COMPLIANCE & VALIDATION SERVICES

In collaboration with: INTEGRITY

Present a 3-Day In-Person Training Course on:

Computer System Validation

Hotel Scandic Copenhagen, Denmark
5, 6 & 7 March 2024

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 - 5, 6 & 7 March 2024 - Hotel Scandic Copenhagen

This course provides delegates 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.

Delegates will be provided with a 3-slide per page printed binder upon arrival on Day 1 and PDF versions of the slides will be sent out by email to each delegate after the course. Day-time meals and refreshments, together with a course dinner, held on the evening of Day 1 (Tuesday 5 Mar 2024), are included in the overall package

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 delegates 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.

Venue & Course Fees

Hotel Scandic Copenhagen: Modern, centrally located hotel with great views of the Lakes and Copenhagen's skyline. The hotel facilities include a gym, bar and restaurant.

Address: Vester Søgade 6, 1601 Copenhagen V, Denmark
Tel: +45 33 14 35 35
Email: copenhagen@scandichotels.com

Click here to view Hotel's location (Google Maps)

Click here to visit the Hotel's website

Course fees are £2,500.00 (GBP) per delegate. Accommodation is NOT included. ***(See Page 4 for further details on fees/bookings)***

Computer System Validation - Scandic Copenhagen Hotel – Course Programme:

Registration (Day 1): 08:45 to 09:00 Central European Time (CET) - Delegates arrive at the meeting room and sign the attendance register.

Day 1 (Tuesday 5 March 2024)

Start: 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: 17:00 18:30 Drinks Reception; 19:30 Course Dinner

Day 2 (Wednesday 6 March 2024)

Start: 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: 17:00 CET

Day 3 (Thursday 7 March 2024)

Start: 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

Course End: 17:00 CET

BOOKING DETAILS - Computer System Validation - 5, 6 & 7 March 2024 - Hotel Scandic Copenhagen, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please click on the link below to visit the web page for this course, 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)*		
***Delegate Information:** *Please let us know if any delegate has any special dietary requirements by emailing the information to info@candvs.com, or by using the space below.*	**Delegate Name(s):**	**Delegate 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** **£2,500 [GBP]** per delegate		NOTE: If your finance centre or delegates are based in the United Kingdom (UK), or delegates are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge (**£3,000** per delegate including UK VAT). For EU Countries where finance centres and delegates are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU delegates, 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 Delegates

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

- More than 28 days will incur a cancellation fee of £200 GBP per registration and qualify for a refund of the remaining course fees
- Between 28 days and 14 days notice will qualify for a 75% refund
- Between 14 days and 7 days notice will qualify for a 50% refund
- No refund will be given for cancellations received with less than 7 days notice
- Substitutions for registered delegates 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 delegates 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 delegates. 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 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. Please be advised that CVS is not responsible for any airfare and/or hotel penalties or other travel charges that delegates may incur.
CVS does not take responsibility for ensuring the well being of delegates during their travel to and from the venue or at any time during their stay at the residential location. We will however do everything within our power to help ensure delegates remain safe and well during the course and related activities.
Where government intervention, military activities, natural phenomenon, strikes or any other circumstances make it impossible or inadvisable to run the course at the designated time and place, the delegate shall waive any claim for damages or compensation except the amount paid for registration after the deduction of actual expenses incurred by CVS in connection with the course that the delegate has registered for and there shall be no future liability on the part of either party.

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