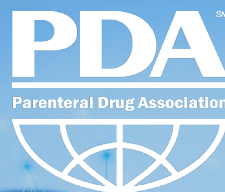




Associazione Farmaceutici Industria
Società Scientifica



Italy
Chapter

Annex 1

One year after

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 since 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 include the interpretation of some requirements which have cast some doubts and opened long debates both among industrial representatives as well as within 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.

Speakers with proven competence and experience will illustrate the interpretation of the requirements and their planned or ongoing application, giving the working groups inspiration to develop questions and suggestions.





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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**
• Matteo Sala - IBSA

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

10:10-10:40 **Q&A: Panel Discussion**

10:40-11:10 **Working groups - Session 4**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

11:10-11:40 **Coffee Break in the Sponsor Area**

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

11:40-12:10 **Environmental Monitoring Performance Qualification of New Facilities Case Study: Application of Industry Harmonized Approach**
• Anna Campanella - Takeda

12:10-12:40 **Holistic approach for Aseptic Process Simulation activities**
• Andrea Pranti - GSK

12:40-13:10 **Q&A: Panel Discussion**

13:10-13:40 **Working groups - Session 5**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

13:40-14:40 **Networking lunch**

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

14:40-15:00 **A qualified method for stopper height detection in lyophilized and liq products: a step towards Annex1 CCI compliance**
• Simon Mills - Ipsen Biopharm Limited

15:00-15:20 **Influence of Annex 1 update on lyo operations**
• Bert Van Meervenne - Pfizer

15:20-15:40 **Case Study: Annex 1 upgrade of existing Lyophilization plant at**
• Enrico Capogna - Sanofi - Anagni

15:40-16:10 **Q&A: Panel Discussion**

16:10-16:40 **Working groups - Session 6**
The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary

16:40-17:10 **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>

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 **July 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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