SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 8 - Required and Additional reading

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

17/03/25 - 21/03/25

Tutors and External experts involved: F. Bariani, A.P. Barreiros

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

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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
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 general presentation	WHO/CNT Global Notify Library: Notify Project general presentation (last update - Sept 2020)	all

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14. 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
15. Notify Commentary	Donor-derived Disease—Who to Notify? Chapman JR. 021 Sep 1;105(9):1909-1910.	all
16. 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
17. 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 (Optional)		SELECTED PARTS
GUIDELINE DOCUMENTS		
1. 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
2. VISTART D6	Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments (VISTART D6)	all
3. GAPP Guideline	GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes	all

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4. 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
5. Notify Article	Donor-derived Disease—Who to Notify? Jeremy R. Chapman, AC, FRACP, MD	
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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