

## **Workshop on exploring a certification system for the validation of rapid microbiological methods (RMMs)**

**15-16 October 2024**

**Draft programme** (subject to change)

**15 October 2024**

**8:00 - 9:00**

**Registration**

**Welcome address**

**9:00 - 9:15**

**Welcome address**

Emmanuelle Charton, EDQM, Council of Europe

**Presentation of the concept**

**9:15 - 10:05**

**Presentation of the concept**

Solène Le Maux, EDQM, Council of Europe

**10:05 - 10:30**

**Introduction of the current certification system (CEP)**

Hélène Bruguera, EDQM, Council of Europe

**10:30 - 11:00**

**Coffee Break**

**11:00 - 11:30**

**A regulator's point of view**

Oleg Krut, Paul Ehrlich Institute (PEI), Germany

**11:30 - 12:00**

**Two manufacturers' points of view**

Marja Claassen-Willemse, Merck Sharp and Dohme Oss, the Netherlands  
and Sven Deutschmann, Roche Diagnostics GmbH, Germany



**12:00 - 13:30**

**Lunch Break**

## **Preparation of the workshop**

**13:30 - 14:00**

**Presentation from the European Coalition of EU suppliers of RMMs**

*13:30 - 13:50*

Virginie Le Coent, bioMérieux, France; Thierry Muller, Merck, France; Jonathan Macron, Redberry, France; Eric Arakel, Sartorius, Germany

*13:50 - 14:00*

Q&A

**14:00 - 15:00**

**Presentations from ATP-bioluminescence equipment suppliers and users**

*14:00 - 14:10*

Miriam Guest, Charles River Microbial Solutions International Ltd., Ireland

*14:10 - 14:20*

Jonas van den Berg, Roche Diagnostics GmbH, Germany

*14:20 - 14:30*

Karen Capper, AstraZeneca UK, UK

*14:30 - 14:40*

Thomas Meindl, Labor LS SE & Co KG, Germany

*14:40 - 15:00*

Q&A

**15:00 - 15:30**

**Presentations from solid phase cytometry equipment suppliers and users**

*15:00 - 15:10*

Amelie Fouque, Microbs, France

*15:10 - 15:20*

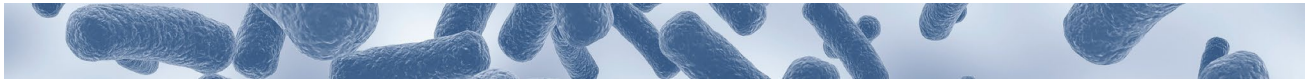
Pauline Silberreis, Redberry, France / Mariella Piredda, Eurofins Biolab Srl, Italy

*15:20 - 15:30*

Q&A

**15:30 - 16:00**

**Coffee Break**



## 16:00 - 17:00

### **Presentations from growth-based and NAT-based equipment suppliers and users**

*16:00 - 16:10*

Owen Griffin, Rapid Micro Biosystems, USA

*16:10 - 16:20*

Félix Montero Julian, bioMérieux, France

*16:20 - 16:30*

Carol Iversen, Merck, UK

*16:30 - 16:40*

Stefanie Bayer, Labor LS SE & Co. KG, Germany

*16:40 - 17:00*

Q&A

## 17:00 - 17:30

### **Presentations from isothermal microcalorimetry and fluorescent-based equipment suppliers and users**

*17:00 - 17:10*

Wilhelm Paulander, Symcel AB, Sweden

*17:10 - 17:20*

Svetlana Kiseleva, Plair SA, Switzerland

*17:20 - 17:30*

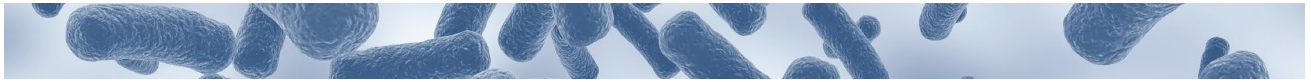
Q&A

## 17:30

### **Wrap-up of the day**

## 19:00

### **Social event**



**16 October 2024**

## **Workshop**

**8:30 - 10:30**

### **Workshop session 1: would a certification system simplify the validation of RMM?**

Topics addressed in this session:

- Primary validation
- Guidance on how to submit data
- Product specific validation
- Interactions between equipment suppliers, users and regulatory authorities

**10:30 - 11:00**

### **Coffee Break**

**11:00 - 12:30**

### **Workshop session 2: would a certification system simplify the filing of RMM?**

Topics addressed in this session:

- Would the proposed system facilitate filing?
- Would the proposed system fit the legal framework?
- Board of Experts composition

**12:30 - 13:00**

### **Final wrap-up**

**13:00**

### **Closure of the workshop**