Compliance & Validation Services

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

Understanding Pharmaceutical Packaging

19, 20 & 21 November 2024
Scandic Copenhagen Hotel, Denmark

November 2024						
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Click here to visit the webpage for this course

- Purpose of pharmaceutical packaging
- Selection criteria and types of packaging available
- Applicable regulatory and industry guidance
- Regulatory submission requirements
- Summary of Product Characteristics and the Common Technical Document
- Glass, plastic and metal primary packaging materials explained in detail
- Secondary packaging requirements
- Tertiary packaging and transit packaging
- Functional testing of packaging
- Stability studies
- Extraction and migration studies
- Safety features, e.g. Anti-Tamper Device, Unique Identifier, Serialisation, Aggregation
- Overview of qualification and validation requirements
- Packaging equipment qualification
- Safety feature qualification
- Packaging process validation

Course Summary: Understanding Pharmaceutical Packaging - 19, 20 & 21 November 2024 - Hotel Scandic Copenhagen, Denmark

This course provides delegates with an overall appreciation of the complex activities/technology involved in the life-cycle of Pharmaceutical Packaging projects, ranging from material/pack selection/design (based on the product dosage form and product material characteristics), through to the final validation of the Packaging Process and subsequent Ongoing Process Verification. Within this range the course covers: applicable regulatory guidance/rules and international standards; emerging legislation on counterfeit, falsified medicines and product security; development goals for new packaging design and the packaging options available; testing and evaluation of packaging/materials involving; stability and functional testing, extraction and migration studies; and leachables. The course also covers key properties of primary packaging materials/forms and will cover the barrier properties offered in terms of temperature resistance, chemical compatibility and physical properties. Example of primary packaging materials will include glass, plastics, and metals and packaging formats including laminates, blisters, tubes and closures.

A general introduction to the qualification and validation of packaging equipment will be given and this will lead into more detailed presentations covering: risk assessments to determine depth and scope of testing; the qualification of pharmaceutical packaging equipment; testing at the key stages of qualification, including packing safety features design and qualification (e.g. Serialization, Anti-tamper and 2D Data Matrix Codes); Packaging Process Validation (scope, approaches and sampling/testing) and Ongoing Process Verification.

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 drinks reception and course dinner, held on the evening of Day 1 (Tuesday 19 November 2024), are included in the overall package.

Presenters

Chris Penfold, Packaging Development Services Ltd: Chris is an experienced Freelance Packaging Development Specialist with a proven track record in general and technical management. He is a packaging professional with over 35 years packaging development and NPD experience working in senior packaging roles on £million-brands in the OTC, healthcare, Rx pharma, veterinary and Medical Device arenas for 'blue-chip' multinational companies such as Glaxo (GSK), CIBA (Novartis), Boots Healthcare International and Reckitt Benckiser Healthcare. Chris is a Chartered Environmentalist & Marketer with extensive cross-functional experience in a broad spectrum of related disciplines, including production, supply chain, QC and marketing. He has experience working in various European countries, Middle East, North America and the Far East; Underpinned by proven interpersonal skills, the ability to make things happen and experience gained from independent international consultancy projects and running his own business. Chris has been delivering a range of highly acclaimed & successful packaging training courses to a Global audience for the past 15 years.

Mike James, Compliance & Validation Services Limited: Mike has 25 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, 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, 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.

Who Should Attend

The course is ideally suited to people who are involved directly in Pharmaceutical Packaging (projects, development, operations and ongoing support staff), or people indirectly involved, whose job roles require them to have a general understanding of the principles, standards and regulations that apply to Pharmaceutical Packaging. People from roles such as new product/packaging development, quality assurance (approval of art-work/documentations relating to packaging operations), technical support, QC testing, production supervisory staff and qualification/validation should benefit from this course. The information imparted should be advantageous to people who are new to Packaging roles, or experienced personal who want to refresh/reinforce/expand their knowledge base in this area.

On completing the course, delegates will have a broad/in-depth understanding of the activities involved in the lifecycle of Packaging projects, be able to apply and share their new knowledge to improve their individual effectiveness and 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)***

Understanding Pharmaceutical Packaging - 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 19 November 2024)

Start: 09:00 CET

Introduction *[John Welbourn]:*
- Purpose of pharmaceutical packaging and an overview of the types of packaging materials
- Selection criteria
- Packaging development, testing and validation
- Key concepts of packaging equipment qualification and process validation

Purpose of Pharmaceutical Packaging *[Chris Penfold]:*
- Key functions/roles of pharmaceutical packaging
- New product development process
- Considerations for pack development
- Summary of Product Characteristics – what's in it
- Packaging formats, material properties/characteristics and material compatibility
- Packaging testing overview

