COMPLIANCE & VALIDATION SERVICES

In cooperation with: eutech VALIDATION

Present a 3-Day Training Course on:

Computer System Validation

(A Very Practical Approach)

12, 13 & 14 June 2012
Radisson Blu Hotel, Amsterdam

- **Regulatory Rules & Guidance and an overview of Good Automated Manufacturing Practice (GAMP)**
- **Key terminology explained**
- **Overview of verification phases for different categories of systems (based on GAMP 5)**
- **Basing the scope & depth of testing on GxP functionality & product / patient risk**
- **Routine system operation and managing change**
- **System, Process and Validation Review**
- **Effective data management and system retirement**
- **'Real-life' based presentations:**
  - **Infrastructure Verification/Qualification (e.g. Networks)**
  - **Packaged Systems Verification/Qualification**
  - **Verification/Qualification of IS/Business Systems**
  - **Verification/Qualification of Complex Plant Control Systems**

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

Each delegate will receive a comprehensive set of example quality management procedures and templates.

Computer System Validation (12, 13 & 14 Jun 2012) - 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. A full set of example quality management procedures and templates will be provided for the areas covered under this section of the course. 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

Per Olsson, Principal Consultant, Eutech Validation: Per has specialised in computer validation for the last 20 years and is familiar with all aspects of validation of computerised systems, including validation planning, assessment, auditing, source code review, qualification and reporting. He is a frequent presenter and trainer on all aspects of computer validation. Per is an active member of the GAMP group, and he led a group that delivered the GAMP guide on Electronic Data Archiving. He is a trained TickIT Lead Auditor and has an extensive background in all aspects of system engineering, including management, system configuration, auditing, system design, programming, testing, commissioning, and documentation. Per has an MSc in Engineering Physics.

Steve Morrell, Director, Steve Morrell Associates Limited.: Steve is a chartered chemical engineer. He has extensive process and process automation experience, gained in a number of industry sectors. Steve has spent the last 13 years providing computer validation support to a number of major healthcare and pharmaceutical clients. He has been involved in all stages of the system lifecycle and worked on a variety of system types, including manufacturing, laboratory and business systems. Latterly he has developed a keen interest in IT systems and infrastructure and has worked closely with a number of IT departments to help them achieve compliance.

Alison Harrington, Senior Consultant, Life Science Integrity Solutions: Alison is a computer systems validation professional with over 23 years of experience in the pharmaceutical industry. For the past 9 years she has been providing consultancy and lead validation governance roles to a number of global IS projects, including global ERP systems (SAP, Oracle and JDE). 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. 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.

Mike James, Director, Compliance & Validation Services Limited.: Mike has over 19 years experience in the pharmaceutical industry, working in a variety of compliance and validation roles. His experience includes preparation and delivery of national/client-based validation training courses, hands-on validation work, validation project management and regulatory compliance consultancy. Previously, Mike spent four years as the Site Validation Manager for GlaxoSmithKline (GSK) at Speke, where he was responsible for all site validation activities, including the development and maintenance of the Site Validation Programme. Before moving to the pharmaceutical industry he spent 15 years as an industry chemist.

David Andrew, Director, Provepark Ltd: David has over 25 years experience in the pharmaceutical, biotech, chemical and nuclear industries. In his 20 years of experience within the pharmaceutical industries, over 14 years have been spent in a Computer Systems Validation role. David has extensive experience in all aspects of computer systems validation and compliance, including managing validation projects, design, specification and testing of systems, performing source code reviews, 21 CFR Part 11 assessments, supplier audits, completing functional risk assessments and writing SOPs. In his latest role, David is completing the commissioning and qualification of an automated Vial Filling Line, which incorporates Isolator technology and Lyophilisers.

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

Radisson Blu Hotel, Amsterdam: Ideally situated in the historical heart of Amsterdam, close to the main tourist attractions, museums, theatres, shopping areas, red-light and business districts. The hotel has a fitness centre and excellent conference and banqueting facilities.

Address:	Rusland 17, NL-1012 CK Amsterdam, Netherlands
Tel:	+31 20 623 1231
Fax:	+31 20 520 8200
Reservations (email):	*reservations.amsterdam@radissonblu.com*

Delegates are kindly requested to arrange their own accommodation. Course fees are £1,395.00 (GBP) per delegate. Accommodation is NOT included in the course fees.

Computer System Validation - Course Programme:

Registration (08:30 to 09:00) – Delegates arrive at the meeting room and sign the attendance register.

