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

Maren Göpfert
Boehringer Ingelheim Pharma

Dr Jean-Denis Mallet
ECA & Former Head of the Pharmaceutical Inspection Dpt. AFSSAPS

Dr Franz Schönfeld
GMP Inspector

Avoiding Non-Compliance in Packaging Operations

11/12 March 2020 | Hamburg, Germany

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
- Workshops & Interactive Sessions:
  - Qualification and Validation
  - Secondary Packaging (including Medical Devices)
  - 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
- New EMA Guideline "GMP for Sterile Containers"

Objective

This GMP 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 Concepts
  - 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

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

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

Packaging facilities & premises

- Requirements for the technical building equipment
- Zone Concepts for primary and secondary packaging
- Air-Lock concepts
- Hygiene
- HVAC

GMP Design Aspects for Packaging Lines

- Design criteria for blister machines, cartoners, labelers
- Differences to aseptic filling / packaging
- What is critical?
- What to write in an URS?

Case Study: Serialization and Aggregation– How we implemented, what worked and what didn't

- Areas to be addressed: IT system – carton – processes
- Challenges in the implementation phase
- Equipment qualification/ process validation
- Packaging material management
- Impact on the Supply Chain
- Handling of Failures / Deviations / Complaints

Workshops

Workshop on Qualification and Validation

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

Workshop on Packaging

- Secondary Packaging (including Medical Devices)

Interactive Session on 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

Case Study: Quality and Compliance systems in the packaging plant

In this case study the different systems in place in a packaging plant of Boehringer Ingelheim GmbH & Co. KG at Ingelheim site are presented, e.g.

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

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)

The application of GxP in packaging supply

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

Reducing risk through supplier auditing

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

Moderator

David Abraham

Social Event

At the end of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

David Abraham
Quality Resource Solutions Associates

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

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.

Dr Jean-Denis Mallet
ECA, former head of the French Inspection Department AFSSAPS, NNE Pharmaplan

Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he is member of the ECA advisory board and works for NNE Pharmaplan.

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, 11/12 March 2020, Hamburg, Germany

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 %
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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
Wednesday, 11 March 2020, 09.00 to approx. 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 12 March 2020, 08.30 to approx. 15.30 h

Venue
Barcelo Hamburg
Ferdinandstr. 15
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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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

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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