PEC PHARMA EDUCATION CENTER

Pharma Microbiology Congress 2021

November 15 – 18 | ONLINE

#PMC2021

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 practice 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.

A BRAND NEW FORMAT

PMC doubles up! ***4 days of virtual conference*** with speeches, keynote lectures, panel discussions and round tables.

GET UPDATED ON THE LATEST TECHNOLOGIES AND TECHNOLOGICAL ADVANCES

Each day, ***3 hours dedicated to new technologies*** and technological advances that are changing the world of sterile manufacturing. Get the chance to watch webinars, interviews and demonstrations, and chat with real experts of the field.

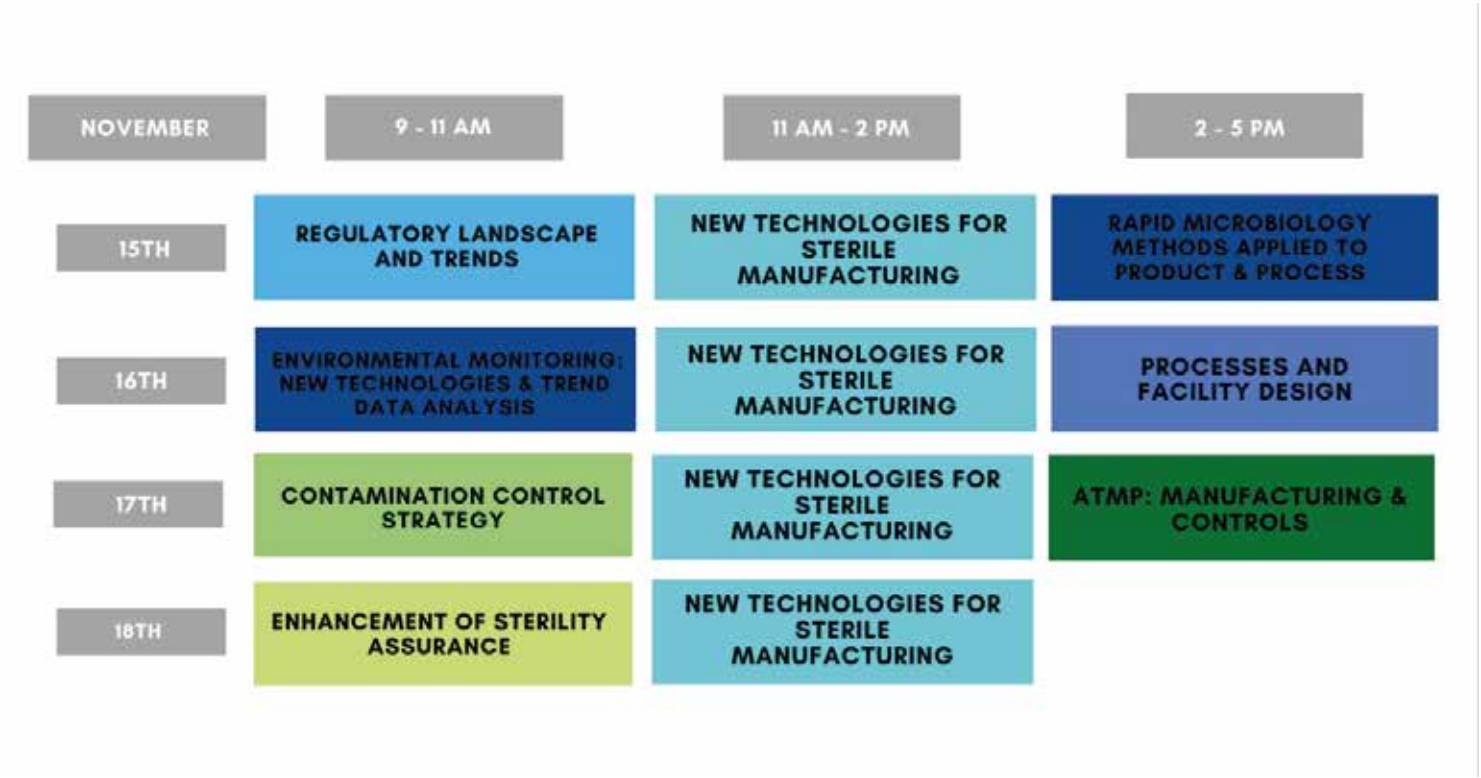
Discover the program!

