



Associazione Farmaceutici Industria
Società Scientifica



Italy
Chapter

Annex 1

One year later

Palazzo dei Congressi, Firenze
18/19 September 2024

INTRODUCTION



The final version of Annex 1 entered into force on 25 August 2023, with the exception of point 8.123 (Freeze Drying), which will be effective from 25 August 2024. At last year's event, changes and new requirements deriving from the need to comply the updated Annex 1 within the established timeframe were discussed.

The challenge, to which the pharmaceutical industry had to respond, finding solutions and resources in a short time, however includes the interpretation of some requirements which have cast some doubts and opened long debates both among industrial representatives and the regulatory agencies.

AFI and **PDA Italy Chapter** are organizing a new two-day event in Florence, with the aim of analyzing the progress and diversified measures that companies have implemented to respond to the quality demands of sterile medicinal products.

The workshop formula, which combines the phase of frontal presentations with that of active participation and discussion of the participants divided into working groups, is confirmed.

Representatives from international regulatory agencies and speakers with international and strong knowledge on aseptic processes will share their highly significant experience in the interpretation of the requirements and their planned or ongoing application, giving the working groups inspiration to develop a productive discussion, and will be available to reply to any question coming from the attendees.

All the elements previously highlighted make the event original, extremely interesting and recommend your presence.





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ORGANIZING COMMITTEE

- | | |
|-----------------------------|---|
| • Marco Adami | AFI |
| • Claudia Bianchi Carnevale | AFI / Pfizer |
| • Francesco Boschi | AFI / Pfizer |
| • Giorgio Bruno | Presidente AFI |
| • Lucia Ceresa | AFI / PDA Italy Chapter |
| • Giovanni Cosmi | AFI / PDA Italy Chapter / Cosmi Consulting |
| • Orazio Cultrera | AFI/ PDA Italy Chapter / Cultrera Consulting |
| • Francesco Esposito | PDA Italy Chapter / Merck |
| • Mirko Gabriele | PDA Italy Chapter President |
| • Mauro Giusti | PDA Italy Chapter Past-president / Lilly |
| • Piero lamartino | AFI |
| • Gabriele Peron | PDA Italy Chapter / Stevanato Group |
| • Lino Pontello | AFI |
| • Claudio Puglisi | PDA Italy Chapter / Entourage |
| • Alessandro Regola | AFI |
| • Francesca Selmin | AFI / PDA Italy Chapter/UniMi |
| • Michele Simone | PDA Italy Chapter / Bracco Suisse SA |
| • Filippo Trionfera | PDA Italy Chapter President elect / BSP Pharmaceuticals |





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PRELIMINARY PROGRAM

FIRST DAY 18 SEPTEMBER 2024

10:00-10:30 **Registration and Welcome Coffee at the Sponsor area**

10:30-10:45 **Welcome and congress introduction**
• Giorgio Bruno - Mirko Gabriele

10:45-11:15 **Summary of survey results**
• F. Boschi - F. Selmin

Session 1: REGULATORY UPDATES

• O. Cultrera - A. Regola

11:15-11:45 **Annex 1: how its implementation looks like after one year from its enforcement. The industry point of view**
• Gabriele Gori - PDA

11:45-12:15 **Annex 1 under FDA perspective**
• Michael Shanks - FDA

12:15-12:45 **Working groups - Session 1**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

12:45-13:15 **Q&A: Panel Discussion**

13:15-14:15 **Networking lunch**

Session 2: QRM & CCS

• G. Cosmi - M. Simone

14:15-14:35 **Implementation of CCS strategy within Annex 1 requirements**
• Barbara Ambruosi - Sara de Pinto - Merck, Bari Plant

14:35-15:05 **QRM principles applied to CCS preparation including CCS business cases covering sterile pharmaceutical medicinal product manufacturing, Biologics and ATMPs**
• Di Morris - PNR Pharma & James Drinkwater - Franz Ziel GmbH

15:05-15:35 **A practical example of QRM for a PUPSIT case study**
• Claudia Rinaldi - GSK

15:35-16:05 **Working groups - Session 2**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

16:05-16:35 **Q&A: Panel Discussion**

16:35-17:05 **Coffee Break in the Sponsor Area**

Session 3: BARRIERS

• M. Giusti - F. Trionfera

17:05-17:25 **Process of packaging and transferring equipment to the cleanrooms& barriers: a case study**
• Toni Valente - Giovanna Spampanato - Pierrel

17:25-17:45 **Gloves management in barrier systems: case study**
• Patrizia Muscas - Lilly

17:45-18:05 **Indirect contact parts in filling operations: sterilization material transfer and set up**
• Fabrizio Gelli - GSK Siena

18:05-18:35 **Working groups - Session 3**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

18:35-19:05 **Q&A: Panel Discussion**

19:05-19:15 **Closing Remarks**
• Giorgio Bruno - Mirko Gabriele

19:15-22:00 **Networking Dinner**





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PRELIMINARY PROGRAM

SECOND DAY 19 SEPTEMBER 2024

08:30-09:00 **Registration and Welcome Coffee at the Sponsor area**

09:00-09:10 **Welcome & short summary of DAY-1 event**
• Giorgio Bruno - Mirko Gabriele

Session 4: UTILITIES/FILTRATION
• F. Esposito - L. Pontello

09:10-09:40 **Sterilizing filtration for filled syringes**
• Simona Carosella - IBSA

