PEC PHARMA EDUCATION CENTER
A ProductLifeGroup Company

PHARMA MICROBIOLOGY CONGRESS 2023

STRATEGIES AND INNOVATION TECHNOLOGIES IN STERILE MANUFACTURING

8 - 9 November | Virtual
14 November | Milan

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

Last year the mixed format reached a great success, so this year as well the first two days**, November 8th and 9th,** will be virtual and will see the participation of worldwide experts and key opinion leaders.

The **third day, November 14, will be a face-to-face meeting in Milan**, where you will have the chance to meet colleagues and the speakers of the conference: 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 PMC2023

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!

About last edition

- 37 *International speakers*
- 200 *Attendees*
- 8 *Round Tables*
- 70+ *Companies*
- 15 *Sponsors + 3 media partners*
- 16 *Technical speeches*

FEATURED TOPICS

VIRTUAL

NOV 8th	Regulatory landscape and gmp inspection trends	Innovation Technologies Webinars	CCS: Regulatory Expectations & not sterile case studies	Innovation Technologies Webinars	Environmental & process monitoring
9th	Contamination Risk control	Innovation Technologies Webinars	PERSONNEL: qualification, training & innovation	Innovation Technologies Webinars	BIOTECH/ATMP: regulatory trends & Innovation Technologies

FACE TO FACE IN MILAN

NOV 14th	Facility design of the future: How to address annex 1 requirements?	Advanced sterile manufacturing Enhancement of sterility assurance in processes	Innovation Technologies Session	Advanced Sterile Controls Enhancement of sterility assurance in controls	Workshop & Q&A time with the experts

PEC PHARMA EDUCATION CENTER
A ProductLifeGroup Company

SPONSORED BY

GOLD SPONSORS

charles river | microbial solutions

Steriline ASEPTIC PROCESSING

Rapidmicro biosystems

C&P ENGINEERING A ProductLifeGroup Company

BIOMÉRIEUX

SILVER SPONSORS

PHARMA D&S PHARMACEUTICAL DEVELOPMENT & SERVICES A ProductLifeGroup Company

IMA LIFE Aseptic Processing & Freeze Drying Solutions

vai VELTEK ASSOCIATES, INC.

Copan innovating together

Associates of Cape Cod Europe GmbH Your Endotoxin & Glucan Experts

cytiva | PALL

BRONZE SPONSORS

BD

MesaLabs

PARTICLE MEASURING SYSTEMS® a spectris company

Tecninox #controlledcontamination

EXHIBITOR SPONSORS

RIGEL LEADING SOLUTIONS

nordtest

vileda PROFESSIONAL

AGENDA - November 8 - VIRTUAL

Times UTC +1

SESSION 1. ANNEX 1 IMPLEMENTATION: REGULATORY LANDSCAPE

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**
Gabriele Gori, SVP Global Quality Operations and Chief Quality Officer | Biogen International GMBH, Chair Science Advisory Board PDA

9.25 Technical speech **Annex 1 implementation: Regulatory Body expectations**
Vimal Sachdeva, Senior GxP Inspector | World Health Organization (WHO) (tbc)

9:50 Technical speech **Annex 1 implementation: challenges and opportunities for companies**
Alan Moon, Director of AM GMP Limited and former Lead Senior GMDP Inspector at MHRA

10.15 **Round Table & Q&A Time**
Annex 1 implementation: challenges with the involvement of Experts and audience
Moderator: G. Gori
Panelists: A. Moon
V. Sachdeva

10.50 **Coffee break & Networking**

11.10 INNOVATION TECHNOLOGIES **introduction**
Silvia Calloni, Project Manager Education & Training | PEC

11.15 2 webinars **| see pag 14**

SESSION 2. CCS: MANAGING THE GAPS & NOT STERILE APPLICATION

11.45 **Introduction to the session**
Isabel Hoenen, Quality Advisor for Sterility Assurance | Eli Lilly France

11.50 Technical speech **CCS implementation: managing the gaps in GMP compliance**
Di Morris, Qualified Person/ Quality Compliance Advisor | PNR Pharma Consulting Ltd

12.15 pm Case study**: CCS application on not sterile product with bioburden control**
Angela Petrigliano, Operational Manager Process & Quality | Pharma D&S, a Product Life Group Company

12.40 **Round Table & Q&A Time**
Moderator: I. Hoenen
Panelists: W. El Azab
D. Morris
A. Petrigliano

1.10 **Lunch Break**

2.00 INNOVATION TECHNOLOGIES **introduction**
Silvia Calloni, Project Manager Education & Training | PEC

2.05 4 webinars **| see pag 14**

SESSION 3. ENVIRONMENTAL & PROCESS MONITORING

2.50 **Introduction to the session**
Francesco Boschi, Senior Manager Technical Services QTO Sterile Injectables & Biotech | Pfizer Global Supply

