

PHARMA MICROBIOLOGY CONGRESS

GIORNATE DI MICROBIOLOGIA X EDIZIONE

**Challenges & Strategies in
Sterile Manufacturing:**

l'evento europeo di microbiologia farmaceutica

NOVEMBER 14-15, 2019 | MILAN

INTERVENTI IN LINGUA ITALIANA E INGLESE CON SERVIZIO DI TRADUZIONE

WWW.PHARMAMICROBIOLOGYCONGRESS.COM

ABOUT

PEC - Pharma Education Center

warmly invites professionals from Pharma Companies to participate at the 1st Edition of **"PHARMA MICROBIOLOGY CONGRESS"**, that will be held on **November 14th-15th 2019, in Milan.**

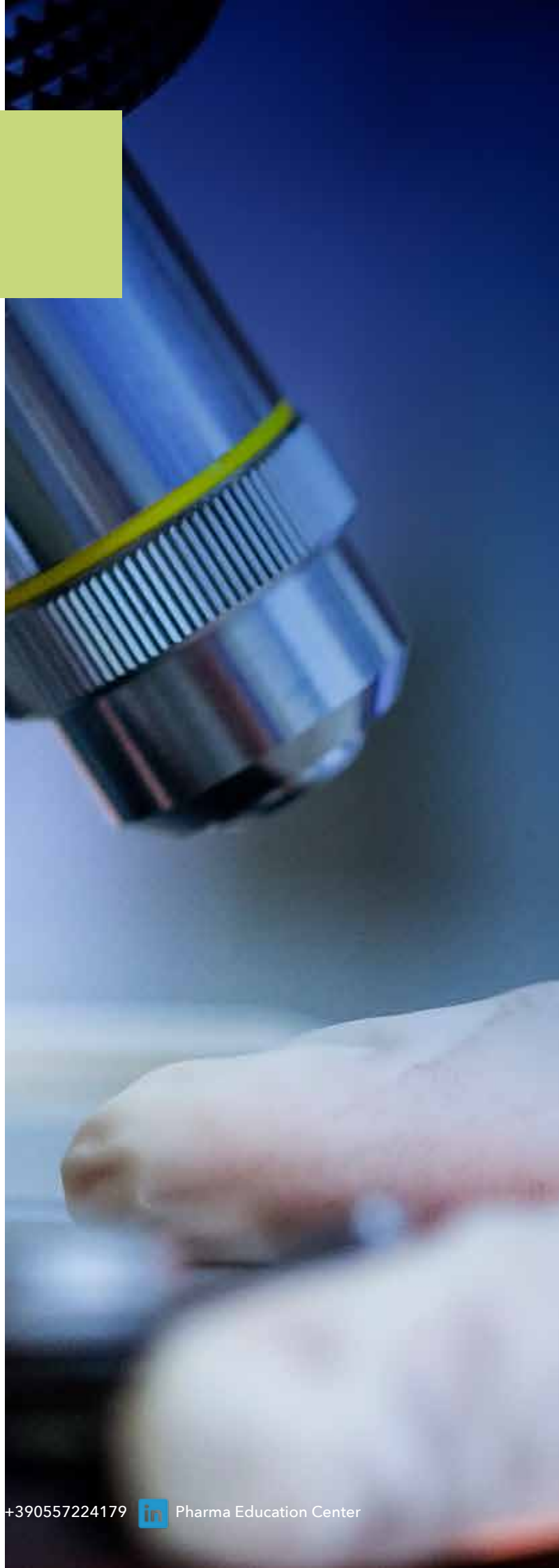
The PMC is the **European evolution** of the Italian **"Days of Microbiology"**, born 11 years ago with the aim of creating an annual meeting where the community of microbiology experts and pharma professionals share last updates on **regulatory trends, innovative technologies and the best practices applied to the manufacturing and control of sterile API and medicinal products.**

WHY TO ATTEND?