GET INVOLVED IN THE DISCUSSION

More panel discussions and more round tables to really make you part of the discussion with the speakers: ask questions, rate the ones coming from the audience and let us know what is important for you.

FOLLOW THE ROAD TO #PMC2021

The initiative ***ROAD TO #PMC2021*** 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 event and don't miss them!



AGENDA - NOVEMBER 15

UTC+1

TIME	SESSION 1 - REGULATORY LANDSCAPE AND TRENDS		
09.00 am	**Welcome and introduction**		**Congress Chairperson - Pharma Education Center**
09.10	Introduction by the Moderator of the Session	**The Regulatory Landscape and sterile manufacturers challenges**	**Gabriele Gori**, VP, *Head of Global Audit & Risk Management, Global Quality* - ***GSK***, *Vice-Chair, PDA Science Advisory Board*
09.20	Technical speech	**Implementing Annex 1 revision: advocacy and governance of managing new requirements and changes**	**Julian Kay,** *Director Sterile Processing and Microbiology, Biopharm and Sterile Supply Chain Quality* - ***GSK***
09.45	Technical speech	**Full implementation of QRM through Annex 1**	**Andrew Hopkins**, *Director of Compliance* - ***Abbvie***, *former MHRA Inspector*
10.10	Round Table + Q&A Session	**Sterile manufacturing regulatory expectations and outcomes**	Moderator: **G.Gori** Panelists: **J. Drinkwater** - *PHSS*, **A. Hopkins**, **J. Kay**, **Di Morris** - Astrazeneca, **Luisa Stoppa** - AIFA
From 11:00 on	Innovation technologies	**Many interactives webinars focused on the new technologies and presented by KOLs/Technicians/Experts**	**KOLs/Technicians/Experts** GO

TIME	SESSION 2 - RAPID MICROBIOLOGY METHODS APPLIED TO PRODUCT AND PROCESS		
02.00 pm	Introduction by the Moderator of the Session	**Regulatory Updates and Current Perspectives for the Validation and Implementation of Rapid Methods**	**Michael J. Miller,** President *Microbiology Consultants* - ***LLC***
02.40	Technical speech	**Reduced time to result with a Rapid Detection system: validation and statistical analysis**	**Tim Sandle**, *Head of Microbiology* - ***Bio Products Laboratory Limited***
03.00	**Q&A TIME**		
03.05	Technical speech	**First final release test of ATMPs prior to treatment – Validation of a qPCR-based rapid sterility test**	**Kai Neseman,** *Product Manager* - ***Sartorius***
03.25	**Q&A TIME**		
03.30	Technical speech	**Real-time microbial detection of air integrated in a complex system solution providing data analysis comparable on view of upcoming Annex1**	**Gaia Malpocher,** *Microbiology Product Manager* - ***Rigel Life Sciences***
03.50	**Q&A TIME**		
03.55	Case Study	**The challenge of implementing a Rapid Microbiology Method in a production line with a traditional monitoring system**	**Luca Pezzano** *Operations Director, Mechanical Engineer & MBB* ***IBI Lorenzini S.p.a.***
04.15	**Q&A TIME**		
04.20	Round Table + Q&A Session	**Rapid microbiological methods: opportunities and new challenges for the manufacturers**	Moderator: **M. J. Miller** Panelists: **G. Malpocher**, **K. Neseman**, **L.Pezzano**, **T. Sandle**
05.00	**End of day 1**		

