

Keeping up with Reality and Quality: A Challenge for European Blood Establishments

Horizon Scanning Methodology

PROGRAMME



**International Conference organised by the
European Directorate for the Quality of Medicines & HealthCare
(EDQM), Council of Europe
in collaboration with the European Commission**

29 SEPTEMBER TO 01 OCTOBER 2020

Strasbourg, France

Duration: 3 days. Working language: English

29 September 2020

- 08:15-09:00** **REGISTRATION**
- 09:00-09:20** **OPENING SESSION & WELCOME ADDRESS**
Susanne Keitel, Director, EDQM, Council of Europe
Martin Seychell, Deputy Director-General for Health and Food Safety, European Commission
- 09:20-12:20** **10 YEARS OF COOPERATION IN THE FIELD OF BLOOD TRANSFUSION**
Moderator: Mr Stefan Schennach, Member & former Chairperson of the Committee on Social Affairs, Health and Sustainable Development (PACE), Austria
Rapporteurs: Stefaan Van der Spiegel, European Commission & Marie-Laure Hecquet, EDQM, Council of Europe
- 09:20-10:00** **European governance in the field**
- **20 years of European Union governance**
Martin Seychell, Deputy Director-General for Health and Food Safety, European Commission
 - **60 years of Council of Europe governance**
Susanne Keitel, Director, EDQM, Council of Europe
- 10:00-10:30** **10 years of EU/EDQM cooperation in the field of blood: Achievements**
Laurent Mallet, EDQM, Council of Europe
- 10:30-10:50** ☕ **Coffee Break** ☕
- 10:50-11:10** **EU/EDQM Collaboration: Towards the future in the blood sector**
Marie-Laure Hecquet, EDQM, Council of Europe
- 11:10-11:30** **EU/EDQM Collaboration: Towards the future in other SoHO sectors**
Marta Lopez-Fraga, EDQM, Council of Europe
- 11:30-11:50** **Setting the Scene**
Marie-Laure Hecquet, EDQM, Council of Europe
- 11:50-12:20** **Questions & Panel Discussion**
- 12:20 -14:00** 🍴 **Lunch Break** 🍴
- 14:00-17:30** **GLOBALISATION OF THE SUPPLIER MARKETPLACE - STATE OF PLAY, OPPORTUNITIES AND ISSUES IN THE BLOOD SECTOR**
Moderator: Stéphane Bégué, Etablissement Français du Sang (EFS), France
Rapporteur: Karen Byrne, Blood Transfusion Service, Ireland
- 14:00-14:30** **Introduction to EU procurement law**
An Baeyens, DG-GROW, European Commission
- 14:30-15:00** **Implementation of the EU procurement law in Blood Establishment (BE) Quality Systems: Challenges and issues**
Paul Behan, Blood Transfusion Service, Ireland

- 15:00-15:30 **Key challenges in supply management, BE perspective**
Alex Aquilina, National Blood Transfusion Centre, Malta, on behalf of the EDQM Blood Quality Management Working Group (B-QM)
- 15:30-15:50 ☕ **Coffee Break** ☕
- 15:50 -16:10 **Challenges in auditing suppliers, BE perspective**
Stéphane Bégué, EFS, France
- 16:10-16:40 **Business continuity to ensure blood supply, viewpoint of a supplier**
Nigel Talboys, Blood Transfusion Association, Belgium
- 16:40-17:00 **A highly competitive supplier marketplace: Impact on BEs**
Michael Cox, Danish Patient Safety Authority, Denmark
- 17:00-17:30 **Questions & Panel Discussion**
- 17:30-18:00 **Exhibition Opening & Poster Session**
- 17:30-19:00 🎧 **Reception** 🎧

