Avoiding Non-Compliance in Packaging Operations

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Speakers

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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

How to avoid Mix-Ups, Contamination and labelling issues

- “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
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).

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.
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