AGENDA – NOVEMBER 16

UTC+1

TIME	SESSION 3 - ENVIRONMENTAL MONITORING: NEW TECHNOLOGIES AND TREND DATA ANALYSIS		
09.00 am	Introduction and technical speech	**A phased approach to environmental classification and qualification leading towards routine environmental monitoring**	**Suzanne Nutter,** *QA Group Manager* - ***AstraZeneca***
09.25	**Q&A TIME**		
09.30	Case Study	**Generation and interpretation of trends in environmental microbiological monitoring**	**Francesca Coltri**, *Senior Microbiologist* - ***ACS Dobfar Verona*** **Damiano Zin**, ***Biotrends*** *Manager*
09.50	**Q&A TIME**		
09.55	Technical speech	**Updates on Process and Environmental Monitoring Methods - PEMM (USA) and Biophorum Group (Europe), workstream PAT Monitoring & Control**	**Gilberto Dalmaso**, *Microbiologist & Quality Assurance expert, Consultant*
10.10	Case Study	**Benefits of using Axcess® System for microbial identifications of bacteria and fungi by MALDI-TOF in the QC microbiological laboratory**	**Alessandro Gasparella**, *Environmental Monitoring Manager* - ***Corden Pharma***
10.30	**Q&A TIME**		
10.35	**Round Table + Q&A Session**	**Environmental monitoring: strategies and technologies for the control/process improvement**	Moderator: **S. Nutter** Panelists: **Karen Capper**-*Astrazeneca*, **Lucia Ceresa** - *VP PDA Italy Chapter*, **F. Coltri**, **G. Dalmaso, A. Gasparella**, **D. Zin**
From 11:00 on	Innovation technologies	**Many interactives webinars focused on the new technologies and presented by KOLs/Technicians/Experts**	**KOLs/Technicians/Experts** GO

TIME	SESSION 4 - PROCESSES AND FACILITY DESIGN		
02.00 pm	Introduction by the Moderator of the Session	**The sterile manufacturing challenges in the processes and facility design**	**Mauro Giusti,** *Director, Technical Services/Mfg Sciences* - ***Eli Lilly***
02.10	Technical speech	**Contamination and Cross Contamination Control for the design of Aseptic Processing**	**Richard Denk**, *Senior Consultant Aseptic Processing & Containment, chair of the* ***ISPE Special Interest Group SIG Future Robotics***
02.35	Case Study	**Pulsed light tunnel: technology and validation**	**Vera Uboldi,** *Project Manager PMP,* ***Steriline***
02.55	**Q&A TIME**		
03.00	Case Study	**Innovative approaches in the design of a new aseptic process for the vaccine production using the state of art technologies**	**Jesus Reyes**, *Plant & engineering director* - ***Liomont*** **Gilberto Dalmaso**, *Microbiologist & Quality Assurance expert, Consultant*
03.20	**Round Table + Q&A Session**	**The future of sterile manufacturing facility: how to meet regulatory requirements and drive innovation**	Moderator: **M. Giusti** Panelists: **G. Dalmaso, R. Denk, F. Parini, J. Reyes, F. Trionfera, V. Uboldi**

AGENDA - NOVEMBER 16-17

UTC+1

03.45	Case Study	**Handling of a complex redesign inside a definite space improving efficiency and quality targets**	**Marco Conti,** *Director* ***C&P Engineering - Pharma D&S Group***
04.05	**Q&A TIME**		
04.10	Case Study	**Onbox-Case study with a focus on Fill-Finish of a Viral Vector and contamination and cross contamination control**	**Vicky Stoyel,** *QA Manager, Projects* - ***Oxford BioMedica***
04.30	**Q&A TIME**		
04.35	**Round Table + Q&A Session**	**The future of sterile manufacturing facility: how to meet regulatory requirements and drive innovation**	Moderator: **M. Giusti** Panelists: **M. Conti, V. Stoyel, Michele Simone** - *Bracco* **Andrea Pranti** - *GSK Vaccines*
05.00	**End of day 2**		

TIME	November 17	SESSION 5 - CONTAMINATION CONTROL STRATEGY	
09.00 am	Introduction by the Moderator of the Session	**Introduction of the session**	**James Drinkwater**, *Head of* ***PHSS Aseptic Processing and Containment Special Interest Group***
09.05	Technical speech	**Published CCS Guidance from the PHSS - AP3 initiative**	**Di Morris**, *Clinical Auditor* - **Astrazeneca**, *former MHRA inspector,* **PHSS CCS Co-Lead**
09.35	Technical speech	**Different strategies for process monitoring for different process applications**	**James Drinkwater**, *Head of* **PHSS** ***(Aseptic Processing and Containment Special Interest Group)***
09.55	**Q&A TIME**		
10.05	Case Study	**Contamination Control Strategy Case Study: GSK CCS deployment strategy**	**Christophe Haentzler** - *Global Director Sterility Assurance Expertise and Knowledge Management* - ***GSK***
10.25	**Q&A TIME**		
10.30	**Round Table + Q&A Session**	**CCS: sharing of different experiences and approaches**	Moderator: **J. Drinkwater** Panelists: **C.Haentzler, Gabriele Gori - *GSK,*** **D. Morris, Michele Simone - *Bracco***
From 11:00 on	Innovation technologies	**Many interactives webinars focused on the new technologies and presented by KOLs/Technicians/Experts**	**KOLs/Technicians/Experts** GO

