

[WWW.PHARMAMICROBIOLOGYCONGRESS.COM](http://WWW.PHARMAMICROBIOLOGYCONGRESS.COM)

# PHARMA MICROBIOLOGY CONGRESS

**MILAN, ITALY**

NOVEMBER 14-15, 2019

1st Edition

**Challenges & Strategies in  
Sterile Manufacturing**

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# ABOUT

## **PEC - Pharma Education Center s.r.l**

warmly invites professionals from Pharma Companies to participate at the first Edition of **"PHARMA MICROBIOLOGY CONGRESS"**, that will be held on November 14th-15th 2019, in Milan.

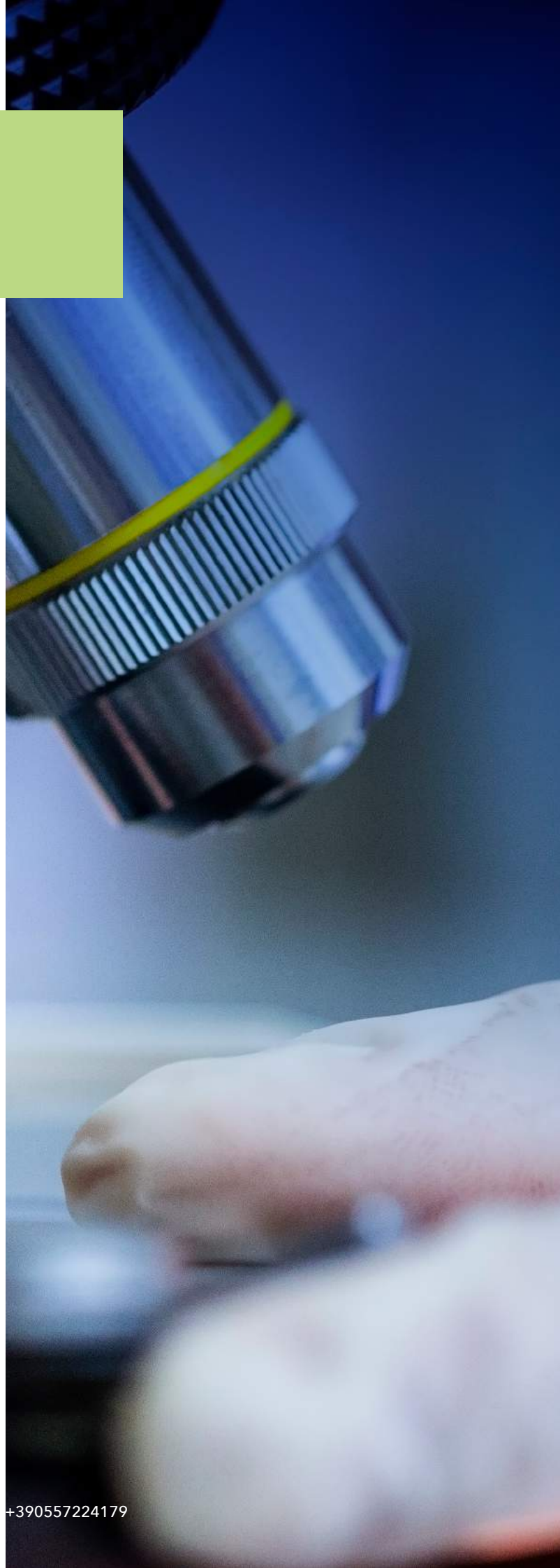
The PMC is the european evolution of the Italian "Days of Microbiology", born 11 years ago with the aim of creating an annual meeting where the community of microbiology experts and pharma professionals share last updates on regulatory trends, innovative technologies and the best practices applied to the manufacturing and control of sterile API and medicinal products.

## **WHY TO ATTEND?**

The involvement of microbiology experts and opinions leaders, regulatory body representatives , new technologies suppliers and consultants from Italy and Europe, made this event unique and highly evaluated by Pharma, Biotech, Medical devices companies and by the technologies Suppliers, for the great opportunity to meet professionals and get and share technical knowledge and strategies about the future of the Sterile manufacturing.

