PEC PHARMA EDUCATION CENTER

28-29 October | Virtual
8 November | Florence

PHARMA MICROBIOLOGY CONGRESS 2024

Facing the Future of Sterile Manufacturing

The Pharma Microbiology Congress, organized by Pharma Education Center, is recognized as one of the most important and appreciated European conferences on sterile topics.
The PMC offers a **high-quality scientific content and an interactive format** that has attracted increasing interest from international speakers, sponsors, and attendees.

The conference gathers pharmaceutical professionals at all career levels, including key decision makers interested in the always evolving manufacturing sterile world and its new trends.

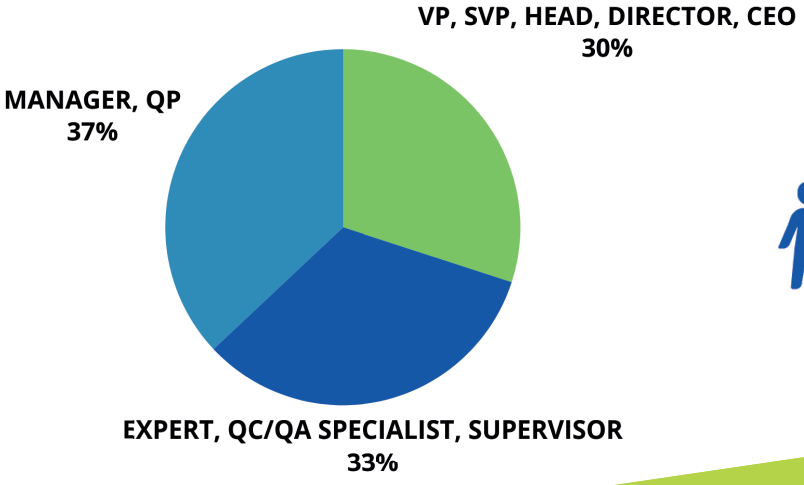
The strength of the Pharma Microbiology Conference is the successful combination of technical talks and technical presentations of emerging technologies.

The Pharma Microbiology Congress offers several benefits, including:

- An **innovative format** that provides opportunities for **knowledge sharing and networking.**
- **High-quality scientific content**, allowing attendees to learn from renowned international ***key opinion leaders.***
- The opportunity to share strategies, innovative ideas, and **cutting edge technologies** on how to face the future of sterile manufacturing.
- The **connection with pharma professionals** including **key decision-makers** at various career levels.

PMC 2023 IN NUMBERS

PMC 2023 - AUDIENCE



70+ COMPANIES

200 ATTENDEES representing

Delegates' feedback 2023 edition

- Good organization, strong speakers, I got a clear understanding
- Perfect organization and very interesting content
- PEC congress was very interesting on topics and speaker, well done.
- Excellent meeting. Thank you very much!

CONFERENCE FORMAT

- 28 - 29 October | Virtual 9 am - 5.30 pm
- 7 November | APERITIF TIME, Palazzo degli Affari in Florence 6-10 pm
- 8 November | Face to face, Palazzo degli Affari in Florence 8.30 am - 6.30 pm

APERITIF TIME - November 7 from 6 to 10 pm
Palazzo degli Affari in Florence

Reserve your place to meet and network with your colleagues and experts!

Sponsored by

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This year the congress will include:

- 11 thematic sessions
- 11 interactives round tables and Q&A Times
- 28 technical speeches
- 12 webinars on cutting-edge technologies
- 1 Lectio Magistralis

Our speakers come from: Regulatory Bodies, Industries, Academia, Associations, Consultants, and Technologies Providers.
The intense, scientific interaction between speakers and delegates is a further invaluable plus of the event.

