Planning, Approach and Early Project Life-cycle Activities:
- Regulations, guidelines and current industry trends
- Basing testing requirements on risk to GMP & Product Quality (incorporating ISPE, ASTM E2500-07 and Quality Risk Assessment [QRA] concepts)
- Organisation and planning for validation (often overlooked)
- Preparing effective validation documentation
- Good Automated Manufacturing Practice (GAMP) overview
  - Verification/Qualification of Computerised Control Systems
- Hygienic Engineering overview
- GMP compliance during equipment system construction
- Design Review (Design Qualification)
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- Mechanical completion, pre-commissioning and commissioning
- Using FAT & commissioning testing documents for qualification/verification (Leveraging)

Equipment System Verification/Qualification Activities:
- Verifying the Installation (Installation Qualification [IQ])
- Functional Testing (Operational Qualification [OQ])
- Verifying system performance (Performance Qualification [PQ])
- Process Validation (Risk Based)
  - Small molecule API manufacture
  - Biopharmaceutical API manufacture
  - Pharmaceutical product manufacture (formulation and filling)
- Maintaining the validated state (key supporting systems)
Course Summary

This course provides delegates with an in-depth appreciation of all project life-cycle activities, ranging from early project planning/design through to the verification/qualification of critical aspects of manufacturing systems/equipment (currently - critical components of direct impact systems) and the final process validation stages. The course also provides up-to-date information on current applicable regulatory and international standards/guidelines, together with a current industry approach to verification/qualification and validation.

The course will be presented by industry experts who collectively have worked the vast majority of areas relating to equipment/manufacturing system qualification/commissioning and process validation. Their considerable and recent hands-on experience/knowledge base will provide up-to-date learning on current industry best practice, using practical real-life examples. There will be many opportunities to put the learning into practice during carefully chosen interactive group exercises/case studies.

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

Presenters

Mike James, Director, Compliance & Validation Services Limited: Mike has over 17 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.

John Welbourn, Director, Compliance & Validation Services Limited: A validation professional with over 20 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.

Brian Collins, Global Operations Manager, GE Healthcare Life Sciences: Brian is responsible for supporting the Global Scientific Asset Services (SAS) team by building robust operational infrastructure, and enforcing adherence to processes to ensure and improve Global Operational excellence in this business unit. He is also accountable for the oversight of the implementation of new SAS programs into customer sites. Brian has held senior management positions covering a variety of quality and validation roles including responsibility for providing technical support to develop best practice, novel solutions and harmonized processes in cold chain and validation whilst working for Wyeth. Brian was also responsible for managing validation activities at Wyeth's UK manufacturing site. He has developed extensive cross-functional experience through a number of quality, pharmaceutical technology and operations management roles.

Peter Whymett, Senior Scientist, Lilly UK: Peter has worked within Lilly, at the Speke Operations manufacturing facility in the United Kingdom for over 30 years. During this time he has gained valuable experience within Quality Control Laboratories, Analytical Development and as a senior scientist in the Manufacturing, Science & Technology (MS & T) department. As a key team member, Peter has overseen the successful technical transfer or commercial manufacturing of several biotechnology processes, including Insulin and growth hormone products. Peter has recently received Eli Lilly's “Palmaris” award, the highest award granted to an individual in the MS & T organisation, recognising his outstanding technical contribution to Lilly.

Bob Lund Quality Specialist IT systems and Validation, 3M HealthCare: Bob is a Pharmacist and Qualified Person with over 20 years experience in Pharmaceutical Quality and manufacturing. His current role includes provision of expert validation advice and quality oversight of IT systems. Prior to joining 3M, Bob held a number of quality and technical roles within both the Pharmaceutical industry and the NHS.

Who Should Attend

Individuals to benefit from attending this course include anyone involved directly or indirectly in equipment system verification/qualification and process validation activities. The course is ideally suited to people who are new to validation roles or people whose job roles require them to have a general understanding of validation activities throughout a project life-cycle. This will involve personnel from production, quality assurance, validation, technical support and engineering departments.

On leaving the course delegates will: have a broad and detailed understanding of the activities involved in the commissioning/verification/qualification of equipment systems and process validation; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on an enjoyable experience.

Venue

Radisson Blu Hotel, Amsterdam: Situated in the historical heart of Amsterdam, in close proximity to main tourist attractions, museums, theatres, shopping areas, red-light and business districts.

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.
## Qualification of Manufacturing Systems & Pharmaceutical/ Biopharmaceutical Process Validation - Course Programme:

Registration (08:30 to 09:00) – Delegates arrive at the meeting room and sign the attendance register. Each day will include at least 2 interactive group exercises.