09:40-10:10 **Implementation of an in-place sterilizable system for peristaltic pumps**
• Cristina Trovò - Haupt Pharma (Aeno-va Group)

10:10-10:30 **Integrity Assurance of Final Sterile Filtration Process Step Using Single-Use Technology**
• Nicola Rutigliani - Production Associate Director Merck Healthcare

10:30-11:00 **Working groups - Session 4**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

11:00-11:30 **Q&A: Panel Discussion**

11:30-12:00 **Coffee Break in the Sponsor Area**

Session 5: EM & APS
• F. Boschi - L. Ceresa

12:00-12:30 **Environmental Monitoring Performance Qualification in New Facilities: Overview and Application of an Industry Harmonized Approach**
• Anna Campanella - Takeda

12:30-13:00 **Holistic approach for Aseptic Process Simulation activities**
• Andrea Pranti - GSK

13:00-13:30 **Working groups - Session 5**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

13:30-14:00 **Q&A: Panel Discussion**

14:00-15:00 **Networking lunch**

Session 6: LYOPHILIZATION
• F. Selmin - M. Adami
C. Bianchi Carnevale

15:00-15:20 **A qualified method for stopper height detection in lyophilised product: a step towards Annex1 CCI compliance**
• Simon Mills - Ipsen Biopharm Limited

15:20-15:50 **Influence of Annex 1 update on lyo operations**
• Bert Van Meervenue - Pfizer

15:50-16:20 **Case Study: Annex 1 upgrade of existing Lyophilization plant at**
• Enrico Capogna - Sanofi - Anagni
• Johan de Hoon - Ima Life

16:20-16:50 **Working groups - Session 6**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

16:50-17:20 **Q&A: Panel Discussion**

17:20-17:30 **Congress' Closing Remarks**
• Giorgio Bruno - Mirko Gabriele





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EVENT VENUE

Palazzo degli Affari - Piazza Adua, 1 - Florence

(walking distance from Santa Maria Novella Station)

<https://www.firenzefiera.it/visita/palazzo-degli-affari>

Official language: **Italian, with course material in English**



PLANE

Amerigo Vespucci International Airport (FLR) is only 4 km away from the center of Florence, and the Tram Line T2 connects it to Santa Maria Novella Central Station in 20 minutes. **Pisa's Galileo Galilei International Airport (PSA)** is an hour from Florence, and it's connected to the city center by hourly trains and buses (Terravision company).



TRAIN

Thanks to the high-speed rail line, reaching Florence by train is a matter of minutes, and the fair district is within walking distance of the Santa Maria Novella central station. From Bologna: 37 min; from Rome: 1 h 30 min; from Milan: 1 h 50 min; from Naples: 2 h 55 min.



TRAM

Line T1: VALFONDA stop - SMN STATION

Line T2: ALAMANNI stop - SMN STATION

PARTICIPATION FEE

- **Euro 480,00** + VAT for AFI and PDA members, for 1 day
- **Euro 730,00** + VAT for AFI and PDA members, for both days
- **Euro 580,00** + VAT for NON-members, for 1 day
- **Euro 830,00** + VAT for NON-members, for both days

The participation fee includes:

- coffee break
- lunch
- networking dinner

For hotel reservations, please send an e-mail to: eventi@newaurameeting.it no later than **August 30, 2024**, specifying the choice of the hotel, dates and number of rooms required.

Subject to availability, New Aurameeting will send the hotel voucher with the method of payment.

It is strongly recommended to make your reservation as early as possible, as September in Florence is very high season and it may be difficult to find hotel accommodations.

- **Hotel Grifone:** 4-star (located in the historic center, 15 minutes by car from the conference venue and Santa Maria Novella Station)

Rate: € 185.00 VAT 10% included per night, in DUS room, breakfast included

<https://www.hotelgrifonefirenze.it/>

- **Hotel The Social Hub:** 4-star (walking distance from the congress venue and SMN Station)

Rate: € 254.00 VAT 10% included per night, in DUS room, breakfast included

<https://www.thesocialhub.co/it/firenze-lavagnini/>

- **B&B Hotel Firenze City Center:** 3-star (located historic center, 15 minutes by car from the congress venue and Santa Maria Novella Station)

Rate: € 145.00 VAT 10% included per night, in DUS room, breakfast included

<https://www.hotel-bb.com/it/hotel/firenze-city-center>



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REGISTRATION AND PAYMENT METHODS

Registration must be made no later than **September 6, 2024** to New Aurameeting; the participation fee can be paid by:

- **Bank transfer to**
NEW AURAMEETING Srl
Banco BPM: Branch 00617
IBAN: IT91J0503401726000000043206
BIC/SWIFT: BAPPIT21617
- **Credit card** upon online registration

Payment of the registration fee must be strictly made before the beginning of the event. New Aurameeting will notify by e-mail confirmation of registration.

Registrations will be accepted subject to availability.

Cancellations received in writing within 7 days of the day will be 100% refunded; after this deadline, no refund will be given except for the possibility of replace the registrant with another name. AFI, PDA Italy Chapter and NEW AURAMEETING reserve the right to suspend or postpone the study day if the minimum number of participants is not reached, in which case the registration fee if already paid will be refunded.

[CLICK HERE TO SUBSCRIBE](#)



ORGANIZING SECRETARIAT

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