SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 1 - Required and Additional reading

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Week 1 - EU LEGAL PROVISIONS

27/01/25 - 31/01/25

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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
2. DIRECTIVE **2001/83/EC**	Community code relating to medicinal products for human use	Article 1.3, 1.10, 3.6, 83, 109, 110 Annex Part II 1 3.2.1.b, Annex Part III 1.1
3. 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	Article 5, 4, 8, 9,10,11,12,13,14,15, ANNEX IV
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	Recital 14, Article 2.c, 6, 7, 10.2, 10.3,11, 15, 16, 17, 18, 20, 24
5. DIRECTIVE **2004/33/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	Article 4 ANNEX III 2.3.
6. 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	

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7. 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	ANNEX 6.3., 6.4.
8. 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	Article 1, 4.1, ANNEX I 2.1.1., ANNEX II 1.
9. 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	ANNEX II B.1.
10. Regulation EC **1394/2007**	Advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004CHAPTER 2 MARKETING AUTHORISATION REQUIREMENTS	Articles 2, 3, 6, 28, Annex 1
11. DIRECTIVE **2010/45/EU**	Standards of quality and safety of human organs intended for transplantation	Article 11, 17 and Annex
12. Commission Decision **2010/453/EU**	Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council	All
GUIDELINE DOCUMENTS		
13. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	6.4.3.
14. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	
15. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	All

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16. EudraLex	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	Part I, Part II, Part III (Site Master File, Q9 Quality Risk Management), Annexes (1,2,8, 14,15,17,19), Part IV.

ADDITIONAL READING (Optional)		SELECTED PARTS
EU LEGAL ACTS		
1. Regulation EU **2017/746**	In vitro diagnostic medical devices	Article 54 IVDR
2. Regulation EU **2017/745**	Medical devices amending Directive 2001/83/EC	Article 59 MDR
3. DIRECTIVE **2015/565/EC**	Amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells	
4. DIRECTIVE **2015/566/EC**	Implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells	
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	
6. Regulation EC **726/2004**	Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Article 2.1c., 3, ANNEX I
7. DIRECTIVE **2009/135/EC**	Allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic (Text with EEA relevance)	

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8. DIRECTIVE **2011/38/EC**	Amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf-life Text with EEA relevance	The amendments are included in the consolidated version of Dir 2005/62/EC already
9. DIRECTIVE **2014/110/EC**	Amending directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations	The amendments are included in the consolidated version of Dir 2005/62/EC already
10. DIRECTIVE **2012/39/EU**	Amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells Text with EEA relevance	The amendments are included in the consolidated version of Dir 2005/62/EC already
11. DIRECTIVE **2016/1214/EC**	Amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	The amendments are included in the consolidated version of Dir 2005/62/EC already

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