



SIGHTSoHO

strengthening overSIGHT through training and networking on
Substances of Human Origin

Week 11 - Required and Additional reading



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Week 11 - INSPECTION PRACTICE, INSPECTION REPORT AND POST INSPECTION ACTIVITIES

07/04/25 - 11/04/25

Tutors and External experts involved: S. Masterson, J. Kurz

REQUIRED READING		SELECTED PARTS
Guideline documents		
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. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	Chapter number 2
3. Operational manual for CAs	Inspection of Tissue and Cell procurement and Tissue Establishments. Operational Manual for Competent Authorities (EUSTITE Guideline)	Chapters number 3 and 6
4. IFA Guide	Guidance on the detection and investigation of suspected illegal and/or fraudulent activity (IFA) related to tissues and cells. SOHO V&S Project (2011).	Annex VI
EU LEGAL ACTS		
5. 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 number 8
6. 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	Article number 7
7. 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 (notified under document C(2010) 5278) Text with EEA relevance	Whereas and Annex