2.55 **Technical speech Process Monitoring: key elements and their correlation with EM and other aspects of CCS**
Tracy Moore, Director at TM Pharma Group Ltd and former MHRA Expert EU GMDP inspector

3.25 **Case study Automatic way for reading of environmental plates and imaging analysis. Streamline the microbiological quality control and secure the safety of your products**
Andrea Stefano Ivaldi, Product Marketing and Business Development Manager | COPAN

3.45 **Q&A Time**

3.50 **Coffee break & Networking**

4.10 **Technical speech Cleaning and disinfection program under the light of Annex 1**
Walid El Azab, Industrial Pharmacist, Senior Manager and Qualified Person

4.30 **Round Table & Q&A Time**
Annex 1 implementation: challenges
with the involvement of Experts and audience
Moderator: **F. Boschi**
Panelists: **W. El Azab**
A. S. Ivaldi
T. Moore

5.00 **Closure of the day 1**

AGENDA - November 9 - VIRTUAL

SESSION 4. CONTAMINATION RISK CONTROL

9.00 **Introduction to the Session**
J. Drinkwater, Head of the PHSS Aseptic processing and Annex 1 focus groups

9.05 **Technical speech Material Transfer between GMP grades**
J. Drinkwater

9.25 **Case study Validation approach for a biodecontamination technology of pre-sterilised RTU (Ready to use) containers in aseptic filling line**
Giancarla Cecere, Microbiology and Sterility Assurance specialist | IMA
Alessandra Benassi, Microbiology and Sterility Assurance specialist | IMA

9.45 **Q&A Time**

9:50 **Technical speech Innovation in Bacterial Endotoxin Testing – from animal based to proven synthetic option**
Veronika Wills, Associate Director, Global Technical Services | Associates of Cape Cod, Inc.

10.10 **Q&A Time with**
Elena Secchi, Technical Sales Representative | Associates of Cape Cod, Inc.
Matthew Stevenson, European Sales Manager | Associates of Cape Cod, Inc.

10.15 **Technical speech Risk Analysis and Practical Solutions for PUPSIT Implementation**
Antonio Pierno, Senior Manager – SLS - MSAT filtration team | Cytiva

10.35 **Q&A Time**

10.40 **Round Table & Q&A Time**
Moderator: **J. Drinkwater**
Panelists: **A. Benassi**
G. Cecere
P. Muscas
A. Pierno
E. Secchi
M. Stevenson

11.10 **Coffee break & Networking**

11.30 **INNOVATION TECHNOLOGIES introduction**
Silvia Calloni, Project Manager Education & Training | PEC

11.35 **2 webinars | see pag 14**

SESSION 5. PERSONNEL: INNOVATION, QUALIFICATION & TRAINING

12.00 pm **Introduction to the session**
Andrea Pranti, Qualification Transformation Engineering Manager | GSK Vaccines

12.05 **Technical speech Capabilities Development for Sterile Manufacturing**
Mauro Giusti, Senior Director, Parenteral Technical Knowledge | Eli Lilly Italia,President PDA Italy Chapter

12.25 **Case study Data Integrity and Traceability Compliance: is the paperless approach the only appliable solution?**
Paola Lazzeri, Technical Sales Manager Europe| Veltek Associates, Inc.

12.45 **Q&A Time**

12.50 **Round Table & Q&A Time**
Moderator: A. Pranti
Panelists: T. Archilletti
M. Giusti
P. Lazzeri
M. Simone

1.15 **Lunch Break**

2.10 **INNOVATION TECHNOLOGIES introduction**
Silvia Calloni, Project Manager Education & Training | PEC

2.15 **4 webinars | see pag 14**

SESSION 6. BIOTECH/ATMP: REGULATORY TRENDS & INNOVATION TECHNOLOGIES

3.00 **Introduction to the session**
Francesco Cicirello, Senior Director, Quality Assurance (Ex PIC/S SCH Deputy Chair, EMA IWG Representative and Annex 2 WG Chair - TGA Expert Inspector) | Evelo Biosciences

3.05 **Technical speech GMP ATMP & ANNEX 1: balancing implementation differences**
Francesco Cicirello

3.30 **Case study EM in Biotech**
tbd

3.55 **Q&A Time**

4.00 **Case study Analyzing the Role of Automation in Enhancing Cell Therapy Drug Product Optimization and Global Accessibility**
Satyakam Singh, Director, Head of Cell Therapy Process and Analytical Development | Simnova Biotechnology
Krisha Patel, Co-Founder of Assurea LLC

4.25 **Q&A Time**

4.30 **Round Table & Q&A Time**
Moderator: F. Cicirello
Panelists: J. Drinkwater
K. Patel
S. Singh
F. Trionfera

5.00 **Closure of the day 2**

AGENDA - November 14 - MILAN

SESSION 7. FACILITY DESIGN FOR THE FUTURE ANNEX 1: HOW TO ADDRESS THE REQUIREMENTS?

