SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 2 - Required and Additional reading

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Week 2 - LICENSING, AUTHORISATION AND ACCREDITATION SYSTEM (INCLUDING OVERVIEW OF INSPECTION TOOLS)

04/12/23 - 07/12/23

Tutors and External experts involved: S. Pupella, R. Barrio

REQUIRED READING		SELECTED PARTS
Guideline documents		
1. 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 document
2. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	All document
3. Code of practice	Code of practice for the Joint Inspections	All document
4. CESIP	Common European SoHO Inspection Programme (CESIP) - VISTART	Manual and annexes
5. GAPP Guideline	GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments	All document
6. Euro-GTP T&C	Euro-GTP Guide Tissue & Cells	All document
7. Euro-GTP Blood	Euro-GTP Guide Blood	All document
EU LEGAL ACTS		
8. 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	All document

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9. 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 document
10. 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

ADDITIONAL READING (Optional)		SELECTED PARTS
Guideline documents		
1. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 18
2. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	
3. EMA Guidance	EMA Guidance on remote GCP inspections during the COVID-19 pandemic (related to distant assessment)	All document
4. ISO 9001	ISO 9001 Auditing Practices Group Guidance on remote Audits-16.04.2020	All document
5. GMP Auditing	The FDA group: GMP Auditing and COVID-19: A Guide to Remote Auditing and Workforce Recovery	All document
6. GAPP 10.1	Deliverable 10.1 “Manual for training CA inspectors that assess and authorise preparation processes of tissue, cell, and blood products.	All document

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