

Rapid-C+ User Interest Group Annual Meeting

11 June 2025 | Geneva, Switzerland

Join us

Meet experts in biofluorescent particle counting technology and alternative rapid microbiological methods.



Fédération des Entreprises Romandes
Geneva, Switzerland

Easy access from the airport or from the main train station

Confirm your attendance by scanning the QR code



Dear fellow partners,

We are excited to invite you to the **Rapid-C+ User Interest Group Annual Meeting** in Geneva, Switzerland.

The event promises to be an insightful gathering, where we'll explore how **biofluorescent particle counting technology**, as an alternative and rapid microbiological method, is revolutionizing **real-time environmental monitoring** and addressing the evolving needs in the pharmaceutical industry. We will dive into key topics such as **validation, implementation** and **user experience**.

We look forward to connecting with you and hope to have the opportunity to collaborate in person.

Warm regards,
The Plair SA Team

The Program

11 June 2025

1:30 pm
Welcome

2:00 pm
Conference
Invited speakers

3:30 pm
Coffee break

4:00 pm
Conference
Plair's presentations

5:00 pm
Round Table

7:00 pm
Cocktail &
Dinner



Key topics addressed

- Rapid-C+ Primary Validation Results as an Alternative and Rapid Microbiological Method
- Customer Validation and Implementation Insights into Aseptic Filling
- Particle Loss Studies
- Decontamination Processes



Guest speakers

- **Dr. Petra Merker** - M3 Modern Microbial Methods Collaboration
- **Dr. Marcel Coverde** - MGP Consulting
- **Dr. Oleksii Ivanov** - Omron

Optional - 12 June 2025

Manufacturing and Validation
site visit

Our Guest Speakers

Dr. Petra Merker, M3 Modern Microbial Methods Collaboration

Moving forward to PQ validation and implementation of BFPCs

Modern isolator technology such as robotics and new pharmaceutical products, e.g., the personalized medicines in Cell and Gene Therapies, constitute the need for fast and reliable viable monitoring. This can be achieved by transition from traditional to alternative monitoring methods, such as BFPC (Bio-fluorescent Particle Counting), as encouraged by the Annex 1 Revision 2022. BFPCs detect and count total and biological particles in Real-time with the advantage to significantly reduce contamination risks by eliminating the human interventions connected with the traditional methods. This transition represents a paradigm shift, because the output-signal is non-equivalent in terms of microbial counts, and a continuous, rather than periodic, data stream is available. This presentation focusses on the implementation of BFPCs in Grade A isolators in the context of the user-specific PQ validation. It discusses main challenges encountered when implementing this modern technology, and the perspective from the M3 Modern Microbial Methods collaboration on navigating these challenges.

Dr. Marcel Goverde, MGP Consulting

Validation of Alternative Microbiological Methods: Regulatory Expectations and Ph. Eur. Chapter 5.1.6 Updates

The validation and implementation of alternative microbiological methods (AMMs) are guided by three principal regulatory documents: Ph. Eur. Chapter 5.1.6, USP Chapter <1223>, and PDA Technical Report No. 33. This presentation will provide a concise overview of these guidelines, highlighting their key differences and areas of convergence. Notably, Chapter 5.1.6 has undergone significant revisions, with the latest version published in Pharmeuropa issue 37.2 and is available for public consultation until end of June 2025. These updates reflect current expectations for validating and implementing alternative and rapid microbiological methods. We will present and discuss these new implementation requirements.

Dr. Oleksii Ivanov, Omron

Future of Robotics & Environmental Monitoring in Pharmaceutical Manufacturing

Advanced robotics is one of the enablers of transformation towards Pharma 4.0. The integration of advanced robotics and environmental monitoring technologies is opening new dimensions of quality control and assurance in the pharmaceutical industry. By merging data about the exact position of the robot in the room, timestamp, and the signal from the air sampler, you can very precisely locate the contamination event and thus more quickly identify the cause. Moreover, it may become a useful QC and QA tool in the context of future adaptable manufacturing networks focused on high variability and low volume.