ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Dr Anthony Bevilacqua
Mettler-Toledo-Thornton, USA

Jesper Hjorth
Novo Nordisk, Denmark

Stephan Löw
CSL Behring, Germany

Markus Multhauf
Senior Consultant GMP Engineering, Germany

Pharmaceutical Water

Generation, Monitoring & Compliance

Live Online Training on 28/29 January 2025

Highlights

- Current Pharmacopoeial requirements and trends
- Engineering of Pharmaceutical Water Systems
  - Pharmaceutical Water Generation
  - WFI by membrane processes
  - Water storage and distribution
- Commissioning and Qualification of a Pharmaceutical Water System
  - Critical components and parameters
  - Validation and sampling
- Microbiological aspects in GMP water systems
  - Modern sanitisation concepts
  - Monitoring and data interpretation
- Life Cycle of a pharmaceutical water system
  - Installation- vs. Operation Cost
  - Maintenance and Calibration
  - Technical Changes

From Design & Qualification to Routine Operation

Objective

The objective of this intensive education course is to enable the participants to pay optimal attention to critical issues during design, qualification and routine operation of pharmaceutical water systems.
You will learn:

- How to meet the pharmacopoeial requirements
- How to find the critical design aspects in a water system
- How to generate pharmaceutical water and steam in the desired quality
- How commissioning and qualification is done today
- How microbial validation and control is achieved
- How the system is maintained in a controlled status during its life cycle

Background

Water is one of the most important raw materials in the manufacture of pharmaceutical products. In order to produce water of an appropriate quality, water systems have to fulfil considerable requirements, which are partly set out in detail in the relevant pharmaceutical regulations. Although the characteristics of pharmaceutical waters are sufficiently defined, a large number of questions remain unanswered as regards to the technical implementation of these bodies of regulations in GMP-conform water systems.
The main focus of the course 'Pharmaceutical Water' is therefore on how to put these requirements into practice. In their lectures, experienced specialists will give you important information and support for your own projects and systems, ranging from regulatory requirements, design, qualification, validation and routine operation.

Target Audience

This GMP course is directed at engineers, production and QA/QC staff, responsible for design, validation and operation of pharmaceutical water systems as well as system suppliers and design engineers.

Moderator

Markus Multhauf

Programme

Overview of Global Pharmacopoeial Requirements and Recent Changes for Pharmaceutical Waters

- Current GMP trends and Pharmacopoeial requirements for pharmaceutical waters
  - Requirements for Bulk Pharmaceutical Waters – Purified Water, WFI and Pure Steam
  - Requirements for Sterile and packaged Pharmaceutical Waters
- Harmonisation and future requirements of the U.S., European, and Japanese Pharmacopoeias

State-of-the-art Pharmaceutical Water Generation

During the planning of a pharmaceutical water generation plant the influence of the feed water is often underestimated. A reliable and economically feasible system is only obtainable under consideration of the unique feed water chemistry. The engineering phase of the project serves to make the important decisions regarding choice of technology, such as double pass RO vs. RO combined with electrodeionization.

- Overview of different water treatment technologies and their suitability for pharmaceutical applications
- PW and HPW generation with membrane processes (RO/EDI)
- WFI generation with and without distillation
- Pure Steam Generation

Water Storage and Distribution

- Engineering details
  - Water storage / water distribution
- Conception of Loops
- Quality attributes to measure in the loop
- Sampling issues

Modern Sanitisation Concepts

- Sanitisation with heat
- Sanitisation with chemicals (incl. Ozone)
- Combination of different methods
- Sanitisation cycles
- Sanitisation after breakdown and deviations

What you need to know: Stainless Steel: Piping and Equipment

- Composition and properties of stainless steels for water and steam systems
- Surfaces of stainless steels and their treatment
- GMP-compliant welding of piping systems
- Rouging of stainless steels: current understanding and strategies to deal with connections, heat exchangers, valves & pumps
- Documentation and material certificates

Speakers

Technical Specialities during the Qualification of Water Systems

- Risk-based approach to validation of a pharmaceutical water system
- Critical components and parameters
- Modern qualification and commissioning
- Package Unit approach
- Critical timelines

Microbiological Control of Water Systems

- Common microbial inhabitants of Pharmaceutical water systems
- Definition of 'objectionable organisms' as pseudomonas
- Sources of contamination and Biofilms
- Microbiological aspects of pharmaceutical water system validation
- The three qualification phases
- Routine microbiological monitoring (sampling frequency and Locations)
- Review, interpretation and reporting of microbiological data
- Handling OOS results in pharmaceutical water systems

GMP-compliant Operation of a pharmaceutical Water System

- Handling of deviations and changes (examples)
- Operating data, periodic review and revalidation
- Maintenance and calibration
- GMP-compliant log book handling

Your benefit

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

Dr Anthony Bevilacqua
Mettler-Toledo-Thornton

Anthony was the Chair of the USP Pharmaceutical Water Expert Committee from 2000-2005 and 2005-2010, and he has been cooperating with EP, JP and other Pharmacopoeias on international harmonization of pharmaceutical water quality standards. He is currently a member of the USP Chemical Analysis Expert Committee and Chair of the Sterile Water Expert Panel.

Jesper Hjorth
Novo Nordisk

Jesper Hjorth was educated as a marine engineer and has worked since 2006 at Novo Nordisk. As Utility Specialist he is mainly responsible for supply of industrial and clean utilities. His support for Novo Nordisk sites within the clean utility area has ranged from daily support tasks to projects and compliance.

Stephan Löw
CSL Behring

Stephan Löw studied Engineering and Biotechnology and works for CSL Behring as Manager Technical Support Laboratories. Before he has worked as Aseptic Expert, Project-Manager and Operation Manager Vaccine Formulation & Filling at GSK Vaccines. In a former position he was head of QA Microbiology at Sandoz Industrial Products and in the Quality Control Laboratory for Microbiology.

Markus Multhauf
Senior Consultant GMP-Engineering

Markus Multhauf studied process engineering. He worked for HOECHST and for plant construction companies like Waldner and Hager+Elsasser. 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.

NEWS

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Reservation Form (Please complete in full)

Live Online Training: Pharmaceutical Water – 28/29 January 2025

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.
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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.

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Date of the Live Online Training

Tuesday, 28 January 2025, 09.00 to approx. 17.15 h
Wednesday, 29 January 2025, 09.00 h to approx. 15.30 h
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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21620. 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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