

**BATCH RELEASE  
FOR HUMAN VACCINES:  
PRINCIPLES, PROCEDURES AND TOOLS**

**15-16 October 2009**

**Location: EDQM, Strasbourg, France**

**Working language: English**

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**Thursday, 15 October 2009**

**13h00-14h00** Registration on site

**14h00-14h15** Opening remarks

***SESSION I***

**14h15-14h35** **The legal framework and regulatory requirements for official control authority batch release in the EU**

Mr Jean-Marc Spieser, EDQM/Council of Europe, Biological Standardisation, OMCL Network & HealthCare Dept.

**14h35-15h05** **Marketing Authorisation Procedure for vaccines in the EU**

Dr Alain Sabouraud, Sanofi Pasteur, Marcy l'Etoile, France

**15h05-15h55** **Vaccines in the European Pharmacopoeia**

Relevant monographs and general chapters and their specific application for vaccines  
Dr Emmanuelle Charton, EDQM/Council of Europe, European Pharmacopoeia Dept.

**15h55-16h20** **Discussion on the 1<sup>st</sup> session's topics**

*16h20-16h40* Coffee break

***SESSION II***

**16h40-17h15** **An overview of the European official control authority batch release procedure and guidelines for vaccines**

Outline of the procedure and key principles  
Dr Catherine Milne, EDQM/Council of Europe, Biological Standardisation, OMCL Network & HealthCare Dept.

**17h15-17h35** **Role of the Marketing Authorisation Holder in official control authority batch release**

Dr Cécile Ponsar, GlaxoSmithKline Biologicals, Rixensart, Belgium

**17h35-17h55** **Role of the OMCL in official control authority batch release**

Dr Joep Bergers, National Institute for Public Health and the Environment (RIVM) Bilthoven, Netherlands

**17h55-18h20** **Discussion on the 2<sup>nd</sup> session's topics**

*18h20* Close of meeting

**Friday, 16 October 2009**

**SESSION III**

**9h00-9h30 The OMCL network: Quality Assurance and Mutual Joint Audit/Visit Schemes**  
Importance of QA for OMCLs performing batch release  
Mr Laurent Lempereur, Agence Française de Sécurité Sanitaire des Produits de Santé  
(AFSSAPS), Lyon, France

**9h30-10h00 EDQM contributions to the quality control of vaccines**  
Biological Standardisation Programme, Reference Standards and Preparations and PTS studies  
Dr Karl-Heinz Buchheit, EDQM/Council of Europe, Depart. Biological Standardisation,  
OMCL Network & HealthCare Dept.

**10h00-10h20 Discussion on the 3<sup>rd</sup> session's topics**

*10h20-10h50 Coffee break*

**SESSION IV**

**10h50-11h20 Replacement, Reduction and Refinement (3Rs): Network Strategies**  
Efforts & Achievements  
Mrs Alexandrine Maes, Scientific Institut of Public Health, Brussels, Belgium

**11h20-11h30 Discussion**

**11h30-12h00 Electronic Tools available for Ph Eur publications**  
Online version of the European Pharmacopoeia, Pharmeuropa and other resources  
Dr Hans-Joachim Bigalke, EDQM/Council of Europe, Publications & Multimedia Dept.

**12h00-12h15 Discussion**

**12h15-12h30 Electronic tools for EU OMCLs**  
Information on Batch Release database and intranet platforms  
Dr Catherine Milne, EDQM/Council of Europe, Biological Standardisation, OMCL  
Network & HealthCare Dept.

*12h30-14h00 Lunch*

**SESSION V**

**14h00-14h15 Control authority batch release beyond the EU**  
EU system as a useful tool  
Mr Jean-Marc Spieser, EDQM/Council of Europe, Biological Standardisation, OMCL  
Network & HealthCare Dept.

**14h15-14h45 Current development on batch release issues from WHO**  
Perspectives on control authority batch release for vaccines ; the importance of  
networking and appropriate strategy development based on available resources  
Dr Ivana Knezevic, World Health Organisation (WHO)

**14h45-15h15 Viewpoint from the manufacturer's perspective on control authority batch  
release beyond the EU**  
Dr Alain Sabourand and Dr Michel Duchêne, representatives of the International  
Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

**15h15-15h30 Viewpoint on control authority batch release from a national control authority  
outside the EU**  
Mrs Teeranart Jivapaisarnpong, Ministry of Public Health, Nonthaburi, Thailand

**15h30-15h45 Discussion on the 5<sup>th</sup> session's topics**

**15h50 End of meeting**

*15h50-16h15 Coffee served*