The involvement of microbiology experts and opinions leaders, regulatory body representatives, new technologies suppliers and consultants from Italy and Europe, made this event unique and highly evaluated by Pharma, Biotech, Medical Devices companies and by the technologies suppliers, for the great opportunity to **meet professionals and get and share technical knowledge and strategies about the future of the Sterile Manufacturing.**

WHO SHOULD ATTEND

Pharma, Biotech and Medical Devices Industries
Regulatory Bodies
Technology Suppliers
Microbiologist Associations
Microbiology Laboratories



SPEAKERS



Chair Person:

Fernanda Ferrazin

Former GMP Senior Inspector
- AIFA, Independent Pharmaceutical Consultant

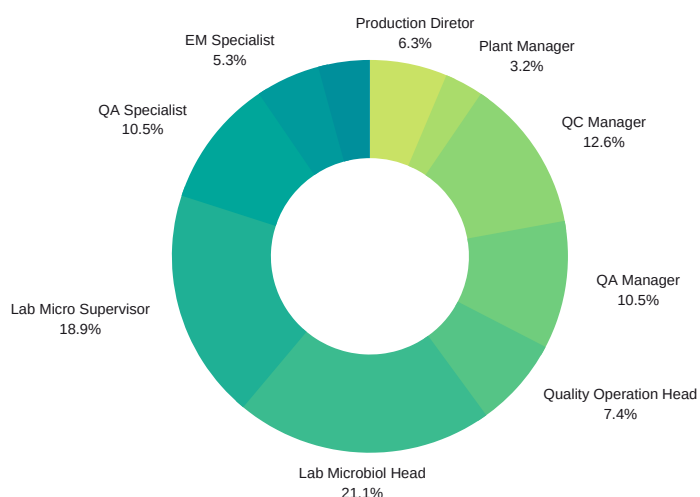
with the participation of Sterile Manufacturing experts, representatives of PHSS (Pharmaceutical & Healthcare Sciences Society), representatives of Sterile Manufacturing companies and Suppliers of New Technologies.

The 2 day Congress will offer several sessions of oral talks about hot and practical topics, case studies, keynotes presentations, including round-tables. Dedicated exhibit area during the coffee break and lunch allow networking and vision of new and emerging technologies.



HISTORY

DAYS OF MICROBIOLOGY 2017-2018



Testimonials....

Dynamic and interactive, relevant to get ideas to improve Sterility Assurance of our operations.
GSK

Well organized, with a good level of very interesting presentations and great opportunity to share practices in Sterility assurance.
Corden Pharma



PHARMA MICROBIOLOGY CONGRESS 2018: LIST of COMPANIES

ABIOTEN , ACS DOBFAR, BAXTER, BD SWITZERLAND, BIEFFE MEDITAL, BSP PHARMACEUTICAL SPA, CATALENT, CHEMI, CHIESI, CORDEN PHARMA, DIASORIN, DOPPEL FARMACEUTICI, ELI LILLY, FABBRI-CA ITALIANA SINTETICI, FACTA FARMACEUTICI, FARMILATHEA, FATRO, GNOSIS BIORESEARCH, GSK, FRESENIUS KABI ITALIA , HAUPT PHARMA, ITALFARMACO, KEDRION, LABORATORIO FARMACEUTICO MILANESE, LABORATORIO FARMACEUTICO SIT, MENARINI, MERCK, OPOCRIN, PATHEON, PFIZER, RECIPHARM, RECORDATI, SANOFI AVENTIS, SHIRE, ZAMBON

SPONSOR

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MEDIA PARTNERS





AGENDA - 14TH

- 08:15 **Registration**
- 09:15 **Welcome**
PEC Chairperson
Lucia Costanzo, Senior conference Manager
- 09:20 **Opening remarks**
Moderator: Fernanda Ferrazin, former GMP Inspector Medicines Italian Agency

SESSION I - ANNEX 1 revision: perspectives and future challenges

- 09:30  **Annex 1 revision regulatory expectation and impacts on Pharmaceutical Industry**
James L Drinkwater, F Ziel GmbH
Head of GMP Compliance, Head of PHSS: Pharmaceutical & Healthcare Sciences Society Aseptic processing & Bio-contamination special interest group
- 10:10 **Q&A**

