



# SIGHTSoHO

strengthening overSIGHT through training and networking on  
Substances of Human Origin

## Week 4 - Required and Additional reading



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## Week 4 - QUALITY MANAGEMENT SYSTEM - GOOD PRACTICES

18/12/23 - 22/12/23

Tutors and External experts involved:

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REQUIRED READING		SELECTED PARTS
<b>EU LEGAL ACTS</b>		
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	Article 10 Personnel
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	Article 18 Personnel Article 20 (1) Equipment
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	Annex (in particular (2) Personnel & Organisation, (3) Premises (4) Equipment & Materials)
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 certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	Annex 1 (in particular B Personnel, C Equipment & Materials, D Facilities / Premises)
<b>GUIDELINE DOCUMENTS</b>		
5. EDQM Blood Guide	Guide to the preparation, use and quality assurance of blood components 20 <sup>th</sup> Edition.	Sections: 2 Personnel & Organisation, 3 Premises, 4 Equipment & Materials, 4.3 Qualification & Validation,

		4.6 Change Control Chapters 5 & 6 (Blood Component Monographs - QC Parameters contained within) Appendix 4 Statistical Process Control
6. EDQM Tissues & Cells Guide	Guide to the quality and safety of tissues and cells for human application 5 <sup>th</sup> Edition.	Part A: Chapter 2 Quality Management & Validation (in particular 2.3 Personnel & Organisation, 2.4 Premises (Also Chapter 8), 2.5 Equipment & Materials, 2.8 Change Control, 2.12 Qualification, Validation, Verification. Part C Good Practice Guidelines Part D Tissue & Cell Monographs (QC Parameters contained within)
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 2 Personnel Chapter 3 Premises & Equipment Chapter 6 Quality Control Part IV (Relevant QMS sections)

		Annex 11 Computerised Systems Annex 14 - Section 3 Annex 15 Qualification & Validation
4. ISO 15189:2022	ISO 15189:2022 Medical Laboratories - Requirements for quality and competence	Sections 7 & 8