PROGRAMME: NEW MICROBIOLOGY CHAPTERS OF THE Ph. Eur. SYMPOSIUM
2-3 October 2006, Location: Pôle Formation CCI, Strasbourg-Meinau, France

NEW MICROBIOLOGY CHAPTERS OF THE EUROPEAN PHARMACOPOEIA

Strasbourg, 2-3 October 2006

Duration: 2 days, Working language: English

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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'Iain 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*
	Application for process control of non-sterile facilities
10:40-11:10	. **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**