FEATURED TOPICS

VIRTUAL

	SESSION I	SESSION II	SESSION III	SESSION IV	SESSION V	
OCT 28th	Facing the future of sterile medicines in the EU landscape	Discovering cutting-edge technologies	QRM: evolution & revolution in sterile manufacturing	Discovering cutting-edge technologies	Advancements in process & environmental monitoring	Lectio Magistralis

	SESSION VI	SESSION VII	SESSION VIII	SESSION IX	SESSION X	SESSION XI
OCT 29th	Alternatives / Rapid Methods: Regulatory Trends And Advancemen-ts For Reliable Sterility Assurance	Discovering Cutting-Edge Technologies	Barrier Systems, Automation & Robotics: Present And Future	Discovering cutting-edge technologies	Lyophilization: Meeting The Needs Of A Changing Landscape	Sterilization, Cleaning & Disinfection: Current Industry Trends And Regulatory

FACE TO FACE IN FLORENCE

	SESSION XII	SESSION XIII	SESSION XIV	SESSION XV	SESSION XVI	
NOV 8th	Regulatory bodies: lead the complian-ce & speed the innovation in the future of sterile manufacturing	Cutting-edge technologies in sterile production & controls	The Digital Age: Application in Microbiology	DISCOVER THE EXHIBITION AREA	Navigating The Future: Innovation Models In Manu-facturing & Controls	DISCOVER THE EXHIBITION AREA

NEW VENUE

Palazzo degli Affari, Florence

A unique exhibition and conference venue in the heart of Florence.

- 2 min walk from Florence Santa Maria Novella Train Station
- 30 minutes from the Florence Airport by tramway.

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We look forward to collaborating with you!

AGENDA 28 OCTOBER

all times are UTC +1 **Virtual**

SESSION I - FACING THE FUTURE OF STERILE MEDICINES IN THE EU LANDSCAPE

In this opening session of the congress, the general themes currently emerging in the regulatory landscape of sterile manufacturing and the prospects in the sterile pharmaceuticals market will be addressed. Experts from regulatory and industry backgrounds will deliver technical speeches and engage in a fruitful roundtable discussion.

Lucia Costanzo, Senior Conference Manager | PEC & Pharma Microbiology Congress chairperson

Gabriele Gori (Chair of the Session,) Quality Consultant, Science Advisory Board Chair | PDA

Alan Moon, Director of AM GMP Limited and former Lead Senior GMDP Inspector | MHRA

Regulatory Body and Pharma representatives (invited)

SESSION II - DISCOVERING CUTTING-EDGE TECHNOLOGIES

The session on cutting-edge technologies, highly appreciated over the years, is inserted into the plenary agenda and includes the selection of engaging webinars on innovative technologies, allowing full interaction with the experts.

SESSION III - QRM: EVOLUTION & REVOLUTION IN STERILE MANUFACTURING

The session faces the topic of QRM by exploring different perspectives and application areas of this important paradigm in the pharmaceutical world. In this session, interesting case studies and in-depth interventions will be presented.

James Drinkwater (Chair of the Session), Head of the PHSS Aseptic processing and Annex 1 focus groups

Tracy Moore, Founder and CEO |TM Pharma Group Ltd and former MHRA Expert EU GMDP Inspector

Angela Petrigliano, Quality & Process Operations Manager | Pharma D&S a Product Life Group

Daniele Calzolari, Quality & Process Team Leader Senior Consultant | Pharma D&S a Product Life Group

Alicia Ruiz Mahillo, Group Quality Microbiology and Sterility Assurance Manager | COMPASS by FAMAR

SESSION IV - DISCOVERING CUTTING-EDGE TECHNOLOGIES

SESSION V - ADVANCEMENTS IN PROCESS & ENVIRONMENTAL MONITORING

The session offers interesting case studies and technical speeches by experts from the pharma companies and representatives of innovative technologies, aimed at sharing advanced practical experiences on environmental control and process monitoring. The importance of adequately identifying the type of contaminant to determine the root cause and to define respective remediation measures will also be highlighted.

Francesco Boschi (Chair of the Session), Sr. Manager Technical Services - Global Microbiology and Aseptic Support Team (MAS) | Pfizer

Petra Merker, Manager - Biological Quality Control - Bayer AG

Holistic approach to Microbial ID program – risks of inaccurate IDs

Frank van der Zanden, Ceo of Sure Laboratories and Chairman of the Dutch Commission 370216 Disinfectants and antiseptics

Innovative Technology applied to RCA of a microbial investigation

Olaf Degen, Director Industry Microbiology | Bruker Microbiology & Infection Diagnostics

LECTIO MAGISTRALIS

AGENDA 29 OCTOBER

all times are UTC +1 **Virtual**

SESSION VI – ALTERNATIVES / RAPID METHODS: REGULATORY TRENDS AND ADVANCEMENTS FOR RELIABLE STERILITY ASSURANCE

The session offers an overview of regulatory trends and emerging technologies in microbiological control, including alternative or rapid methods. It aims to explore regulatory updates, validation approaches, and technological applications, reflecting on the "microbiological tests of the future."

