Pharma Microbiology Congress

November 23 - 24, 2022
Virtual
&
November 30, 2022
Milan - ANNEX 1 WORKSHOP

PEC PHARMA EDUCATION CENTER

The **Pharma Microbiology Congress** is the European annual meeting point of professionals involved in the sterile manufacturing of medicinal products and medical device.
A full immersion on the **latest regulatory updates**, new technologies for the detection and containment of contamination, best practices and **strategies to improve the sterility assurance** of the manufacturing and control of sterile medicines.
Professionals belonging to different areas of expertise (Production, Engineering, Quality Control, Quality Assurance, R&D, Maintenance) will get together to **share and discuss the hottest topics** with experts coming from Regulatory Bodies, Pharmaceutical Companies, Consultancy, Associations and New Technologies providers.
The program will see the contribution of **international Top Speakers** as experts, key opinion leaders and representatives of institutions.

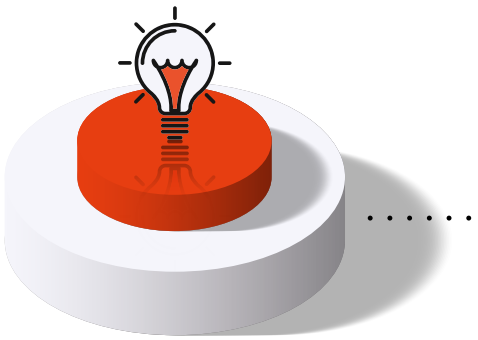
WHO SHOULD ATTEND?

The event is aimed specifically at Pharma, Biotech and Medical Device Companies, Regulatory bodies and Technology Suppliers involved in the manufacturing and control of Sterile medicines.

VIRTUAL + FACE TO FACE

PMC comes back with a mixed format!

The **first two days, November 23 and 24th**, will be virtual and will see the participation of worldwide experts and key opinion leaders.
The **third day, November 30th, will be a face-to-face meeting in Milan**, where you will have the chance to meet colleagues and the speakers of the congress: a great opportunity for the sterile manufacturing community to get together!

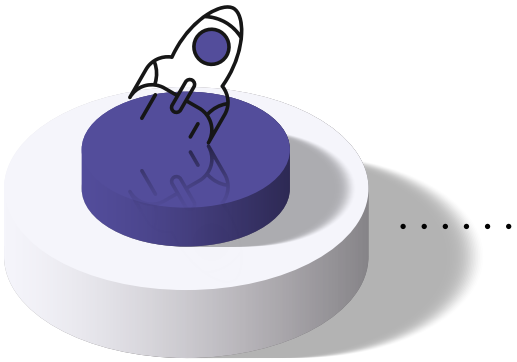


EXPERTS & KOLs OF THE FIELD WILL SHARE THEIR EXPERIENCES AND KNOW HOW:

From regulatory issues to the most technical aspects, our speakers will share their deep expertise with the audience through **speeches, round tables and question times:** ask questions, rate the ones coming from the audience and let us know what is important for you to know.

STAY UPDATED ON THE LATEST TECHNOLOGIES AND TECHNOLOGICAL ADVANCES

Each day, a session dedicated to new technologies and technological advances that are changing the world of sterile manufacturing. **Don't miss webinars, interviews and demonstrations, and chat with real experts of the field.**



FOLLOW THE ROAD TO PMC2022

The initiative will see us and the sponsors working in synergy before the conference by organizing a series of thematic webinars and interviews: subscribe to the LinkedIn page and don't miss them!

