BATCH RELEASE FOR MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD AND PLASMA: PRINCIPLES, PROCEDURES AND TOOLS

10-11 May 2012

Location: EDQM, Strasbourg, France
Duration: 1 day; Working language: English

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PROGRAMME

THURSDAY, 10TH MAY 2012

13:30-14:15 Registration

14:15-14:30 **Opening & Welcome address**
Dr Susanne Keitel, Director, EDQM, Council of Europe

SESSION I: REGULATORY REQUIREMENTS & FRAMEWORK

Moderator: Dr Karl-Heinz Buchheit
Biological Standardisation, OMCL Network & HealthCare Dept., EDQM, Council of Europe

14:30-15:00 **Marketing authorisation procedure for medicinal products derived from human blood and plasma in the EU**
Dr Aurore Blasenhauer Bordereau, LFB Biomédicaments, France

15:00-15:45 **An overview of the European official control authority batch release procedure and guidelines for medicinal products derived from human blood and plasma; legal context, key principles, outline of the procedure and tools**
Dr Catherine Milne, Biological Standardisation, OMCL Network & HealthCare Dept., EDQM, Council of Europe

15:45-16:05 **Discussion**

16:05-16:30 *Coffee break*

SESSION II: FUNCTION AND ROLE OF THE KEY PLAYERS

Moderator: Dr Uwe Unkelbach
Paul Ehrlich Institut (PEI), Germany

16:30-17:00 **Role of the Marketing Authorisation Holder in official control authority batch release**
Dr Martin Krah, CSL Behring, Germany

17:00-17:30 **Role of the OMCL in official control authority batch release**
Dr Berber de Vries, Dutch National Institute for Public Health and the Environment (RIVM), the Netherlands

17:30-18:00 **Discussion**

18:00 *Close of first day*

FRIDAY, 11TH MAY 2012

SESSION III: EDQM/OMCL NETWORK SUPPORT

Moderator: Dr Berber de Vries
Dutch National Institute for Public Health and the Environment, the Netherlands

9:00-9:30 **The OMCL network: Quality Assurance and Mutual Joint Audit/Visit Schemes**
Importance of QA for OMCLs performing batch release
Dr Carlo Pini, Istituto Superiore di Sanità (ISS), Italy

9:30-10:00 **EDQM contributions to the quality control of medicinal products derived from human blood and plasma**
Biological Standardisation Programme, Reference Standards and Preparations and PTS studies
Dr Karl-Heinz Buchheit, Biological Standardisation, OMCL Network & HealthCare Dept., EDQM, Council of Europe

10:00-10:20 **Discussion**

10:20-10:50 *Coffee break*

SESSION IV: OCABR'S IMPACT BEYOND THE EU

Moderator: Dr Carlo Pini
Istituto Superiore di Sanità (ISS), Italy

10:50-11:20 **Control authority batch release beyond the EU**
EU system as a useful tool
Dr Uwe Unkelbach, Paul Ehrlich Institut (PEI), Germany

11:20-11:50 **A Manufacturer's Perspective: viewpoint on control authority batch release beyond the EU**
Dr Ilka von Hoegen, Plasma Protein Therapeutics Association (PPTA) Europe

11:50-12:20 **Discussion**

12:25 *Close of the meeting*