SESSION II - Environmental Monitoring - Bioburden - PUPSIT

- 10:20  **Agar-free, Continuous Air Monitoring using Unique Gelatin Membrane Filters for Compliant Testing**
Kai Nesemann, Product Manager Microbiology
Sartorius Lab Instruments GmbH & Co. KG
- 10:50 **Q&A**
11:00 **Coffee break & networking time**
- 11:30  **Bioburden and PUP SIT - Updates from PDA**
Consideration from Annex 1 revision and from "Sterilisation of the medicinal product, active substance, excipient and primary container" guideline published by EMA
Lucia Ceresa, PDA Italy Chapter Vice President

- 11:55  **How to Safely and Reliably Implement Filter Pre-Use Post-Sterilization Integrity Testing**
Antonio Pierno, Principal Engineer, Scientific Laboratory Services - Pall Biotech


- 12:20 **Discussion**
12:40 **Sponsorship presentation**

- 13:10 **Lunch**

SESSION III - Sterility Assurance Controls: Innovation Technologies

- 14:20  **Monocyte Activation Test (MAT) product validation and comparison to bacterial endotoxin test**
Simone Bertolacci, Biotechnology Laboratory Manager, Eurofins BioPharma Product Testing Italy
- 14:50 **Q&A**
- 15:00  **Sterility Testing for Batch Release, Status and Improvement to zero positive false result**
Giacomo Guidi, R&D Manager - COMECER SpA
Relatore Novartis
Simone Penazzi, Sales Area Manager Pharma Division COMECER SpA
- 15:30 **Q&A**

SESSION IV - Aseptic Process Simulation

- 15:40  **Saving opportunity for the QC micro lab by reading the ASP (Mediafill) by automatic and semiautomatic Visual inspection machine - case study**
Barbara Pirola, Senior Manager Quality Control presso Thermo Fisher Scientific
- 16:10 **Coffee break**

AGENDA - 14TH

SESSION V - WORKSHOP - Tech & Material Exhibition

- 16:30  Participants are invited in small groups to interact with Sponsors taking vision of innovative technologies, products and processes, sharing best practices and trends for pharmaceutical microbiology strategies for Sterile manufacturing.
Where?
Inside the Foyer at Sponsor's Desk


SESSION VI - Round table

- 17:30  **Challenges & Strategies for Sterile manufacturers**
Moderator: **Gori Gabriele**, VP, Head of Global Audit and Risk Management - Quality - GSK Vaccines, member of PDA Science Advisory Board (SAB), co-chair of PDA task force for Annex 1
- Participants:**
- **L. Ceresa**, PDA Italy Chapter,
 - **G. Dalmaso**, Particle Measuring Systems
 - **J. Drinkwater**, PHSS
 - **P. Muscas**, QA & Sterility Assurance New Line project at Eli Lilly Italia
 - **A. Pranti**, QA Engineering & MSAT Process Science Manager - GSK Vaccines
 - **M. Simone**, Quality Risk Management & Continual Improvements Director, Corporate Quality Management - Bracco, Co-chair of PDA Worldwide Interest Group "Quality System" Steering Committee
 - **F. Trionfera**, Quality Operation Manager & Qualified Person at BSP Pharmaceuticals
- 18:20  **Closure key remarks**
Fernanda Ferrazin, Former GMP Inspector AIFA - Independent Pharmaceutical Consultant
- 18:30 **Networking buffet and drinks**

AGENDA - 15TH

08:30 Registration
09:10 Summary Key Highlights day 1
PEC Chairperson: Lucia Costanzo,
Senior Conference Manager - PEC

SESSION VII - Contamination Control Strategy

09:20  **Contamination Control Strategy and Aseptic Containment Strategy**
• Preparation of a Contamination Control strategy (CCS): Case study.
• Preparation of an Aseptic - Containment strategy (ACS) for processing hazardous potent, biological and therapeutic products.
James L Drinkwater, F Ziel GmbH
Head of GMP Compliance, Head of PHSS: Pharmaceutical & Healthcare Sciences Society Aseptic processing & Bio-contamination special interest group.

