SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

D4 Final content of on-line training incl. remaining weekly training

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Introduction

The present report includes the final content of the eLearning training (Round 1).
Each module is structured as follows:

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  - Assignment(s)
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From weekly training module 3 to weekly training module 11, the selection of the specific parts of the required and the additional readings is not finalised given that major attention has been given to the first two modules material. Moreover, it was deemed appropriate by the tutors to complete that task when the preparation of each module material is in progress.

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Week 1 - EU LEGAL PROVISIONS

27/11/23 - 01/12/23

Tutors and External experts involved:

J. Kurz, S. Pupella, DG SANTE, W. Ecker, S. Masterson, U. La Rocca, R. Barrio

Learning objectives:

- To facilitate a harmonised interpretation of the EU legislative framework,
- To deepen awareness of the connection and interaction of SoHO legal provisions with medical devices and ATMP regulations as well as Regulation and Directive of medicinal products and their impact on inspections and authorisation of novel processes.

SYNCHRONOUS LIVE APPOINTMENTS

27-Nov	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
	Live opening event	14:00 - 15:30
28-Nov	**Tuesday**	
	Independent asynchronous study	
29-Nov	**Wednesday**	**When (CET)**
	Synchronous live session on **Overlaps between SoHO, ATMPs and Medical Devices frameworks**	14:00 - 15:30
30-Nov	**Thursday**	
	Independent asynchronous study	
01-Dec	**Friday**	**When (CET)**
	Forum - discussion on assignment on **EU Directives**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **EU current directives**	J. Kurz
Assignment on **EU current directives**	J. Kurz
Pre-recorded presentation on **Intro to the new regulation**	DG SANTE
Pre-recorded presentation on **Basic info on current Medical Device Regulations relevant for BTC establishments**	W. Ecker
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
EU LEGAL ACTS		
1. DIRECTIVE **2001/83/EC**	Community code relating to medicinal products for human use	Article 1.3, 1.10, 3.6, 83, 109, 110 Annex Part II 1 3.2.1.b, Annex Part III 1.1
2. 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, 4, 8, 9,10,11,12,13,14,15, ANNEX IV
3. 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	Recital 14, Article 2.c, 6, 7, 10.2, 10.3,11, 15, 16, 17, 18, 20, 24
4. DIRECTIVE **2004/33/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	Article 4 ANNEX III 2.3.
5. DIRECTIVE **2005/61/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	
6. 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 6.3., 6.4.

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7. DIRECTIVE **2006/17/EC**	Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells including ANNEX I, ANNEX II	Article 1, 4.1, ANNEX I 2.1.1., ANNEX II 1.
8. 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 II B.1.
9. Regulation EC **1394/2007**	Advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004CHAPTER 2 MARKETING AUTHORISATION REQUIREMENTS	Articles 2, 3, 6, 28, Annex 1
10. DIRECTIVE **2010/45/EU**	Standards of quality and safety of human organs intended for transplantation	Article 11, 17 and Annex
11. 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	All
GUIDELINE DOCUMENTS		
12. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	6.4.3.
13. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	

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14. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	All
15. EudraLex	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	Part I, Part II, Part III (Site Master File, Q9 Quality Risk Management), Annexes (1,2,8, 14,15,17,19), Part IV.

ADDITIONAL READING		SELECTED PARTS
EU LEGAL ACTS		
1. Regulation EU **2017/746**	In vitro diagnostic medical devices	Article 54 IVDR
2. Regulation EU **2017/745**	Medical devices amending Directive 2001/83/EC	Article 59 MDR
3. DIRECTIVE **2015/565/EC**	Amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells	
4. DIRECTIVE **2015/566/EC**	Implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells	
5. Commission Decision of **3.7.2015**	Establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code	

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6. Regulation EC **726/2004**	Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Article 2.1c., 3, ANNEX I
7. DIRECTIVE **2009/135/EC**	Allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic (Text with EEA relevance)	
8. DIRECTIVE **2011/38/EC**	Amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf-life Text with EEA relevance	The amendments are included in the consolidated version of Dir 2005/62/EC already
9. DIRECTIVE **2014/110/EC**	Amending directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations	The amendments are included in the consolidated version of Dir 2005/62/EC already
10. DIRECTIVE **2012/39/EU**	Amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells Text with EEA relevance	The amendments are included in the consolidated version of Dir 2005/62/EC already
11. DIRECTIVE **2016/1214/EC**	Amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	The amendments are included in the consolidated version of Dir 2005/62/EC already

