ECA Academy
Your GMP/GDP Information Source

Avoiding non-Compliance in Packaging Operations

How to avoid Mix-Ups, Contamination and Labelling Issues

SPEAKERS:

Maren Göpfert
Boehringer Ingelheim Pharma

Buket Hekiman Bayraktar
PharmaVision

Dr Afshin Hosseiny
ECA & former Director of Quality Assurance, GSK

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

1-2 March 2017, Copenhagen, Denmark

PROGRAMME:

- GMP requirements & guidelines for packaging operations
- Requirements for packaging facilities
- Cleaning and hygienic concepts for packaging areas
- Specific QA systems for packaging operations
- GMP-compliant design of packaging equipment
- Fundamentals of primary and secondary packaging materials
- Printing, coding, reading: authentication of medicinal products
- Qualification and validation of packaging processes and equipment
- Packaging of highly potent products
- Qualification of suppliers of packaging materials

This education course is recognised for the ECA GMP Certification Programme „Certified Packaging Manager“.
Please find details at www.gmp-certification.eu

Avoiding non-Compliance in Packaging Operations

1-2 March 2017, Copenhagen, Denmark

Objectives

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 about 30% of recalls of tablet products during the last 5 years were caused by label mix-ups, incorrect packaging or incorrect products insert. The number of field alerts tripled between 2009 and 2012. 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 will be applied from 9th of February 2019 onwards except for some member states with an existing Verification System. Packaging lines will have to be equipped with systems for printing and reading two dimensional codes (2D-Codes) and these systems will 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

Packaging facilities & premises

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

Handling of Packaging Materials

- Handling and storage of packaging materials
- Testing
- Stability issues

Compliance for Packaging Operations

- Material storage, returned goods, quarantine
- Line Clearance
- Documentation practice
- Practical GMP aspects
- Good and bad practice

GMP Design for packaging equipment

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

Product Serialization and Authentication - 7 Years of experience: how to cope with country specific requirements and implementation of new technology?

- Authentication & Serialization –basic information
- Scope and main characteristics of Track & Trace System in Turkey
- General aspects on required equipment for Serialization and Authentication
- Regulatory aspects and timeline for implementation in phases

- Impact of Serialization and Authentication on production processes
- Case Study:
  - Implementation at PharmaVision, a pure CMO
  - Frequently faced problems & Facts as of 2017
  - Management assessment: Challenges & Proposed solutions

Qualification and Validation

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

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

Packaging of highly potent products in a GMP environment

- Avoidance of cross contamination
- What has to be considered for packaging of (solid) highly potent medicines (primary + secondary)

Special requirements for the packaging (filling) of sterile products

- The two manufacturing modes for sterile products: aseptic filling and terminal sterilization
- The physical characteristics of the primary packaging components and their physico-chemical attributes (the challenge of departiculated & depyrogenated packaging materials
- The microbiological quality of the primary packaging components
- Integrity of the product: importance of the resistance of primary packaging components; importance of the integrity testing

Audit of packaging material suppliers

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

Moderator

Dr Afshin Hosseiny

Speakers

Maren Göpfert
Boehringer Ingelheim Pharma GmbH & Co. KG
Maren Göpfert is a chemical engineer. She is Head of Product and ProcessTechnology 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.

Buket Hekiman Bayraktar
PharmaVision San. ve Tic. A.S.
Mrs Bayraktar studied Pharmacy and received her Executive MBA degree from Bogazici University. She works as General Coordinator at PharmaVision, a pure pharmaceutical contract manufacturing company in Turkey. She is the Secretary General of ISPE Turkey Affiliate since 2011 and was also Chair of ISPE European Affiliate Council for 2013-2014.

Dr Afshin Hosseiny
Tabriz Consulting Limited, Great Britain
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

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.

Social Event

On the evening of the first 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Avoiding non-Compliance in Packaging Operations
1-2 March 2017, Copenhagen, Denmark

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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)

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, 1 March 2017, 09.30 to approx. 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 2 March 2017, 08.30 to approx. 15.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 (0)33 96 50 00
Fax +45 (0)33 96 55 00

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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andrea Kühn-Hebecker (Operations Director) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Rouwen Schopka (Organisation Manager) at +49-62 21/84 44 13, or per e-mail at schopka@concept-heidelberg.de.