10:10  **Microbiological risk containment using a custom pharma packaging**
Lavinia Gastaldelli, Product Manager
Isolation Technology and Transfer Systems - AM Instruments
Massimiliano Frasca
Environmental Monitoring e Sampling QC Supervisor in BSP Pharmaceuticals

10:40 Q&A

10:50 Coffee break & networking time

Session VIII - QRM and new Sterility Assurance concepts applied to the new Facilities/Lines


11:20  **QRM Approach Applied to Define a SUS Integrity Control Strategy and Associated Control Technologies**
Evrard Patrick, Sr. Principal Engineer,
Single-use Technologies, Scientific Laboratory Services - Pall Biotech

11:50 Q&A

12:00  **QbD, QRM and Innovation Technology applied to a new fill**
Patrizia Muscas, QA & Sterility Assurance New Line project at Eli Lilly Italia

12:30 Lunch

SESSION IX - Inspection trends in sterile manufacturing: sharing of experiences


13:40  **Inspections: sharing of experiences with different regulatory Bodies**
Terenzio Ignoni, VP Quality and Qualified Person at Jazz Pharmaceutical and trends


14:10  **Inspections: sharing of experiences with different regulatory Bodies**
Filippo Trionfera, Quality Operation Manager & Qualified Person at BSP Pharmaceuticals

14:40 Q&A

SESSION X - Sterility Assurance: best practices

14:50  **Microbial Data Deviation Management**
Angela Petrigliano, Quality & Process Operational Manager - Pharma D&S

15:20  **Sterility Assurance & Data Integrity - case study**
Andrea Pranti, QA Engineering & MSAT Process Science Manager - GSK Vaccines

15:50  **The new role of a modern microbiologist: skills, expertise and training**
Gilberto Dalmaso Sterility Assurance-Scientific Officer - Particle Measuring Systems

16:20 Chairperson closure remarks

16:30 Closing of the congress

CONGRESS VENUE



PEC Staff will organize in the relaxing area of Melià at the end of first day course, on 14th evening (6,30 pm), a refreshment and aperitif for speakers and delegates!!
Don't forget to book your seat for evening Aperitif!!



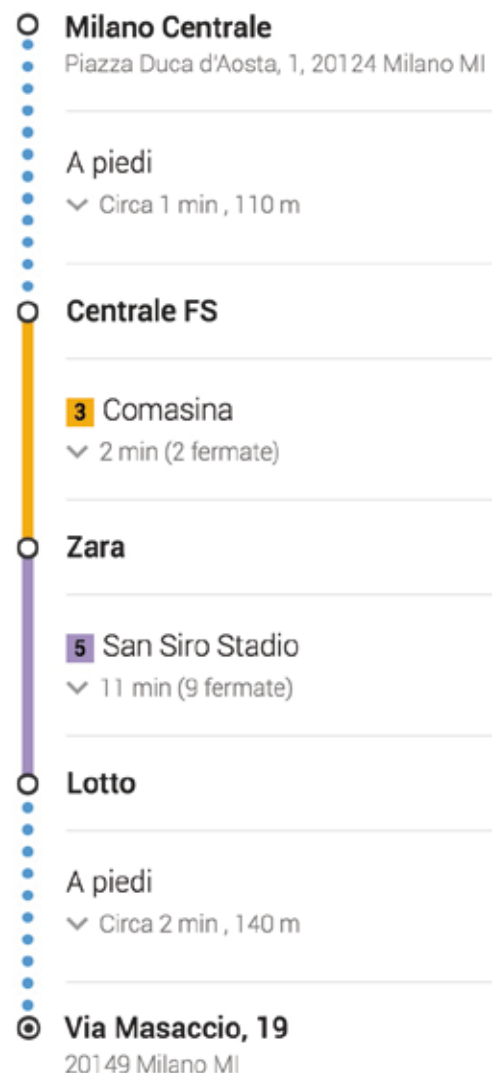
Hotel Melià

is perfectly located in the most dynamic district in Milan, a short walk from CityLife, just 15 minutes away from the historical city centre, using the nearby subway.

