SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Preliminary Face-to-Face Programme (Round 1)

Funded by the European Union

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Workshop 1 - INSPECTION PRACTICE

15, 16, 17 May 2024

Tutors and External experts involved:

J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat, Experts from EC Inspection Expert Sub-group (IES, to be invited)

Learning objectives:

- To share the common European standards and criteria for preparing and conducting an inspection of BTC establishments, including MAR;
- To harmonise interpretation of inspection findings and inspection reports;
- To exchange experiences on risk management including data management in the inspectorates;
- To assess the feasibility of cooperation among Member States in case of joint inspections.

SUB-TOPICS	METHODOLOGY
EU legal provisions	Frontal lectures followed by plenary discussion with facilitators
Preparation and performance of inspection	Intro presentation, working groups' exercises followed by plenary discussion
Assessment of non-compliances and classification of deficiencies	Intro lecture with case studies to be discussed in plenary
Joint inspections	Frontal lecture and role play

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Workshop 2 - PREPARATION PROCESS AUTHORISATION

5, 6, 7 June 2024

Tutors and External experts involved:

S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, F. Bariani, A. Vassanelli, Euro-GTP expert, Experts from EC Inspection Expert Sub-group (IES, to be invited)

Learning objectives:

- To understand the approach concerning the SoHO preparation process authorisation system, joint SoHO preparation assessments, authorisation of imported/exported SoHO;
- To further familiarize with the GAPP guideline application, including the assessment of clinical efficacy as a part of PPA of innovative SoHO products/processes;
- 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 processes.

SUB-TOPICS	METHODOLOGY
EU legal provisions (CAs obligations, conditional authorisation, how to build a bridge between Medical Devices/ATMPs sectors/CA)	Frontal lectures followed by plenary discussion with facilitators
Taking into account the best current practice according to scientific development, assessment of the state-of-the-art of: - collection/procurement - processing - testing laboratories - facilities - storage - transport, transplantation/transfusion	Intro lecture, expert talk and working group's exercises
EuroGTP II risk assessment tool application	Intro lecture, plenary exercise with simulation and discussion

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Workshop 3 - BIOVIGILANCE AND HEMOVIGILANCE

3, 4, 5 July 2024

Tutors and External experts involved:

A. P. Barreiros, R. Barrio, S. Pupella, Experts from EC Vigilance Expert Sub-group (VES, to be invited) and International Haemovigilance Network (IHN, to be invited), F. Teskrat, DG SANTE, U. La Rocca

Learning objectives:

- To know the EU common approach on the vigilance management and reporting according to the different SoHO fields and organs;
- To share the EU classification of SARE and to exchange experiences on the follow-up activities;
- To know how to interact with ATMPs and Medical Devices fields in order to downstream from the recipient to the donation organisation related to the vigilance procedure.

SUB-TOPICS	METHODOLOGY
EU legal provisions	Frontal lectures followed by plenary discussion with facilitators
Principles of donor and patient protection in the different SoHO fields	Intro lecture, lecture by expert, followed by discussion
Serious adverse events and reactions reporting	Intro lecture, RAB/RATC platforms, role play
Vigilance data reporting, analysis and follow-up actions	Intro lecture, working group exercises

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