ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Nikolaus Ferstl
University Hospital of Regensburg

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

Manuel Kress
gempex

Markus Multhauf
Senior Consultant GMP-Engineering

Tim Ohlrich
gempex

Dr Jan Rau
Dockweiler

Dr Georg Schwarz
gempex

Dr Georg Sindelar
Bayer

GMP-compliant Equipment Design

From Process & Product Requirements to an appropriate Equipment Design

Live Online Conference on 22/23 November 2023

Highlights

- Relationship between GMP Design and Qualification
- Hygienic Design as basis for cleanability and GMP-Design
- Risk based Approach to Selection of Materials
- Requirements for Product Contact Surfaces
- Pipework, Fittings & Welding
- Process Environment
- Electrical Engineering & Measurements
- Automation & Control
- Documentation in the Life Cycle of Equipment
- Quality Assurance for Equipment Suppliers

All participants receive ECA's Guide on GMP-Design of Equipment plus the ECA Validation Group's Guide on Integrated Qualification and Validation

Objective

The goal of this event is to understand how to translate GMP requirements of process or product into an adequate equipment design. Wherever possible, concrete materials, values, parameters that have proven themselves – or are required by authorities – are mentioned.

Background

What does "GMP-compliant equipment design" mean? Why is there no authority approval of GMP equipment? These questions are asked quite often, both by plant engineers and by employees of the pharmaceutical industry itself.

This is relatively easy to answer. There is not ONE plant or equipment design that can be compliant for all pharma manufacturing plants or processes.

There are numerous pharmaceutical manufacturing processes, ranging from dry granulation and tableting to fermentation or sterile filling. Adding manufacturing processes from the classical (chemical) production of active pharmaceutical ingredients increases their number considerably. To some extent, however, pharmaceutical requirements are also observed when producing medical devices such as implants. The equipment used for these processes is as varied as the processes themselves. The product itself can place multiple requirements on the production equipment, too. For the design of equipment, it makes a big difference whether the product to be produced needs to be sterile or not, or whether it is a highly effective product. In the latter case, not only do GMP design criteria have to be observed, but also requirements for personal protection. A product or intermediate may, however, also be sensitive to oxygen or moisture. Obviously, all this affects the design of equipment.

Consequently, this is no course or guidance document illustrating the requirements for every possible type of production equipment.

Back to the question: What is GMP-compliant equipment design? In principle, this vague requirement can be broken down to four very obvious requirements for pharmaceutical manufacturing equipment:

1. the equipment must not have a negative impact on product quality
2. the equipment must be easy to clean
3. the equipment must comply with the applicable technical regulations
4. the equipment must be suitable for its purpose

These four points can also be found in different wording in numerous guidelines of GMP-relevant authorities, but are still so little concrete that they require a more detailed explanation. For that it is important to understand the principle of "GMP design" – how the requirements of a process or equipment can be translated into a plant design. Many points play a role here, such as

- Material selection
- Surface qualities
- Hygienic design
- Geometries
- Documentation
- Quality assurance in plant construction

How this can look in detail is part of this event. Values, details or materials considered as standard will be mentioned and this will be shown by means of examples.

The speakers of the event are the authors of the ECA Guide on GMP-compliant Equipment Design. They will walk you through the individual chapters and give further explanations.

As a participant of this event, you will also receive the 115-page ECA Guide GMP Equipment Design as PDF file.
The document is divided into 13 chapters. In addition to an understanding of GMP-compliant equipment design, chapters 1-4 elaborate the pharmaceutical principles of risk analysis and documented evidence of a GMP-relevant issue. Chapters 5 to 13 provide guidance on specific aspects of equipment that may be used in the manufacture of medicinal products.
Additionally you will receive the ECA Guide on Integrated Qualification and Validation as a PDF file. This guide assists you in streamlining qualification activities in practice as much as possible, while remaining GMP-compliant.

Target Audience

This event will be of interest to anyone involved in equipment design, evaluation and qualification. Addressed are executives and employees of equipment suppliers, engineering service providers, engineering technology and quality assurance of pharmaceutical companies.

Moderator

Markus Multhauf

Programme

Introduction: What is cGMP-compliant Design?

- Overview: GMP rules & guides, interest groups and state of the art
- Proof of concept:
  - URS, DQ, RA
  - GMP design (PID, Layout, Component-list, FDS, SDS, HDS)
  - Qualification
- GEP, SME, CQA & CPP: new keys for a successful commissioning & qualification process

Basic Aspects of hygienic Design and Material Selection

- Risk-based approach for the selection of suitable materials
- Equipment-specific definition of the hygiene-critical area
- Open & closed equipment
- Construction aspects
  - Cleanability
  - Drainability
  - Pipe connections
  - Screw joints
  - Inner corners and angles

Process Contact Surfaces: Specifications and Surface Treatments

- Definitions of surface qualities
- Surface quality requirements
- Surface treatment methods
  - Mechanical treatment
  - Chemical methods
  - Electrochemical treatment

