ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

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

Renovation and Upgrading of GMP Facilities

Live Online Training on 15/16 November 2023

Image: CSL Behring

Highlights

- 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

Objective

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 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.
Another 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.

Participants' comments:

"Many thanks for valuable & practical discussions and advice."
Vjaceslavs Krauklis, JSC Olainfarm, Latvia

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, personnel 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 non-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 personnel flow during the construction time
- Monitoring and documentation

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 learned

Lessons learned – 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. He has almost 20 years of experience in the design of pharmaceutical facilities. He has been working for M&W (former LSMW), for example as Senior Project Manager and as 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

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 and Head of Engineering from 2008 to 2020. In 2021 he became Head of Maintenance & Utilities in Marburg. Since 2022 he has the global responsibility for Maintenance & Utilities at CSL Behring.

Dr Jean-Denis Mallet
Former head of the French Inspection Department, 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 and member of the ECA Advisory Board. Now he works for Pharmaplan.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

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

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Reservation Form (Please complete in full)

Live Online Training: Renovation and Upgrading of GMP Facilities – 15/16 November 2023

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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 of the Live Online Training

Wednesday, 15 November 2023,
09.00 to approx. 17.15 h
Thursday, 16 November 2023,
09.00 to approx. 14.45
Times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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