



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 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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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.

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ORGANIZING SECRETARIAT

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