SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 7 - Required and Additional reading

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Week 7 - SoHO VIGILANCE AND BIOVIGILANCE

10/03/25 – 14/03/25

Tutors and External experts involved: A.P. Barreiros, F. Bariani

REQUIRED READING		SELECTED PARTS
EU LEGAL ACTS		
1. SoHO Regulation (EU) 2024/1938	Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC	all
BLOOD		
2. DIRECTIVE **2002/98/EC**	Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC	Art. 3 (l) Chapter V Haemovigilance Chapter VII Data Protection
3. DIRECTIVE **2005/61/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	all
TISSUE		
4. DIRECTIVE **2004/23/EC**	Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	all
5. DIRECTIVE **2006/86/EC**	Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	all
ORGANS		
6. DIRECTIVE **2010/53/EU**	Standards of quality and safety of human organs intended for transplantation	Art. 3 (n) (o) (s) Art. 4 Framework for quality and safety Art. 10 Traceability

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		Art. 11 Reporting system and management concerning serious adverse events and reactions Annex Part B
7. DIRECTIVE **2012/25/EU**	Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation Text with EEA relevance	all
GUIDELINE DOCUMENTS		
8. EDQM Guide	EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition	2.3.4. Interventions and treatment Chapter 10 Haemovigilance 11.12. Traceability and haemovigilance
9. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 16 Traceability Chapter 17 Vigilance

ADDITIONAL READING (Optional)		**SELECTED PARTS**
GUIDELINE DOCUMENTS		
1. Deceased donation article	The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transpl Int. 2011 Apr;24(4):373-8. doi: 10.1111/j.1432-2277.2011.01243.x. (Domínguez-Gil B, Delmonico FL, Shaheen FA, Matesanz R, O'Connor K et al.)	All
2. TRANSPOSE D5.2	Report and a scientific paper on donor eligibility criteria	All
3. TRANSPOSE D5.3	Criteria for the selection and protection of donors	All
4. VOX SANGUINIS 2020	Putting the spotlight on donation-related risks and donor safety – are we succeeding in protecting donors?	All
5. VOX SANGUINIS 2022	Blood donor eligibility criteria for medical conditions: A BEST collaborative study	All

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6. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Appendices 28, 29, 30, 31
EU LEGAL ACTS		
1. DIRECTIVE **2005/62/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments	Art. 1 (g) Annex - 9. Non-Conformance
2. DIRECTIVE **2016/1214/EC**	Amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	Art. 1
3. DIRECTIVE **2006/17/EC**	Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells including ANNEX I, ANNEX II	Art. 1 (g) Traceability Art. 2.11. Annex IV 1.4.4.
4. Commission Decision of **3.8.2010**	Establishing TC guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials	all
5. Commission Decision of **3.7.2015**	Establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code	all
6. EC REPORT on standards of quality and safety of human organs	Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation	Part 4

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