8.30 **Registration of participants**

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

9.20 Technical speech **Premises - Regulatory point of view: findings and expectations**
Alfonso Annunziata, Senior GMP Inspector Medicinal Products | AIFA

9.45 Case study **Small Volume Parenteral Products multipurpose department: a multilevel approach for Annex 1 remediation plan**
Marco Conti, CEO di C&P Engineering, Pharma D&S Group, a Product Life Group Company

10:10 Technical speech **Aseptic Filling & Lyo under Annex 1 perspective**
Mirko Gabriele, Pharma Innovation and Strategies Advisor, PDA Board of Director, PDA Italy Chapter President-Elect

10.30 **Coffee break & Networking**

11.00 **Round Table & Q&A Time**
Moderator: J. Drinkwater
Panelists: A. Annunziata
M. Conti
M. Gabriele
A. Moon
T. Moore

SESSION 8. ADVANCED STERILE IN MANUFACTURING & CONTROLS

11.35 INNOVATION TECHNOLOGIES **introduction**
Silvia Calloni, Project Manager Education & Training | PEC

11.40 Case study **Pharma 4.0 and new Annex 1: aseptc fill&finish robotic application case study**
Andrea Tanzini, Local Head of Business - Pharma & Medical - Italy | Staubli Robotics
Filippo Parini, Area Sales Manager | STERILINE

12.00 pm Technical speech **Automated detection of Mold: how to improve product quality, safety and efficiency with the Growth Direct System**
Steven Higgins, Global Technical Lead Validations | Rapid Micro Biosystem

12.20 Case study **Rapid Microbial Method implemented for fast release of sterile primary packaging containers: a case study**
Greta Franzoso, Quality Compliance Manager/Quality Assurance | Stevanato Group

12.40 Technical speech **Next stage of the Environmental Monitoring, Introduction to advanced automated solutions advantages**
Laurent Leblanc, R&D Manager | bioMérieux Healthcare business

1.00 **Q&A Time**

1.10 **Lunch Break**

WALK THROUGH THE NEW TECHNOLOGIES FOR STERILE MANUFACTURING

SESSION 9. ANNEX 1 WORKSHOP

2.35 **Introduction to the session**
Lucia Costanzo, Senior Conference Manager | PEC & Pharma Microbiology Congress chairperson

2.40 **Technical speech Cleanroom microbiota: What is my data telling me?**
Tim Sandle, Pharmaceutical Microbiologist & Contamination Control Expert -Bio Product Laboratory Limited

3.00 **Technical speech Annex1: Points to consider and the context to interpretation**
Tracy Moore, Director at TM Pharma Group Ltd and former MHRA Expert EU GMDP inspector
Alan Moon, Director of AM GMP Limited and former Lead Senior GMDP Inspector at MHRA

Workshop - Q&A Time to the Experts - MANUFACTURING

3.25 **Introduction to the Workshop**
Fernanda Ferrazin, Life Sciences Expert

Moderator: **Stefano Scorsini,** Experienced Advisor in Industrial Pharmaceutical Technologies and Quality System management / QP and Lead Auditor| Pharma D&S, a Product Life Group Company

Panelists: **J. Drinkwater**
A. Moon
P. Muscas

Workshop - Q&A Time to the Experts - CONTROLS

4.35 *Moderator:* **Gabriele Gori,** SVP Global Quality Operations and Chief Quality Officer | Biogen International GMBH, Chair Science Advisory Board PDA

Panelists: **F. Boschi**
L. Ceresa
T. Moore
T. Sandle

5.30 **Closure of congress**

14 November
Venue
HOTEL MELIÁ *****
Milan

CONFIRMED SPEAKERS

Tiziana Archilletti
Quality Unit Director | Biomedica Foscama and Special Product's Line

Alessandra Benassi
Microbiology and Sterility Assurance specialist | IMA

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

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

Adriana Elsa Cotti
Consultant Quality Expert & QP | C&P Engineering - Pharma D&S Group, a Product Life Group Company

