INTERNATIONAL MICROBIOLOGY SYMPOSIUM  
10-11 OCTOBER 2017, STRASBOURG, FRANCE  
Duration: 2 days  
Working language: English  
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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’Iain 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’Iain 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
MORNING SESSION

RAPID MICROBIOLOGICAL METHODS: EXAMPLES OF SUCCESS STORIES

MODERATOR: V’Iain 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 Bonnevay, 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-Willemsen, 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

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

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