Rapid Microbial Methods: a long journey between challenges and real implementation.

Lucia Ceresa, (Chair & Speaker), Pharmaceutical Consultant - PDA Italy Chapter Board

Regulatory Updates in Recombinant Technologies for Bacterial Endotoxin Testing: Understanding the upcoming USP Chapter <86> and its implications for European manufacturers.

Veronika Wills, Associate Director, Global Technical Services | Associates of Cape Cod, Inc.

Realtime Microbiological Quality Control online of Water for Pharma production (Bioburden, Purified and WFI)

Wolfgang Vogl, CEO-Founder | VWS

SESSION VII - DISCOVERING CUTTING-EDGE TECHNOLOGIES

The session on cutting-edge technologies, highly appreciated over the years, is inserted into the plenary agenda and includes the selection of engaging webinars on innovative technologies, allowing full interaction with the experts.

SESSION VIII - BARRIER SYSTEMS, AUTOMATION & ROBOTICS: PRESENT AND FUTURE

Session VIII explores the future perspectives of pivotal regulatory and technological aspects of Barrier systems, highlighting the latest advancements in automation and robotics technologies. The final roundtable, facilitated by experts, fosters engagement and interaction with attendees.

Patrizia Muscas, Sterility Assurance Director, Global TS.MS | Eli Lilly and Company

Closed, gloveless isolators for Clinical and Commercial Drug Products

Cytiva representative

SESSION IX - DISCOVERING CUTTING-EDGE TECHNOLOGIESES

SESSION X- LYOPHILIZATION: MEETING THE NEEDS OF A CHANGING LANDSCAPE

The Annex 1 requirements have brought about a significant impact on the implementation of the latest technological advancements, including the adoption of automatic or semi-automatic loading/unloading systems in conjunction with barrier technologies. This will herald a revolution in the processes surrounding lyophilization, affecting equipment, processes, and methods, with various implications for organization and production. The session will delve into the technical and regulatory aspects of this important technology with the help of interesting case studies.

Marisa Delbò, (Chair & Speaker), AIFA Consultant As former Head of GMP API Inspections and Manufacturing

How to reach the Annex 1 compliance for existing freeze dryers: case studies on sterile bulk products and filled vials

Marco Conti, CEO di C&P Engineering a Product Life Group

Lyophilization product transfer vs Annex 1

Simone Penazzi, Business Development Manager | QS Group Srl

SESSION XI – STERILIZATION, CLEANING & DISINFECTION: CURRENT INDUSTRY TRENDS AND REGULATORY EXPECTATIONS

Disinfection can seem like a never-ending race against microorganisms, but with appropriate cleaning, disinfection, sterilization practices, and innovative technologies, these objectives can be achieved. During this section, technical presentations will explore regulatory trends, technological innovations and best practices in sterilization, cleaning and disinfection. The aim is to develop a robust, science-based cleaning and disinfection program for success.

AGENDA 8 NOVEMBER

all times are UTC +1 **Florence**

SESSION XII - REGULATORY BODIES: LEAD THE COMPLIANCE & SPEED THE INNOVATION IN THE FUTURE OF STERILE MANUFACTURING

The opening session of the last day of the congress in Florence gives the floor to representatives from the Italian and European regulatory agencies, addressing the delicate topic of innovation drive and regulatory compliance. Expert industry speakers will complete the session with a final roundtable discussion involving the audience.

Italian and European Regulatory Bodies representatives (invited)

Pharma Companies representatives

SESSION XIII - APPLYING CUTTING-EDGE TECHNOLOGIES IN STERILE PRODUCTION & CONTROLS

This session is dedicated to exploring two key themes in Sterility Assurance: Low Endotoxin Recovery studies and emerging technologies supporting the visual inspection of Media Fill. Experts will answer audience questions in the Q&A session.

