SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 10 - Required and Additional reading

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Week 10 - INSPECTION PRACTICE, INSPECTION REPORT AND POST INSPECTION ACTIVITIES

31/03/25 - 04/04/25

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

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. 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	All
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 Designation, authorisation, accreditation or licensing of blood establishments & Article 8 Inspection and control measures
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	Article 5 Supervision of human tissue and cell procurement & Article 6 Accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes & Article 7 Inspections and control measures
GUIDELINE DOCUMENTS		
5. 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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6. RVI GUIDE	Remote Virtual Inspection guidance document for EU Competent Authorities responsible for the inspection and authorisation of blood and tissue establishments	All
7. Code of practice	Code of practice for the Joint Inspections	All
8. 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).	All
9. EMA Compilation of Union Procedures	European Medicines Agency Compilation of Community Procedures on Inspections and Exchange of Information	Section on Procedures relating to GMP Inspections

ADDITIONAL READING (Optional)		SELECTED PARTS
1. PIC/S guidance for inspectors	Pharmaceutical Inspection Co-operation Scheme (PIC/S) Aide Memoire for the Inspection of Blood Establishments, Hospital Blood Banks and Plasma Warehouses (2021)	All
2. PIC/S Recommendation	A Recommended Model for Risk-Based Inspection planning in the GMP environment	All
3. PIC/S guidance for BE	Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Practice Guidelines for Blood Establishments (2007)	All
4. Common EU SoHO Inspection Report	Common Format for a Tissue and Blood Establishment Inspection Report	All
5. Operational manual for CAs	Inspection of Tissue and Cell procurement and Tissue Establishments. Operational Manual for Competent Authorities (EUSTITE Guideline)	All

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