Regulatory Requirements and Industry Guidance *[John Welbourn]:*
- Global regulations and standards
- Key European legislation and guidance
- GMP regulations and guidance
- Pharmacopoeia
- ICH and Pharmaceutical Quality Group guidance

Regulatory Submission Requirements *[Chris Penfold]:*
- Registration Dossier and Drug Master File (DMF) contents
- The submission /approval process
- Common Technical Document (CTD) and CTD modules

Glass Pharmaceutical Packaging *[Chris Penfold]:*
- Types of glass
- Manufacture of glass containers, e.g., moulding
- Surface coating
- Potential issues with glass containers
- Product interactions
- Benefits and limitations of using glass
- Testing of glass containers

Plastic Packaging *[Chris Penfold]:*
- Manufacturing process
- Types of plastics
- The use of thermoplastics, e.g. polyethylene (low and high density), polypropylene and polystyrene (including expanded polystyrene)
- Thermosetting plastics
- Rubbers and elastomers
- Benefits and limitations

Moulding Techniques for Plastic Packaging *[Chris Penfold]:*
- Injection moulding
- Compression
- Blow moulding
- Extrusion
- Injection, stretch and blow moulding

Metal Packaging *[Chris Penfold]:*
- Types of packaging
- Benefits and limitations

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

DAY 2 (Wednesday 20 November 2024)

Start: 09:00 CET

Cartons (Secondary Packaging) *[Chris Penfold]:*
- Paperboard
- Carton format, shapes and styles
- Carton materials
- Creasing and cutting
- Carton testing

Artwork and Leaflets *[Chris Penfold]:*
- General requirements
- Information leaflets:
  - Materials, folds, issues and testing
- Readability
- Brail
- Labelling - materials, construction and requirements
- Key challenges
- Label adhesives
- Testing

Tertiary and Transit Packaging *[Chris Penfold]:*
- Types and measurements
- Issues
- Testing

Choice of Packaging *[Chris Penfold]:*
- Selection criteria
- Regulatory Context

Stability – Testing and Evaluation *[Chris Penfold]*
- Purpose of testing
- Types of testing involved
- Ongoing monitoring, after approval
- Post approval changes
- Climatic Zones
- Photo Stability

Functional Testing *[Chris Penfold]:*
- How to ensure packs are fit for purpose
- Protection testing
- Safety testing
- Compatibility testing
- Performance Testing

Extraction/Migration Studies *[Chris Penfold]:*
- Extractables and leachables explained
- Extraction and leaching studies
- Case studies
- Sorpion studies
- Reference guides and practical application of rules and guidance

Pack Safety Features Design *[John Welbourn]:*
- Child resistant packaging
- Safety features and why they are required
- Unique Identifier and Anti-Tamper Devices
- Regulatory requirements
- Serialistion – serial numbers, aggregation and data matrix codes explained

Finish: 17:00 CET

DAY 3 (Thursday 21 November 2024)

Start: 09:00 CET

Introduction to The Qualification and Validation of Packaging Equipment *[John Welbourn]*
- Key concepts, e.g. what's the difference between validation and qualification
- Regulations and terminology used (US Vs Europe)
- Typical sequence of activities
- Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs) and Critical Process Parameters (CPP's) explained for different types of packaging operations.
- Determining the scope of qualification, i.e. What do we need to qualify / validate.
- Key considerations for packaging lines, e.g. line clearance

Qualification of Packaging Equipment *[Mike James]*
- Overall qualification sequence of events explained
- Impact assessments and risk assessments to determine the scope and depth of testing required, examples for a range of packaging operations
- Typical testing carried out at Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ)
  - What quality testing is required
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
  - Documentation and material requirements
  - What testing can we carryout at these stages and what tests can we leverage into the IQ and OQ to avoid repetition

Packing Safety Features Qualification *[John Welbourn]:*
- Serialisation qualification
- Anti-Tamper Device (ATD) qualification
- Unique Identifier qualification
  - Bar code
  - 2-D Matrix Code print quality
  - Test parameters and grade levels
- Human readable data verification

Packaging Process Validation *[Mike James]*
- Links to CQAs/CMAs and CPPs
- Lengths and numbers of batches required
  - Can we use a matrix approach?
- Documentation requirements and acceptance criteria
- Sampling and testing requirements – Monitoring of CQAs and CMAs
- Controlling/monitoring of CPPS
- Ensuring personnel variables are covered, e.g. breaks and shift changes
- Reporting
- Ongoing process verification
- Revalidation

Finish: 17:00 CET

BOOKING DETAILS: Understanding Pharmaceutical Packaging - 19, 20 & 21 November 2024 - Hotel Scandic Copenhagen, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please use the 'click here' link below to visit the web page for this course and use either of the 'book onto this course' links to view and complete the online booking form, 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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