AGENDA – NOVEMBER 17

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TIME	SESSION 6 - ATMP: MANUFACTURING AND CONTROL		
02.00 pm	Introduction by the Moderator of the Session	**Brief Introduction of ATMP: manufacturing aspects**	**Francesco Cicirello,** *Director, Quality Assurance -* ***Evelo Biosciences***
02.05	Technical speech	**GMP challenges for ATMP manufacturing**	**Francesco Cicirello**, *Director, Quality Assurance -* ***Evelo Biosciences*** **Richard Denk**, *Senior Consultant Aseptic Processing & Containment*
02.30	Technical speech	**New available technologies can shorten the time-to-market of ATMP projects**	**Marco Fadda,** *ATMP Solutions Manager* - **Comecer**
02.50	**Q&A TIME**		
02.55	Technical speech	**Novel isolator solutions to manufacture ATMPs and Biologics**	**Silvia Aldi,** *Product Manager for Cell & Gene Therapy-* ***SKAN AG***
03.15	**Q&A TIME**		
03.20	**Panel discussion + Q&A Session**	**ATMP process: strategies and new manufacturing technologies**	Moderator: **F. Cicirello** Panelists: **S. Aldi, M. Fadda, Simona Guidi** - *ProPharma Group,* **Expert from Pharma ATMP company**
03.45	Introduction by the Moderator of the Session	**Brief Introduction of ATMP: control aspects**	**Francesco Cicirello,** *Director, Quality Assurance -* ***Evelo Biosciences***
03.50	Technical speech	**The biotech revolution: the new concept of sterility assurance**	**Maria Luisa Nolli,** *Co-founder and CEO of* ***NCNbio srl***
04.10	**Q&A TIME**		
04.15	Case Study	**Case Study on Rapid Sterility Testing for ATMP Products**	**Michael J. Miller,** *President, Microbiology Consultants -* ***LLC***
04.35	**Q&A TIME**		
04.40	**Panel discussion + Q&A Session**	**ATMP controls: strategies and control technologies**	Moderator: **F. Cicirello** Panelists: **M. Miller, M. L. Nolli, Massimiliano Petrini** - *QP - IGTF, IRCCS - I.R.S.T.*
05.05	**End of day 3**		

AGENDA – NOVEMBER 18

UTC+1

TIME	SESSION 7 - ENHANCEMENT OF THE STERILITY ASSURANCE		
09.00 am	Introduction by the Moderator of the Session	**Introduction of the session**	**Patrizia Muscas,** *Sterility Assurance Sr Research Scientist Global TS.MS* - ***Eli Lilly and Company***
09.10	Technical speech	**Good Cleanroom Practice**	**Matts Ramstorp,** *Professor, CEO Founder BioTekPro Founder* ***Rentforum,*** *Chief Editor RenaRum QA M Clean Education Cleanroom GMP expert*
09.30	**Q&A TIME**		
09.40	Technical speech	**The new challenge for Pharma: enhancing the effectiveness and robustness of decontamination strategies**	**Paola Lazzeri,** *Technical Sales Manager Europe* - ***Veltek Associates, Inc***
09.55	**Q&A TIME**		
10.00	Technical speech	**No-touch-transfer systems for introducing pre-sterilised primary packaging material into filling isolators: a case study**	**Maria Paola Baini,** *QA Strategic Growth Investment & Engineering Sr. Manager* - ***Lonza Biologics***
10.20	**Q&A TIME**		
10.25	**Round Table + Q&A Session**	**Enhancement of sterility assurance: sharing of experiences**	Moderator: **P. Muscas** Panelists: **M.P. Baini, Francesco Boschi** - ***Pfizer*** **P. Lazzeri, M. Ramstorp,**
From 11:00 on	Innovation technologies	**Many interactives webinars focused on the new technologies and presented by KOLs/Technicians/Experts**	**KOLs/Technicians/Experts** GO
02.00 pm	**End of the congress and greetings by Pharma Education Center Team**		

Stay tuned to discover all the webinars of the "Innovation Technologies" session!