DAY 1 (12 June 2012)

09:00 Opening / Welcome *[Mike James]*

Introduction to the Validation of Computer Systems *[Mike James]:*
- Brief history
- Where did it originate and how has it changed over the years?
- Why is validation of GxP Computer Systems so essential?
- Types of systems in use today
- Brief overview of applicable regulations and guidance

Regulatory Rules & Guidance and GAMP *[Mike James]:*
- Key requirements summarised and explained from all key regulatory guidelines and rules, including:
  - FDA 21 CFR Part 211.68
  - FDA 21 CFR Part 11 Electronic records & signatures
  - EU EudraLex Volume 4, Annex 11 Computer systems
  - EU Directive 1999/93/EC Framework for electronic signatures
- Overview of Good Automated Manufacturing Practice guidance

Glossary/Terminology *[Per Olsson]:*
- Definition / Explanation of key terms used in automated Systems and the validation of those systems
- Introduction to comprehensive quality manual (distributed to each delegate)

Validation (Verification) Phases *[Per Olsson]:*
- Initial Risk Assessment
- Setting system requirements and system specification development
- Supplier Assessment
- Part 11 compliance assessments
- Design Review
- Installation and Operational Verification
- Performance Verification
- Example life-cycles for GAMP category 3, 4 & 5 systems
- Managing deviations

Basing The Scope & Depth of testing on GxP Parameters & Product / Patient Risk *[Mike James]:*
- Scope of testing
- Advantages of adopting a risk based approach
- GxP Parameters and related testing
- Functional Risk Assessments (using worked examples

Finish: 17:30; Drinks Reception: 19:00 ; Course Dinner: 20:00

Day 2 (13 June 2012)

Day 2 Introduction (09:00)

Routine Operation/Managing Change *[Per Olsson]:*
- Importance of effective operating procedures / processes for:
  - System management
  - Error reporting and Corrective & Preventative Action (CAPA) [Incident Management]
  - Change Management/Change Control
  - Configuration Management

System/Process/Validation Review *[Per Olsson]:*
- Purpose of regular reviews
- Frequencies (how often do we perform them?)
- What data should be included and how should it be reviewed?
- Procedures/templates involved
- Reporting and CAPA

Data Management *[Per Olsson]:*
- What data do we handle?
- Why do we need to effectively manage the data?
- What do the regulators say?
- System attribute requirements and quality management procedures for effective control
  - E.g. security, retention, retrieval
- System retirement considerations

Infrastructure Qualification *[Steve Morrell]:*
- Why do we qualify infrastructure?
- What do we need to qualify?
- How do we qualify?
- What are the typical challenges?
- Maintaining the qualified state
- Virtualisation
- Cloud computing

Packaged Systems Verification/Validation *[David Andrew]:*
- Definition and examples of packaged system
- Typical GAMP categories of hardware and software
- Unique challenges to verification/qualification
- Typical approaches to verification/qualification
- Integration with equipment verification/qualification
- Worked example:
  - Typical tests / documentation
  - Use of Risk Assessments for determining depth and scope of testing

Finish: 17:00

Day 3 (14 June 2012)

Day 3 Introduction (09:00)

Verification/Qualification of IS (Business) Systems *[Alison Harrington]:*
- Examples of business systems used in the pharmaceutical industry
- Why do we test?
- What do we validate?
- Typical configuration/structure and interfaces
- Tools for Document Management, Testing, Training, Change Management, Data Migration
- Data Management and Data Migration
- Cutover, Release Management and ongoing deployment
- Ongoing maintenance - restructuring, acquisitions and divestitures

Verification/Qualification of Complex Plant Control Systems *[Dave Andrew]:*
- Overview of complex control systems, e.g. Distributed Control Systems (DCS's)
  - Types of hardware and software involved and typical configuration, including GAMP categories
- Typical approaches to the verification/qualification of complex control systems
- Example functional risk assessments to determine depth and scope of testing
- Integration of controls and equipment systems verification and tests unique to control system verification
- Practical worked example:
  - Typical tests / documentation

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

Finish: 16:30

BOOKING DETAILS: Computer System Validation
12, 13 & 14 June 2012 – Radisson Blu Hotel, Amsterdam

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).
- 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:**		
***Company Name & Address:**		
***Billing Address** *(Only complete if different to Company Address)*		
***Number of Delegates:**		
***Delegate Name(s):** *(if different to booking contact)*		
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** **£1,395 [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 (£1674 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.