COMPLIANCE & VALIDATION SERVICES

In cooperation with: Integrity Solutions

Present a 3-Day Training Course on:

Computer System Validation

(A Very Practical Approach)

26, 27 & 28 March 2019

Copenhagen Marriott Hotel, Denmark

Principal Speaker

Christopher Reid, CEO, Integrity Solutions Member of ISPE's International Board of Directors, European Forum, European Leadership Team, Co-chair of the Knowledge Network Council and member of the Global and European GAMP® Steering Committees.

- Regulatory Rules & Guidance and an overview of GAMP
- Key terminology explained
- Overview of verification phases for different categories of systems (based on GAMP 5)
- Risk Assessments and how they can help determine the depth and scope of testing required
- Routine system operation and managing change
- System, Process and Validation Review
- Effective DATA INTEGRITY, data management and system retirement
- 'Real-life' based presentations:
  - Infrastructure Verification/Qualification (e.g. Networks & Servers)
  - Verification/Qualification of IS/Business Systems
  - Verification/Qualification of Packaged and Complex Plant Control Systems

This is a very interactive course that uses group activities to aid learning, e.g. compiling test scripts.

The course has been fully updated with the very latest guidance on DATA INTEGRITY from the USFDA, MHRA and WHO.

Computer System Validation (26, 27 & 28 March 2019) - Copenhagen Marriott Hotel, Denmark - Course Summary

Unlike many computer validation courses, this training course concentrates on what actually works in real life with respect to the quality management, operation and qualification of computerised data management (business) systems, equipment control systems (packaged and complex) and the associated infrastructure. This will be supported by the high level of relevant and recent practical knowledge of the presenters involved. The first part of the course covers the general theory and terminology relating to the validation phases and will encompass current applicable regulatory rules/guidance and international standards/guidelines (including GAMP 5). It will also cover the operational and quality management activities relating to: routine operation/management; system/process/validation review; data management and system retirement. **DATA INTEGRITY** will be covered in-depth with practical examples. The second and major part of the course will be dedicated to working through, in a very practical way, qualification activities/testing relating to key areas of computerised systems such as: infrastructure qualification/verification; packaged system qualification/verification; IS Systems (data management systems); and plant /equipment control systems. This will be heavily supported by example test sheets and real-life examples.

Day-time meals and refreshments together with a drinks reception and course dinner, held on the evening of Day 1, are included in the overall package.

Presenters

Christopher Reid, CEO of Integrity Solutions Ltd: Chris has worked for over 50 regulated companies (small local to multinational pharmaceutical companies). He has worked in life sciences industries for 25 years, prior to which he was a computerised system development engineer. Chris currently works with leading global organisations, developing and implementing quality/compliance solutions including defining and implementing strategic quality initiatives, corporate quality policies/standards and system validation. He has worked across pharmaceutical, biotechnology, medical device and cosmetic industries, working in many regulatory domains. Chris is a former member of ISPE's International Board of Directors, member of the ISPE Foundation Board, Global Chair of ISPE 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, Life Science Integrity Solutions 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 an enjoyable experience.

Venue

Marriott Hotel, Copenhagen: The Hotel is close to the city centre and located right at the water's edge of the harbour canal. It is around 8 minutes walk from Copenhagen Central Station and Tivoli Gardens (the Gardens are opposite the station). An excellent location to explore the city from.

Address: Copenhagen Marriott Hotel, Kalvebod Brygge 5, Copenhagen 1560, Denmark
Tel: +45-88-33-99-00

Click on images to visit the Hotel's website

Delegates are kindly requested to arrange their own accommodation. Course fees are £1,995.00 (GBP) per delegate. Accommodation is NOT included in the course fees.

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

Computer System Validation - Copenhagen Marriott Hotel, Denmark - Course Programme:

Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register.

DAY 1 (Tuesday 26 March 2019)

09:00 Opening / Welcome *[John Welbourn]*

Introduction to the Validation of Computer Systems *[John Welbourn]:*
- The need for regulations
- Brief history of CSV
- Key regulations
- What makes computers different
- Different types of computers and their elements
- Which computers to validate

Regulatory Rules & Guidance and GAMP *[John Webourn]:*
- FDA 21 CFR Part 211.68
- EU GMP Volume 4 Annex11
- FDA 21 CFR Part 11
- FDA 2003 Guidance
- EU Directive 910/2014
- Possible solutions for Electronic Signatures
- Introduction to GAMP
- The five GAMP Principles
- GAMP Classification of hardware and software
- GAMP Lifecycles for each class of software

Validation Documentation *[Chris Reid]:*
- Validation terminology and principles
- The importance of documentation
- Glossary
- Overview of a simplified QMS for CSV
  You will be provided with PDF copies of the QMS including policy, procedures, templates and forms
- Worked examples discussed

