFR 211.68, 21 CFR 11
- GAMP 5, 2nd Edition
- EU GMP Annex 11, 15

Data Management and Data Integrity [*Chris Reid*]:
- Regulatory expectations
- Principles:
  - ALCOA+
  - Data Lifecycle
  - People vs. Technology vs. Process
  - Critical Thinking
  - Assessing DI risks / Maturity Models / GEMBA
  - Managing a DI Program
  - Establishing a DI culture and DI by Design
  - Data and audit trail reviews
  - DI Program Case Studies

Principles of Risk Based CSV [*Chris Reid*]:
- GAMP Principles
  - Risk Based Approach
  - Scalability
  - Leveraging Supplier Effort
  - Role of SME vs Quality

Validation Planning and Methodologies *[Chris Reid]:*
- Different methodologies
  - Iterative
  - Waterfall / V-model
  - Agile
- Planning validation based on risk - scalability
- What does scaling mean in practice?
- Validation roles?
- The art of Validation Plan to add value

Validation Activities & Information Requirements *[Chris Reid]:*
- Expectations of all validation phases
- Defining the documentation requirements for each phases and responsibilities
- Use of Tools in place of documents

Finish: 16:00 London/Dublin; 17:00 CET

Day 2 (Wednesday 23 October 2024)

Start: 08:00 London/Dublin; 09:00 CET

Supplier Governance *[Chris Reid]:*
- Supplier Risk Assessment
- Approaches to supplier assessment for different supplier types product, service, SaaS, IaaS
- Supplier governance

Data Migration *[Chris Reid]:*
- Data Migration Processes:
  - Analyze and discover, extract and profile, data cleansing, validation, target system loading and reconciling
- Scoping the source data for migration
  - Analyzing source system documentation and gathering metadata - determining business rules and conversion logic
- Use of data profiling tools to analyze and profile data in the source systems.
- De-duplication, matching, and merging (source-to-target fields)
- Key data validation requirements prior to loading
- Cutover and go-live and data loading tools
- Statistical sampling techniques to measure load success

Current Trends *[Chris Reid]:*
- CSV to Computer Systems Quality Assurance
  - Focus on high risk elements - Computer System Assurance critical thinking
  - Indirect vs. Direct Computer System Assurance
  - Flexible test strategies
- Agile development models
- Machine learning and Data Quality management
- Implementation of robotics in the production environment
- Robotic Process Automation BOTS
- Remote working – virtual FAT's, Audits etc.

Operational Phase *[Chris Reid]:*
- System Inventories
- Change Management and Configuration Management
- Business Continuity and Disaster Recovery
- Security and User Access Management
- Patch Management and incident and Problem Management
- Backup and Restoration
- Data Archiving
- Decommissioning
- Training

Infrastructure Management and Control *[Chris Reid]:*
- Different types of IT Infrastructure, e.g. Business System, Production site networks, virtualised / cloud-based IT Infrastructure.
- Infrastructure as Code, virtual environments and IaaS
- IT Quality Frameworks

Finish: 16:00 London/Dublin; 17:00 CET

Day 3 (Thursday 24 October 2024)

Start: 08:00 London/Dublin; 09:00 CET

Example IT Infrastructure Project *[Alison Harrington]:*
- New example IT Infrastructure Project **(Last Pres. – Day 2)**

Qualification of Packaged Systems (Equipment Control Systems) *[John Welbourn]:*
- Characteristics of automated packaged systems
- Using risk assessment to develop the qualification testing strategy
- Steps involved in qualifying automated packaged systems
- Techniques / considerations for integrating commissioning to support qualification

Qualification of Laboratory Systems *[Chris Reid]:*
- Types of Laboratory systems that require qualification
- Risk assessment for Laboratory systems
  - A range of complexities (LIMS to Bench top balance)
  - Assessing risk to patient safety
- Steps involved in qualifying laboratory systems
  - Alignment between USP 1058 and GAMP Lab Guide