Good practice in LER study: the choice of the endotoxin

Alessandro Pauletto, Global LER Business Manager | bioMérieux

A Science-Based Approach to APS: Using Headspace Analysis for Automated Analytical Media Fill Inspection

Suzanne Kuiper, Application Manager | Lighthouse Instruments

SESSION XIV - THE DIGITAL AGE: APPLICATION IN MICROBIOLOGY

In this session, the theme of digitalization is explored through two insightful presentations by experts, aiming to highlight the potential of the digital revolution in pharmaceutical microbiology and its practical applications.
The subsequent Q&A session will provide an opportunity for interaction, allowing participants to pose questions to the experts.

Embracing Digitalisation & Pharma 4.0: Innovations Shaping the Future of Pharmaceutical manufacturing

Johannes Oberdofer, Field Application Scientist | Rapid Micro Biosystems

Title under definition

Nicole Schepis, Senior Laboratory Product Validation Specialist | Copan Group

SESSION XV - LUNCH & VISIT TO THE TECHNOLOGY EXHIBITION

After lunch, attendees can visit the exclusive area of Palazzo Affari, where the numerous technology exhibitors will be present. This provides an opportunity to delve into the technologies and engage in networking.

SESSION XVI - NAVIGATING THE FUTURE: INNOVATION MODELS IN MANUFACTURING & CONTROLS

The last technical session of the congress day is dedicated to showcasing innovative case studies and inspirational technical speeches.
Representatives from the invited companies will share their experiences, challenges, and outcomes in implementing innovative systems and organizational models related to drug control and production. You will be invited to participate by asking questions during the final Q&A session.

Ferrazin Fernanda, (Chair of the Session), Life Sciences Expert, Former GMP Inspector - AIFA

Case study 1: Towards a Paperless Future: Navigating the Transition in Quality Control Labs

Aneta Leszczynska, QC Microbiology Scientist | Biogen
Corina Nitu, QC Microbiology Associate | Biogen

OPEN EXIBITION & NETWORKING TIME

In the exclusive area of the Palazzo Affari, the numerous exhibitors of technologies will showcase technological innovations through videos and demonstrations.
The exhibition area will be open from 4:30 pm onwards for all attendees, and representatives of non-registered companies are welcome to visit with free admission.

CONFIRMED SPEAKERS

Gabriele Gori
Quality Consultant, Science Advisory Board Chair | PDA

Angela Petrigliano
Quality & Process Operations Manager | Pharma D&S a Product Life Group

Fernanda Ferrazin
Life Sciences Expert

James Drinkwater
Head of the PHSS Aseptic processing and Annex 1 focus groups

Marco Conti
CEO of C&P Engineering, Pharma D&S a Product Life Group Company

Marisa Delbò
AIFA Consultant As former Head of GMP API Inspections and Manufacturing

Susanne Kuiper
Application Manager | Lighthouse Instruments

Petra Merker
Manager - Biological Quality Control | Bayer AG

Francesco Boschi
Senior Manager Technical Services QTO Sterile Injectables & Biotech | Pfizer Global Supply

Tracy Moore
Director | TM Pharma Group Ltd and former MHRA Expert EU GMDP inspector

Patrizia Muscas
Sterility Assurance Sr Research Scientist Global TS.MS | Eli Lilly and Company

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Corina Nitu
QC Microbiology Associate | Biogen

Alessandro Pauletto
Sales and Tech Support in Pharma Industry - Global LER Business Development Manager | Biomerieux

Alicia Ruiz Mahillo
Group Quality Microbiology and Sterility Assurance Manager | COMPASS by FAMAR

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Veronika S. Wills
Associate Director, Global Technical Services | Associates of Cape Cod, Inc.Group

ENTRY FEES

	Face to Face only	Virtual only	Virtual + Face to Face
Early bird	400 €	750 €	1100 €
Full Price	500 €	800 €	1200 €

Early bird fees expire on September 28th

VAT not included

Hospitals, universities and freelance professionals get a 40 % discount to be applied to published prices

Discounts are not cumulative

For multiple registrations contact:
info@pharmaeducationcenter.it

TEL (+39) 055 7224179
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REGISTER HERE

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

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.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

ATTENDEE REPLACEMENT

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

PEC PHARMA EDUCATION CENTER

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