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FEATURED TOPICS

VIRTUAL

23th	ANNEX 1 REGULATORY LANDSCAPE AND TRENDS	Innovation Technologies Webinars	ENHANCEMENT OF STERILITY ASSURANCE	Innovation Technologies Webinars	ENVIRONMENTAL MONITORING
24th	CONTAMINATION CONTROL STRATEGY	Innovation Technologies Webinars	ENHANCEMENT OF STERILITY ASSURANCE	Innovation Technologies Webinars	PROCESS & FACILITIES

FACE TO FACE IN MILAN

30th	GMP INSPECTIONS AND TRENDS	ANNEX 1 WORKSHOP (Technical speeches + Q&A with involvement of audience)	Innovation Technologies SESSION	ANNEX 1 WORKSHOP (Technical speeches + Q&A with involvement of audience)

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CONFIRMED SPEAKERS

José Sergio Ávila González
Sterilization and environmental control Senior Engineer | Foxconn - Baja California

Frederic Ayers
Advisor Global Quality Systems | Eli-Lilly Indiana - US

Maria Paola Baini
QA Strategic Growth Investiments & Engineering Associate Director | Lonza

Alessandra Benassi
Microbiology and Sterility Assurance specialist | IMA

Francesco Boschi
Global Quality Sterile Injectables MAS - Microbiological and Aseptic Support Team | Pfizer

Andrea Buzzigoli
QC microbiology laboratory supervisor | Kedrion Biopharma

Giancarla Cecere
Microbiology and Sterility Assurance specialist | IMA

Lucia Ceresa
Board PDA Italy Chapter

Francesco Cicirello
Director, Q. A. (Ex PIC/S SCH Deputy Chair, EMA IWG Representative and Annex 2 WG Chair - TGA Expert Inspector) | Evelo Biosciences

Marco Conti
Director C&P Engineering | Pharma D&S Group

Adriana Elsa Cotti
Consultant Quality Expert & QP | C&P Engineering - Pharma D&S Group

Gilberto Dalmaso
Microbiologist & Quality Assurance expert

Richard Denk
Senior Consultant Aseptic Processing & Containment

James Drinkwater
Head of PHSS - Aseptic Processing and Containment | Special Interest Group

Walid El Azab
Senior Manager Technical | STERIS | A3P member

Fernanda Ferrazin
Life Sciences Expert

Alessandro Gasparella
Environmental Monitoring Manager | Corden Pharma - Caponago

Mauro Giusti
Director, Technical Services/Mfg Sciences | Eli - Lilly

Gabriele Gori
Site Quality Head | Thermo Fisher, Vice - Chair Science Advisory Board PDA Board PDA

Rainer Gnibl
GMP-Inspector & Deputy Head of Inspectorate of Government of Upper Bavaria | Inspector for EMA Board PDA

Isabelle Hoenen
Quality Advisor for Sterility Assurance | Eli Lilly France

Andrew Hopkins
Director of Compliance | Abbvie, former MHRA Inspector

Arjan Langen
Global Sterility Assurance Director | GE Healthcare

Paola Lazzeri
Technical Sales Manager Europe | Veltek Associates, Inc.

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

Di Morris
Clinical Auditor, former MHRA inspector | Astrazeneca

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

Suzanne Nutter
QA Group Manager | Astrazeneca

Ornella Pace
Quality System Manager | BSP Pharmaceuticals

Tiziano Petrucciani
Qualified Person, Direttore Quality & Development | L. MOLTENI & C.

Ulrich Pflugmacher,
Director Microbiology and Sterile Technologies | Sanofi Global Quality

Giuseppina Pichierri
Associate researcher | Merck

Andrea Pranti
Qualification Transformation Engineering Manager | GSK Vaccines

Davide Ravasio
Innovation Manager – Innovation – R2B | SKAN AG

Tim Sandle
Pharmaceutical Microbiologist & Contamination Control Expert | Bio Product Laboratory Limited

Andrea Raso
Sterility Assurance Lead | GSK

Michele Simone
Corporate Quality Director | Bracco Group

Amber Sims
Principal Scientist TS/MS-SAT | Eli Lilly and Company - US

Luisa Stoppa
Senior GMP Inspector | AIFA (Agenzia Italiana del Farmaco)

AGENDA - November 23th - VIRTUAL

Times UTC +1

SESSION 1- REGULATORY LANDSCAPE AND TRENDS

9.00 **Welcome by the Chairperson of the congress**
Lucia Costanzo, Senior Conference Manager | PEC & Pharma Microbiology Congress chairperson

9.10 **Introduction by the Chairperson of the Session**
James Drinkwater, Head of PHSS - Aseptic Processing and Containment Special Interest Group

