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**

AGENDA 13th

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 **Autoclave sterilization: the selection of protection and packaging systems to a GMP compliant process**
Sara Iacoponi - *Product Specialist Pharmaclean® by 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*

AGENDA 13th

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**
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

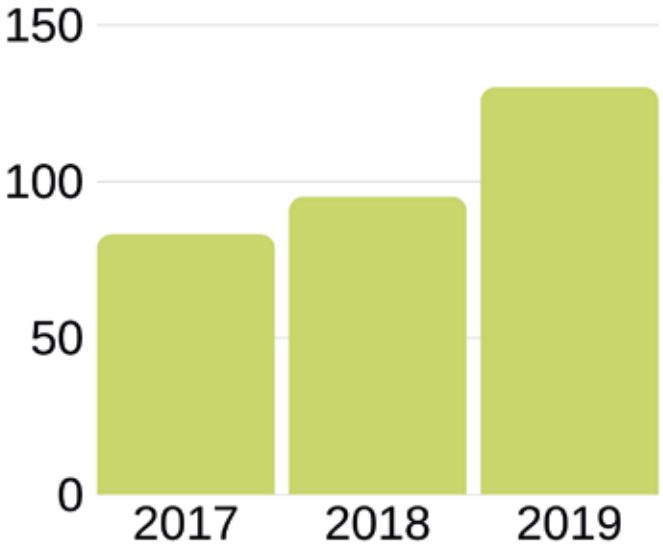
PATRIZIA MUSCAS
Sterility Assurance Sr Research Scientist Global TS.MS at Eli Lilly and Company

VICKI PEARSON
Global Solution Architect – Life Science – Schneider Electric

CRISTINA TESTONI
Business Development – Pharma Integration

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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HOW TO REGISTER

ENTRY FEE

950 € early bird before September 30, 2020
1050 € early bird before October 31, 2020
1250 € full price
VAT not included

BOOK NOW

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 refound 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 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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