

RIGEL ACADEMY 2024

ANNEX 1 IN FORCE:

Overview about solutions adopted in accordance to the new EU GMP Annex 1 requirements for sterile application

May 7, 2024 - **Novotel Milano Nord Ca' Granda,**
Viale Suzzani 13, 20162 Milan

May 9, 2024 - **Grand Hotel Palatino,**
Via Cavour 213/M, 00184 Rome



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Moderators: *Fernanda Ferrazin - Life Sciences expert*
Antonio Rachini - CEO of Rigel S.p.A.

9:00 REGISTRATION

9:30 WELCOME

Antonio Rachini - CEO of Rigel S.p.A.

10:00 Annex 1: History and Evolution of Filling and Lyo Containment Technologies

Orazio Cultrera - Cultrera Consulting

10:30 Interpretation of the new requirements of Chapter 9 (Environmental & Process Monitoring) Viable & Total Particle

Diego Bompadre - Rigel Life Sciences

11:00 COFFEE BREAK

11:30 VHP and Cleaning in Isolator

Alessandra Benassi - IMA Group (Milan)

Case Study VHP

Luca Bonanomi - Amira (Rome)

12:00 Key points for correct material and staff flow in classified areas

Ilaria Scappaticci - Catalent

12:30 Q&A Session

13:00 LUNCH BREAK

14:30 Critical issues in the implementation of continuous and area microbiological sampling

Gaia Malpocher - Rigel Process&Lab

15:00 Particle and microbiological trends in view of the new Annex 1 requirements: review of data and management of outliers

Beatrice Baldon - Thermo Fisher Scientific

15:30 The importance of accredited calibrations according to ISO 17025

Emanuele Massa - Rigel Life Sciences

16:00 Q&A Session

16:30 Closing of the day

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