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Week 2 - CERTIFICATION AND AUTHORISATION SYSTEM (INCLUDING OVERVIEW OF INSPECTION TOOLS)

04/12/23 – 07/12/23

Tutors and External experts involved:

S. Pupella, R. Barrio, F. Teskrat, R. Piteira, J. Kurz, A. Vassanelli, A. Kurzreiter, U. La Rocca

Learning objectives:

- To improve knowledge of the new inspection tools in order to harmonize the inspection methodology,
- To understand the common approach for authorising new product/process and activities.

SYNCHRONOUS LIVE APPOINTMENTS

04-Dec	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
05-Dec	**Tuesday**	
	Independent asynchronous study	
06-Dec	**Wednesday**	**When (CET)**
	Synchronous live session on **EuroGTP II risk assessment tool**	14:00 - 15:30
07-Dec	**Thursday**	**When (CET)**
	Forum - survey results on **Mutual recognition tools (e.g., CESIP, Joint inspections - Code of practice)**	14:00 - 16:00
08-Dec	**Friday**	
	Independent asynchronous study/Bank Holiday	

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments**	S. Pupella
Pre-recorded presentations on **GAPP Guideline for Preparation Process Authorisation (PPA)**	R. Barrio
Survey on **Mutual recognition: tools (e.g., Common European SoHO Inspection Programme - CESIP, Joint inspections)**	S. Pupella R. Barrio
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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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
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

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ADDITIONAL READING		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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Week 3 - QUALITY MANAGEMENT SYSTEM - OVERVIEW

11/12/23 – 15/12/23

Tutors and External experts involved:

S. Masterson, A. Vassanelli, A. Kurzreiter, Expert from EDQM, J. Kurz, S. Pupella, U. La Rocca, F. Teskrat, F. Bariani

Learning objectives:

- To establish a common understanding of how to inspect various/assorted components of a quality system,
- To discuss examples of difficulties, issues that arise on inspection relating to QMS Inspection will be requested from participants and a common approach agreed and noted.

SYNCHRONOUS LIVE APPOINTMENTS

11-Dec	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
12-Dec	**Tuesday**	
	Independent asynchronous study	
13-Dec	**Wednesday**	**When (CET)**
	Synchronous live session (Intro lecture and breakout rooms) on **Classification of real-life non compliances**	14:00 - 15:30
14-Dec	**Thursday**	
	Independent asynchronous study	
15-Dec	**Friday**	**When (CET)**
	Forum	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **Documentation, Data processing Third parties Management**	A. Vassanelli S. Masterson
Pre-recorded presentation on **Non-conformance/deviation system/recall** (NCs and risk assessment tool)	S. Masterson A. Kurzreiter
Pre-recorded presentation on **Self-Inspection/Internal & External Audit**	Expert from EDQM
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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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 & Annex: 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 certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	General Section on Quality Management & Annex 1: Section E Documentation & Records Section A (6) Organisation & Management (Third Parties) Section F (1) Quality Review (Audits) Section F (2&3) Quality Review (Non-Conformances) Section D Distribution & Recall

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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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Week 4 - QUALITY MANAGEMENT SYSTEM - GOOD PRACTICES

18/12/23 – 22/12/23

Tutors and External experts involved:

J. Kurz, A. Kurzreiter, S. Masterson, F. Teskrat, A. Vassanelli, S. Pupella, U. La Rocca,

Learning objectives:

- To establish a common understanding of how to inspect various/assorted components of a quality system,
- To discuss examples of difficulties, issues that arise on inspection relating to QMS Inspection will be requested from participants and a common approach agreed and noted.

