SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Week 5 - Required and Additional reading

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Week 5 - QUALITY RISK ASSESSMENT (INCLUDING TOOLS)

08/01/24 - 12/01/24

Tutors and External experts involved: S. Masterson, R. Barrio, S. Pupella, F. Bariani

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

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ADDITIONAL READING (Optional)		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
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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