ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

David Abraham
QRS & Project Leader in the development of PS 9000:2016, UK

Maren Göpfert
Boehringer Ingelheim Pharma, Germany

Jérémy Jacquart
PHARMAPLAN, France

Dr Franz Schönfeld
GMP Inspector, Germany

Avoiding Non-Compliance in Packaging Operations

Live Online Training on 8/9 March 2022

How to avoid Mix-Ups, Contamination and Labelling Issues

Highlights

- GMP Requirements & Guidelines for Packaging Operations
- Requirements for Packaging Facilities
- Cleaning and Hygienic Concepts for Packaging Areas
- Specific QA Systems for Packaging Operations
- GMP Design Aspects for Packaging Lines
- Fundamentals of Primary and Secondary Packaging Materials
- Printing, Coding, Reading: Authentication of Medicinal Products
- Qualification and Validation
- Packaging of Highly Potent Products
- Qualification/Auditing of Suppliers of Packaging Materials according to PS 9000:2016

- "GMP for Packaging Materials": PS 9000:2016
- Experiences with Serialization
- EU GMP Annex 1 Draft: Implications for Sterile Containers?

Programme

Objective

This GMP Live Online Training Course aims at easily explaining the GMP requirements for packaging of medicinal products.
This includes requirements for premises and equipment but also for QA operations like documentation, line clearance, validation etc.

Background

Packaging of medicinal products, blistering as well as cartoning for example, plays a crucial role in the quality and safety of a medicine. Deficiencies of primary packaging may alter the efficacy or stability of a product; failures in secondary packaging may do harm to patients even worse when products or the folding boxes are mixed up. Therefore, packaging is defined as (the last) pharmaceutical manufacturing step and one of the most critical ones. It is not surprising that the biggest part of recalls is caused by failures during packaging. The FDA reported that more than 30% of recalls of tablet products during the last 5 years were caused by label mix-ups, incorrect packaging or incorrect products insert. On the other hand, despite the high criticality of the packaging process, the packaging plants are required to cut the costs and raise their efficiency.
Another challenge for the packaging units is the **new EU Directive**, requiring **safety features and authentication measures** in order to raise the hurdle for drug counterfeiters. As a consequence of the "COMMISSION DELEGATED REGULATION (EU) 2016/161", the rules apply from **9th of February 2019** onwards except for some member states with an existing Verification System. Packaging lines have to be equipped with systems for printing and reading two dimensional codes (2D-Codes) and these systems have to be linked to the materials management system. Companies already shipping serialized products have been reporting from technical hurdles which should not be underestimated. Most companies without experience in this field will need external help. But technical expertise could become rare in the near future.

There are **numerous requirements** which have to be fulfilled in the packaging plant. During this GMP course we will focus on:

- Compliance & QA requirements
  - QA Systems
  - Hygiene and Cleaning
  - Qualification / Validation
- Technological aspects
  - Facility and Zone Concept
  - Design of packaging equipment
- Packaging materials:
  - Handling, storage and mix-ups
  - Suppliers
- Special topics:
  - Serialisation & Authentication
  - Highly Potent Products

Target Audience

Staff from QA and production engaged in packaging operations is the target group of this course as well as suppliers for equipment and packaging material used for packaging of medicinal products.

Programme Day 1

Provisional timetable, the actual schedule may vary depending on the situation.

09.00 – 09.15 h Welcome & Introduction

09.15 – 10.15 h
GMPs and QA Oversight for Packaging Operations

- GMP requirements in the packaging unit
- Important Guidelines and standards
- QA Systems relevant for packaging operations
- Frequent inspection findings

10.15 – 10.20 h Short Break

10.20 – 11.30 h
General GMP Requirements for Packaging Operations / Key Compliance Challenges for Packaging Operations

- Handling and storage of packaging materials
- Testing
- Stability issues
- Material storage, returned goods, quarantine
- Line Clearance
- Documentation practice
- Practical GMP aspects
- Good and bad practice

11.30 – 11.45 h Break

11.45 – 12.30 h
Quality and Compliance Systems in the Packaging Plant

- Hygiene and Zone Concepts
- Material flow
- Line clearance procedure
- IPCs in the packaging process
- Documentation and control
- Handling of variable printing data

12.30 – 13.00 h
Q&A Session 1

13.00 – 14.00 h Break

14.00 – 15.00 h
Packaging of Highly Potent Products / Q&A Dynamic Session on Packaging (Tips & Problems)