SYNCHRONOUS LIVE APPOINTMENTS

18-Dec	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
19-Dec	**Tuesday**	
	Independent asynchronous study	
20-Dec	**Wednesday**	**When (CET)**
	Synchronous live session - Lecture followed by open discussion on **Quality Control and Statistical Process Control**	14:00 - 15:30
21-Dec	**Thursday**	
	Independent asynchronous study	
22-Dec	**Friday**	**When (CET)**
	Forum - discussion on assignment on **Personnel (Training and competences of the staff)**	14:00 - 15:00
	Forum - discussion on assignment on **Validation and Change control**	15:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Assignment on **Personnel (Training and competences of the staff)**	S. Masterson S. Pupella
Assignment on **Validation and Change control**	A. Vassanelli A. Kurzreiter
POST SELF- ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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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	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)
GUIDELINE DOCUMENTS		
5. EDQM Blood Guide	Guide to the preparation, use and quality assurance of blood components 20th 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

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6. EDQM Tissues & Cells Guide	Guide to the quality and safety of tissues and cells for human application 5th 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 (P. 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

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Week 5 - QUALITY RISK ASSESSMENT (INCLUDING TOOLS)

08/01/24 – 12/01/24

Tutors and External experts involved:

S. Masterson, F. Bariani, R. Barrio, External expert (IES), S. Pupella

Learning objectives:

- How to select the most appropriate and effective tools to perform quality risk management, including mitigation

SYNCHRONOUS LIVE APPOINTMENTS

08-Jan	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
09-Jan	**Tuesday**	
	Independent asynchronous study	
10-Jan	**Wednesday**	**When (CET)**
	Synchronous live session - Frontal lesson followed by discussion and Q&A on **Risk Assessment Methods (e.g., HACCP, FMEA, FTA, Root Cause Analysis, Risk Mitigation Strategies, Risk register etc.)**	14:00 - 15:30
11-Jan	**Thursday**	
	Independent asynchronous study	
12-Jan	**Friday**	**When (CET)**
	Forum - discussion on assignment on **Management of non-compliances: follow-up activities**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	**Who**
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **Quality risk management**	S. Masterson
Assignment on **Management of non-compliances: follow-up activities**	F. Bariani
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. ICH Q9	Quality Risk Management Guideline	All document
2. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 3
3. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	Relevant sections referring to Quality Risk Management
EU LEGAL ACTS		
4. 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
5. 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
6. 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		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. WHO HACCP methodology	Application of hazard analysis and critical control point (HACCP) methodology to pharmaceuticals. World Health Organization. Technical Report Series, No. 908, Annex 7, 2003.	All document

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2. HACCP as QRM tool scientific article	Opportunities, challenges and benefits of using HACCP as a quality risk management tool in the pharmaceutical industry. Dahiya S, Khar R, Chhikara A., Qual Assur J 2009: 12(2): 95-104.	All document
3. FMEA scientific article	Failure mode and effect analysis: FMEA from theory to execution. Stamatis DH., Milwaukee WI, USA: ASQC Quality Press, 1996. ISBN 0-87389-300-X	All document
4. Risk analysis and management scientific article	Analysis and management of the risks related to the collection, processing and distribution of peripheral blood haematopoietic stem cells. Bambi F, Spitaleri I, Verdolini G et al., Blood Transfus 2009; 7(1): 3-17.	All document
5. EDQM Guidance	Guidance for root-cause analysis of non-satisfactory external quality assessment results. 1st Edition, 2017	All document
6. PIC/S guidance on GMP deficiencies	PIC/S Guidance on classification of Good Manufacturing Practice (GMP) deficiencies. PI 040-1 3 Appendices, 1 January 2019	All document
7. Treaceability scientific article	Comprehensive protocol of traceability during in vitro fertilization: the result of a multicentre failure mode and effect analysis (FMEA)", L. Rienzi, F. Bariani, M. Dalla Zorza, E. Albani, F. Benini, S. Chamayou, M.G. Minasi, L. Parmegiani, L. Restelli, G. Vizziello, A. Nanni Costa, in Human Reproduction, 31/5/2017: 1-9	All document

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Week 6 - BTC PREPARATION PROCESS AUTHORISATION

15/01/24 - 19/01/24

Tutors and External experts involved:

R. Barrio, External expert (IES), A. Vassanelli, U. La Rocca, J. Kurz, A. Kurzreiter, S. Pupella

Learning objectives:

- To gain awareness on quality, safety and clinical efficacy of new preparation processes.

