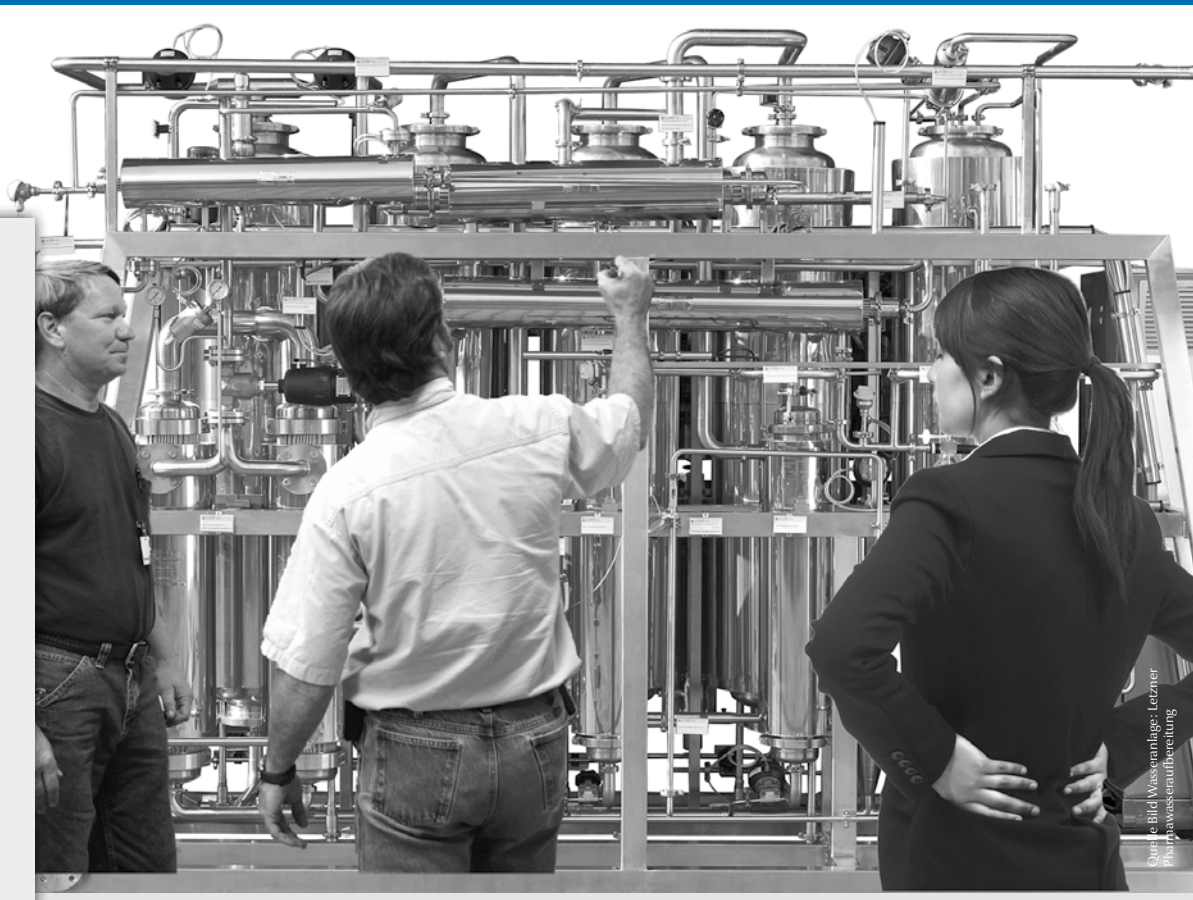
ECA Academy
Your GMP/GDP Information Source

# Pharmaceutical Water

## Manufacture, Monitoring & Compliance




SPEAKERS:

Anthony Bevilacqua
*Mettler-Toledo-Thornton, USA*

Stephan Löw
*CSL Behring, Germany*

Markus Multhauf
*Senior Consultant GMP Engineering, Germany*

Dr Alexander Sterchi
*F. Hoffmann-La Roche, Switzerland*

10-11 May 2017, Berlin, Germany

LEARNING GOALS:

- Current Pharmacopoeial requirements and trends
- Engineering of Pharmaceutical Water Systems
  - Pharmaceutical Water Generation incl. Steam
  - Water storage and distribution
  - Measurement technology: online and offline
- 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 systems
  - Installation vs. Operation Cost
  - Maintenance and Calibration
  - Technical Changes

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

# Pharmaceutical Water

10-11 May 2017, Berlin, Germany

## Objectives

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 systems 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 to 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

Anthony C. Bevilacqua, USA

## 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.

## 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, Highly 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. Another question for pharmaceutical manufacturers arises from the EMEA: is the use of Highly Purified Water or treatment with Reverse Osmosis for generation of WFI quality acceptable?

- Overview of different water treatment technologies and their suitability for pharmaceutical applications
- PW and HPW generation with membrane processes (RO/EDI)
- WFI generation with 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

### Required Measurements in a Pharmaceutical Water System

- Instrumentation and monitoring for modern pharmaceutical water systems
  - Purpose and implementation of non-critical measurements for real-time process control
  - Critical measurements such as temperature, TOC, Conductivity, pressure, flow, ozone
- Current requirements in global Pharmacopoeias
- Evaluation of on-line vs. off-line measurement technologies for high purity water process control

### 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

### 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

- From qualification to routine operation
- Handling of deviations and changes
- Review of operating data
- Maintenance and Calibration
- Calibration cycles
- GMP-compliant log book handling
- The Water system in the Product Quality Review (PQR)

## Speakers

Anthony Bevilacqua
*Mettler-Toledo-Thornton Inc.*
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.

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, Germany*
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.

Dr Alexander Sterchi,
*F. Hoffmann-La Roche AG*
Since 2008 A. Sterchi is heading Logistics, Services & Infrastructure. From beginning of planning and construction for the new facility in Kaiseraugst in 2006 he was the user-representative for building and infrastructure within the project. Alexander Sterchi is pharmacist by training and is holding a Ph.D. in pharmaceutical analytics from ETH Zürich, Switzerland.

## 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@concept-heidelberg.de**

**Internet:**
**www.gmp-compliance.org**

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

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

**Pharmaceutical Water**
10-11 May 2017, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

**Important: Please indicate your company's VAT ID Number** | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone | Fax

E-Mail (please fill in)

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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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### Date

Wednesday, 10 May 2017, 09.00 to approx. 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 11 May 2017, 08.30 h to approx. 15.30 h

### Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fax +49 (0)30 212 7 - 117

### 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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

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

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