Pipework and Fittings, Connections, Welding & Seam Control

- Piping & Tubing standards
- Cleanability & Dead Legs
- Detachable Connections
- Welding Technology & Welding Quality Criteria

Requirements for the Process Environment: the Clean Room

- Clean Room standards and classes
- Selection and procurement – factors influencing the selection of components
- Wall and ceiling systems
  - Acceptance tests for wall and ceiling
  - Requirements for clean room doors
- Floor systems
  - Acceptance tests for floors
- Critical clean room interfaces
- Application of components for different cleanliness classes

Electrical Engineering, Measurement and Control Technology in the GMP-regulated Environment

- Technical design of devices in the GMP-regulated environment
- Selection of the appropriate measurement procedures for (quality) critical process parameters
- Maintenance and Calibration – Relevance for Qualification and the Life Cycle Approach

Requirements for Automation and Control Systems

- Qualification or validation
- Delimitation of the subsystems
- Special feature – configuration management
- Data Integrity
- Integration of FAT and SAT in the validation

Documentation in the Life Cycle of GMP Equipment

- Documentation in basic engineering
- Documentation in detail engineering & implementation
- Important documents for qualification
- Operating documentation
- Material certificates
  - Material certificates for metallic materials
  - Material certificates for product or media-contacting plastics
- Formal aspects

Requirements for the Quality Assurance System of Equipment Suppliers

- Quality management systems: DIN ISO 9001 as a basis
- Quality management systems: overlap with GMP
- Qualification and validation at the equipment supplier
- Further supplier quality systems
- Documentation
- Production conditions
- Differences between suppliers and pharmaceutical manufacturers

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 in Vienna. In 2009 he changed from the planning to the user's side as technical director of the university hospital of Regensburg.

Dr Markus Keller
Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)

Dr Markus Keller is a biologist and project manager at the Fraunhofer Institute for Manufacturing Engineering and

Automation (IPA), Department of Cleanroom and Microproduction. His area of expertise includes the qualification of plants with regard to their cleanroom suitability.

Manuel Kress
gempex
Manuel Kress, a biotechnology engineer, has carried out and managed many qualification and validation projects for different types of products. His expertise in the field of qualification ranges from clean rooms/ventilation systems and monitoring systems to utilities and a wide variety of production facilities in the pharmaceutical/life science industry.

Markus Multhauf
Senior Consultant GMP-Engineering
Markus Multhauf studied process engineering. He worked for HOECHST and for plant construction companies like Waldner and H+E. At LSMW/M+W he was design engineer for utility systems and project manager for 9 years. Then he was head engineering at Aeropharm (SANDOZ/ Novartis). Since 2013 he is a freelancing engineer for pharmaceutical technology.

Tim Ohlrich
gempex
Tim Ohlrich is an engineer in biotechnology and has been working in the GMP-regulated environment for more than 15 years. He gained first contact with GMP during process development of cellular USP & DSP processes. Since his start at gempex in 2008 he has executed and led several Qualification & Validation projects for different product types and clients.

Dr Jan Rau
Dockweiler
Jan Rau has worked in the field of austenitic CrNi steel tube systems since 1998. He is responsible for Quality Management and research projects with major focus on metallurgy and surface analyses at Dockweiler. He is chair of the DIN committee NA 003-01-14 AA Tubes and Components for the Food, Chemical and Pharmaceutical Industry, chair of the ASME BPE subcommittee on Metallic Materials (MM), and member of the ASME BPE Standards Committee and the subcommittee on Surface Finish (SF).

Dr Georg Schwarz
gempex
Dr Georg Schwarz is a chemist and has been working in the pharmaceutical IT environment for over 20 years. Among other things, he was responsible for IT training at AstraZeneca and in IT quality management at Novartis. Since 2016 he is Principal Consultant at gempex, among others for IT Security and Risk Management as well as Qualification & Validation.

Dr Georg Sindelar
Bayer
Dr Georg Sindelar is Head of Commissioning & Qualification at Bayer in Leverkusen. Prior, he worked as a consultant and manager in the areas of pharmaceutical compliance, qualification and auditing.

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Conference: GMP-compliant Equipment Design
22/23 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 %.

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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 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 Live Online Conference

Wednesday, 22 November 2023,
09.00 to appprox. 16.30 h
Thursday, 23 November 2023,
09.00 to approx. 16.15 h
All 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 EUR 1690
APIC Members EUR 1790
Non-ECA Members EUR 1890
EU GMP Inspectorates EUR 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.

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

For questions regarding content please contact:
Dr Robert Eicher (Operations Director) at
+49(0)62 21/84 44 12 or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Julia Grimmer(Organisation Manager) at
+49(0)62 21/84 44 44, or at
grimmer@concept-heidelberg.de.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

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 Live Online Training in detail and with which you document your training.

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.

Why not online? GMP/GDP Training Courses/Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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