Walid El Azab
Industrial Pharmacist and Qualified Person

Fernanda Ferrazin
Life Sciences Expert

Greta Franzoso
Quality Compliance Manager/-Quality Assurance | Stevanato Group

Mauro Giusti
Senior Director Parenteral Technical Knowledge | Eli Lilly Italia, President PDA Italy Chapter

Gabriele Gori
SVP Global Quality Operations and Chief Quality Officer | Biogen International GMBH, Chair Science Advisory Board PDA

Steven Higgins
Global Technical Lead Validations | Rapid Micro Biosystem

Isabelle Hoenen
Quality Advisor for Sterility Assurance | Eli Lilly France

Alfonso Annunziata
Senior GMP Inspector Medicinal Products | AIFA

CONFIRMED SPEAKERS

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

Andrea Stefano Ivaldi
Product Marketing and Business Development Manager | COPAN

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

Vimal Sachdeva
Senior GxP Inspector at World Health Organization

Laurent Leblanc
R&D Manager | bioMérieux Healthcare business

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

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

Stefano Scorsini
Experienced Advisor in Industrial Pharmaceutical Technologies and Quality System management / QP and Lead Auditor| Pharma D&S, a Product Life Group Company

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

Elena Secchi
Technical Sales Representative | Associates of Cape Cod, Inc.

Di Morris
Qualified Person/ Quality Compliance Advisor | PNR Pharma Consulting Ltd., PHSS Vice-Chair

Michele Simone
Corporate Quality Director | Bracco Group, PDA Regulatory Affairs and Quality Assurance Board (RAQAB) member.

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

Satyakam Singh
Director, Head of Cell Therapy Process and Analytical Development |Simnova Biotechnology

Filippo Parini
Area Sales Manager | STERILINE

Matthew Stevenson
European Sales Manager | Associates of Cape Cod, Inc.

CONFIRMED SPEAKERS

Krisha Patel
Co-Founder of Assurea LLC

Andrea Tanzini
Local Head of Business - Pharma & Medical - Italy | Staubli Robotics

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

Filippo Trionfera
Quality Operation Manager & Qualified Person | BSP Pharmaceuticals, PDA Italy Chapter

Andrea Pranti
Qualification Transformation Engineering Manager | GSK Vaccines

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

Mirko Gabriele
Pharma Innovation and Strategies Advisor, PDA Board of Director, PDA Italy Chapter President-Elect

Antonio Pierno
Senior Manager – SLS - MSAT filtration team | Cytiva

INNOVATION TECHNOLOGIES

webinars

November 8th

11:15 - 11:35	Biomérieux **Simplifying bacterial endotoxin testing: unveiling the power of recombinant factor C**	Mesalabs **Moist heat sterilization - What are the requirements of a Regulatory Agency for an Overkill cycle?** Maria Luisa Bernuzzi
02:05 - 2:25	Copan **Automatic way for reading of environmental plates and imaging analysis. Streamline the microbiological quality control and secure the safety of your products.** Andrea Stefano Ivaldi	Tecninox **RABS, nothing new, but some innovative news** Simone Penazzi
2.30 - 2.50	Rapid Micro Biosystems **Know it Before You Grow It: Case Studies and Approaches Using RMBNucleus Mold Alarm** Danielle DeCesaro	BD **How to reduce the risk of contamination with safe and rapid transfer of settle plates into isolator** Marijke Van Rumst

INNOVATION TECHNOLOGIES

webinars

November 9th

11:35 - 11:55	IMA Life **Injecta: full robotic solution for flexible and high-speed vials and syringes filling** Stefano Specchia	Associates of Cape Cod, Inc. **Innovation in Bacterial Endotoxin Testing – from animal based to proven synthetic option** Veronika Wills
02:15 - 02:35	VAI **Modern and effective solutions designed for pharma – breaking news from Veltek** Paola Lazzeri	Charles River **Application of Next Generation Sequencing for microbial identification, typing and profiling.** Lauren Salvitti
02:40 - 03:00	Particle Measuring Systems **Mastering Continuous Microbial Monitoring: Annex 1-2022 Compliance In Practice** Giulia Artalli Daniele Pandolfi	Steriline **Fill & Finish: Machine for Gene Therapy (ATMP) Technical agility & flexibility for small / tiny batches** Matteo Tagliabue

ENTRY FEES

	Face to Face only	Virtual only	Virtual + Face to Face November, 8 - 9 - 14
Early bird	400 €	725 €	1050 €
Full Price	450 €	800 €	1250 €

Early bird fees expire on October 8th

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
(+39) 055 7224076
FAX (+39) 055 7227014

REGISTER HERE

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.

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.

PARTICIPANT 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 course/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
A ProductLifeGroup Company

TO STAY UPDATED ON
OUR COURSES FOLLOW US ON