Information/Business Systems Qualification *[Alison Harrington]:*
- Information/Business Systems used in the pharma industry
  - Typical configuration/structure and interfaces
- Risk assessments to establish qualification requirements
- Common issues and findings
- Data Management, Data Cleansing and Data Migration
- Cut-over and Release to live environment
- Ongoing user management, maintenance and change control
- Tools and methodologies for Document Management, Testing, Training and Change

Distributed Control System Qualification *[John Welbourn]:*
- Characteristics of DCS
- Commissioning and Qualification activities

Spreadsheet Validation *[Chris Reid]:*
- Types of spreadsheets
- Risk assessment
- Design Considerations for Multi-Use Spreadsheets
- Security
- Data integrity considerations
- Documentation requirements for spreadsheet validation

Periodic Review of Computerised Systems *[Chris Reid]:*
- Risk Based approach to periodic reviews Periodic review activities
- Metrics driven processes
- Planning remediation
- Recovering from the loss of validated state

Finish: 16:00 London/Dublin; 17:00 CET

BOOKING DETAILS - Computer System Validation - 22, 23 & 24 October 2024 - Online Training Course

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to our web-site, find the online course you are interested in and follow the simple instructions (link included below), or
- Print out this page, complete the form below by hand and return by fax, email or post.

CLICK HERE TO BOOK ONLINE

Fax: +44 (0)1625 800833 **Tel: +44 (0)1625 500833 or +44 (0)1270 760882** **E-mail: info@candvs.com**

Alternative Booking Form *('*' indicates required fields)*

***Booking Contact Name:**		
***Booking Contact E-mail Address:**		
***Booking Contact Telephone Number:**		
***Company Name & Address:**		
***Billing Address** *(Only complete if different to Company Address)*		
***Attendee Information:**	**Attendee Name(s):**	**Attendee Email Address:**
Company VAT Number (or Sales Tax Number) – *EU Countries Only		
***Method of payment, e.g. card or invoice payment**		NOTE: For card payments by telephone, please ensure you have entered your telephone number above and we will contact you. Alternatively, call +44 (0)1625 500833 to make your payment.
Payment Reference (if available)		NOTE: For invoice payments we will need a valid purchase order number to fully confirm the booking.
*** Total Fees Due** **£1,750 [GBP]** **per attendee**		NOTE: If your finance centre or attendees are based in the United Kingdom (UK), or attendees are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge (**£2,100** per attendee including UK VAT). For EU Countries where finance centres and attendees are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU attendees, VAT is not applicable.

Booking Terms & Conditions

Booking Confirmation
Bookings will only be confirmed upon payment by credit card, or in the case of invoice payment (bank transfer), upon receipt of a valid purchase reference number.

Cancellation by Attendees
Cancellation refunds will depend on how long before the course start date the cancellation is received. The following refund structure will apply:

- More than 7 days will quality for a refund of the course fee paid after the deduction of actual expenses incurred by CVS in connection with the course that the attendee has registered for and there shall be no future liability on the part of either party.
- No refund will be given for cancellations received with less than 7 days' notice.
- Substitutions for registered attendees from the same company will be accepted without notice, but for administration purposes, we kindly ask you to let us know as soon as you can.

Cancellation by CVS
CVS does not issue refunds for attendees unless:

- We have cancelled a course.
- We have changed the time or date of a course.

If we do cancel or reschedule an event, CVS is not responsible for any costs incurred by attendees. Only the course fee will be refunded.
Please be assured that we are not in the habit of cancelling events. We only cancel events in exceptional circumstances.

Speaker/Presenter Changes
We reserve the right to change a speaker without notice.

Course Fee & VAT Liability
For the majority of participating countries, VAT will be ZERO rated. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) the indicated course fee will be subject to an additional 20% UK VAT charge. Also, anyone booking as a private individual (not through a company) will be charged UK VAT. CVS has to charge this by law.
All participating EU / EEA based companies (based on the site location), must provide CVS with a valid VAT/Sales Tax reference number, in order for the booking to be completed. CVS is required by law to collect this information.

Liability
CVS reserve the right to cancel or reschedule any course and/or change presenters.
CVS will not provide a refund for an online course if an attendee cannot use the online system, because of local IT restrictions/issues.

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