



ISPE

Italy
Affiliate

Evento

New Annex 1 2022

Implicazioni su Sistemi GMP e su Facility Nuove ed Esistenti

Chairs

Micaela Prati - External Manufacturer Director Project Management, J&J
Mariangela Magnano - Quality Audit & Compliance Manager/QP, Pfizer
Germana Molinari - Manager of Pharmaceutical Process Design, Wood

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ISCRIVERTI



Milano, 18 Maggio 2023

13:30 - 18:00

Workstream #3

Deadline for coming into operation 25 August 2024: LYO product transfer and impact

Agenda

13:30-14:00	Registrazione dei partecipanti
14:00-14:10	Saluto del Presidente ISPE Affiliata Italiana
14:10-14:15	Presentazione introduttiva
14:15-14:20	New Annex 1 2022 - Prima sessione: su cosa ci siamo confrontati
14:20-14:25	New Annex 1 2022 - Seconda sessione: su cosa ci siamo confrontati
14:25-14:35	Annex 1 implementation timeline: issues and possible approaches
14:35-15:00	Drug product transfer in existing lyo facilities: a risk analysis-based approach for gap assessment
15:00-15:30	How to harness robotics in the pharmaceutical industry: a focus on freeze-dryers
15:30-16:00	Bulk lyophilization: technologies for sterile drug substance transfer - IN ENGLISH
16:00-16:30	Spazio per gli Sponsor
16:30-17:00	Break
17:00-17:25	Existing drug products facilities with lyos: technical solutions for remediation projects
17:25-17:50	Case study on a new department for lyo products: how product transfer has been approached
17:50-18:00	Freeze drier sterilization: keep calm and CCS approach

Enzo Lacchini, Presidente ISPE Italy Affiliate

M. Alberio, Pharmaprocess
G. Molinari, Wood LifeSciences

M. Prati, J&J

M. Magnano, Pfizer

F. Ferrazin, LifeScience Consultant, former
Senior GMP Inspector

F. Intoccia, CSL Behring
G. Molinari, Wood LifeSciences

A. Tanzini, Staubli

G. Carbone, Wood LifeSciences
J. Gemmecker, HOF
M. Alberio, Pharmaprocess

**LIFEBEE, PALL, PHARMAPROCESS,
PQE GROUP, QSGROUP, STAUBLI**

M. Alberio, Pharmaprocess

E. Giudici, Sirton

A. Pranti, GSK