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

21-23 APRIL 2020

Strasbourg, France

Duration: 3 days. Working language: English
21 APRIL 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: To be confirmed
Rapporteurs: Stefaan Van der Spiegel, European Commission & Marie-Laure Hecquet, EDQM, Council of Europe

09:20-10:00  The European governance in the field
- 20 years of European Union’s governance
  Martin Seychell, Deputy Director-General for Health and Food Safety, European Commission
- 60 years of Council of Europe’s 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 SUPPLIERS MARKET PLACE - STATE OF PLAY, OPPORTUNITIES AND ISSUES IN THE BLOOD SECTOR
Moderator: Caroline Lefort, Etablissement Français du Sang (EFS), France
Rapporteur: Karen Byrne, Blood Transfusion Service, Ireland

14:00-14:30  Introduction to the EU procurement law
An Bayens, DG-GROW, European Commission

14:30-15:00  Implementation of the EU procurement law in Blood Establishment’s (BEs) Quality Systems: Challenges and issues
Paul Behan, Blood Transfusion Service, Ireland
15:00-15:30  Key challenges in supplies management, BE’s 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 ☕

15:50-16:20  Business continuity to ensure blood supply, viewpoint from a supplier  
Nigel Talboys, Blood Transfusion Association, Belgium

16:20-16:40  A highly competitive suppliers market place: Impact on BE’s  
Michael Cox, Danish Patient Safety Authority, Denmark

16:40-17:00  Questions & Panel Discussion

17:00-17:30  Exhibition Opening & Poster Session

17:00-19:00  🎉 Reception 🎉
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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 regulation
Representative from the European Commission (speaker to be confirmed)

09:30-10:00 Impact of MD/IVD EU regulation on the suppliers and their relations with BEs
Pascale Van Haydonck, Terumo BTC, Belgium

10:00-10:30 Impact of MD/IVD EU regulation 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
Representative from the European Blood Alliance (EBA) (speaker to be confirmed)

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 PRACTICES: STATE OF PLAY, OPPORTUNITIES AND ISSUES IN THE BLOOD SECTOR
Moderator: Tamara K. Hervey, University of Sheffield, UK
Rapporteur: Marielle 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 practices 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 practices of health professionals in BEs, Finnish experience
Johanna Castren, Finland Red Cross, Finland
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<th>Time</th>
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| 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                                             |
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

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

The Council of Europe regulatory framework on personal data protection: a regulatory but also a societal need
Jeanne Bossi Malafosse, Consultant, Council of Europe

Practical implementation in the field of blood, viewpoint from a BE data protection officer
Katrina Smith, NHS Blood and Transplant, UK

Coffee Break

Practical implementation in the field of blood, viewpoint from a BE data protection officer
Jan Ceulemans, Flemish Red Cross, Belgium

A focus on data integrity implementation in BEs, regulatory viewpoint
Speaker to be confirmed

Questions & Panel Discussion

Lunch Break

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 Service, Finland

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

Supporting initiatives for European BEs
Stefaan Van der Spiegel, European Commission
Marie-Laure Hecquet, EDQM, Council of Europe

Oral Testimonies of BEs from EU and CoE Member States

Closing Session: Presentations by the Moderators & Discussions on the Conference outcomes
16:00-16:15  Closing Remarks

16:15  Close of the conference