



Pharmaceutical Water & Steam Systems: Current International Industry Practices, Technological Trends and Regulatory News

21-22 November 2019 - Masco Headquarter -Settala, Milan (Italy)

Purpose of the Training:

The Training is addressed to the Professionals and Managers of the Pharmaceutical Industries involved in the Pharmaceutical Water and Steam Systems Applications as Quality Systems(Q.A. and QC), Regulatory & Validation, Pharmaceutical Engineering & Maintenance and Manufacturing (API & Dosage Forms).

The Seminar will explore the topics “PHARMACEUTICAL WATER” & “PHARMACEUTICAL STEAM” giving a complete overview from the European Union (EDQM/EMA), from the USA (FDA/USP) as well as from the international cGMP (e.g. Anvisa, WHO, PIC/S, ecc) and sharing Stilmas-DOC international experience on Plants Inspection with all participants. The Seminar material is updated as per current 2019 Regulatory Requirements, especially due to the New Revised EP monograph for Water for Injection released on April 2017 and Revised EU GMP Annex 1 (Draft December 2017).

Training Content:

The Training will explore and address in detail the following aspects:

REGULATORY REQUIREMENTS

- USA Regulation (i.e. USP & FDA Guidelines);
- E.U. Regulation (i.e. EP & EMA Guidelines), including revised WFI monograph as per EP 9.1 and EU-GMP ANNEX 1
- Other International Regulatory References (e.g. BRASIL,WHO, PIC/S, etc);

CURRENT DESIGN CRITERIA as per Good Engineering Practices (G.E.Ps) and Technological Trends (e.g. WFI by Membranes Technologies)

VALIDATION LIFE-CYCLE (Initial Validation)

- Design Qualification
- Installation Qualification
- Instruments Calibration
- Operational Qualification
- Performance Qualification

SYSTEMS MAINTENANCE, MONITORING & CONTROL

- Routine Monitoring Program;
- Change Control & Revalidation, Recalibration and Maintenance Plan;
- Inspectional Aspects (“Points to consider” approach)
- Rouge on Pharma Water & Steam Systems
- Focus on Revamping Activities



21 November 2019 (Day 1)

08.30 – 09.00 Event Registration

09.00 – 09.15 Introduction to the Event (DOC & Stilmas)

09.15 – 10.45 Regulatory Requirements as per International GMPs (including WFI new Regulatory trend by EMA/EDQM) , by Mr. Paolo Curtò (DOC)

10.45 – 11.15 **Coffee Break**

11.15 – 12.30 Good Engineering Practices (GEPs) as per International Design Standards, by Mr. Paolo Curtò (DOC)

12.30 – 14.00 **Lunch Break**

14.00 – 15.30 PW, WFI and Pure Steam: Process Technology Aspects , by Mr. Demetrio Barbitta (Stilmas)

15.30 – 16.00 **Coffee Break**

16.00 – 17.00 Critical Maintenance Aspects , by Mr. Demetrio Barbitta (Stilmas)

17.00 – 17.30 Questions/Answers Session

19.30 **Event Gala Dinner**



22 November 2019 (Day 2)

09.00 – 10.30 Validation Life-Cycle for a Pharmaceutical Water & Steam Systems as per latest EU GMP Annex 15, by Mr. Paolo Curtò

10.30 – 11.00 **Coffee Break**

11.00 – 11.45 Validation Maintenance Aspects (Routine Operation, Revalidation , Recalibration and Change Control), by Mr. Paolo Curtò (DOC)

11.45 – 12.30 Pharmaceutical Steam-Regulatory, Design, Validation & Operational Aspects, by Mr. Paolo Curtò (DOC)

12.30 – 14.00 **Lunch Break**

14.00 – 15.00 WFI Production by Membrane Processes, by Mr. Paolo Leani (Stilmas)

15.00 – 15.30 Rouge in Pharma Water and Steam systems: regulatory and technical trends

15.30 – 16.30 Stilmas Facility Tour including cross reference to Training case studies

16.30 – 16.45 **Coffee Break**

16.45 – 17.30 Questions/Answers Session

17.30 TRAINING CLOSURE



Speakers:



DOC - Paolo Curtò, graduated in 1984 in Chemical Engineering at Padua University (Italy). He has worked in DOC since 1997 as Managing Director. In the past he worked

for well known companies like Fidia S.p.a. , Foster & Wheeler Group, Enichem S.p.a., in different areas like process engineering, project management, Validation & GMP Compliance. He is active member of many recognized organization like Parenteral Drug Association (PDA Italy Chapter), ISPE and International Federation Pharmaceutical (FIP) and qualified trainer for many Regulatory Agencies throughout the world (Brazil, China, Italy, Greece, Romania, Egypt).



STILMAS - Demetrio Barbitta, graduated in 1997 in Hydraulic Engineering at Milan Polytechnic (Italy). He has worked in Stilmas since 2001 at first as

Senior Commissioning Engineer and since 2009 as Service & Spare parts Manager, being part of the Stilmas Steering Committee.

He works actively throughout the world as Qualified Trainer of Pharmaceutical Water & Steam Systems for Pharmaceutical Companies, Engineering Contractors and Training Organization.



STILMAS - Paolo Leani, graduated in Chemical Engineering at Milan Polytechnic (Italy), Paolo brings 19 years of experience in the pharmaceutical water

treatment field.

Today, as Stilmas Technical Director, he is managing strategic planning, conceptual design, engineering, risk assessment and compliance up to validation of Stilmas equipment.

Active member of the ISPE and a co-author of the ISPE Sustainability guide for the specific chapter for Clean Utilities. Active member of PDA.



The Venue:

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Lectures will take place
 @ Masco Training Center
 (max 35 seats available)



At the end of Day One,
 participants are kindly invited to
 the Event Gala Dinner that will
 take place at the Hotel Ibis Style
 in Settala.



Participation Fee:

Participation Fee
 1.200,00 € (Two Days)
 700,00 € (Single Day)

Participation Fee for any additional person of the same company
 1.000,00 € (Two Days)
 600,00 € (Single Day)

The subscription fee includes lunches, daily coffee breaks and the Gala Dinner (end Day 1).
 Lodging and board expenditure are not included.

For subscription please fill in the form below and return it to the following mail address:
alessandro.zanoni@docvalidation.it. An e-mail will be sent to to the address communicated to
 confirm the success of the subscription.

The payment of the subscription fee will have to be done by the 1st November 2019.

Important: no charge will be asked for subscription cancellation communicated within 15 days from
 the Event; from 15 to 5 days before the Event 50% of the total fee will be charged, subscription
 cancellation received after this period won't be subject to any refund.

Registration Form

Name and Family Name:

Job Position:

Company:

Address:

E-Mail:

Two Days Participation

Food Restriction (Optional):

Accommodation Booking Necessary?

Do you want us to take care of your accommodation booking?

ZIP Code:

Phone:

City:

One Day Participation (specify the Day)

Country:

Mobile Phone:

Date:

Signature:

