



# SIGHTSoHO

strengthening overSIGHT through training and networking on  
Substances of Human Origin

## Week 9 - Required and Additional reading



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## Week 9 - STOCK AND CRITICAL SUPPLIES, IMPORT/EXPORT, SINGLE CODING

24/03/25 - 28/03/25

Tutors and External experts involved: S. Masterson, S. Pupella

REQUIRED READING		SELECTED PARTS
<b>EU LEGAL ACTS</b>		
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 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	Recital Paragraph 17, Articles 4, 14 & 21 in relation to Import
3. 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	2004/23/EC: Articles 4 & 9 in relation to Import/Export
4. DIRECTIVE 2015/565/EC	Amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells	All
5. 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	All
<b>GUIDELINE DOCUMENTS</b>		
6. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	Chapter 1, 1.1.2 & 1.3.1.3 for Import/Export
7. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 12

ADDITIONAL READING (Optional)		SELECTED PARTS
1. EC PBM Guide for Hospitals	Supporting Patient Blood Management (PBM) in the EU - A practical implementation guide for hospitals, Publications Office, 2017. European Commission, Consumers, Health, Agriculture and Food Executive Agency, Gombotz, H., Kastner, P., Nørgaard, A. et al., , <a href="https://data.europa.eu/doi/10.2818/533179">https://data.europa.eu/doi/10.2818/533179</a>	Relevant Sections
2. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	Chapter 4 (4.2.9 Import), Annex 7 Import-Export
3. EDQM B-SCEP	Blood Supply Contingency and Emergency Plan B-SCEP, Recommendations Model Preparedness Plan. EDQM 2022	All
4. ECDC Covid-10 Guide	Guidance for health system contingency planning during widespread transmission of SARS-CoV-2 with high impact on healthcare services	All