9.20 Technical speech **Annex 1: Selection of new topics & inspector's expectation**
Rainer Gnibl, GMP-Inspector & Deputy Head | Inspectorate of Government of Upper Bavaria, Inspector for EMA

10:10 Technical speech **Annex 1 implementation: key challenges for manufacturers**
Andrew Hopkins, Director of Compliance | Abbvie, former MHRA Inspector

10.35 **Round Table & Q&A Time**
Annex 1 implementation: challenges with the involvement of Experts and audience
Moderator: J. Drinkwater
Panelists: A. Hopkins
Tracy Moore | TM Pharma Group Ltd (tbc)
R. Gnibl
Di Morris | Astrazeneca

11.00 **Coffee break & Networking**

11.20 INNOVATION TECHNOLOGIES **introduction**
Matteo Gentili, Project Manager Education & Training | PEC

11.25 2 webinars | **see page n.12**

SESSION 2 - RAPID MICROBIOLOGY METHODS APPLIED TO PRODUCT & PROCESS

11.50 Technical speech **Rapid Microbiological Methods: from regulatory requirements to use in routine**
Lucia Ceresa, Board PDA Italy Chapter

12.10 Case study **Detection of microbial contaminants in cell lines and viral sample using ATP Bioluminescence Technology**
Giuseppina Pichierri, Associate researcher | Merck

12.30 **Q&A time**

12.35 Case study **Enzyme Indicators: Real application and evaluation of a new system for rapid monitoring and validation of Vapor Hydrogen Peroxide Decontamination Process**
Alessandra Benassi, Microbiology and Sterility Assurance specialist | IMA
Giancarla Cecere, Microbiology and Sterility Assurance specialist | IMA

12.55 **Q&A time**
1.0pm **Lunch time**

2.00 INNOVATION TECHNOLOGIES **introduction**
Matteo Gentili, Project Manager Education & Training | PEC

2.05 4 webinars | **see page n.12**

SESSION 3 - ENVIRONMENTAL MONITORING & DIGITALIZATION

2.50 **Introduction to the Session**
Chaiperson PEC

2.55 Technical speech **EM Overview: impacts of Annex 1 new requirements**
Tim Sandle, Pharmaceutical Microbiologist & Contamination Control Expert | Bio Product Laboratory Limited

3.25 Case study **Environmental Monitoring & Data Integrity improvement: a case study**
Alessandro Gasparella, Environmental Monitoring Manager | Corden Pharma - Caponago

3.45 **Q&A**

3.50 **Coffee break & Networking**

4.10 Technical speech **Process data robustness – The importance of robust data management strategy in Pharma Manufacturing**
Paola Lazzeri, Technical Sales Manager Europe | Veltek Associates, Inc.

4.30 **Q&A**

4.35 Case study **RM model for sampling points evaluation (as defined by the work done inside the Bioforum Group)**
Amber J. Sims, Principal Scientist TS/MS-SAT | Eli Lilly and Company - US

5.0 **Round Table + Q&A Time**
Moderator: T. Petrucciani | L. MOLTENI & C.
Participants: A. Gasparella
P. Lazzeri
T. Sandle
A.Sims

5.30 **Closure of the day 1**

AGENDA - November 24th - VIRTUAL

SESSION 4 - CONTAMINATION CONTROL STRATEGY: MODELS & TEMPLATES

9.00 **Introduction by the Moderator of the Session**
Isabelle Hoenen, Quality Advisor for Sterility Assurance | Eli Lilly-France

9.05 Technical speech **How to use the ECA CCS guideline to set up your CCS?**
Arjan Langen, Global Sterility Assurance Director | GE Healthcare, ECA member

9.25 Technical speech **PHSS-A3P CCS guidance on scope, structure, contents, plus supporting Templates of contents and points to consider for preparation of a Site Master CCS and individual Area Unit CCS's**
Walid El Azab, Senior Manager Technical Service | STERIS, A3P member
Una Hearty, Pfizer Global Microbiology (tbc) | PHSS member
Di Morris, Astrazeneca Clinical Auditor, former MHRA inspector | PHSS member

