Image: CSL Behring

Includes Workshop on real upgrading case study

Renovation and Upgrading of Manufacturing Facilities

Maintaining GMP-compliant manufacturing during construction

9 - 10 October 2012, Prague, Czech Republic

SPEAKERS:

Gordon Farquharson
Critical Systems Ltd.

Dr Johannes Krämer
CSL Behring

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

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 these measures
- Involvement of authorities in upgrading projects

ECA
EUROPEAN COMPLIANCE ACADEMY

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 the 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.

Moderator

Gordon Farquharson

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

- Understanding and defining the objectives
- Gap analysis, identifying the main issues
- Risk Assessment, ranking and prioritising
- Managing the compromises
- Planning the work: Scope, phasing, and implementation

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

- How much documentation do you need?
- Dealing with incomplete validation records
- Performance testing
- Condition assessment
- 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 learned - Practical experience with fabric/ finishes, HVAC systems, utilities, and automation

- Discovering problems
- It always takes longer than you think!
- Problem of guarantees and responsibilities
- The right kind of contract relationship
- Managing the inevitable changes

Social Event

On 9 October 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

Gordon Farquharson, *Critical Systems Ltd.*
Gordon is a chartered consulting engineer with 30 years experience of quality & safety critical processes and facilities used by industries such as healthcare, life science, etc. Technology Division's global operation. In recent years he has focused on technologies such as isolators, barrier technology, and mini-environments, critical utility systems. He has been involved in the development of new regulatory standards, e.g. CEN/ISO cleanroom and contamination control standards, WHO GMP guidance and ISPE Baseline® Guides. He has recently worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in Annex 1 of the EU and PIC/S GMPs. Gordon is Managing Director at Critical Systems Ltd.

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, *ECA, former head of the French Inspection Department SNC LAVALIN, France*
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). 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 SNC LAVALIN.

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@gmp-compliance.org

Internet:
www.gmp-compliance.org

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

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

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GERMANY

Reservation Form (Please complete in full)

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Renovation and Upgrading of Manufacturing Facilities
9-10 October 2012, Prague, Czech Republic

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

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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 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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)!

Date

Tuesday, 9 October 2012, 10.00 to approx. 18.15 h
(Registration and coffee 09.30 – 10.00 h
Wednesday, 10 October 2012, 09.00 to approx. 16.15 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and 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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "CON081012B" to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 10 September 2012. 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

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