SYNCHRONOUS LIVE APPOINTMENTS

15-Jan	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
16-Jan	**Tuesday**	
	Independent asynchronous study	
17-Jan	**Wednesday**	**When (CET)**
	Synchronous live session - Lecture followed by breakout sessions on **Quality and safety assessment (product/process)**	14:00 - 15:30
18-Jan	**Thursday**	
	Independent asynchronous study	
19-Jan	**Friday**	**When (CET)**
	Forum - discussion on selected documents on **Clinical assessment as part of PPA (risk-based)**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **A common approach on PPA (a focus on Technical Annexes of the GAPP Guideline for PPA)**	R. Barrio
Assignment on **Clinical assessment as part of PPA (risk-based)**	S. Pupella External Expert (IES)
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. Euro-GTP T&C	Euro-GTP Guide Tissue & Cells	All
2. Euro-GTP Blood	Euro-GTP Guide Blood	All
3. GAPP Guideline	GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes	Scope; Annex B; Appendix 6; Technical Annex I, II and III
4. 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
EU LEGAL ACTS		
5. DIRECTIVE **2002/98/EC**	DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 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	
6. DIRECTIVE **2004/23/EC**	DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	1); 2); 4); 28); Art. 1; Art. 20; Art. 24
7. DIRECTIVE **2005/62/EC**	COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 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; 1.2.2; 6.3.5
8. DIRECTIVE **2006/17/EC**	COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells	Annex IV, 1.5.2; 1.7; 2.3

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9. DIRECTIVE **2006/86/EC**	COMMISSION DIRECTIVE 2006/86/EC of 24 October 2006 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	Art. 2; Art. 5; Art. 6

ADDITIONAL READING		SELECTED PARTS
1. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Paragraphs: 1.2; 1.4 Chapters 6, 11, 12 and 18
2. EDQM Guide	EDQM Guide to the preparation, use and quality assurance of blood components 21st Edition	Paragraphs: 1.2.17; 4.3.1.3; 4.3.2.6. Chapters 9, 10, 11 and Appendix 3
3. SEC	The Single European Code for Tissues and Cells (SEC) - Reference Compendia for the Application of a single European Coding System for Tissues and Cells	All
4. NOTIFY Guide	WHO/CNT Global Notify Library. The NOTIFY Guide on Vigilance and Surveillance. Vigilance and Surveillance (V&S) of Medical Products of Human Origin (MPHO)	All

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Week 7 - SoHO VIGILANCE AND BIOVIGILANCE

22/01/24 – 26/01/24

Tutors and External experts involved:

A. P. Barreiros, F. Bariani, A. Vassanelli, S. Pupella, A. Kurzreiter, R. Barrio, External expert (VES), U. La Rocca

Learning objectives:

- To gain awareness on Vigilance principles applied on BTC and organs,
- To know the common approach to assess the compliance with vigilance requirements (scientifically evidence-based tools for fostering patient safety within the competence of inspectorates and inspectors, methodology for donor selection evaluation and living donor protection).

SYNCHRONOUS LIVE APPOINTMENTS

22-Jan	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
23-Jan	**Tuesday**	
	Independent asynchronous study	
24-Jan	**Wednesday**	**When (CET)**
	Synchronous live session - Webinar followed by Q&A on **Biovigilance: organs**	14:00 - 15:30
25-Jan	**Thursday**	
	Independent asynchronous study	
26-Jan	**Friday**	**When (CET)**
	Forum	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentations on **Donor selection and donor and recipient protection: Blood, T&C, MAR**	F. Bariani A. Vassanelli S. Pupella
Pre-recorded presentations on **Biovigilance: Blood, T&C, MAR**	A. Kurzreiter R. Barrio External Expert (VES)
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
EU LEGAL ACTS		
BLOOD		
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	Art. 3 (l) Chapter V Haemovigilance Chapter VII Data Protection
2. DIRECTIVE **2005/61/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	all
TISSUE		
3. 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
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	all
ORGANS		
5. DIRECTIVE **2010/53/EU**	Standards of quality and safety of human organs intended for transplantation	Art. 3 (n) (o) (s) Art. 4 Framework for quality and safety Art. 10 Traceability Art. 11 Reporting system and management concerning serious adverse events and reactions Annex Part B
6. DIRECTIVE **2012/25/EU**	Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation Text with EEA relevance	all
GUIDELINE DOCUMENTS		

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7. EDQM Guide	EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition	2.3.4. Interventions and treatment Chapter 10 Haemovigilance 11.12. Traceability and haemovigilance
8. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 16 Traceability Chapter 17 Vigilance