Join the LinkedIn event by clicking here
Updates coming soon...

CONFIRMED SPEAKERS

Andrew Hopkins
Director of Compliance at Abbvie, former MHRA Inspector

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

Michael J. Miller
PhD, President, Microbiology Consultants - LLC

Francesco Cicirello
Director, Quality Assurance - Evelo Biosciences

Gabriele Gori
VP, Head of Global Audit & Risk Management, Global Quality - GSK, Vice-Chair, PDA Science Advisory Board

Richard Denk
Senior Consultant Aseptic Processing & Containment, chair of the ISPE Special Interest Group SIG Future Robotics

Christophe Haentzler
Global Director Sterility Assurance Expertise and Knowledge Management - GSK

Tim Sandle
Ph.D, Head of Microbiology - Bio Products Laboratory Limited

Di Morris
Clinical Auditor - AstraZeneca, former MHRA Inspector, PHSS CSS Co-Lead

Luisa Stoppa
Senior GMP Inspector - AIFA

Gilberto Dalmaso
Microbiologist & Quality Assurance expert, Consultant

Julian Kay
Director, Sterile Processing and Microbiology, Quality for the Sterile and Biopharm Supply Chain - GSK

Andrea Pranti
Qualification Transformation Engineering Manager - GSK Vaccines

CONFIRMED SPEAKERS

Matts Ramstorp
Professor, PhD CEO Founder BioTekPro
Founder Rentforum Chief Editor
RenaRum QA M Clean Education
Cleanroom GMP expert

Filippo Trionfera
Quality Operation Manager
& Qualified Person -
BSP Pharmaceuticals

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

Karen Capper
Head of Microbiology Product
Development - AstraZeneca

Kai Nesemann
Product Manager - Sartorius

Lucia Ceresa
Senior Technology and Market
Development Manager -
Charles River Laboratories,
PDA Italy Chapter Vice President

Michele Simone
Corporate Quality Director at Bracco

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

Gaia Malpocher
Microbiology Product Manager -
Rigel Life Sciences

Jesus Reyes
Plant & Engineering Director -
Liomont

Suzanne Nutter
QA Group Manager - Astrazeneca

Marco Fadda
ATMP Solutions Manager -
Comecer

Massimiliano Petrini
QP - Immuno-Gene Therapy Factory
(IGTF), IRCCS Istituto Romagnolo
per lo Studio dei Tumori
Dino Amadori (I.R.S.T.)

CONFIRMED SPEAKERS

Maria Paola Baini
QA Strategic Growth Investment & Engineering Sr. Manager

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

Silvia Aldi
Product Manager for Cell & Gene Therapy - SKAN AG

Luca Pezzano
Operations Director, Mechanical Engineer & MBB - IBI Lorenzini S.p.a.

Damiano Zin
BioTrends Manager

Vicky Stoyel
QA Manager, Projects - Oxford BioMedica

Vera Uboldi
Project Manager, PMP Steriline

Paola Lazzeri
Technical and Sales Manager - Veltek Associates, Inc.

Maria Luisa Nolli
Co-founder and CEO of NCNbio srl

Simona Guidi
Senior Consultant, Product Lifecycle Management,
ATMP Subject Matter Expert - ProPharma Group

Alessandro Gasparella
Environmental Monitoring Manager - Corden Pharma

Francesca Coltri
Senior Microbiologist - ACS Dobfar

Francesco Boschi
Global Quality Sterile Injectables MAS - Microbiological and Aseptic Support
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ENTRY FEE

850€ until October 15

500€ freelance professionals, University & Research Centers

1250€ full price

VAT not included

Discounts are not cumulative

For multiple registrations contact: info@pharmaeducationcenter.it

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 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

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HOW TO REGISTER
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