30 September 2020

- 09:00-12:20** **NEW REGULATORY ENVIRONMENT FOR MEDICAL DEVICES: STATE OF PLAY, OPPORTUNITIES AND ISSUES IN THE BLOOD SECTOR**
Moderator: Stephen Vardy, NHS Blood and Transplant, UK
Rapporteur: Beate Rothe, Klinikum Wolfsburg, Germany, on behalf of the EDQM Blood Quality Management Working Group
- 09:00-09:30** **Introduction to the Medical Devices and *in vitro* Medical Devices (MD/IVD) EU regulations**
Representative from the European Commission (speaker to be confirmed)
- 09:30-10:00** **Impact of MD/IVD EU regulations on suppliers and their relations with BEs**
Pascale Van Hoydonck, Terumo BCT, Belgium
- 10:00-10:30** **Impact of MD/IVD EU regulations on IT systems and in-house testing methods in BEs**
Ulrik Sprogøe, Odense University Hospital, Denmark
- 10:30-10:50** 🍵 **Coffee Break & Poster Session** 🍵
- 10:50-11:20** **Reclassification of DEHP: Impact on BEs**
Peter Van Den Burg, European Blood Alliance (EBA)
- 11:20-11:50** **EDQM Blood Proficiency Testing Scheme (B-PTS) Programme: Considerations for Common Technical Specifications**
Richard Forde, EDQM, Council of Europe
- 11:50-12:20** **Questions & Panel Discussion**
- 12:20-14:00** 🍴 **Lunch Break** 🍴
- 14:00-17:30** **HEALTH PROFESSIONALS, CHANGING SCOPE OF PRACTICE: STATE OF PLAY, OPPORTUNITIES AND ISSUES IN THE BLOOD SECTOR**
Moderator: Tamara K. Hervey, University of Sheffield, UK
Rapporteur: Mariëlle van Roosmalen, Sanquin, Netherlands
- 14:00-14:20** **Impulse presentation: State of Play**
Marie-Laure Hecquet, EDQM, Council of Europe
- 14:20-14:50** **EU legislation on Healthcare Professionals - what does it say?**
Tamara K. Hervey, University of Sheffield, UK
- 14:50-15:20** **Change of scope of practice of health professionals in BEs, Austrian experience**
Christof Jungbauer, Austrian Red Cross, Austria
- 15:20-15:50** 🍵 **Coffee Break & Poster Session** 🍵
- 15:50-16:20** **Change of scope of practice of health professionals in BEs, Finnish experience**
Johanna Castrén, Finnish Red Cross Blood Service, Finland

- 16:20-16:50 **Towards model approaches**
EDQM Blood Quality Management Working Group (B-QM) (speaker to be confirmed)
- 16:50-17:30 **Questions & Panel Discussion**
- 17:30 **Close of day**

1 October 2020

- 08:45-12:00** **DATA PROTECTION AND INTEGRITY IN THE BLOOD SECTOR: STATE OF PLAY, OPPORTUNITIES AND ISSUES**
Moderator: Andy Kelly, European Blood Association (EBA)
Rapporteur: Jan Ceulemans, Flemish Red Cross, Belgium
- 08:45-09:10 **Impulse presentation/mapping of data collected & State of Play after 2 years**
Beate Rothe, Klinikum Wolfsburg, Germany, on behalf of the EDQM Blood Quality Management Working Group
- 09:10-9:35 **The Council of Europe regulatory framework on personal data protection: a regulatory but also a societal need**
Jeanne Bossi Malafosse, DELSOL Avocats & Council of Europe Expert
- 09:35-10:05 **Practical implementation in the field of blood, viewpoint from a BE data protection officer**
Katrina Smith, NHS Blood and Transplant, UK
- 10:05-10:30 ☕ **Coffee Break** ☕
- 10:30-10:55 **Practical implementation in the field of blood, viewpoint from a BE data protection officer**
Jan Ceulemans, Flemish Red Cross, Belgium
- 10:55-11:20 **A focus on data integrity implementation in BEs, regulatory viewpoint**
Speaker to be confirmed
- 11:20-12:00 **Questions & Panel Discussion**
- 12:00-13:20 🍴 **Lunch Break** 🍴
- 13:20-16:15** **WORKING TOGETHER TO SUPPORT BLOOD ESTABLISHMENTS**
Moderator: Alex Aquilina, National Blood Transfusion Centre, Malta, on behalf of the EDQM Blood Quality Management Working Group (B-QM)
Rapporteur: Virpi Kiuru, Finnish Red Cross Blood Service, Finland
- 13:20-13:50 **Introduction to the EDQM/EU initiative on Contingency planning, a concerted effort**
Lorenzo Montrasio, EDQM, Council of Europe
Andy Kelly, Chair of the EBA Working Group on Contingency Planning
- 13:50-14:20 **Supporting initiatives for European BEs**
Stefaan Van der Spiegel, European Commission
Marie-Laure Hecquet, EDQM, Council of Europe
- 14:20-15:10 **Oral Testimonies of BEs from EU and CoE Member States**
- 15:10-16:00 **Closing Session:** Presentations by the Moderators & Discussions on the Conference outcomes

16:00-16:15 **Closing Remarks**
16:15 ***Close of the conference***