ADDITIONAL READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. Deceased donation article	The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transpl Int. 2011 Apr;24(4):373-8. doi: 10.1111/j.1432-2277.2011.01243.x. (Domínguez-Gil B, Delmonico FL, Shaheen FA, Matesanz R, O'Connor K et al.)	All
2. TRANSPOSE D5.2	Report and a scientific paper on donor eligibility criteria	All
3. TRANSPOSE D5.3	Criteria for the selection and protection of donors	All
4. VOX SANGUINIS 2020	Putting the spotlight on donation-related risks and donor safety – are we succeeding in protecting donors?	All
5. VOX SANGUINIS 2022	Blood donor eligibility criteria for medical conditions: A BEST collaborative study	All
6. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Appendices 28, 29, 30, 31
EU LEGAL ACTS		
8. 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	Art. 1 (g) Annex - 9. Non-Conformance

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9. DIRECTIVE **2016/1214/EC**	Amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	Art. 1
10. DIRECTIVE **2006/17/EC**	Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells including ANNEX I, ANNEX II	Art. 1 (g) Traceability Art. 2.11. Annex IV 1.4.4.
11. Commission Decision of **3.8.2010**	Establishing TC guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials	all
12. Commission Decision of **3.7.2015**	Establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code	all
13. EC REPORT on standards of quality and safety of human organs	Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation	Part 4

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Week 8 - SERIOUS ADVERSE OUTCOMES/ RAPID ALERTS AND HARMONIZING DATA COLLECTION

29/01/24 – 02/02/24

Tutors and External experts involved:

A. P. Barreiros, F. Bariani, R. Barrio, J. Kurz, S. Pupella, U. La Rocca, A. Vassanelli, External expert (VES), Notify expert

Learning objectives:

To deepen the awareness of the positive impact on donor and patient safety by implementing and utilising:

- an efficient and effective upstream and downstream harmonised reporting system;
- a harmonised definitions and agreed denominators all supporting continuous improvement feeding into an appropriate data management system;
- the WHO/CNT Global Notify Library.

SYNCHRONOUS LIVE APPOINTMENTS

29-Jan	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
30-Jan	**Tuesday**	
	Independent asynchronous study	
31-Jan	**Wednesday**	**When (CET)**
	Synchronous live session - Intro lecture followed by simulation on **WHO/CNT Global Notify Library**, simulation of evaluation of examples of medical records through cases study, followed by comparison of the results in plenary	14:00 - 15:30
01-Feb	**Thursday**	
	Independent asynchronous study	
02-Feb	**Friday**	**When (CET)**
	Forum - discussion on assignment on **Harmonising data collection, Common approach and definitions, Denominators**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentations on **Severe adverse reactions/Events (SARE) Reporting: Blood, T&C, Organs**	External Expert (EDQM) A.P. Barreiros
Assignment on **Harmonising data collection, Common approach and definitions, Denominators**	F. Bariani R. Barrio
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
EU LEGAL ACTS		
BLOOD		
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	Art. 3 (l) Chapter V Haemovigilance Chapter VII Data Protection
2. DIRECTIVE **2005/61/EC**	Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	All
3. Common approach BLOOD	Common Approach for definition of Reportable Serious Adverse Events and Reactions (SARE) as laid down in the Blood Directive 2002/98/EC and Commission Directive 2005/61/EC	All
4. SARE BLOOD	Summary of the 2022 annual reporting of Serious Adverse Reactions and Events for Blood and Blood Components	All
TISSUES & CELLS		
5. 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
6. 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	all
7. Common approach T&C	Common Approach for definition of Reportable Serious Adverse Events and Reactions (SARE) as laid down in the Tissues and Cells Directive 2004/23/EC and Commission Directive 2006/86/EC	All
8. SARE T&C	Summary of the 2022 annual reporting of Serious Adverse Reactions and Events for Tissues and Cells	All
BLOOD - T&C		
9. RATC - RAB	Rapid Alert system for human Tissues and Cells (RATC) and for human Blood and Blood Components (RAB) - Summary of 2022 activities	All

