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
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| 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  

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| 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: