Rigel Academy

focus on the new EU GMP Annex 1 2022 Environmental and Process Monitoring

Rigel Life Sciences organizes the event "Rigel Academy: focus on the new EU GMP Annex 1 2022 Environmental and Process Monitoring", a full day dedicated to environmental and process monitoring that regulate the production of sterile drugs, practical and operational approaches regarding the adaptation to the new Annex 1 to better face the necessary changes.

Moderators and Speakers

Alessandra Benassi

Microbiology and Sterility Assurance specialist - IMA

Diego Bompadre

Director of Sales and EMS - Rigel Life Sciences

Mirko Gabriele

President Elect - PDA Italy Chapter

Gaia Malpocher

Microbiology Sales Director - Rigel Process and Lab

Petra Merker

Biological Quality Control Manager - Bayer

Conor Murray

Contamination Contamination Control Expert 3dimension Cleanrooms and Biosafety, Convener of ISO/TC209 WG2 on Microbiological Contamination Control, Chair of TC5, Healthcare Standards, NSAI (National Standards Association of Ireland)

Antonio Rachini

CEO - Rigel Life Sciences

Alessio Rosati

GMP Compliance Advisor & Auditor, Associate Partner - PQE

Allison Scott

Principal Scientist - MicronView



April 18, 2023 The Building Hotel Via Montebello 126, Rome

Environmental and Process Monitoring

Start	End	Title	Language	Speakers/Moderators
9:00	9:30	Check-in		
9:30	9:45	Introduction	Italian	Moderators: Antonio Rachini Rigel Mirko Gabriele PDA Italy Chapter
09:45	10:30	Management of microbiological contamination in the new Annex 1 - connecting the dashes in the ISO 14644 family of cleanroom standards	English	Conor Murray Convener of ISO/TC209 WG2 on Microbiological Contamination Control
10:30	11:00	Environmental and process monitoring: viable and total particle new requirements and upcoming challenges	Italian	Diego Bompadre Rigel Life Sciences
11:00	11:30	COFFEE BREAK		
11:30	12:15	Viable environmental monitoring: solutions for continuous sampling and expectation for culture media	Italian	Gaia Malpocher Rigel Process and Lab
12:15	12:45	The Potential of Air Based Bio-Fluorescent Particle Counting Technology to Support Annex 1:2022	English (remote)	Allison Scott MicronView
12:45	14:00	LUNCH		
14:00	14:30	Case Study on the Implementation of a Real-Time Viable Particle Counter in an Aseptic Isolator Robotic Line	English	Alessandra Benassi IMA Petra Merker Bayer
14:30	15:00	EM Data Trending	Italian	Alessio Rosati PQE
15:00	15:30	COFFEE BREAK		
15:30	16:00	Q&A Panel	Italian English	All Speakers and Moderators





Environmental and Process Monitoring

April 18, 2023 The Building Hotel Via Montebello 126, Rome

General Information

Your participation includes two coffee breaks and a buffet lunch. At the end of the day a certificate of participation will be issued.

Cost: Free

How to Register: Registration for the conference must be made by filling out the contact

form.

Language: Italian and English

For hotel reservations at The Building Hotel, please send an email to: info@thebuildinghotelrome.com no later than 5 March 2023, specifying the date and number of rooms requested, and any request for internal parking.

Special rate: € 158.00 VAT 10% included per night, in DUS room, breakfast included.

Tourist tax not included, to be paid locally € 6.00 per person per night.

Based on availability, The Building Hotel will send you the payment methods

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