



COMPLIANCE & VALIDATION SERVICES

In cooperation with:



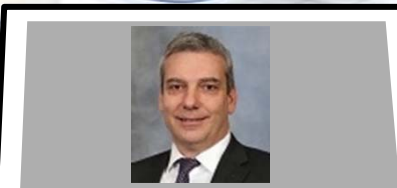
Present a 3-Day Online Training Course on:

# Computer System Validation

(A Very Practical Approach)

22, 23 & 24 September 2020

Online Training Course



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.



September 2020						
Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

- 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.*

## Course Summary: Computer System Validation - 22, 23 & 24 September 2020 - Online Training Course

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 supported by example test sheets and real-life examples.

### 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 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 the industry leading GotoWebinar®, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the 'CHECK SYTEM COMPATIBILITY' link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the 'HOW IT WORKS' link provided below.

[CHECK SYSTEM COMPATIBILITY](#)

Course fees are **£1,495.00 (GBP)** per attendee.  
(See Page 4 for further details on fees/bookings)

[HOW IT WORKS](#)



DAY 1 (Tuesday 22 September 2020)	Day 2 (Wednesday 23 September 2020)	Day 3 (Thursday 24 September 2020)
Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam	Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam	Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam
<b>Introduction to the Validation of Computer Systems</b> <i>[John Welbourn]:</i> <ul style="list-style-type: none"> <li>The need for regulations</li> <li>Brief history of CSV</li> <li>Key regulations</li> <li>What makes computers different</li> <li>Different types of computers and their elements</li> <li>Which computers to validate</li> </ul>	<b>Operations</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Change control</li> <li>Operating procedures</li> <li>Incident management</li> <li>Configuration management &amp; baseline concept</li> <li>Training</li> <li>Support model and data integrity</li> <li>Periodic Reviews</li> </ul>	<b>Data Integrity &amp; Data Management</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Importance of data management</li> <li>Types of data and data classifications</li> <li>Data considerations</li> <li>Data integrity and how to manage it</li> <li>Guidance on data integrity by MHRA, FDA, PIC/S, PDA, WHO and ISPE</li> <li>Archiving of data.</li> </ul>
<b>Regulatory Rules &amp; Guidance and GAMP</b> <i>[John Welbourn]:</i> <ul style="list-style-type: none"> <li>FDA 21 CFR Part 211.68</li> <li>EU GMP Volume 4 Annex11</li> <li>FDA 21 CFR Part 11</li> <li>FDA 2003 Guidance</li> <li>EU Directive 910/2014</li> <li>Possible solutions for Electronic Signatures</li> <li>Introduction to GAMP</li> <li>The five GAMP Principles</li> <li>GAMP Classification of hardware and software</li> <li>GAMP Lifecycles for each class of software</li> </ul>	<b>Infrastructure Qualification</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Elements of IT infrastructure and its characteristics</li> <li>IT processes</li> <li>Outsourced services</li> <li>Cloud computing: how to manage the challenges of virtualisation and managed services</li> <li>A pragmatic qualification approach</li> </ul>	<b>Verification/Qualification of Information Systems (IS) Business Systems</b> <i>[Alison Harrington]:</i> <ul style="list-style-type: none"> <li>Typical configuration/structure and interfaces</li> <li>Risk assessments to establish qualification requirements</li> <li>Common issues and findings</li> <li>Data Management, Cleansing &amp; Migration</li> <li>Cut-over and Release to live environment</li> <li>User management, maintenance &amp; change control</li> <li>Tools and methodologies for Document Control, Testing, Training, &amp; Change Control</li> <li>An Example: HP Quality Centre is discussed</li> </ul>
<b>Validation Documentation</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Validation terminology and principles</li> <li>The importance of documentation</li> <li>Glossary</li> <li>Overview of a simplified QMS for CSV You will be provided with PDF copies of the QMS including policy, procedures, templates and forms</li> <li>Worked examples discussed</li> </ul>	<b>Verification/Qualification of Packaged Systems</b> <i>[John Welbourn]:</i> <ul style="list-style-type: none"> <li>Overview of Packaged Systems and their characteristics</li> <li>How to validate Packaged Systems by integrating controls and equipment verification</li> <li>Practical worked examples</li> </ul>	<b>Verification/Qualification of Complex Plant Control Systems</b> <i>[John Welbourn]:</i> <ul style="list-style-type: none"> <li>Overview of complex control systems, e.g. Distributed Control Systems (DCSs) and their characteristics</li> <li>The importance of the Factory Acceptance Test for a DCS</li> <li>Test organisation for a DCS</li> <li>The typical site phases and how to manage integration of a DCS with its plant</li> <li>Practical worked examples</li> </ul>
<b>Validation (Verification) Phases</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>User requirements</li> <li>Risk assessments</li> <li>Supplier &amp; Compliance assessments</li> <li>Functional and design specifications</li> <li>DQ and Design review</li> <li>Validation Plan</li> <li>IQ, OQ and PQ</li> <li>Deviations</li> <li>Validation Report</li> <li>Example documents provided and discussed</li> </ul>	<b>Scalability of Validation</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Factors to consider for scaling validation</li> <li>Determining validation deliverables</li> <li>What to test – and how</li> <li>The use of test tools</li> <li>Determining the sample size</li> </ul>	<b>Hot Topics</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>Current computer validation trends and issues</li> <li>Spreadsheet validation</li> </ul>
	<b>Validation of an Existing Systems</b> <i>[Chris Reid]:</i> <ul style="list-style-type: none"> <li>A pragmatic approach to address existing systems that should have been validated (but were not!)</li> </ul>	<b>Course Closure</b> <i>[All]:</i> <ul style="list-style-type: none"> <li>Final questions and answers</li> <li>Course evaluation (how did we do?)</li> <li>Course certificates</li> </ul>
Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam	Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam	Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam <b>3</b>

**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](mailto:info@candvs.com)

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

**Booking Terms & Conditions**

<b>*Booking Contact Name:</b>		
<b>*Booking Contact E-mail Address:</b>		
<b>*Booking Contact Telephone Number:</b>		
<b>*Company Name &amp; Address:</b>		
<b>*Billing Address</b> <i>(Only complete if different to Company Address)</i>		
<b>*Attendee Information:</b>	<b>Attendee Name(s):</b>	<b>Attendee Email Address:</b>
<b>Company VAT Number (or Sales Tax Number) – *EU Countries Only</b>		
<b>*Method of payment, e.g. card or invoice payment</b>	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.	
<b>Payment Reference (if available)</b>	NOTE: For invoice payments we will need a valid purchase order number to fully confirm the booking.	
<b>* Total Fees Due</b> <b>£1,495 [GBP]</b> 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 ( <b>£1,794</b> 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 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 qualify 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 Attendees**

If you click 'yes' to 'include my name/company' on the attendees list', when completing the online booking form, your name and company will be included on the list and distributed to all the participants.

Before you commit to booking onto a webinar, we expect you to check your system compatibility with the GoToWebinar® platform using the links provided.

**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 GoToWebinar® (by LogMeIn) system, because of local IT restrictions.

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