



From Theory to Practice: Methods, Tools & Innovation for Monitoring of Clean Rooms and Clean Utilities

April, 16th-17th, 2025

QSGGroup, Barlassina (MB)



INTRODUCTION

Monitoring is one of the KEY requirements emerging from the Annex 1.

Analogous attention to a well-structured monitoring program is also underlined into the FDA GMP Guideline and PDA Technical Report n. 13-2..

Starting from the highlights and consideration related to regulatory requirement, during those 2 days event we will approach case studies and open sharing experiences related to water and clean air/gas within clean facilities including interesting information on statistical aspect to properly settling Monitoring Alert Limits.

Agenda will include presentation focuses on key aspects of samplers' calibration, on clarification about uncertainty and tolerance meaning and discussion around parameters influencing accurate results.

Practical session will include the visit of the ACCREDIA particle counter calibration-Lab, to the MOBILE LAB and will include a practical testing into a particle loss testing room.

ORGANIZING COMMITTEE

Aldo Xhango / QSGroup Sales Area & Marketing Manager

Claudio Puglisi / Entourage / PDA Italy Chapter Treasurer

Filippo Trionfera / BSP Pharmaceuticals / PDA Italy Chapter President-Elect

Lucia Ceresa / PDA Italy Chapter Board

Mauro Giusti / PDA Italy Chapter Past-President

Mirko Gabriele / PDA Italy Chapter President

Paolo Curto' / PDA Italy Chapter Steering Committee

Simone Penazzi / QSGroup Business Development Manager

AGENDA DAY 1 – April, 16th 2025



- 12:30-14:00 Arrival, registration DAY-1 & Welcome buffet at **QSGROUP** facility
- 14:00-14:10 Opening remarks and proposed discussion topic,
Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter' President-Elect
- 14:10-14:20 Welcome and Introduction,
Mauro Petrone - QSGroup Srl & Altiorlab
- 14:20-14:50 Environmental monitoring: challenges vs opportunities? **Lucia Ceresa & Stefano Ceccanti**
- 14:50-15:20 Annex1 compliance and Pharma 4.0 - Advantages of accurate and reliable online results for TOC and Conductivity in Pharmaceutical water systems, **Daniel Kellner-Steinmetz - VEOLIA Analytical Instruments**
- 15:20-15:50 Endotoxin Monitoring: Biofilm assessment in water systems,
Fabio Da Roit - Charles River Microbial Solutions
- 15:50-16:20 **Sponsors' presentation & demos**
- 16:20-16:50 **Coffee Break with the sponsors**
- 16:50-17:20 WFI microbial monitoring: a case study from initial qualification to routine monitoring of a new facility department, **Elisa Baretta - IBSA Group**
- 17:20-17:50 Clean Utilities monitoring following chapter 6 of Annex 1,
Paolo Curtò – D.O.C & PDA Italy Chapter
- 17:50-18:20 Clean Utilities monitoring: a practical case study,
Massimiliano Frasca - BSP Pharmaceuticals
- 18:20-18:50 Panel discussion with all speakers,
Chairs: **Marisa Delbò**, former **AIFA Chief GMP** Inspectorate and **Fernanda Ferrazin**, Life Science Consultant, former Senior **AIFA GMP Senior Inspector**
- 18:50-19:00 Wrap-up and final remarks from Day-1, **Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter**
- 19:00-19:30 **Happy hour with the Sponsors**
- 20:00-22:00 **Networking dinner**

AGENDA DAY 2 – April, 17th 2025



- 08.45-09:00 Arrival & registration DAY-2 at **QSGROUP** facility
- 09.00-09:10 Opening remarks and proposed discussion topic, **Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter' President-Elect**
- 09:10-09:40 Accreditation vs regulation requirements, **Ilaria Narretti - QS Group**
- 09:40-10:10 Total Particles Monitoring: requirements to comply and decay in pipes solution, case study, **Francesco Romano - Politecnico di Milano**
- 10:10-10:40 Biofluorescent Particle Counting - A Solution for Meeting Annex 1 Viable Air Testing Requirements, **Michael Dingle - TSI Incorporated**
- 10:40-11:10 **Coffee Break with the sponsors**
- 11:10-11:40 Environmental Monitoring Annex 1 compliance: a practical case study **Francesco Diroma - Thermo Fisher Scientific, Ferentino**
- 11:40-12:20 Setting Alert Limits for Air and Water Monitoring in Pharmaceuticals - Ensuring Compliance and Control in Microbiological Monitoring, **Riccardo Bonfichi - Entourage**
- 12:20-13:30 **Lunch with the sponsors**
- 13:30-15:00 **QSGROUP tour of accredited laboratories: practical sessions**
- 15:00-15:30 Particle's microsensors calibration: criticality and state of the art, **Mauro Petrone - QSGROUP**
- 15:30-16:00 **Panel discussion** with all speakers.
Chairs: **Marisa Delbò**, former **AIFA Chief GMP** Inspectorate and **Fernanda Ferrazin**, Life Science Consultant, former Senior **AIFA GMP Senior Inspector**
- 16:00-16:15 Wrap up and closing remarks, **Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter' President-Elect**

GENERAL INFORMATION

LANGUAGE

The official language is Italian. No simultaneous translation is provided.
All presentations (.ppt slides) are in English.

CONGRESS VENUE



QSGROUP SRL

Via Torquato Tasso 5 - 20825 – Barlassina (MB)
From AFORI Yellow M3 stop/terminus, train to Seveso (direction Camnago-Lentate)
+ 10 minutes on foot

Transfers from/back to Seveso station and QSGroup facility as well as from QSGroup to the Restaurant and from the Restaurant, to AS HOTEL DEI GIOVI will be arranged by QSGroup based on the scheduled timing.

CONVENTIONED HOTELS

Participants are responsible for their own travel costs and accommodation. A suitable number of rooms have been reserved at discounted rate at the: [AS HOTEL DEI GIOVI](#), Via A. Manzoni, 99/bis, Cesano Maderno (MB)

NOTES: Promo Code (active till April16th): **QSGROUP**

Cancellation Policy: free cancellation up to 12pm, 7 days before arrival

For more information write to grp@ashotels.it, with reference to the Promo Code

PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l.
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web: www.pda-it.org - [linkedin.com/company/pda-italy](https://www.linkedin.com/company/pda-italy).

GENERAL INFORMATION



HOW TO REGISTER

For registration, general information, and payment enquiry, please visit www.pda-it.org at the page dedicated to the Event.

REGISTRATION FEES (VAT 22% included)

- € 122,00 University and Regulators
- € 366,00 PDA and AFI members (**1-day only**: € 219)
- € 549,00 PDA and AFI NON-members (1-day only: € 329)
- € 732,00 for 2 colleagues for the conference at the same time
- € 1.038,00 for 3 colleagues for the conference at the same time
- Free of charge AIFA Regulators

Direct competitors will not be able to participate in the guided tour.

Early bird discount: **10%** discount for confirmation received within **April, 4th 2025**

Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, welcome cocktail, coffee breaks, lunches, networking dinner.

METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl

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SPONSORSHIP OPPORTUNITIES

Exhibition and Sponsorship Opportunities are available. Exhibit at PDA Italy Chapter events and let your company's products or services become a valuable tool or resource for our attendees. Contact the CCI Organizing Secretariat at pda@pda-it.org to know the opportunities for this event (CCI, Via Guarini, 4, 10123 Torino, Tel.: 011 244 6911)