Validation (Verification) Phases *[Chris Reid]:*
- User requirements
- Risk assessments
- Supplier & Compliance assessments
- Functional and design specifications
- DQ and Design review
- Validation Plan
- IQ, OQ and PQ
- Deviations
- Validation Report
- Example documents provided and discussed

Finish: 17:30

Drinks Reception: 19:00 (Marriott)
Course Dinner: 20:00 (Marriott)

Day 2 (Wednesday 27 March 2019)

Day 2 Introduction (09:00) *[John Welbourn]*

Operations *[Chris Reid]:*
- Change control
- Operating procedures
- Incident management
- Configuration management & baseline concept
- Training
- Support model and data integrity
- Periodic Reviews

Infrastructure Qualification *[Chris Reid]:*
- Elements of IT infrastructure and its characteristics
- IT processes
- Outsourced services
- Cloud computing: how to manage the challenges of virtualisation and managed services
- A pragmatic qualification approach

Example Infrastructure IT Project *[Alison Harrington]*
- Presentation of a real-life IT infrastructure example, including the various elements, risk assessments, training, installation and managing the evidence.

Verification/Qualification of Packaged Systems *[John Welbourn]:*
- Overview of Packaged Systems and their characteristics
- How to validate Packaged Systems by integrating controls and equipment verification
- Practical worked examples

Scalability of Validation *[Chris Reid]:*
- Factors to consider for scaling validation
- Determining validation deliverables
- What to test – and how
- The use of test tools
- Determining the sample size

Validation of an Existing Systems *[Chris Reid]:*
- A pragmatic approach to address existing systems that should have been validated (but were not!)

Finish: 17:10

Day 3 (Thursday 28 March 2019)

Day 3 Introduction (09:00) *[John Welbourn]*

Data Integrity & Data Management *[Chris Reid]:*
- Importance of data management
- Types of data and data classifications
- Data considerations
- Data integrity and how to manage it
- Guidance on data integrity by MHRA, FDA, PIC/S, PDA, WHO and ISPE
- Archiving of data.

Verification/Qualification of Information Systems (IS) Business Systems *[Alison Harrington]:*
- Typical configuration/structure and interfaces
- Risk assessments to establish qualification requirements
- Common issues and findings
- Data Management, Cleansing & Migration
- Cut-over and Release to live environment
- User management, maintenance & change control
- Tools and methodologies for Document Control, Testing, Training, & Change Control
- An Example: HP Quality Centre is discussed

Verification/Qualification of Complex Plant Control Systems *[John Welbourn]:*
- Overview of complex control systems, e.g. Distributed Control Systems (DCSs) and their characteristics
- The importance of the Factory Acceptance Test for a DCS
- Test organisation for a DCS
- The typical site phases and how to manage integration of a DCS with its plant
- Practical worked examples

Hot Topics *[Chris Reid]:*
- Current computer validation trends and issues
- Spreadsheet validation

Course Closure *[All]:*
- Final questions and answers
- Course evaluation (how did we do?)
- Course certificates

Finish: 16:40

BOOKING DETAILS: Computer System Validation – 26, 27 & 28 March 2019 - Copenhagen Marriott Hotel, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to the CVS web-site, find the course you are interested in and follow the simple instructions (link included below – takes you directly to the relevant web page).
- Alternatively, download a booking form, complete it electronically or print and annotate, and return it to us by fax or email (link and contact details included below).
- Or finally, print out this page, complete the form below by hand and return by fax, email or post.

<< CLICK HERE TO GO TO CVS WEBSITE >> **<< CLICK HERE FOR BOOKING FORM >>**

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:**	**Number of delegates:**	**Delegate Name(s):**
Delegate E-mail Address(es): *(if different to booking contact)*		
Special dietary requirements?		
Disability Requirements?		
Company VAT Number (or Sales Tax Number) – *EU Countries Only		
***Method of payment, e.g. card, bank transfer or cheque**		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. Cheques should be sent with a completed booking form to Compliance & Validation Services Limited, 8 Sedgefield Close, Macclesfield, Cheshire, SK10 2WF, United Kingdom.
Payment Reference (if available)		NOTE: For bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking.
***Total Fees Due** **£1,995 [GBP]** **per delegate**		NOTE: If your finance centre or delegates are based in the United Kingdom (UK), the course fee will be subject to an additional 20% UK VAT charge (**£2394** 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: A booking confirmation will be sent to the delegate or booking contact on receipt of payment, or in the case of bank transfer, following receipt of a valid purchase order reference.

Course Fee & VAT Liability: For the majority of participating countries, VAT will be ZERO rated or not applicable. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) or delegates are UK based, the indicated course fee will be subject to an additional 20% UK VAT charge. CVS has to charge this by law. 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.

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.

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

- 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

CVS reserves 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. 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.

Please visit our web site for full terms and conditions (see the link at the top of this page).

Please note that by completing the booking form (opposite) you are agreeing to our Terms and Conditions.

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