

Challenges & Innovations in Sterile Manufacturing

With simultaneous
translation in
English and Italian

#PMC2020

ONLINE
November 12 - 13, 2020

Pharma Microbiology Congress 2020

Giornate di Microbiologia

www.pharmamicrobiologycongress.com

PEC PHARMA
EDUCATION
CENTER



ABOUT

The **PHARMA MICROBIOLOGY CONGRESS** is the European evolution of the Italian "**Giornate di Microbiologia**", born 12 years ago with the aim of creating an annual meeting where the community of microbiology/sterility assurance experts and pharma professionals share the latest updates on **regulatory trends, innovative technologies and best practices** applied to the manufacturing and control of sterile API and medicinal products.

JOIN US TO DISCUSS THE LATEST NEWS ON ANNEX 1 REVISION & TECHNICAL INNOVATIONS

The long process of revision EU GMP Annex 1 for Manufacture of Sterile medicinal is approaching the end; therefore, it becomes very important to get an in-depth analysis of key points with the involvement of Annex1 experts, opinions leaders and regulatory body representatives.

2 DAYS OF CONGRESS

TO:

- **discuss technical & regulatory news** with sterility assurance experts from Italy and Europe.
- **meet professionals** from international Companies
- **become aware of the opportunities** offered by new technologies
- **get and share technical knowledge and strategies** about the future of the sterile manufacturing.

PLENARY SESSION

- 12** Technical speeches
- 10** Q&A time
- 8** Multimedial contents
- 4** Round tables
- 2** Lecture
- 26** Speakers

WHO SHOULD ATTEND?

Pharma, Biotech and Medical devices Industries
Regulatory Bodies
Technology Suppliers
Microbiology Laboratories
Academics

AGENDA 12th

09:00 **Welcome and Introduction**
Chairperson PEC
Lucia Costanzo, *Senior conference Manager*

1. ANNEX 1 REVISION & INSPECTION TRENDS IN STERILE MANUFACTURING

Chairperson: **Gabriele Gori**, *VP, Head of Global Audit and Risk Management - Quality GSK Vaccines, Science, PDA Science Advisory Board member*

09:20 **Key points identified in revision of Annex 1 Version 12 through the Targeted Consultation process via appointed commenting platforms**
James Drinkwater PHSS: *Pharmaceutical & Healthcare Sciences Society Head of Annex 1 Focus group.*

09:50 **Inspections Findings in Sterile Manufacturing**
Luisa Stoppa: *Senior GMP inspector - GMP Inspection and Certification Dept. - Italian Medicines Agency - AIFA*

10:20 **Round table & Q&A Time**
Moderator: **G. Gori**, *VP, Head of Global Audit and Risk Management - Quality - GSK Vaccines, Science, PDA Science Advisory Board member*
Participants: **L. Ceresa**, *PDA Italy Chapter*
J. Drinkwater, *PHSS*
Di Morris, *Clinical Auditor at AstraZeneca, former GMP Audit manager and MHRA Inspector*
L. Stoppa, *AIFA*

11:00 **Coffee break & networking**

2. INNOVATION TECHNOLOGIES IN STERILE MANUFACTURING CONTROLS

Chairperson: **Andrea Pranti**, *Qualification Transformation Manager - GIO Engineering at GSK Vaccines*

11:40 **ANNEX1 seen from the microbiological point of view: which challenges, what changes, which solutions to use**
Gilberto Dalmaso, *Pharma and Medical Devices Consulting Owner at GDM Pharma Consulting*

12:05 **Q&A**

AGENDA 12th

- 12:10 **MAT implementation: from validation to use in routine in a GMP QC Lab**
Chiara Celli, *Scientist - Biotech Process Applications Global Healthcare Operations - Merck RBM S.p.A.*
- 12:35 **Q&A**
- 12:40 **Lunch & networking**
- 14:10 **Sterility Test: why is the right time to implement the RMM?**
Lucia Ceresa, *Senior Technology and Market Development Manager Microbial Solutions, Charles River*
- 14:35 **Q&A**
- 14:40 **Total particles environmental monitoring system on the view of upcoming EU GMP Annex 1 guideline**
Diego Bompadre, *Sales Manager - RIGEL*
- 15:05 **Q&A**
- 15:10 **Round table**
The Future in Sterile manufacturing Controls *discussion with the involvement of Speakers and participants*
Moderator: **A. Pranti**, *GSK Vaccines*
Participants: **D. Bompadre**, *RIGEL*
C. Celli, *MERCK RBM*
L. Ceresa, *CRL*
G. Dalmaso, *GDM Pharma Consulting*
- 15:40 **Coffee break & networking**
- 16:10 **LECTURE SESSION - Missteps - EMA Annex 1 Sterile Medicinal**
James Agalloco, *Sterilization and sterile process expert, USP's Microbiology Committee member, Agalloco & Associates CEO*
- 16:40 **Q&A Session**
- 16:55 **Chairman's closing remarks**
Gabriele Gori, VP, *Head of Global Audit and Risk Management - Quality - GSK Vaccines, Science, PDA Advisory Board member*
- 17:00 **End of day one**

