

# 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*

# 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
- 5** Round tables
- 2** Lectures
- 24** Speakers

## WHO SHOULD ATTEND?

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

# AGENDA 12<sup>th</sup>

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 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 Advisory Board member*  
Participants: **L. Ceresa**, *PDA Italy Chapter VicePresident*  
**J. Drinkwater**, *PHSS*  
**L. Stoppa**, *AIFA*  
**Speaker** (*tbc*)

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 12<sup>th</sup>

- 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 Life Sciences*
- 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 Life Sciences*  
**C. Celli**, *MERCK RBM*  
**L. Ceresa**, *Charles River*  
**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 13<sup>th</sup>

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, Director, Technical Services/Mfg Sciences*  
**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      **Autoclave sterilization: choosing of the protection and packaging systems to a GMP compliant process**  
**Sara Iacoponi** - *Project manager 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. Iacoponi**, *Pharmaclean® by AM Instruments*

**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



**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



**CLAUDIO BECHINI**

Managing Director, Pharma integration



**FERNANDA FERRAZIN**

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



**DIEGO BOMPADRE**

Sales Manager - RIGEL Life Sciences



**MAURO GIUSTI**

Eli Lilly, Director, Technical Services/Mfg Sciences



**CHIARA CELLI**

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



**GABRIELE GORI**

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



**LUCIA CERESA**

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



**SARA IACOPONI**

Project manager Pharmaclean® 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 Euro-  
pe/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 Mana-  
gement, QRM & Continual Impro-  
vement- Bracco Corporate;  
Co-Chair PDA Interest



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



**LUISA STOPPA**  
Senior GMP-Inspector at AIFA



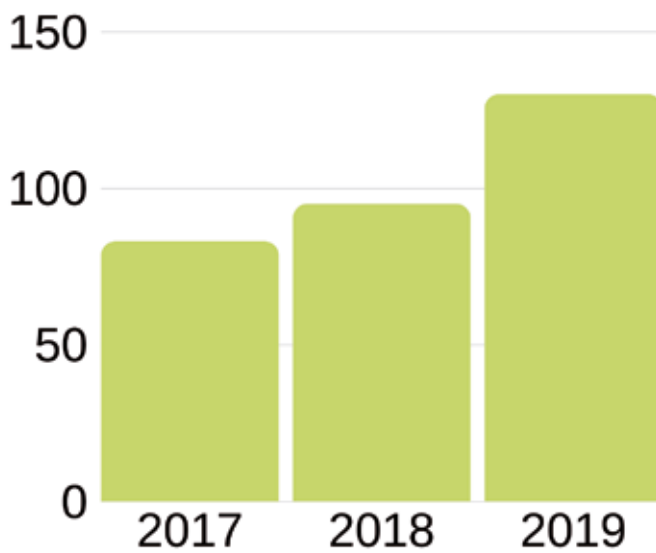
**VICKI PEARSON**  
Global Solution Architect - Life  
Science - Schneider Electric



**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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## SILVER



The Pharma Microbiology Congress 2020 provides an excellent opportunity to get in touch with microbiology/sterility assurance professionals and decision makers.

To sponsor the event, contact us at: [info@pharmaeducationcenter.it](mailto:info@pharmaeducationcenter.it)

## MEDIA PARTNER



# 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](mailto: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](mailto: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](mailto: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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