Includes Workshop on the calculation of cleaning limits in accordance to the new EMA Guideline

Cross Contamination

The new EU requirements for the use of multipurpose equipment

19-20 April 2016, Vienna, Austria

SPEAKERS:

Richard M. Bonner
Chairman of ECA and the European QP Association, formerly Eli Lilly, UK

Dr Andreas Flückiger
F. Hoffmann-La Roche, Switzerland

Dr Jean-Denis Mallet
ECA & former head of the AFSSAPS, France

LEARNING GOALS:

- Most frequent findings during GMP Inspections
- Update on regulatory requirements including dedicated & shared facilities
- How to detect potential contamination risks
- How to minimize the risk of cross contamination
- Cross Contamination risks through:
  - Facility Design
  - HVAC
  - Equipment
- Toxicological risk evaluation
- Determination of cleaning limits: how much cross contamination is allowed?

ECA ACADEMY

Each participant receives an industrial guidance document on the derivation of ADE/PDE values

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

Cross Contamination

19-20 April 2016, Vienna, Austria

Objectives

This GMP training course aims at unveiling possible risks of cross contamination during the production process of pharmaceutical products and APIs. This is especially important as chapters 3 and 5 of EU GMP Guideline have been updated updated with a new focus on the avoidance of cross contamination.

Learn
- how to detect possible risks,
- how to avoid cross contamination,
- how to determine exposure limits.

Background

Cross Contamination is one of the highest risks for patients using pharmaceutical products. Not only the presence of small amounts of antibiotics or other highly potent compounds in medicines can cause severe damage but also carryover of products into another pharmaceutical product is of high risk to the patient. According to the Medicines & Healthcare Products Regulatory Agency in the United Kingdom Product contamination is the second to third highest reason for recalls in the UK in recent years.

It is therefore not surprising that the EU commission published an update of the chapters 3 (premises & equipment) and 5 (production) with the focus on minimizing the risk of cross contamination. Almost at the same time a new EMA Guide on setting health based exposure limits was published. This new guide has massive impact on the dedication of facilities and also on the calculation of limits for cleaning validation. The formerly accepted 1/1000 dose or 10 ppm criteria have become obsolete. Now limits for the maximum carryover have to be calculated by taking into account the toxicological/pharmacological properties of each single product.

Reasons for cross contamination can be manifold and caused by technical as well as organisational deficiencies. Insufficient cleaning of equipment, poor facility design or inappropriate design of the HVAC system may be reasons as well as contamination due via personnel or primary packing material. But also the design of the production process itself can be the cause for cross contamination, for example due to open product handling during transfer or sampling operations in shared plants.

It is therefore extremely important to avoid or minimise the risk of cross contamination, starting when process and equipment are designed. It is also important to learn how contamination risks can be detected, either by visits on-site or by reviewing of the documents which can be SOPs or technical drawings.

Target Group

Inspectors & QA staff are target group of this course but also responsible persons from production and engineering.

Programme

Cross Contamination
- Most frequent findings during GMP Inspections
  - inspector's approach to detect cross contamination risks
  - poor practices observed
  - examples of deficiencies
  - recalls related to cross contamination
- Update on the regulatory requirements: EU GMP and handling of potent compounds
  - Dedicated vs shared facilities
  - EU GMP-Guide chapters 3.6 and 5.17-21: what are the consequences
  - Risk Management

Principles of assessing toxicological risks – the basis for calculating limits

The toxicological and pharmacological basis of assessing APIs with the objective of worker protection is the same as the one justifying GMP cleaning validation criteria and acceptance of multi-product use of a facility.
- Assessing the hazard: potency and toxicity of the compounds. Occupational exposure limits and health hazard categories
- Definitions: ADE, PDE, NOEL, LOEL, OEB, OEL
- Classification of substances into hazard categories
- How is patient safety connected with the occupational exposure limit ?
- Use of correction factors to fill data gaps

Cross Contamination through poor facility design and maintenance practices
- A model for identifying cross-contamination risks
- Cross-contamination due to poorly designed facilities (surfaces, cracks and other sources)
- Contamination and cross-contamination due to equipment and their maintenance
- Inadequate segregation of processes involving sensitising products from other products

Environmental Control – Cross Contamination Risks through failures in the HVAC System
- Airborne contamination and airborne cross-contamination
- Capture of contaminants where dust is generated
- Air handling and prevention of dust dissemination
- Failures in HVAC design (filtration, airflow pattern, pressure differentials)
- Failures in HVAC operation (e.g. energy saving, unbalanced pressure differentials)

Risk of Contamination in non-sterile production processes

- What is a risk-based approach to understanding contamination control? How do you decide if the risk is acceptable or not?
- Where can you apply Q9 principles to assess contamination risk during production?
  - In Drug substance manufacture
  - In Drug product manufacture and packaging
  - During sampling, weighing/material transfers
  - In the warehouse and distribution chain.

Contamination caused by inappropriate cleaning of equipment

- What is clean?
- What is "worst case"
- Inadequate cleaning procedures
- The use of non-validated cleaning practices
- The use of non-validated analytical test methods

How much cross contamination is allowed? Cleaning limits in accordance with the new EMA guideline

- Controlling cross contamination
- Old and new approach for the determination of cleaning validation limits
- Requirements from the new EMA Guideline on the setting of risk/health based limits
- RiskMaPP in the cleaning of pharmaceutical equipment
- Concrete examples / calculation examples

Workshop: Calculation of cleaning validation limits according to the new EMA requirements

In this workshop you will learn how the new EMA guideline on setting health-based limits can be applied in practice. You will learn how to calculate substance-specific limits, also called ADEs (acceptable daily exposures) and PDEs (permitted daily exposures).

To do this, you will learn how to determine the right starting point for each calculation, the NOEL (No-observed-effect-level) and how correction factors are used.

Social Event

On Tuesday, 19 April 2016 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

Richard M. Bonner
Chairman of ECA and the European QP Association, formerly with Eli Lilly, UK
Richard Bonner was a Senior Quality Adviser for Eli Lilly and Company. Mr Bonner is a Qualified Person in Europe, Chairman of the ECA and of the Qualified Person Association Advisory Board. He has 31 years experience within the pharmaceutical industry and has been involved in multiple inspections from the MHRA & FDA and has also immense experiences as a GMP auditor.

Dr Andreas Flückiger
F. Hoffmann-La Roche
An occupational physician by training, Andreas Flückiger has been the head of the occupational health services of the Roche Group for 20 years. He is active in leading roles in numerous national and international associations such as the International Association for Occupational and Environmental Health in the Chemical Industry (Medichem), in the Scientific Committee of the European Council for Ecotoxicology and Toxicology of Chemicals (ECETOC).

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 Inspection Department at the French Health Products Regulatory Agency (Afssaps). 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.

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)

+ 49 6221 84 44 34

Cross Contamination
19-20 April 2016, Vienna, Austria

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number 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

Tuesday, 19 April 2016, 10.00 to approx. 18.00 h
(Registration and coffee 09.30 - 10.00 h)
Wednesday, 20 April 2016, 08.30 to approx.. 15.30 h

Venue

Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day and 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

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

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

For questions regarding content:
Dr Robert Eicher (Operations Director) at
+49-62 21/84 44 12, or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Katja Kramer (Organisation Manager) at
+49-62 21/84 44 16, or per e-mail at
kramer@concept-heidelberg.de.