AGENDA 13th

09:00 **Welcome**
Chairperson PEC
Lucia Costanzo, *Senior conference Manager*

3. PHARMA 4.0: AUTOMATION AND ADVANCED ASEPTIC MANUFACTURING TECHNOLOGIES

Chairperson: Michele Simone, *Director, Corporate Quality Management, Quality Risk Management & Continual Improvement- Bracco Corporate; Co-Chair PDA Interest Group "Quality System"*

09:20 **Empowering an innovative, advanced aseptic robotic filling technology with no human intervention and a new environmental monitoring approach**
Claudio Bechini, *Managing Director - Pharma Integration*
Cristina Testoni, *Business Development - Pharma Integration*

09:45 **Q&A**

09:50 **Microbio Lab automation: case study of implementation from installation, validation to LIMS connection for data security**
Serge Ohresser, *Sales Director Southern Europe/Asia- Rapid Micro Biosystems*

10:15 **Q&A**

10:20 **Round table**
Pharma 4.0: Innovations and advanced aseptic manufacturing technologies: challenges and opportunities *discussion with the involvement of Speakers and participants*
Moderator: **Michele Simone**, *Bracco Corporate*
Participants: **C. Bechini, C. Testoni** - *Pharma Integration*
M. Giusti, *Eli Lilly, Advisor, Site External Network*
S. Ohresser, *Rapid Micro Biosystems*
Vicki Pearson, *Global Solution Architect - Life Science*
Schneider Electric

11:00 **Coffee Break**

4. INNOVATION TECHNOLOGIES & BEST PRACTICES TO ENHANCE STERILITY ASSURANCE

Chairperson: **Angela Petrigliano**, *Pharmaceutical Senior Consultant at Pharma D&S*

- 11:40 **Sterile Cleanrooms: Protect processes and products from operator's contamination**
Luciano Maggiore - *Kimberly Clark Professional - Scientific Area Manager South Europe*
- 12:05 **Q&A**
- 12:10 **Sterilizzazione in autoclave: scelta dei sistemi di protezione e confezionamento per un processo GMP compliant**
Sara Iacoponi *Pharmaclean Product Specialist AM Instruments*
- 12:35 **Q&A**
- 12:40 **Lunch & networking**
- 14:00 **Round table**
Innovation Technologies & Best Practices to enhance Sterility Assurance: sharing of experiences
Moderator: **Angela Petrigliano**, *Pharmaceutical Senior Consultant at Pharma D&S*
Participants: **S. Lancaster**, *Global Compliance Manager at Novartis AAA*
L. Maggiore, *Kimberly*
P. Muscas, *Sterility Assurance Sr Research Scientist Global TS.MS at Eli Lilly and Company*

5. DESIGN AND IMPLEMENTATION OF THE CONTAMINATION CONTROL STRATEGY: SHARING OF EXPERIENCES

*Chairperson: **Fernanda Ferrazin**, Life Sciences Expert, former GMP Senior Inspector AIFA*

14:40 **Update on PHSS Guidance's "Clarity on GMP" that supports Annex 1 and GMP regulations- CCS case study**

James Drinkwater PHSS: Pharmaceutical & Healthcare Sciences Society
Head of Annex 1 Focus group

15:10 **Q&A**

15:20 **Round table 3**

Contamination Control Strategies: sharing of experiences

Moderator: **Fernanda Ferrazin**, Life Sciences Expert, former GMP Senior Inspector AIFA

Participants: **G. Dalmaso**, GDM Pharma Consulting

J. Drinkwater, PHSS

A. Petrigliano, Pharma D&S

M. Simone, Bracco Corporate

15:50 **Coffee break & networking**

16:20 **LECTURE SESSION - Changes to USP Informational Chapters on Sterilization & Sterility Assurance**

James Agalloco, Sterilization and sterile process expert, USP's Microbiology Committee member, Agalloco & Associates CEO

16:50 **Q&A**

17:00 **Chairman's closing remarks**
Fernanda Ferrazin

17:10 **End of the congress**

SPEAKERS



JAMES AGALLOCO

Sterilization and sterile process expert, USP's Microbiology Committee member, Agalloco & Associates CEO



CLAUDIO BECHINI

Managing Director, Pharma integration



DIEGO BOMPADRE

Sales Manager - RIGEL Life Sciences



CHIARA CELLI

Scientist - Biotech Process Applications Global Healthcare Operations-Merck RBM S.p.A



LUCIA CERESA

Technology & Market Development Manager at Charles River Microbial Solution, PDA Italy Chapter Vicepresident