## **WHO SHOULD ATTEND**

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



# SPEAKERS



**Chair Person:**

**Fernanda Ferrazin**

Former GMP Senior Inspector  
- AIFA, Independent Pharma-  
ceutical Consultant

with the participation of Sterile manu-  
facturing experts, representatives of  
PHSS (Pharmaceutical & Healthcare  
Sciences Society), representatives of ste-  
rile manufacturing companies and Sup-  
pliers of new Technologies .

**The 2 day Congress** will offer several  
sessions of oral talks about hot and  
practical topics, case studies, keynotes  
presentations, including round-tables.  
Dedicated exhibit area during the  
coffee break and lunch allow networ-  
king and vision of new and emerging  
technologies.



# TOPICS

## **ANNEX 1 revision: perspectives and future challenges**

Annex 1 revision regulatory expectation and impact on Pharmaceutical Industry.

## **ANNEX 1 revision: Environmental Monitoring and Innovation Technologies**

- Environmental Monitoring: What is changing?
- Agar-free, Continuous Air Monitoring using Unique Gelatin Membrane Filters for Compliant Testing

## **Sterility Assurance controls: Innovation Technologies**

- Monocyte Activation Test (MAT) product validation and comparison to bacterial endotoxin test
- Sterility Testing for Batch Release, Status and Improvement to zero positive false result

## **Sterility Assurance: Best practices**

- Saving opportunity for the QC micro lab by reading the ASP by automatic and semi automatic Visual inspection machine - **case study**
- Microbiological Data Lab Automation - **case study**

## **WORKSHOP – Tech & Material Exhibition**

Vision of new technologies and materials for Sterility Assurance improvements  
Where?: Inside the Foyer at Sponsor's Desk

## **Round table**

**Challenges & Strategies for Sterile manufacturers discussion**  
*with Sterile manufacturing Experts*

## **QbD and new Sterility Assurance concepts applied to the new Facilities/Lines**

- QbD and Innovation technology applied to a new filling line project - case study

## **Contamination Control Strategy & Containment Systems**

- Contamination Control Strategy and Aseptic Containment Strategy
- Preparation of a Contamination Control strategy (CCS): Case study
- Preparation of an Aseptic – Containment strategy (ACS) for processing hazardous potent, biological and therapeutic products
- Containment of the microbiological risk by the custom pharmaceutical packaging
- CCS: are you ready for the future?

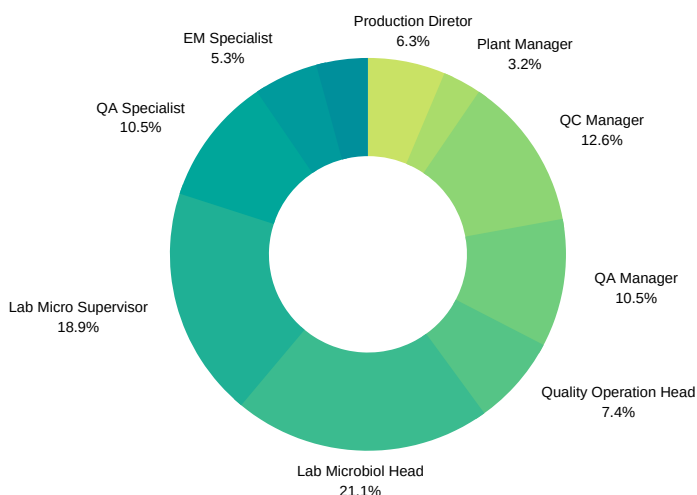
## **Regulatory Inspections in Sterile manufacturing**

Inspections: sharing of experiences with different regulatory Bodies

**Other topics in progress.....**

# HISTORY

## DAYS OF MICROBIOLOGY 2017-2018



## Testimonials....

*Dynamic and interactive, relevant to get ideas to improve Sterility Assurance of our operations.*

**GSK**

*Well organized, with a good level of very interesting presentations and great opportunity to share practices in Sterility assurance.*

