



INTERNATIONAL MICROBIOLOGY SYMPOSIUM **10-11 OCTOBER 2017, STRASBOURG, FRANCE**

Duration: 2 days
Working language: English

PROGRAMME *(subject to change)*

TUESDAY 10 OCTOBER 2017

OPENING SESSION

- 8:00-9:00** Registration
- 9:00-9:10** **Opening & Welcome address**
Susanne Keitel, Director, EDQM, Council of Europe
- 9:10-9:50** **EU Regulations for Medicines**
Mrs Cathie Vielle, Head of the European Pharmacopoeia Dept., EDQM, Council of Europe

MORNING SESSION

STERILISATION AND BIOLOGICAL INDICATORS (BI)

- MODERATOR:** V'lain Fenton-May, Chair of the Ph. Eur. Group of Experts on Microbiology (Group 1), UK
- 9:50-10:20** **Highlight on the principal changes described in revised chapters (5.1.1 and 5.1.2) and their impact on microbiological control**
V'lain Fenton-May, Chair of the Ph. Eur. Group of Experts on Microbiology (Group 1), UK
- 10:20-10:30** **Q&A**
- 10:30-11:00** *Coffee break*
- 11:00-11:30** **Role of BIs in the sterilisation process**
Peter Annel, Novo Nordisk, Denmark & Ph. Eur. Expert on Microbiology (Group 1)
- 11:30-11:40** **Q&A**
- 11:40-12:00** **Poster session**
- 12:00-13:30** *Lunch break*



TUESDAY 10 OCTOBER 2017

AFTERNOON SESSION

RAPID MICROBIOLOGICAL METHODS: REGULATORY PERSPECTIVES

MODERATOR: Emmanuelle Charton, Head of Division B, European Pharmacopoeia Dept., EDQM, Council of Europe

13:30-14:00 The new structure and content of the revised chapter entitled "Alternative methods for control of microbiological quality (5.1.6)"

Sébastien Jouette, European Pharmacopoeia Dept., EDQM, Council of Europe

14:00-14:10 Q&A

14:10-14:50 Perspective of other Pharmacopoeias

▪ **U.S. Pharmacopeia (USP) perspective**

Radhakrishna S. Tirumalai, U.S. Pharmacopeial Convention, United States of America

▪ **Japanese Pharmacopoeia (JP) perspective**

Yutaka Kikuchi, National Institute of Health Sciences, Japan

14:50-15:00 Q&A

15:00-15:30 Coffee break & Poster session

15:30-16:30 Regulatory acceptance: Policies and Expectations

- Karen Longstaff, Therapeutic Goods Administration, Australia
- Lynne Ensor, U.S. Food and Drug Administration, United States of America
- Oleg Krut, Paul-Ehrlich-Institut, Germany

16:30-17:00 Q&A and Panel Discussion

Additional Panelist: Ioana Venet, Medicines and Healthcare Products Regulatory Agency (MHRA), UK

Close of first day

WEDNESDAY 11 OCTOBER 2017

MORNING SESSION

RAPID MICROBIOLOGICAL METHODS: EXAMPLES OF SUCCESS STORIES

MODERATOR: V'lain Fenton-May, Chair of the Ph. Eur. Group of Experts on Microbiology (Group 1), UK

- 8:30-9:00** **Rapid Microbiological Methods validation and the role of statistics**
Edwin van den Heuvel, Eindhoven University of Technology, the Netherlands & Ph. Eur. Expert on Microbiology (Group 1)
- 9:00-9:05** **Q&A**
- 9:05-9:35** **Rapid sterility testing method**
David Roesti, Novartis, Switzerland
- 9:35-9:40** **Q&A**
- 9:40-10:10** **PCR-based Adventitious Agents Testing**
Sven Deutschmann, Roche, Germany & Ph. Eur. Expert on Microbiology (Group 1)
- 10:10-10:15** **Q&A**
- 10:15-10:45** *Coffee break & Poster session*
- 10:45-11:15** **Development, validation, and implementation of an alternative NAT Mycoplasma detection method in replacement of the compendial methods as release testing in viral vaccine for human use**
Thierry Bonnevey, Sanofi, France & Ph. Eur. Expert on Microbiology (Group 1)
- 11:15-11:20** **Q&A**
- 11:20-11:50** **Rapid Detection of Micro-organisms by Direct Detection: A Solution for Time Critical In-process Monitoring**
Marja Claassen-Willemse, Merck Sharp & Dohme, the Netherlands & Ph. Eur. Expert on Microbiology (Group 1)
- 11:50-11:55** **Q&A**
- 11:55-12:30** **Q&A and Panel Discussion**
- 12:30-14:00** *Lunch break*



WEDNESDAY 11 OCTOBER 2017

AFTERNOON SESSION

**MICROBIOLOGICAL CONTROL OF CELL THERAPY PRODUCTS
& MICROBIOLOGICAL QUALITY OF WATER**

MODERATOR: Emmanuelle Charton, Head of Division B, European Pharmacopoeia Dept., EDQM, Council of Europe

14:00-14:30 The new structure and content of the revised chapter entitled "Alternative methods for control of microbiological quality (2.6.27)"
Giovanni Migliaccio, Chair of the Ph. Eur. Working Party on Cell Therapy Products (CTP WP), Italy

14:30-14:40 Q&A

14:40-15:10 Regulatory overview on Rapid Microbiological Methods

Violaine Closson-Carella, Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM), France

15:10-15:20 Q&A

15:20-15:50 Microbiological Safety Concepts for Cell and Gene Therapy Medicinal Products – From Status Quo to Paradigm Change

Jan-Oliver Karo, Paul-Ehrlich-Institut (PEI), Germany & Ph. Eur. Expert on Cell Therapy Products (CTP WP)

15:50-16:00 Q&A

16:00-16:30 Coffee break & Poster session

16:30-17:00 Interest of ATP metry for the microbiological control of haemodialysis water

Alain Ragon, Hôpital de la Conception, France & Ph. Eur. Expert on Water for Pharmaceutical Use (WAT) Working Party

17:00-17:10 Q&A

17:10-17:30 Online Bioburden Monitoring of Water Systems - Feasibility Studies

Sven Deutschmann, Roche, Germany & Ph. Eur. Expert on Microbiology (Group 1)

17:30-17:40 Q&A

17:40-18:00 Rapid Microbiological Methods and process water quality

Karen Longstaff, Therapeutic Goods Administration, Australia & Ph. Eur. Expert on Microbiology (Group 1)

18:00-18:10 Q&A

Close of the meeting