Address
Via Masaccio 19
Milano

Contact
Tel (39) 02444061
Fax (39) 02444066

How to reach the Hotel by subway (Metro) from Milan Central Station



ENTRY FEE

ENTRY FEE

€ 1750

Save 200 € for 2 day full immersion course
by 14 September 2019

Multiple registrations

15% discount on the 2nd member
20% discount on the 3rd member

Discounts are not cumulative

TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa - Florence (Italy), IBAN: IT90U0503402815000000001400, Bic/SWIFT: BAPPIT21G74 made payable to Pharma Education Center S.r.l., Via dei Pratonì 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling.

Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

For further information and/or further assistance please contact (+39) 055 7224179 or email: amministrazione@pharmaeducationcenter.it

COURSE/EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date.

Formal communication will be given within 5 days before the event date.

In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

PEC PHARMA
EDUCATION
CENTER

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 5 days before the starting date of the event. Once this term will be expired, the entire fee will be charged.

PARTICIPANT REPLACEMENT

It is possible to replace a participant attendance without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

HOW TO REGISTER

Please, fill the form on the web site :<https://www.eupharmacovigilance.com/>, or fill the form and submits by email to info@pharmaeducationcenter.it.

A confirmation email will be sent to confirm the registration.

Aperitif & refreshments 14th

Yes ☐ No ☐

COMPANY

ZIP TOWN ADDRESS COUNTRY

PHONE FAX

VAT NUMBER

SURNAME NAME PHONE

E-MAIL COMPANY'S ROLE/POSITION

E-MAIL to send invoice DEGREE/QUALIFICATION

PROTECTION OF PERSONAL DATA - INFORMATION In accordance with Legislative Decree 196/2003 and with article 13 of 2016/679 UE Regulation, the information provided will be processed for the purpose of administrative management of courses (accounting, logistics, directory training). The data may be used for the creation of an archive for the purpose of sending proposals for future courses and study initiatives. Our Privacy Policy is available on the site: www.pharmaeducationcenter.it.

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KEY SPEAKERS



SIMONE BERTOLACCI

Head of Molecular Biology
Laboratory in Eurofins Biolab
Biologics Division



LUCIA CERESA

Senior European Product Specialist Microbial Solutions at Charles River - PDA Italy Chapter Vice President



GILBERTO DALMASO

Global Life Science Scientific Officer at Particle Measuring Systems



JAMES L. DRINKWATER

Head of Aseptic processing technologies & GMP Compliance at F Ziel GmbH & Chairman of PHSS -Pharmaceutical & Healthcare



FERNANDA FERRAZIN

Chair Person of PMC Former GMP Senior Inspector - AIFA Independent, Pharmaceutical



MASSIMILIANO FRASCA

Environmental Monitoring e Sampling QC Supervisor in BSP Pharmaceuticals



LAVINIA GASTALDELLI

Product Manager Isolation Technology and Transfer Systems - AM Instruments



GABRIELE GORI

VP, Head of Global Audit and Risk Management - Quality - GSK Vaccines, member of PDA Science Advisory Board (SAB), co-chair of PDA task force for Annex 1



GIACOMO GUIDI

R&D Group Manager - Comecer Spa



TERENZIO IGNONI

VP Quality and Qualified Person at Gentium



PATRIZIA MUSCAS

QA & Sterility Assurance New Line project at Eli Lilly Italia



KAI NESEMANN

Product Manager Microbiology Sartorius Lab Instruments GmbH & Co.KG

KEY SPEAKERS



EVARD PATRICK

Sr. Principal Engineer, Single-use Technologies, Scientific Laboratory Services - Pall Biotech



SIMONE PENAZZI

Sales Area Manager - Pharma Division at COMECER SpA



ANGELA PETRIGLIANO

Operational Manager
Pharma D&S



ANTONIO PIERRO

Principal Engineer, Scientific Laboratory Services - Pall Biotech



BARBARA PIROLA

Senior Manager Quality Control presso Thermo Fisher Scientific



ANDREA PRANTI

QA Engineering & MSAT Process Science Manager at GSK Vaccines



MICHELE SIMONE

Quality Risk Management & Continual Improvements Director, Corporate Quality Management - Bracco, Co-chair of PDA Worldwide Interest Group "Quality System" Steering Committee



FILIPPO TRIONFERA

Quality Operation Manager & Qualified Person at BSP Pharmaceuticals