11th INTERNATIONAL SYMPOSIUM ON PHARMACEUTICAL REFERENCE STANDARDS

Symposium organised by the
European Directorate for the Quality of Medicines & HealthCare (EDQM),
Council of Europe

3-4 September 2012, Strasbourg, France

Duration: 2 days, Working language: English

FINAL PROGRAMME

Registration and welcome coffee/tea: from 8h00 onwards

Monday, 3rd September 2012

08:45 - 09:00 **Welcome address**
Dr Susanne Keitel, Director, EDQM, Council of Europe

SESSION 1
Pharmaceutical Reference Standards: Regulatory aspects

Moderators:
Dr Marianne Ek, Chair of the European Pharmacopoeia Commission
Dr Susanne Keitel, Director EDQM, Council of Europe

09:00 - 09:20 Assessors viewpoint: expectations and findings in dossiers
Dr Jean-Louis Robert, Chair of the Joint CHMP/CVMP Quality Working Party (EMA)

09:20 - 09:40 Inspectors viewpoint: expectations and findings in GMP inspections
Dr Thomas Hecker, Scientific Officer, EDQM, Council of Europe

09:40 - 10:00 Pharmaceutical Reference Standards at US FDA: Review and cGMP
Mr Jon Clark, Associate Director, Office of Pharmaceutical Science FDA-CDER

10:00 - 10:30 *Coffee Break*

10:30 - 11:30 Use of Reference Standards and Quality Control: experiences and unmet needs
Dr Bernhard Wolf, Head of Quality Control, Teva/Ratiopharm
Dr Joachim Ermer, Head of Quality Control Services, Global Reference Standards Co-ordinator, Sanofi-Aventis Deutschland GmbH

11:30 - 12:30 Establishment of Reference Standards: point of views of international authorities
Dr Li Bo, Deputy Director NIFDC, China
Dr Shigeki Tsuda, Senior Managing Director, Pharmaceutical and Medical device Regulatory Science Society of Japan (PMRJ), Japan
Dr In-kyu Kim, Director of Pharmaceutical Standardization Research and Testing Division, NIFDS (KFDA), South Korea

12:30 - 13:00 Discussion with the panel of speakers

13:00 - 14:15 *Lunch*

SESSION 2a
Pharmaceutical Reference Standards for Biologicals

Moderators:
Mr Peter MJM Jongen, RIVM, Centre for Biological Medicines and Medical technology and Chair, European Pharmacopoeia group of expert on biological substances
Dr Karl-Heinz Buchheit, Deputy Head, Department for Biological Standardisation, OMCL Network & HealthCare, EDQM, Council of Europe

14:15 - 14:35 International Biological Standards: How to face the future challenges?
Dr Hye Na Kang, WHO Family and Community Health

14:35 - 14:45 Discussion

14:45 - 15:05 Reference Standards for recombinant biopharmaceuticals: expectations and limitations
Dr Adrian Bristow, Head Division Endocrinology, NIBSC, UK

15:15 - 15:45 Discussion

15:45 - 16:15 Coffee Break

16:15 - 16:35 Reference Standards for Cell and Gene Therapy Products: Regulators' expectations
Dr Paula Salmikangas, FIMEA, Finland

16:35 - 16:45 Discussion

16:45 - 17:05 Reference Standards for Cell Therapy Products: Manufacturers' expectations?
Dr Christopher A. Bravery, Consulting on Advanced Biologicals Ltd

17:05 - 17:30 Discussion with the panel of speakers

17:30 Reception

SESSION 2b
Pharmaceutical Reference Standards: Addressing the challenges in the characterisation of Small Molecules

Moderators:
Dr Matthew Borer, Advisor, Corporate Reference Standards, Eli Lilly and Company
Dr Andrea Lodi, Head of the Laboratory Department, EDQM, Council of Europe

14:15 - 14:35 Advanced characterisation technologies: qNMR
Dr Ian McEwen, Swedish Medical Products Agency
14:35 - 14:45 Discussion

14:45 - 15:05 Characterization of secondary standards: key challenges addressed
Dr Matthew Borer, Advisor, Corporate Reference Standards, Eli Lilly and Company

15:05 - 15:15 Discussion

15:15 - 15:35 Role of WHO ICRS
Dr Herbert Schmidt, Medicines Quality Assurance Programme, WHO
15:35 - 15:45 Discussion

15:45 - 16:15 Coffee Break

16:15 - 16:35 Matrix Reference Materials
Prof. Hendrik Emons, Head of Reference Materials Unit, Institute for Reference Materials and Measurements (IRMM) and Chair of Committee on Reference Material ISO/REMCO (*Slides presented by Dr Andrea Held*)

16:35 - 16:45 Discussion

16:45 - 17:05 How to monitor Reference Substances for continuous fitness for purpose: novel approaches or solutions to challenges?
Ms Jane Weitzel, member of USP Reference Standard Expert Committee, USP