09.45 Technical speech **PDA Technical Report on Contamination Control Strategy**
Frederick Ayers, Advisor Global Quality Systems | Eli-Lilly Indiana - US

10.05 Case study **An approach to CCS**
Andrea Raso, Sterility Assurance Lead | GSK

10.20 **Case study Sanofi's approach for the implementation of the Contamination Control Strategy (CCS) according to the new Annex 1**
Ulrich Pflugmacher, Director Microbiology and Sterile Technologies | Sanofi Global Quality

10.35 **Round Table + Q&A Time**
CCS: Sharing of different experiences and approaches
Moderator: **I. Hoenen**
Participants: **F. Ayers**
R. Denk
W. El Azab
U. Hearty (TBC)
A. Langen
D. Morris
A. Raso
U. Pflugmacher

11.00 **Coffee break & networking**

SESSION 5 - TECHNOLOGY INNOVATION APPLIED TO PERSONNEL AND PRODUCT

11.20 **INNOVATION TECHNOLOGIES introduction**
Matteo Gentili, Project Manager Education & Training | PEC

11.25 **2 webinars | see page n.12**

11.50 **Introduction by the Moderator of the Session**
Francesco Boschi, Global Quality Sterile Injectables MAS - Microbiological and Aseptic Support Team | Pfizer

11.55 **Case study Applying Virtual Reality to Training in Aseptic Processing and Microbiology**
Suzanne Nutter, QA Group Manager | Astrazeneca

12.15 **Q&A time**

12.20 **Case study Endotoxin Recombinant Factor C: ENDONEXT™ evaluation process**
Andrea Buzzigoli, QC microbiology laboratory supervisor | Kedrion Biopharma

12.40 **Q&A time**

12.45 **Round Table & Q&A Time**
Moderator: **F. Boschi**
Panelists: **A. Buzzigoli**
S. Nutter
Michele Simone | Bracco Group

1.10 **Lunch time**

SESSION 6 - INNOVATION IN PROCESS & FACILITIES

2.00 **INNOVATION TECHNOLOGIES introduction**
Matteo Gentili, Project Manager Education & Training | PEC

2.05 **4 Webinars | see page n.12**

2.50 **Introduction by the Moderator of the Session**
A. Pranti, Qualification Transformation Engineering Manager | GSK Vaccines

2.55 **Technical speech Innovation & Sterility Assurance in the design of a sterile manufacturing facility**
José Sergio Ávila González, Sterilization and environmental control Senior Engineer | Foxconn - Baja California

3.20 **Case study Aseptic processing equipment requirements: case study**
Davide Ravasio,Innovation Manager, Innovation – R2B | SKAN AG

3.40 **Q&A**

3.45 **Coffee break**

4.00 **Case study Single Use Systems: applications for sterile & non sterile biotech manufacturing**
Ornella Pace, Quality System Manager | BSP

4.20 **Q&A**

4.25 **Case study RABS adoption in filling lines modules: comparison between different design solutions**
Marco Conti, Director C&P Engineering | Pharma D&S Group

4.45 **Q&A**

4.50 **Round Table + Q&A Session**
Moderator: A. Pranti
Panelists: JS Avila Gonzales
Maria Paola Baini | Lonza
Francesco Cicirello | Evelo Biosciences
Mauro Giusti | Eli Lilly
O. Pace
D. Ravasio

5.30 **Closure of the day 2**

AGENDA - November 30th - MILAN

SESSION 7 - ANNEX 1 IMPLEMENTATION: THE NEW PARADIGM

8:30 **Registration**
9.00 **Welcome**
Chairperson PEC

9.10 **Technical speech Annex 1 and potential challenges**
Tracy Moore, Director | TM Pharma Group Ltd and former MHRA Expert EU GMDP inspector

9.35 **Technical speech Inspection trends**
Luisa Stoppa, Senior GMP Inspector | AIFA (Agenzia Italiana del Farmaco)

10.00 **Technical speech Annex 1: an Industry Perspective**
Gabriele Gori, Site Quality Head | Thermo Fisher, Vice - Chair Science Advisory Board | PDA

