13TH INTERNATIONAL SYMPOSIUM ON PHARMACEUTICAL REFERENCE STANDARDS

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

13-14 March 2019, Strasbourg, France

Working language: English

PROGRAMME

Registration: from 8h00 am onwards

Day 1: 13 March 2019

09h00 - 09h10 **Welcome Address**
Dr Susanne Keitel, Director, EDQM, Council of Europe

SESSION 1
Compendial Reference Standards

Moderators:
Dr Andrea Lodi, EDQM, Council of Europe
Dr Fouad Atouf, the United States Pharmacopeial (USP), USA

09h10 - 09h30 **Intended use of Reference Standards (RS): Key role of compendial RS / quality measurement**
Dr Andrea Lodi, EDQM, Council of Europe

09h30 - 09h40 *Discussion*

09h40 - 10h00 **Reference Standards and Traceability (to documentary standards and secondary standards)**
Dr Ravi Reddy, USP, USA

10h00 - 10h10 *Discussion*

10h10 - 10h30 **Reference Standards for System Suitability**
Dr Bart Blanchaert, EDQM, Council of Europe

10h30 - 10h40 *Discussion*

10h40 - 11h10 *Coffee Break*

11h10 - 11h30 **Use of Reference Standards and Quality Control: Experiences and Unmet Needs**
Dr Joachim Ermer, Sanofi-Aventis Deutschland GmbH, Germany

11h30 - 11h40 *Discussion*

11h40 - 12h00 **USP chapter 11: Feed-back public enquiry (label/certificate/configuration RS) including non-documentary reference standards**
Mrs Holly Chang, USP, USA

12h00 - 12h20 *Discussion & Session wrap up*

12h20 - 13h00 *Lunch*

13h00 -14h00 *Poster Session*

SESSION 2
Pharmaceutical Reference Standards: Small Molecules

Moderators:
Dr Stefan Almeling, EDQM, Council of Europe
Dr Jeffrey Calvin Moore, USP, USA

14h00 - 14h20 **Uses of Reference Standards**
Mrs Tal Hadad, Teva Pharmaceutical Industries, Israel

14h20 - 14h30 *Discussion*

14h30 - 14h50 **Use of qNMR and Characterisation of Reference Standards**
Dr Torgny Rundlöf, Medical Products Agency, Sweden

14h50 - 15h00 *Discussion*

15h00 - 15h30 **EMA Guideline on Antibiotics Reference Standards, semi-synthetic products**
Dr Bernhard Wolf, Ph. Eur. Expert on Antibiotics and Chromatographic Separation Techniques, European Pharmacopoeia Commission

Microbiological Reference Standards
Dr Sylvie Jorajuria, EDQM, Council of Europe

15h30 - 15h40 *Discussion*

15h40 - 16h00 **Reference Standards for Equipment Verification**
Dr Stefan Almeling, EDQM, Council of Europe

16h00 - 16h10 *Discussion*

16h10 - 16h40 *Coffee Break*

16h40 - 17h00 **Joint presentation EDQM and USP on FAQs**
Dr Matthias Weber, EDQM, Council of Europe
Dr Ravi Reddy, USP, USA

17h00 - 17h15 *Discussion & Session wrap up*

Day 2: 14 March 2019

SESSION 3
Pharmaceutical Reference Standards for Biologicals

Moderators:
Dr Karl Heinz Buchheit, EDQM, Council of Europe
Dr Fouad Atouf, USP, USA

09h00 - 09h20 **Biological Reference Standards: How to face the future challenges?**
Dr Chris Burns, National Institute for Biological Standards and Control (NIBSC), UK

09h20 - 09h30 *Discussion*

09h30 - 09h50 **Reference Standards for mAb characterisation: infliximab case**
Dr Frank Jung, EDQM, Council of Europe
Dr Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe

09h50 - 10h00 *Discussion*

10h00 - 10h20 **Developing Reference Standards for Gene Therapy Products: Needs and Challenges**
Dr Boro Dropulic, Lentigen Corporation, USA

10h20 - 10h30 *Discussion*

10h30 - 11h00 *Coffee Break*

11h00 - 11h20 **USP Reference Standards to address Methods Performance**
Dr Fouad Atouf, USP, USA

11h20 - 11h30 *Discussion*

11h30 - 12h10 **Use of non-compendial Reference Standards for multi-valent vaccines**
OMCL Guideline: Dr Maria Silvana Bellini, EDQM, Council of Europe
Practical Examples: Dr Lorenzo Tesolin, Sciensano, Belgium

12h10 - 12h20 *Discussion & Session wrap up*

12h20 - 13h00 *Lunch*

13h00 -14h00 *Poster session*

SESSION 4
Regulatory Aspects

Moderators:
Dr Michael Wierer, EDQM, Council of Europe
Dr Ravi Reddy, USP, USA

14h00 - 14h20 **How reference standards are used pre/post approval medicines framework**
Dr Matthew Borer, Eli Lilly and Company, USA

14h20 - 14h30 *Discussion*

14h30 – 14h50 **WHO standards: tools for regulatory convergence**
Dr Ivana Knezevic, WHO

14h50 - 15h00 *Discussion*

15h00 - 16h00 **Establishment of Reference Standards: Authorities' Viewpoints**
- Dr Evangelos Bakopanos, Health Canada, Canada
- Dr Tsuyoshi Ando, Pharmaceutical and Medical Devices Agency, Japan

16h00 - 16h10 *Discussion*

16h10 - 16h40 *Coffee Break*

16h40 - 17h00 *Final Session discussion*

17h00-17h10 *Closing remarks*

Programme Committee:
EDQM, Council of Europe: Andrea Lodi, Karl-Heinz Buchheit, Stefan Almeling and Michael Wierer; USP: Fouad Atouf and Ravi Reddy; NIBSC: Chris Burns; Industry Representatives: Matthew Borer, Eli Lilly and Company, and Joachim Ermer, Sanofi-Aventis Deutschland GmbH**.**