

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.









ORGANIZING COMMITTEE



Marco Adami AFI

Claudia Bianchi Carnevale
 Francesco Boschi
 Giorgio Bruno
 AFI / Pfizer
 AFI / Pfizer
 Presidente AFI

Lucia Ceresa
 AFI / PDA Italy Chapter

Giovanni Cosmi
 Orazio Cultrera
 AFI / PDA Italy Chapter / Cosmi Consulting
 AFI/ PDA Italy Chapter / Cultrera Consulting

Francesco EspositoMirko GabrielePDA Italy Chapter / MerckPDA 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









PRELIMINARY PROGRAM



FIRST DAY	18 SEP	TEMBER	2024
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10:00-10:30	Registration and Welcome Coffee at the Sponsor area Welcome and congress introduction	15:05-15:35	A practical example of QRM for a PUPSIT case study • Claudia Rinaldi - GSK • Dario Bonanni - Merck
10:45-11:15	Giorgio Bruno - Mirko GabrieleSummary of survey resultsF. Boschi - F. Selmin	15:35-16:05	Working groups - Session 2 The participants, divided into working groups, will discuss the updates and any doubts or clarifications still
Session 1:	REGULATORY UPDATES • O. Cultrera - A. Regola		necessary
l	Annex 1: how its implementation looks like after one year from its enforcement. The industry point of view	16:05-16:35	Q&A: Panel Discussion
		16:35-17:05	Coffee Break in the Sponsor Area
	· Gabriele Gori - PDA	Session 3:	BARRIERS • M. Giusti - F. Trionfera
11:45-12:15 12:15-12:45	A Former U.S. FDA Inspector's Perspective on Annex 1 • Michael Shanks - Retired US FDA Working groups - Session 1	17:05-17:25	Process of packaging and transfer- ring equipment to the cleanrooms& barriers: a case study • Toni Valente - Giovanna Spampanato
	The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary		 Pierrel Gloves management in barrier systems: case study Patrizia Muscas - Lilly
12:45-13:15	Q&A: Panel Discussion	17:45-18:05	Indirect contact parts in filling
13:15-14:15	Networking lunch		operations: sterilization material transfer and set up
Session 2:	• G. Cosmi - M. Simone		• Fabrizio Gelli - GSK Siena
14:15-14:35	Implementation of CCS strategy within Annex 1 requirements • Barbara Ambruosi - Sara de Pinto - Merck, Bari Plant		Working groups - Session 3 The participants, divided into working groups, will discuss the updates and any doubts or clarifications still necessary
14:35-15:05 QRM principles applied to CO preparation including CCS busine			Q&A: Panel Discussion
	cases covering sterile pharmaceutical medicinal product manufacturing, Biologics and ATMPs	19:05-19:15	Closing Remarks • Giorgio Bruno - Mirko Gabriele
	Di Morris - PNR Pharma & James Drinkwater - Franz Ziel GmbH	19:15-22:00	Networking Dinner









PRELIMINARY PROGRAM



SECOND DAY 19 SEPTEMBER 2024

08:30-09:00	Registration and Welcome Coffee at the Sponsor area Welcome & short summery of DAY-1	13:00-13:30	Working groups - Session 5 The participants, divided into working groups, will discuss the updates and any doubts or clarifications still
	event • Giorgio Bruno - Mirko Gabriele		necessary
Session 4:	UTILITIES/FILTRATION	13:30-14:00	Q&A: Panel Discussion
	• F. Esposito - L. Pontello	14:00-15:00	Networking lunch
09:10-09:40	Sterilizing filtration for filled syringes • Simona Carosella - IBSA	Session 6:	LYOPHILIZATION • F. Selmin - M. Adami C. Bianchi Carnevale
09:40-10:10	Implementation of an in-place sterilizable system for peristaltic pumps Cristina Trovò - Haupt Pharma (Aenova Group)	15:00-15:20	A qualified method for stopper height detection in lyophilised product: a step towards Annex1 CCI compliance
10:10-10:30	Integrity Assurance of Final Sterile Filtration Process Step Using Sin-		• Simon Mills - Ipsen Biopharm Limited
	gle-Use TechnologyNicola Rutigliani - Production Associate Director Merck Healthcare	15:20-15:50	Influence of Annex 1 update on lyo operations • Bert Van Meervenne - Pfizer
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	15:50-16:20	Case Study: Annex 1 upgrade of existing Lyophilization plant at • Enrico Capogna - Sanofi - Anagni • Johan de Hoon - Ima Life
11:00-11:30	Q&A: Panel Discussion	16:20-16:50	Working groups - Session 6 The participants, divided into work-
11:30-12:00	Coffee Break in the Sponsor Area		ing groups, will discuss the updates and any doubts or clarifications still necessary
Session 5:	EM & APS	10:20 17:00	
	• F. Boschi - L. Ceresa	16:50-17:20	Q&A: Panel Discussion
12:00-12:30	Environmental Monitoring Performance Qualification in New Facilities: Overview and Application of an Industry Harmonized Approach • Anna Campanella - Takeda	17:20-17:30	Congress' Closing Remarks • Giorgio Bruno - Mirko Gabriele
12:30-13:00	Holistic approach for Aseptic Process Simulation activities • Andrea Pranti - GSK		









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.



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









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

NEW AURAMEETING Srl Via Rocca D'Anfo, 7 – 20161 Milan Ph. +39 02 66203390 – Fax +39 02 66200418 eventi@newaurameeting.it – www.newaurameeting.it









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