20 YEARS ECA Academy Your GMP/GDP Information Source

Reconstruction and Upgrading of GMP Facilities

Maintaining GMP-compliant manufacturing during the construction phase

Includes Workshop on real reconstruction case study

Image: CSL Behring

SPEAKERS:

Nikolaus Ferstl
University Hospital of Regensburg

Dr Johannes Krämer
CSL Behring

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

10-11 September 2019, Vienna, Austria

LEARNING OBJECTIVES:

- Current GMP requirements for facilities and premises
- Project management in modernising projects
- Risk management & gap analysis
- Zone concepts for existing buildings
- Dealing with poorly documented systems
- Measures for protecting the ongoing manufacture
  - Protection from dust
  - Protection from unauthorised access
  - Protection of already installed in equipment
  - Monitoring of the protective measures
- Involvement of authorities in upgrading projects

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

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Objectives

This course aims at showing GMP-compliant layout and state of the art clean room technology for GMP production areas, which have to be built in existing manufacturing premises. Next to project management, the securing of the GMP status of the ongoing manufacture during the construction work is a main topic of this course.

Background

The number of new factory buildings in the pharmaceutical industry in Europe decreases while upgrading and renovation of existing manufacturing sites is getting more and more relevant. Regardless of whether the upgrade is done in order to extend the facilities' capacity or if whether it was necessary due to GMP issues: upgrading is much more challenging than construction in the Greenfield. For example, the existing infrastructure of the building has to be taken into account, although the existing documentation is most often not complete. Nevertheless the users' requirements for layout and process flow have to be fulfilled as well as the demands from authorities with regard to the cGMP requirements. Anther common issue is that the actual state is differing from the documented status. And, also quite frequent, the available space is restricted, and bringing in new equipment is sometimes tricky.

But one of the biggest issues and most important differences to construction on the Greenfield is the ongoing manufacture in the existing building. It is unavoidable to take measures to secure the manufacturing area from the parallel construction work and dust and from the uncontrolled access through foreign workers. Moreover, it has to be proven that construction work had no influence on the quality of the batches.

The existing personnel and material flow also has to be considered. For example, bringing in raw materials can possibly be a problem during the construction phase.

Target Audience

This course is targeting professionals responsible for the planning and realisation of upgrading and refurbishment projects. It further addresses engineers and project mangers from pharmaceutical companies as well as from engineering companies.

Programme

Basic requirements for pharmaceutical facilities

Before starting renovation of an existing facility or doing a GMP upgrade, it is important to know what today's cGMP requirements for sterile and non-sterile facilities are.

- Layout, air-locks, personal and materials flow
- HVAC systems
- Ceiling, walls & floor (cleanability & persistence) - assignment of different systems to the clean room classes A-D (E)
- Barrier systems vs. clean room class A
- Clean media
- Equipment

Gap Analysis, Risk Assessment, and Planning

- Definition of Project Targets
- Guidelines and Cleanliness classes
- Approach with not-sterile dosage forms
- Typical project model
- Project management

How authorities consider facility modifications?

- What are the regulatory expectations before starting construction work?
- How to document the change file from a technical and regulatory point of view?
- Communication with the authority in charge
- Implementing the changes & modifications

The real world - Dealing with poorly documented facilities/systems

- Clarify the feasibility of a rebuild
- Preparation and processing of missing documentation
- Involvement of authorities and consultants
- Authority documentation
- Risks

Measures for protecting the ongoing manufacture

- Protection of floor, ceiling and walls
- Protection of bulk and finished products
- Protection from dust
- HVAC
- Handling external workers, access control, training
- Material and personal flow during the construction time
- Monitoring and documentation

Workshop: GMP upgrade at CSL Behring

In this practical workshop you are confronted with the real situation of CSL Behring. You will find the real initial layout, process and material flow and the requirements which have to be fulfilled. You will define the risks, define a project schedule and define a new layout with help from the teaching team. Your results will be discussed in the group and will be compared to the real conditions of CSL Behring after the re-modelling project.

Case Study: GMP-Upgrade at CSL Behring: Upgrading of a manufacturing area to clean room class C

The premises of CSL Behring in Marburg did not meet the actual GMP requirements. Therefore, process equipment, HVAC system and the clean rooms themselves underwent a GMP upgrade. Another aim was to optimise the whole flow of the process. All was done during ongoing manufacture under GMP conditions.

- Starting situation and objective
- Project plan, milestones, timelines
- GMP requirements
- HVAC
- Clean room interior
- Specifics for renovation work during ongoing manufacture
- Lessons learnt

Lessons learnt - Practical experience with layout, HVAC systems, utilities

- Initial Situation and Objectives
- Definition of Requirements
- Development of layout and zone concept
- Structural Measures
- Concept development technical building services

Speakers

Nikolaus Ferstl
University Hospital of Regensburg
Nikolaus Ferstl has a bachelor degree in mechanical engineering with the emphasis on power engineering. He has almost 20 years of experience in design, especially in technical infrastructure in the field of pharmaceutical facilities. He has been working for M&W (former LSMW) since 2001, for example as Senior Project Manager for pharmaceutical projects worldwide. In 2007 he became deputy head of the subsidiary of M&W in Vienna. In 2009 he changed from the planning to the user's side as technical director of the university hospital of Regensburg.

Dr Johannes Krämer, *CSL Behring GmbH*
Dr Krämer studied energy- and process engineering. He has been Project-Engineer for Sanofi-Aventis for several years before he changed to Biopharmaceutical Operations at CSL Behring in 1999. Between 2003 and 2007 he was head of the department Plant Engineering. Since 2008 he is head of Engineering at CSL Behring in Marburg.

Dr Jean-Denis Mallet, *former head of the French Inspection Department, 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. He has been member of the ECA advisory board and works now for Pharmaplan.

Social Event

In the evening 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.

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

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Title, first name, surname

Company Department

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Date

Tuesday, 10 September 2019,
09.00 to approx. 18.00 h
(Registration and coffee 08.30 – 09.00 h
Wednesday, 11 September 2019,
08.30 to approx. 16.00 h

Venue

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
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Phone +43 (1) 891 10 - 0
info.parkroyalpalace.vienna@radissonblu.com

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, lunch on both days, dinner on the first day 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 event. 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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