

NEW MICROBIOLOGY CHAPTERS OF THE EUROPEAN PHARMACOPOEIA

Strasbourg, 2-3 October 2006

Duration: 2 days, Working language: English

MONDAY 2 OCTOBER 2006

- 9:00-9:10** **Opening remarks**
Dr Michael Morris, Chair of the European Pharmacopoeia Commission
- 9:10-9:30** **International Harmonisation and microbiology: the regulatory environment in Europe**
Mr Peter Castle, Secretary of the European Pharmacopoeia Commission, EDQM/Council of Europe
- 9:30-9:50** **Microbiological Harmonisation in the Antipodes**
Ms Vivienne Christ, Therapeutics Goods Administration Laboratory (AUS)
- Session I: Microbiological contamination of non-sterile products:
The new internationally harmonised chapters of the Ph. Eur.**
Moderator: Prof. Henning G. Kristensen,
Chairman of Group of Experts N° 1 on Microbiology of the European Pharmacopoeia
- 9:50-10:00** **Historical background: How the chapters were elaborated**
Dr Emmanuelle Charton, Principal Scientific Officer, EDQM/Council of Europe
- 10:00-10:30* *Coffee break*
- 10:30-11:15** **Chapter 2.6.12: What is new? Why? What will users have to validate?**
Dr Hans Van Doorne, University Centre for Pharmacy (NL)
- 11:15-11:30** Discussion
- 11:30-12:15** **Chapter 2.6.13: What is new? Why? What will users have to validate?**
Dr Klaus Haberer, Compliance GmbH (D)
- 12:15-12:30** Discussion
- 12:30-14:00* *Lunch*
- 14:00-14:20** **The acceptance criteria for the microbiological quality
Chapter 5.1.4: What is new? Why?**
Mr Patrick Louis, Association Pharmaceutique Belge (B)
- 14:20-14:40** **The impact on European Pharmacopoeia monographs**
Mr V'lain Fenton May, SMPU (UK)
- 14:40-15:00** Discussion
- 15:00-15:20** **Practical issues for users of the methods**
Dr Lothar Bomblies, Lab L&S AG (D)
- 15:20-15:40** **Practical issues and validations for culture media manufacturers**
Dr Renaud Jonquières, BioMérieux (F)
- 15:40-16:10* *Coffee break*
- 16:10-16:40** **The implementation programme for the new chapters**
- Ph. Eur: Mr Peter Castle, Secretary of the European Pharmacopoeia Commission, EDQM/Council of Europe
- USP: Dr Scott Sutton, Vice-chair, USP Microbiology Committee of Experts
- JP: Ms Michiko Sekiguchi, Japan Food Research Laboratories (J)
- 16:40-17:40** **The implementation programme for the new chapter
Round Table Discussion: Moderator: Prof. Dr H. G. Kristensen
Invited Speakers: Dr Michael Morris, Mr Peter Castle, Ms Vivienne Christ, Dr Scott Sutton, Ms Michiko Sekiguchi and Dr Brian S. Riley**

TUESDAY 3 OCTOBER 2006

Session II: Alternative methods for control of microbiological quality:

How to facilitate their regulatory acceptance

Moderator: Dr Emmanuelle Charton

- 9:00-9:10** **Historical background**
Dr Emmanuelle Charton, Principal Scientific Officer, EDQM/Council of Europe
- 9:10-9:40** **Where USP and JP stand with chapters on rapid microbiological methods**
- USP: Dr Scott Sutton, Vice-chair, USP Microbiology Committee of Experts
- JP: Prof. Masao Nasu, Osaka University
- 9:40-10:10** **The contents of the new European Pharmacopoeia chapter**
Mr Bruce Madsen, Novo Nordisk A&S (DK)
- 10:10-10:40* *Coffee break*
- 10:40-11:10** **Application for process control of non-sterile facilities**
• **Monitoring microbiological quality of water**
Dr Sylvie Guyomard Devanlay, Sanofi-Aventis (F)
- 11:10-11:30** • **The role of the supplier in supporting regulatory requirements for validation of rapid microbiological innovative method**
Dr Lucia Ceresa, Pall Italia Srl (I)
- 11:30-11:50** • **The application of rapid microbiological methods to increase process understanding**
Dr Gilberto Dalmaso, GlaxoSmithKline SpA (I)
- 11:50-12:10** **Towards an improved sterility test**
Dr Scott Sutton, Vectech Pharmaceutical Consultants Inc. (USA)
- 12:10-12:30** **Automated rapid microbiological detections for the pharmaceutical industry: Experience with validation and implementation for an autologous cell therapy product**
Dr Gary Du Moulin, Genzyme Biosurgery (USA)
- 12:30-12:45** **Discussion: Has general chapter facilitating the introduction of modern methods in microbiological laboratories?**
Moderator: Mr Peter Castle
- 12:45-14:00* *Lunch*
- Session II (Continued): Regulatory acceptance of alternative methods**
Moderator: Mrs Emer Cooke
Head of Inspection Unit, European Agency for Medicines
- 14:00-14:25** **A current FDA viewpoint on the use of alternative microbiological methods**
Dr Bryan S. Riley, U.S. Food and Drug Administration (USA)
- 14:25-14:50** **The perspective from regulatory authorities in Europe**
Mrs Maria Arfwedson, Medical Products Agency (S)
- 14:50-15:15** **Use of blood culture for cellular products: The Afssaps experience**
Dr Béatrice Panterne, Afssaps - DLC (F)
- 15:15-15:40** **Alternative microbiological methods: MHRA inspectors perspective**
Mr Paul Hargreaves, Medicines & Health Products Regulatory Agency (UK)
- 15:40-16:10* *Coffee break*
- 16:10-17:10** **Conclusion on regulatory acceptance: The way to move forward**
Round Table Discussion: Moderator: Mrs Emer Cooke
Invited speakers: Mr Peter Castle, Dr Scott Sutton, Prof. Masao Nasu, Dr Brian Riley, Mrs Maria Arfwedson, Dr Paula Korhola, Mr Paul Hargreaves