10.25 **Sponsors Introduction**

10.50 **Coffee break & networking**

SESSION 8 - ANNEX 1 WORKSHOP: PREMISES - ENVIRONMENTAL MONITORING - PERSONNEL

11.20 **Introduction by the Moderator of the Session**
Chairman PEC

11.25 **Technical speech Environmental Classification and Qualification and connection to ISO14644 - part 1 (Classifications) and part 3 (Testing)**
James Drinkwater, Head of PHSS - Aseptic Processing and Containment Special Interest Group

11.45 **Panel discussion with involvement of the audience and Experts**
Experts: G. Dalmaso
j. Drinkwater
I. Hoenen
G. Gori
A. Langen
T. Moore
D. Morris
Facilitators: F. Boschi
M. Simone | Bracco Group

12.35 **Lunch Break**

1.35 **WALK THROUGH THE NEW TECHNOLOGIES FOR STERILE MANUFACTURING**

SESSION 9 - ANNEX1 WORKSHOP Process & Equipment

2.15 **Introduction by PEC**

2.20 Technical speech **Points to consider for the implementation of Annex 1 for Barrier Systems**
Richard Denk, Senior Consultant Aseptic Processing & Containment

2.40 Technical speech **Decontamination of isolator contact parts: Implementation of a Risk Assessment tool as support of risk evaluation to comply with Annex 1 requirements**
Patrizia Muscas, Sterility Assurance Sr Research Scientist Global TS.MS | Eli Lilly and Company

3.00 **Panel discussion with involvement of the audience and Experts**
Experts: L. Ceresa
R. Denk
J. Drinkwater
A. Hopkins
A. Langen
D. Morris
P. Muscas
T. Moore
Facilitators: A. Pranti | GSK
A. E. Cotti | Pharma D&S Group

SESSION 10 - ANNEX 1 WORKSHOP

4.10 **ANNEX 1 Implementation: Key Messages take away**
Chairman: Fernanda Ferrazin, Life Sciences Expert
Participants: F. Boschi
L. Ceresa
R. Denk
G. Dalmaso
J. Drinkwater
G. Gori
I. Hoenen
P. Muscas
A. Langen
D. Morris (tbc)
T. Moore
A. Pranti
M. Simone

5.00 **End of Congress**

VENUE

MELIÁ ***** Milan

INNOVATION TECHNOLOGIES

webinars

November 23th

11.30 - 11.50	IMA **Choice of environmental sample points in isolated robotized rtu line using risk analisys approach** Stefano Specchia	BD **Environmental monitoring according to the new Annex 1** Gunter Neuer
2.10 - 2.30	Biotrends **BioTrends 2.5: latest news and improvements** Antonio Borellini Damiano Zin	Merck **Sterility testing: selecting the right membranes and tools** Mauro Anglana
2.30 - 2.50	Veltek **Learning from experiences: Understanding Test Failures Critical parameters to consider in disinfectant efficacy test protocol** Paola Lazzeri	

INNOVATION TECHNOLOGIES

webinars

November 24th

11.30 - 11.50	Biomerieux **Automation & Digitalization of the EM manual steps** Arnaud Paris	
2.10 - 2.30	Microgenetics **How SmartControl technology will support your contamination control strategy** Andrew Davies	Skan **SKANalytix Services – Process, Product and Operator Safety Secured by Analytical Data** Max Mittelviefhaus
2.30 - 2.50	Sievers **Centripetal Microfluidic Automation for Optimized Endotoxin Testing** Giovanni De Martino	Mesalabs **Why perform a product D-value study?** Beatrice Romeo & Silvia Rizzi

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MED TECH OUTLOOK

ENTRY FEES

	Face to Face only	Virtual only	Virtual + Face to Face November, 23 - 24 - 30
Early bird	350 €	675 €	950 €
Full Price	400 €	750 €	1150 €

Early bird fees expire on October 23rd

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

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TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Florence (Italy), IBAN IT81P0503402801000000007431, Bic/SWIFT: BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant. 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

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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.

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