17:05 - 17:30 Discussion with the panel of speakers

17:30 Reception

Tuesday, 4th September 2012

SESSION 3
Pharmaceutical Reference Standards: Material Management/ Technology Changes

Moderators:
Dr Tina Morris, Vice President, Project and Portfolio management, United States Pharmacopeia (USP)
Mr Vincent Egloff, Head of the Reference Standards & Samples Division, EDQM, Council of Europe

08:30 - 08:55 Managing Third Parties for the Preparation and Maintenance of Reference Standards
Mr Vaughn Stultz, Eli Lilly and Company

08:55 - 09:20 Procurement issues for those who would like to establish reference substances
(Procuring source material including biologicals)
Dr Anu Bansal, Genentech

09:20 - 09:45 Compendial Reference Standards Manufacturing
Dr Li Bo, Deputy Director NIFDC

09:45 - 10:10 Storage and Distribution of Reference Standards
Dr Robert Watters, Associate Director, NIST

10:10 - 10:30 *Coffee Break*

10:30 - 10:55 Guides from the ISO Committee on Reference Materials (ISO/REMCO)
Prof. Hendrik Emons, Head of Reference Materials Unit, Institute for Reference Materials and Measurements (IRMM) and Chair of Committee on Reference Material ISO/REMCO (*Slides presented by Dr Andrea Held*)

10:55 - 11:20 GHS Classification and labelling of pharmaceutical reference substances
Mrs Jonna Sunell Huet, Deputy Head Quality, Safety & Environment Unit, EDQM, Council of Europe

11:20 - 11:45 Challenges associated with import and export of RS
Dr Steve Wood, Head of Reference Materials Calibration, LGC Limited

11:45-12:30 Frequently Asked Questions addressed to compendial organisations
Dr Shawn Dressman, Vice-President, Standards Acquisition, United States Pharmacopeia (USP)
Mr Vincent Egloff, Head of the Reference Standards & Samples Division, EDQM, Council of Europe

12:30 - 13:00 Discussion with the panel of speakers

13:00 - 14:15 Lunch

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CLOSING SESSION

Moderators:
Dr Andrea Lodi, Head of the Laboratory Department, EDQM, Council of Europe and
Dr Karl-Heinz Buchheit, Deputy Head, Biological Standardisation,
OMCL Network & HealthCare Department

14:15 - 14:30 Summary of the presentations & discussions - Reference standards for Biologics
Mr Peter MJM Jongen, RIVM, Centre for Biological Products and Medical technology and Chair, European Pharmacopoeia group of expert on biological substances

14:30 - 14:45 Summary of the presentations & discussions - Addressing the challenges in the characterisation of Small Molecules
Dr Matthew Borer, Advisor, Corporate Reference Standards, Eli Lilly and Company

14:45 - 15:45 **Round Table Discussion**

With the participation of: **Dr Marianne Ek**, Chair of the European Pharmacopoeia Commission; **Dr Susanne Keitel**, Director, EDQM, Council of Europe; **Dr Tina Morris**, Vice President, Project and Portfolio management, United States Pharmacopeia (USP); **Dr Bernhard Wolf**, member of European Generic Medicines Association (EGA); **Prof. Dr Jos Hoogmartens** vice chair European Pharmacopoeia Commission and **Mr Peter MJM Jongen**, RIVM, Centre for Biological Products and Medical technology and Chair, European Pharmacopoeia group of expert on biological substances

15:30 - 15:45 **Closing remarks**
Dr Susanne Keitel, Director, EDQM, Council of Europe

Scientific Programme Committee:
Dr M. Borer, Advisor, Corporate Reference Standards, Eli Lilly and Company (USA)
Dr K. H. Buchheit, Deputy Head, Biological Standardisation, OMCL Network & HealthCare Department, EDQM, Council of Europe
Mr V. Egloff, Head of the Reference Standards & Samples Division, EDQM, Council of Europe
Prof. H. Emons, Head of Reference Materials Unit, Institute for Reference Materials and Measurements IRMM/ ISO Committee on reference materials (REMCO)
Mr P. MJM Jongen, RIVM, Centre for Biological Medicines and Medical technology and Chair, European Pharmacopoeia group of expert on biological substances
Dr S. Keitel, Director, EDQM, Council of Europe
Dr A. Lodi, Head of the Laboratory Department, EDQM, Council of Europe
Dr J. L. Robert, Chair of the Joint CHMP/CVMP Quality Working Party (QWP, EMA
Dr J. H. Trouvin, Chair CHMP Biologics Working Party (BWP)
Dr P. Tyle, former Executive VP and Chief Science Officer, United States Pharmacopeia (USP)
Dr M. Wierer, Deputy Head of the European Pharmacopoeia Department, EDQM, Council of Europe

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