- Cross Contamination – how to avoid it:
  1 – dedicated vs multi product facility
  2 – production planning
  3 – cleaning procedures
  4 – people movement

15.00 – 15.30 h
Secondary Packaging (Interactive Session)

15.30 – 15.45 h Break

15.45 – 16.30 h
The Application of GxP in Packaging Supply

- Relevant ISO standards
- Introduction to British "GMP for Packaging Materials": PS 9000:2016

16.30 – 17.00 h
Q&A Session 2

Programme Day 2

09.00 – 10.00 h
Packaging Facilities & Premises / GMP Design Aspects for Packaging Lines

- Requirements for the technical building equipment
- Zone Concepts for primary and secondary packaging
- Air-Lock concepts
- Hygiene
- HVAC
- Design criteria for blister machines, cartoners, labelers
- Differences to aseptic filling / packaging
- What is critical?
- What to write in an URS?

10.00 – 10.45 h
Reducing Risk through Supplier Auditing

- How much GMP must a supplier have?
- Practical audit aspects: what to examine?
- Qualification of suppliers

10.45 – 11.00 h Break

11.00 – 11.45 h
Qualification and Validation

- Equipment qualification
- Process validation
- Critical issues which have to be tested
- How to test?

11.45 – 12.15 h
Q&A Session 3

12.15 – 13.15 h Break

13.15 – 14.00 h
Serialization and Aggregation – How it was implemented, what worked and what didn't

- Challenges in the implementation phase
- Equipment qualification/ process validation
- Packaging material management
- Impact on the Supply Chain
- Handling of Failures / Deviations / Complaints

14.00 – 15.00 h
How to minimize Risk in Sterile Packaging

- What can go wrong in sterile packaging?
- How to minimize these incidents applying QRM principles.
- Aseptic filling and terminal sterilization:
  - Microbiological quality of the primary packaging components
  - Media Fill
  - Container Closure Integrity (CCI)

15.00 – 15.05 h Short Break

15.05 – 15.30 h
Q&A Session 4

Participants' comments of March 2020 course:
„Really enjoyed discussion and working groups. Workshops very useful for putting the lecture topics into action and returning knowledge of materials."
Anthony Cummins, Tolmar International Ltd., Ireland

Speakers

David Abraham
Quality Resource Solutions Associates, UK
David has extensive experience in both business and Quality Management. David's background has seen him working both with and within the print and packaging arena as well as pharmaceutical manufacturing organizations; designing, developing, implementing, maintaining and improving business processes in line with the application of pharmaceutical Good Manufacturing Practices. He provided input in the development of a number of industry guidance and standards and was project leader in the development of the PS 9000 series of standards and guidance. His work continues to see his engagement across the industry, supply chain and training organisations providing resource, awareness, training and consulting in quality management and the application of GXP.

Maren Göpfert
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Maren Göpfert is a chemical engineer. She is Head of Product- and Process-Technology including the Center of Competence for Device- and Packaging-Technology at Boehringer Ingelheim GmbH & Co. KG at Ingelheim site. She was previously Head of packaging solid forms at the Pharma Production Department. She also used to work in the automotive and aerospace industry during many years at various positions including Production Management, Project Management, Engineering and Consulting.

Jérémy Jacquart
PHARMAPLAN SAS, France
Jérémy has been working for Pharmaplan since 2010. He has more than 22 years of experience in packaging and aseptic process equipment for the Pharmaceutical industry. His expertise includes aseptic filling & packaging equipment (e.g. freeze dryer, loading and unloading systems for vials and cartridges, pen assembly lines, vials packaging lines), customized equipment, upgrade of old equipment, quality risk assessment, and project management.

Dr Franz Schönfeld
District Government of Upper Franconia, Germany
Franz Schönfeld is GMP Inspector and Head of the Expert Working Group for APIs and excipients at the German Central Authority of the Federal States for Health Protection (EFG 07/ ZLG).

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GERMANY

Reservation Form (Please complete in full)

Avoiding Non-Compliance in Packaging Operations
Live Online Training on 8/9 March 2022

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 8 March 2022, 09.00h – approx. 17.00 h
Wednesday, 9 March 2022, 09.00h – approx. 15.30 h
All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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Your Benefit

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „… All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training…."

This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

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