**Corden Pharma**



### PHARMA MICROBIOLOGY CONGRESS 2018: LIST of COMPANIES

ABIOTEN , ACS DOBFAR, BAXTER, BD SWITZERLAND, BIEFFE MEDICAL, BSP PHARMACEUTICAL SPA, CATALENT, CHEMI, CHIESI, CORDEN PHARMA, DIASORIN, DOPPEL FARMACEUTICI, ELI LILLY, FABBRI-CA ITALIANA SINTETICI, FACTA FARMACEUTICI, FARMILATHEA, FATRO, GNOSIS BIORESEARCH, GSK, FRESENIUS KABI ITALIA , HAUPT PHARMA, ITALFARMACO, KEDRION, LABORATORIO FARMACEUTICO MILANESE, LABORATORIO FARMACEUTICO SIT, MENARINI, MERCK, OPOCRIN, PATHEON, PFIZER, RECIPHARM, RECORDATI, SANOFI AVENTIS, SHIRE, ZAMBON

# SPONSOR

## GOLD SPONSOR

**MERCK**

 **COMECER**<sup>®</sup>

 **PHARMA D&S**  
PHARMACEUTICAL DEVELOPMENT & SERVICES

 **sartorius**

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 **BIOMÉRIEUX**

## SILVER SPONSOR

  
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## BRONZE SPONSOR

**BioTrends**<sup>™</sup>  
 Software for environmental monitoring

 **PARTICLE MEASURING SYSTEMS**<sup>®</sup>  
a spectris company

## MEDIA PARTNERS

  
**rapidmicrobiology**  
focused on microbiology

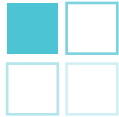
 **microbiologia italia**

# SPONSORSHIP



## BRONZE SPONSOR

- Desk in the foyer within F&B area
- Short Company presentation (2/3 min)
- 1 Hour Tech&Material Exhibition (day 1)
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 1 Free Conference Pass



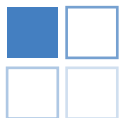
## SILVER SPONSOR

- Desk in the foyer within F&B area
- Short Company presentation (2/3 min)
- 1 Hour Tech&Material Exhibition (day 1)
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 2 Free Conference Pass



## GOLD SPONSOR

- 1 Technical Speech agreed with the provider (25 min)
- Desk in the foyer within F&B area
- Short Company presentation (2/3 min)
- 1 Hour Tech&Material Exhibition (day 1)
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 4 Free Conference Pass
- List of participants
- Company logo slideshare during the breaks

