

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

February, 5th-6th 2026 QSGroup, Barlassina (MB)





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 Steering Committee 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 – February, 5th 2026



| 12:30-14:00 | Arrival, registration DAY-1 & Welcome buffet at QSGROUP facility |
|-------------|---|
| 14:00-14:10 | Opening remarks and proposed discussion topic, <i>Filippo Trionfera</i> - BSP Pharmaceuticals & PDA Italy Chapter President-Elect |
| 14:10-14:20 | Welcome and Introduction, Mauro Petrone - QSGroup & Altiorlab |
| 14:20-14:50 | Environmental monitoring: challenges vs opportunities? <i>Lucia</i> <i>Ceresa - PDA Italy Chapter Steering Committee & Stefano</i> <i>Ceccanti</i> |
| 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, <i>Daniel Kellner-Steinmetz - VEOLIA Analytical Instruments</i> |
| 15:20-15:50 | Endotoxin Monitoring: Biofilm assessment in water systems, <i>Fabio Da Roit - Charles River Microbial Solutions</i> |
| 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, <i>Elisa Baretta - IBSA Group</i> |
| 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, <i>Massimiliano Frasca - BSP Pharmaceuticals</i> |
| 18:20-18:50 | Panel discussion with all speakers. Chairs: <i>Marisa Delbò</i> , former AIFA Chief GMP Inspectorate and <i>Fernanda Ferrazin</i> , Life Science Consultant, former Senior AIFA GMP Senior Inspector |
| 18:50-19:00 | Wrap-up and final remarks from Day-1, <i>Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter President-Elect</i> |
| 19:00-19:30 | Happy hour with the Sponsors |
| 20:00-22:00 | Networking dinner |



- 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, *llaria Narretti QSGroup*
- 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

To be defined

PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l. Via Guarino Guarini, 4 – 10123 Torino Tel. 011/2446911 – fax 011/2446950 e-mail: <u>pda@pda-it.org</u> web: www.pda-it.org - linkedin.com/company/pda-italy.

GENERAL INFORMATION

HOW TO REGISTER

Registration procedures will be available online soon.

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 **January**, **15th 2026**. Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, welcome cocktail, coffee breaks, lunches, networking dinner.

Chapter

METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl Bank: INTESA SANPAOLO SPA Mandatory causal: **(commessa 2026)** + Name/Surname of the participant and Company IBAN: IT08X0306901000100000067336 BIC SWIFT: BCITITMM Copy of the bank transfer should be sent to the CCI Organizing Secretariat at pda@pda-it.org. After receiving the payment, the Organizing Secretariat (Centro Congressi Internazionale srl) will issue a regular invoice.

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)