SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 6 - Required and Additional reading

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Week 6 - BTC PREPARATION PROCESS AUTHORISATION

15/01/24 - 19/01/24

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REQUIRED READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. Euro-GTP T&C	Euro-GTP Guide Tissue & Cells	All
2. Euro-GTP Blood	Euro-GTP Guide Blood	All
3. GAPP Guideline	GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes	Scope; Annex B; Appendix 6; Technical Annex I, II and III
4. VISTART D5.4	Principles for Competent Authorities for the evaluation and approval of clinical follow-up protocols for blood, tissues and cells prepared with newly developed and validated processing methodologies (VISTART D5.4)	All
EU LEGAL ACTS		
5. DIRECTIVE **2002/98/EC**	DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 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	
6. DIRECTIVE **2004/23/EC**	DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	1); 2); 4); 28); Art. 1; Art. 20; Art. 24
7. DIRECTIVE **2005/62/EC**	COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 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	Annex; 1.2.2; 6.3.5

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8. DIRECTIVE **2006/17/EC**	COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 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	Annex IV, 1.5.2; 1.7; 2.3
9. DIRECTIVE **2006/86/EC**	COMMISSION DIRECTIVE 2006/86/EC of 24 October 2006 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	Art. 2; Art. 5; Art. 6

ADDITIONAL READING (Optional)		SELECTED PARTS
1. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Paragraphs: 1.2; 1.4 Chapters 6, 11, 12 and 18
2. EDQM Guide	EDQM Guide to the preparation, use and quality assurance of blood components 21st Edition	Paragraphs: 1.2.17; 4.3.1.3; 4.3.2.6. Chapters 9, 10, 11 and Appendix 3
3. SEC	The Single European Code for Tissues and Cells (SEC) - Reference Compendia for the Application of a single European Coding System for Tissues and Cells	All
4. NOTIFY Guide	WHO/CNT Global Notify Library. The NOTIFY Guide on Vigilance and Surveillance. Vigilance and Surveillance (V&S) of Medical Products of Human Origin (MPHO)	All

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