### DAY 1 (28 SEP 2010)

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

**General Introduction [Mike James]:**
- Course structure and content explained
- Brief overview of current applicable guidelines and regulations
- Icebreaker exercise

**Risk-Based Approach to Qualification / Verification [Mike James]:**
- Defining Systems and their boundaries
- Importance of understanding the process
- System Impact Assessments and Component Criticality
- Quality Risk Assessments/Functional Risk Assessments and how these can be used to determine scope/depth of testing and routine control requirements (how they form the basis of a qualification/validation plan)

**Organisation for Validation [Brian Collins]:**
- Chronology of events
- Different ways validation documentation can be structured (modular and non-modular approaches)
- Validation project planning
- Engineering documentation/systems and operating procedures
- Producing a qualification testing matrix that shows where and when qualification testing will be carried out, i.e. at Factory Acceptance Testing, Commissioning, Site Acceptance Testing, or during Qualification stages.

**Preparing Protocols/ Reports and Validation Plan Documentation [Brian Collins]:**
- Procedures (numbering, document control, data management and documentation standards)
- Effective discrepancy/deviation management
- Validation (Master) Plans, summary reports and protocols/reports

**Design Review/ Qualification [Mike James]:**
- Importance of Design Review (why carry it out)
- Vendor assessments and audits
- GMP review of design
- Links to component impact assessment and Quality Risk Assessments
- Compilation of key documentation into a design dossier

**Factory Acceptance Testing (FAT) [Mike James]:**
- Why is acceptance testing performed at the vendor’s site?
- What are the differences between FAT and Site Acceptance testing (SAT)?
- Key components of FAT and working effectively with vendors
- Documentation requirements and integrating FAT/SAT with Qualification activities (use of vendor’s documentation)
- Execution and close-out

### DAY 2 (29 SEP 2010)

**Day 2 Introduction (09:00)**

**Hygienic Engineering and GMP Compliance During Construction [john Welbourn]:**
- Overview of hygienic engineering
- Control of materials, fabrication processes and work practices
- Consequences of poor practice
- Construction testing/verification
- Handover of systems from construction to commissioning

**Mechanical Completion, Pre-commissioning and Commissioning [john Welbourn]:**
- Construction/mechanical completion process
- Stages/activities associated with pre-commissioning
- Commissioning activities and examples of the type and level of testing carried out
- Integration with qualification (Leveraging)
- Site Acceptance Testing (SAT)
- Documentation involved

**Installation Verification/ Qualification of Equipment Systems [Mike James]:**
- Overview of testing/checking carried out
- General documentation requirements
- Leveraging of information from FATs & SATs
- Supporting documentation and storage
- Integration with change control and maintenance

**Functional Testing of Equipment Systems (Operational Qualification) [Brian Collins]:**
- Overview of testing carried out
- Testing based on GMP risks
- Documentation requirements
- Supporting documentation and storage
- Integration with change control and maintenance

**Good Automated Manufacturing Practice (GAMP) [Mike James]:**
- GAMP 5 approach to the validation/qualification/verification of computerised/automated systems
- Integration of automated systems and equipment system qualification (avoiding duplication of effort)
- Documentation requirements

**Performance Testing of Equipment Systems (Performance Qualification) [Brian Collins]:**
- What systems does it apply to?
- What is the purpose and how does it differ from process validation?
- Sampling and sampling plans
- Overview of testing carried out (using example systems)
- Documentation involved and protocol requirements

### DAY 3 (30 SEP 2010)

**Day 3 Introduction (09:00)**

**Process Validation (General Overview) [Mike James]:**
- Defining the process
- Overview of requirements from regulatory guidelines (including latest FDA guideline)
- Linking of testing to the critical quality attributes and the control parameters that affect them
- Process validation approach to small molecule API validation approach

**Process Validation - Biopharmaceutical API Manufacturing [Peter Whyman]:**
- Real-life case study
  - Process definition
  - Critical process control parameters
  - Sequence of events involved in a complex project
  - Process validation testing strategy
  - Resolving issues

**A Risk Based Approach to Process Validation (Pharmaceutical Product Manufacture) [Bob Lund]:**
- Modern, scientific and risk based approach versus the ‘traditional’ approach
- Importance of process definition/rationalisation activities
- Alignment of validation strategy with current regulatory expectations
- Critical process control parameter examples (typical filling process) and application of a risk based testing strategy

**Maintaining The Validated State [Mike James]:**
- Importance of good failure investigation processes
- Ongoing risk management and how this integrates with validation
- Periodic Validation Review
- When is revalidation required?
- Other important supporting systems (e.g. calibration)

**Course Closure [All]:**
- Questions and answers
- Change Management (Change Control)
- Certificates

**Finish: 17:00; Drinks Reception: 19:30; Course Dinner: 20:30**
BOOKING DETAILS – Qualification of Manufacturing Systems & Pharmaceutical/Biopharmaceutical Process Validation
28, 29 & 30 September 2010, Radisson Blu Hotel, Amsterdam

How to book on this course:
- The simplest and quickest way is to book online. Please visit/return to our 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 or email.

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.

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.

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| 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 | |
| Payment Reference (if available) Please note that for bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking | |
| * Total Fees Due (£1,295 [GBP] per delegate) | |
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