GILBERTO DALMASO

Pharma and Medical Devices Consulting Owner at GDM Pharma Consulting



JAMES L. DRINKWATER

PHSS: Pharmaceutical & Healthcare Sciences Society Head of Annex 1 Focus group



FERNANDA FERRAZIN

Former Head of Pharmacovigilance Dept. - Italian Medicines Agency, Scientific Board EUPV Congress



MAURO GIUSTI

Advisor, Site External Network, Eli Lilly Italia



GABRIELE GORI

VP, Head of Global Audit and Risk Management - Quality - GSK Vaccines, PDA Science Advisory Board member



SARA IACOPONI

Pharmaclean Product Specialist by AM Instruments

SPEAKERS



SABINA LANCASTER

Global Compliance Manager at Novartis AAA



ANGELA PETRIGLIANO

Pharmaceutical Senior Consultant at Pharma D&S



SERGE OHRESSER

Sales Director Southern Europe/Asia- Rapid Micro Biosystems



ANDREA PRANTI

Qualification Transformation Manager - GIO Engineering at GSK Vaccines



LUCIANO MAGGIORE

Kimberly Clark Professional - Scientific Area Manager South Europe



MICHELE SIMONE

Director, Corporate Quality Management, QRM & Continual Improvement- Bracco Corporate; Co-Chair PDA Interest "Group Quality System"



DI MORRIS

Clinical Auditor at AstraZeneca, former GMP Audit manager and MHRA Inspector



LUISA STOPPA

Senior GMP-Inspector at AIFA



PATRIZIA MUSCAS

Sterility Assurance Sr Research Scientist Global TS.MS at Eli Lilly and Company



CRISTINA TESTONI

Business Development - Pharma Integration

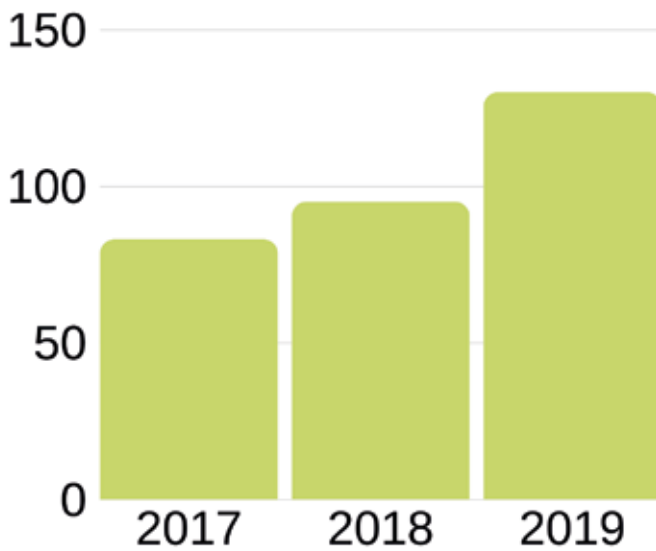


VICKI PEARSON

Global Solution Architect - Life Science - Schneider Electric

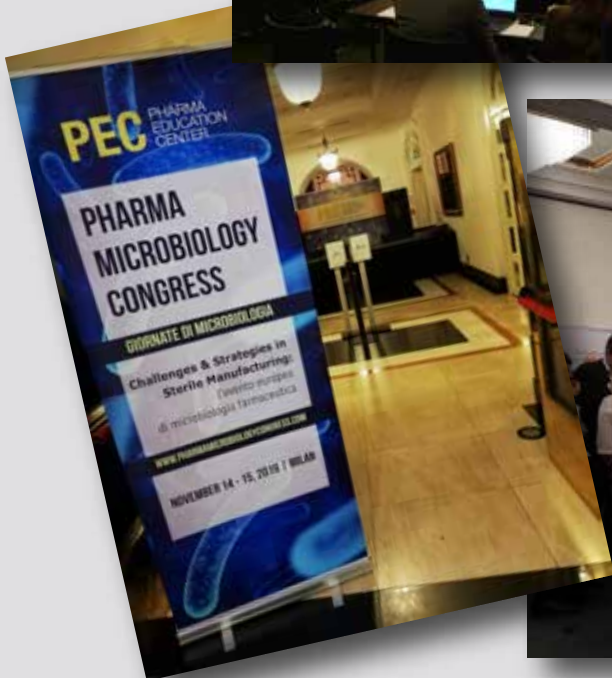
ATTENDANCE

PMC: Attendees/year



LAST EDITION

18	TOPICS
12	EMERGING TECHNOLOGIES EXHIBITION
2	MEDIA partners
20	SPEAKERS
130	ATTENDEES
42	COMPANIES



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MEDIA PARTNER



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ONLINE CONGRESS



HOW TO REGISTER

ENTRY FEE

950 € early bird before September 30th

1050 € early bird before October 31th

1250 € full price

VAT not included

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 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

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.

BOOK NOW

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.pharmamicrobiologycongress.com/>

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