

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

Speaker to be confirmed, 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

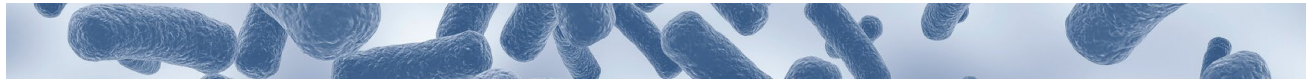
A regulator's point of view

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

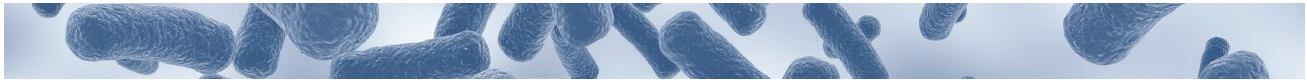
Q&A

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