SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 3 - Required and Additional reading

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Week 3 - QUALITY MANAGEMENT SYSTEM - OVERVIEW

10/02/25 – 14/02/25

Tutors and External experts involved:

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	REQUIRED READING	SELECTED PARTS
EU LEGAL ACTS		
1. 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	General Sections on Quality Management & Articles 12 Documentation & 13 Record Keeping
2. 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	General Sections on Quality Management & Article 16(3): Quality Management - Documentation Article 24: Relations with Third Parties Article 11(5): Recall
3. 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	General Sections on Quality Management & <u>Annex:</u> Section 5 Documentation, Section 4 (paragraph 5 Computerised Systems) Section 1 (1.1 paragraph 2) & Section 8 Contract Management) Section 1 (1.1 paragraph 2) & Section 10 Self-Inspection Section 1 (1.1 paragraph 2) & Section 9 Non-conformance Section 1 (1.1 paragraph 2) & Section 9.3 Recall
4. 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	General Section on Quality Management & <u>Annex 1:</u> Section E Documentation & Records Section A (6) Organisation & Management (Third Parties)

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	certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	Section F (1) Quality Review (Audits) Section F (2&3) Quality Review (Non-Conformances) Section D Distribution & Recall
GUIDELINE DOCUMENTS		
5. EDQM Blood Guide	Guide to the preparation, use and quality assurance of blood components 20th Edition.	GPGs (Page 36-114) Appendix 3 Data Processing Systems
6. EDQM Tissues & Cells Guide	Guide to the quality and safety of tissues and cells for human application 5th Edition.	GPGs (Part C) & Chapter 2 Quality Management & Validation Chapter 14 Computerised Systems
7. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	Inspection Methodology Section (Page 15)

ADDITIONAL READING		**SELECTED PARTS**
1. PIC/S guidelines for BE and hospital blood banks	Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Practice Guidelines for Blood Establishments and Hospital Blood Banks (2021)	ALL
2. 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
3. EudraLex	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	Chapter 1 QMS Chapter 4 Documentation Chapter 7 Outsourced Activities Chapter 9 Self Inspection Annex 11 Computerised Systems Annex 14 – Section 3
4. ISO 15189:2022	ISO 15189:2022 Medical Laboratories – Requirements for quality and competence	Sections 7 & 8

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