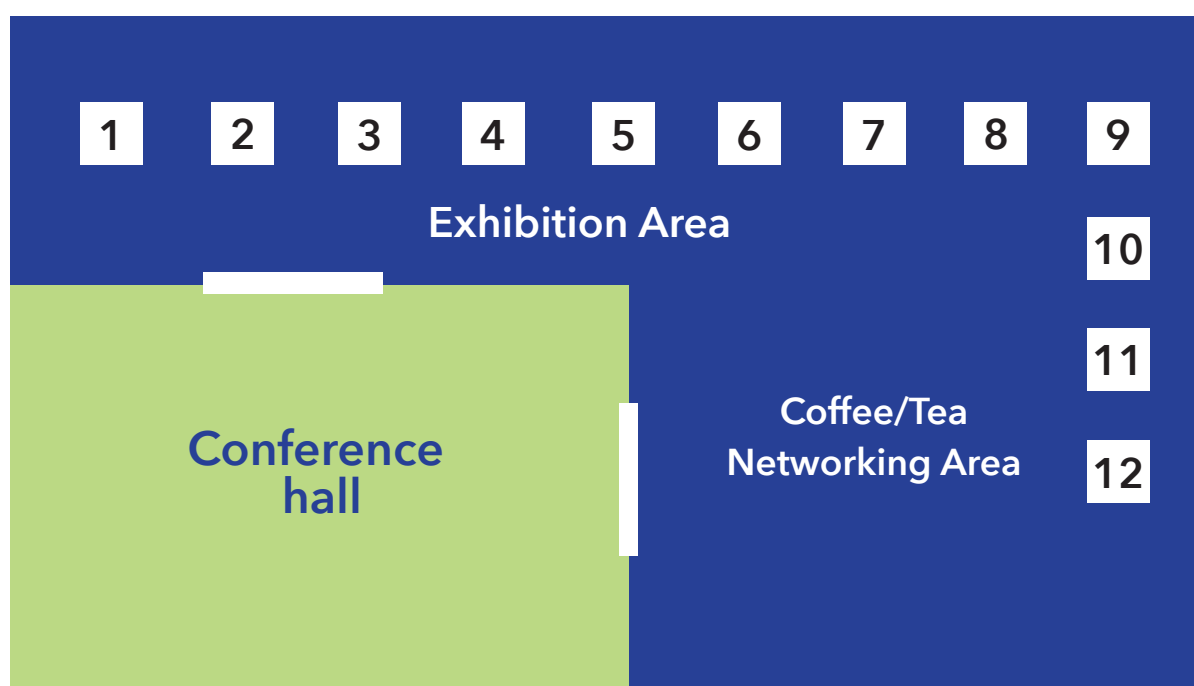


## PLATINUM SPONSOR

- 1 Technical Speech agreed with the provider (25 min)
- Desk in the foyer within F&B area
- Short Company presentation (2/3 min)
- 1 Hour Tech&Material Exhibition (day 1)
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 4 Free Conference Pass
- List of participants
- Company logo slideshare during the breaks
- Banner Roll up at the top of the Congress Room
- Coffee break sponsored by your Company

# FLOOR PLAN

Book your Desk inside the Exhibition area (400m<sup>2</sup>)!!!



For further information on Sponsorship Opportunities, please contact  
Lucia Costanzo  
Conference Senior Manager  
phone: + 39 3480094076  
[lcostanzo@pharmaeducationcenter.it](mailto:lcostanzo@pharmaeducationcenter.it)

**Note:** The floorplan is subject to change at the discretion of the organisers



# CONGRESS VALUE



## Hotel Melia

is perfectly located in the most dynamic district in Milan, a short walk from CityLife, just 15 minutes away from the historical city centre, using the nearby subway.

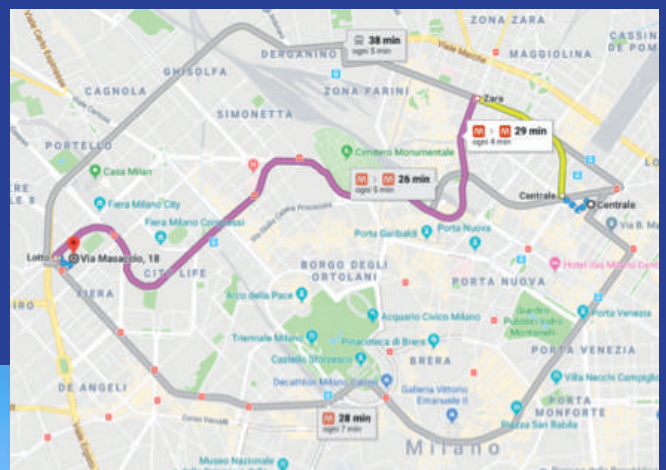
Address  
Via Masaccio 19  
Milano

Contact  
Tel (39) 02444061  
Fax (39) 02444066

PEC Staff will organize in the relaxing area of Melià at the end of first day course, on 14<sup>th</sup> evening (6,45 pm), a refreshment and aperitif for Speakers and delegates!!

Don't forget to book your seat for evening Aperitif!!

How to reach the Hotel by subway (Metro) from Milan Central Station



# ENTRY FEE

## ENTRY FEE

€ 1750

Save 200 € for 2 day full immersion course  
by 14 September 2019

## Multiple registrations

15% discount on the 2nd member  
20% discount on the 3rd member

## 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 Pratonì 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.

**PEC** PHARMA  
EDUCATION  
CENTER

## 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.eupharmacovigilance.com/>, or fill the form and submits by email to info@pharmaeducationcenter.it.

A confirmation email will be sent to confirm the registration.

**Aperitif & refreshments 14<sup>th</sup>**

Yes  No

COMPANY			
ZIP	TOWN	ADDRESS	COUNTRY
PHONE	FAX		
VAT NUMBER			
SURNAME	NAME	PHONE	
E-MAIL	COMPANY'S ROLE/POSITION		
E-MAIL to send invoice	DEGREE/QUALIFICATION		

**PROTECTION OF PERSONAL DATA - INFORMATION** In accordance with Legislative Decree 196/2003 and with article 13 of 2016/679 UE Regulation, the information provided will be processed for the purpose of administrative management of courses (accounting, logistics, directory training). The data may be used for the creation of an archive for the purpose of sending proposals for future courses and study initiatives. Our Privacy Policy is available on the site: [www.pharmaeducationcenter.it](http://www.pharmaeducationcenter.it).