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ORGANS		
10. DIRECTIVE **2010/53/EU**	Standards of quality and safety of human organs intended for transplantation	Art. 3 (n) (o) (s) Art. 4 Framework for quality and safety Art. 10 Traceability Art. 11 Reporting system and management concerning serious adverse events and reactions Annex Part B
11. DIRECTIVE **2012/25/EU**	Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation Text with EEA relevance	all
GUIDELINE DOCUMENTS		
12. ISBT-IHN	ISBT-IHN working party	
13. Notify Review	Vigilance for Medical Products of Human Origin—Progress on the Notify Library's Global Effort to Share Information and Learning Petrisli E, Carella C, Navarro A, Fehily D, Strong DM, Cardillo M; on behalf of the Notify Editorial Board. 2021 Sep 1;105(9):1921-1929.	all
14. Notify Commentary	Donor-derived Disease—Who to Notify? Chapman JR. 021 Sep 1;105(9):1909-1910.	all
15. EDQM Guide	EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition	3.10. Management of adverse reactions in donors 11.11. Management and reporting of transfusion reactions

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16. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	2.10 Investigation and reporting of deviations, adverse events and adverse reactions 13.14. Recipient follow-up and clinical outcome registries 13.15. Adverse events and adverse reactions

ADDITIONAL READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. NOTIFY general presentation	WHO/CNT Global Notify Library: Notify Project general presentation (last update - Sept 2020)	all
2. NOTIFY Guide	WHO/CNT Global Notify Library. The NOTIFY Guide on Vigilance and Surveillance. Vigilance and Surveillance (V&S) of Medical Products of Human Origin (MPHO)	all
3. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	all
4. GAPP Guideline	GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes	all
5. RBMO Commentary	Learning from incidents in medically assisted reproduction: the Notify Library as a learning tool. Alteri A, Petrisli E, Nolan P, Pisaturo V, Fehily D, Navarro A, Strong DM, Cardillo M, Costa M.	all

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EU LEGAL ACTS		
6. 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	Art. 1 (g) Annex - 9. Non-Conformance
7. DIRECTIVE **2016/1214/EC**	Amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	Art. 1
8. DIRECTIVE **2006/17/EC**	Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells including ANNEX I, ANNEX II	Art. 1 (g) Traceability Art. 2.11. Annex IV 1.4.4.
9. Commission Decision of **3.8.2010**	Establishing TC guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials	all
10. Commission Decision of **3.7.2015**	Establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code	all

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Week 9 - STOCK AND CRITICAL SUPPLIES, IMPORT/EXPORT, SINGLE CODING

05/02/24 – 09/02/24

Tutors and External experts involved:

S. Masterson, S. Pupella, J. Kurz, A. Kurzreiter, A. Vassanelli, F. Bariani, U. La Rocca

Learning objectives:

To deepen the awareness of:

- possible challenges critical for the SoHO in a logistic chain,
- the impact of epidemic or pandemic outbreaks as well as preparation breakdown on the donor safety and the supply for patients, respectively,
- limitations and advantages of Single Coding in the distribution of TC,
- the system in place for traceability of all the process from donor – donation – preservation/storage- distribution and application is under control and managed according to the minimum requirements defined in the EU BTC Directives and matching the current EDQM BTC guides

SYNCHRONOUS LIVE APPOINTMENTS

05-Feb	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
06-Feb	**Tuesday**	
	Independent asynchronous study	
07-Feb	**Wednesday**	**When (CET)**
	Synchronous live session - Intro lecture and problem-solving exercise in breakout rooms (contingency planning) on **Stock and critical supplies (reagents, etc)**	14:00 - 15:30
08-Feb	**Thursday**	
	Independent asynchronous study	
09-Feb	**Friday**	**When (CET)**
	Forum - discussion on assignment on **Single Coding of tissues and cells**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **Imports and exports**	S. Masterson - J. Kurz
Assignment on **Single Coding of tissues and cells**	A. Kurzreiter - A. Vassanelli
Pre-recorded presentation on **Traceability**	F. Bariani
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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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	Recital Paragraph 17, Articles 4, 14 & 21 in relation to Import
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	2004/23/EC: Articles 4 & 9 in relation to Import/Export
3. DIRECTIVE **2015/565/EC**	Amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells	All
4. DIRECTIVE **2015/566/EC**	Implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells	All
GUIDELINE DOCUMENTS		
5. EDQM Guide	EDQM Guide-to-the-preparation-use-and-quality-assurance-of-blood-components-21st-edition	Chapter 1, 1.1.2 & 1.3.1.3 for Import/Export
6. EDQM Guide	EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition	Chapter 12

ADDITIONAL READING		SELECTED PARTS
1. EC PBM Guide for Hospitals	Supporting Patient Blood Management (PBM) in the EU – A practical implementation guide for hospitals, Publications Office, 2017. European Commission, Consumers, Health, Agriculture and Food Executive Agency, Gombotz, H., Kastner, P., Nørgaard, A. et al., https://data.europa.eu/doi/10.2818/533179	Relevant Sections

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2. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	Chapter 4 (4.2.9 Import), Annex 7 Import-Export
3. EDQM B-SCEP	Blood Supply Contingency and Emergency Plan B-SCEP, Recommendations Model Preparedness Plan. EDQM 2022	All
4. ECDC Covid-10 Guide	Guidance for health system contingency planning during widespread transmission of SARS-CoV-2 with high impact on healthcare services	All

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

12/02/24 – 16/02/24

Tutors and External experts involved:

S. Pupella, S. Masterson, F. Teskrat, A. Vassanelli, J. Kurz, A. Kurzreiter, U. La Rocca

Learning objectives:

- To harmonise interpretation of inspection methodology,
- To strengthen cooperation of inspectorates.

SYNCHRONOUS LIVE APPOINTMENTS

12-Feb	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
13-Feb	**Tuesday**	
	Independent asynchronous study	
14-Feb	**Wednesday**	**When (CET)**
	Synchronous live session on **Inspection report**	14:00 - 15:30
15-Feb	**Thursday**	
	Independent asynchronous study	
16-Feb	**Friday**	**When (CET)**
	Forum - discussion on assignment and ppt on **Special requirements and protocol for initiating and performing joint inspections upon justified request of a EU MS**	14:00 - 16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on **Inspection practices (pre and post inspection activities)**	S. Pupella
Pre-recorded presentation on **Illegal and fraudulent activities**	F. Teskrat J. Kurz
Presentation on **Remote Virtual Inspection guidance document**	F. Teskrat
Pre-recorded presentation on **Special requirements and protocol for initiating and performing joint inspections upon justified request of an EU MS**	J. Kurz A. Kurzreiter
Assignment on **Special requirements and protocol for initiating and performing joint inspections upon justified request of an EU MS**	J. Kurz A. Kurzreiter
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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REQUIRED READING		SELECTED PARTS
EU LEGAL ACTS		
1. 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
2. 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
3. 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		
4. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	All
5. RVI GUIDE	Remote Virtual Inspection guidance document for EU Competent Authorities responsible for the inspection and authorisation of blood and tissue establishments	All
6. Code of practice	Code of practice for the Joint Inspections	All
7. 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

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8. 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		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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Week 11 - RISK FOR INSPECTORATE

19/02/24 – 23/02/24

Tutors and External experts involved:

S. Masterson, S. Pupella, R. Barrio, U. La Rocca, A. Vassanelli, F. Bariani

Learning objectives:

- To exchange experiences for effective and efficient quality management in the inspectorates,
- To raise awareness of risks for inspectorates.

SYNCHRONOUS LIVE APPOINTMENTS

19-Feb	**Monday**	**When (CET)**
	Intro message launched in the "Announcements"	10:00 - 11:00
20-Feb	**Tuesday**	
	Independent asynchronous study	
21-Feb	**Wednesday**	**When (CET)**
	Synchronous live session - Frontal lesson followed by discussion on **Inspectors management (skills, competences, responsibilities, independence and conflict of interest/impartiality)**	14:00 - 15:30
22-Feb	**Thursday**	
	Independent asynchronous study	
23-Feb	**Friday**	**When (CET)**
	Forum - discussion on assignment on **Procedure for products sampling for analysis purposes by independent laboratories on the request of the CAs**	14:00 -16:00

INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on Pre-recorded presentation on **Quality Management System & Quality Risk Management for Inspectorates**	S. Masterson
Assignment on **Empowerment of Inspectors and Taking of Samples for examination and analysis** to be discussed in the Forum	S. Masterson S. Pupella
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

SYNCHRONOUS LIVE APPOINTMENTS

01-Mar	**Friday**	**When (CET)**
	Live closing event	14:00 - 15:30

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REQUIRED READING		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	Chapter number 2
2. 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
3. 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		
4. 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
5. 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
6. 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

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