SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

Joint Meeting of the Competent Authorities on:
Blood and Blood Components
Tissues and Cells
Organs

May 24,2023

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On behalf of the SIGHTSoHO Team

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Tender Objectives

To develop a training programme addressed to Substances of Human Origin (SoHO) national competent authorities' (CAs) staff involved in oversight tasks, particularly inspections, vigilance and BTC preparation processes assessment, aiming to:

- reinforce **the skills of CAs staff** involved in the above-mentioned activities
- facilitate a **harmonized interpretation of the EU legislative framework**
- promote **common practices** for oversight activities
- facilitate **exchanges and networking among NCAs staff**, and foster for possible **collaborations** among them (for joint inspections, peer audits)
- promote **trust between EU CAs** in the SoHO field

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Launch of the tender
August 4th, 2022

We have been selected
December 14th, 2022

Istituto Superiore di Sanità (ISS) is the **Contractor** through the **Italian National Blood Centre (CNS)** and the **Italian National Transplant Centre (CNT)**
In collaboration with the **Joint Tenderer Zadig ltd**

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Scope of the Service

Strengthening the implementation of oversight in the field of SoHO in the EU Member States (MS), and also EFTA associated countries, through training and networking of SoHo competent authorities for oversight.

Duration

36 months starting from February 1st 2023

Fields

blood and blood componets, T&C, MAR (Organs just for Vigilance modules)

Main training areas

Vigilance Inspection Authorisation preparation process

Target groups

Inspectors Vigilance officers Preparation process assessors

2 Rounds

Round 1: 01/02/2023 to 31/10/2024

Round 2: 01/11/2024 to 31/01/2026

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Forthcoming appointments for CAs (1/2)

Within end of **June / early July 2023** → Announcement to CAs, including

Application form

and

Launch of the Platform

In the Application Form participants will be requested to specify:

- field of competence,
- years of experience in the field,
- professional activity,
- previous participation in other European courses.

Participants will be invited to indicate the weekly training modules they would like to attend.

Please, take into consideration that some weekly training modules will be considered as preparatory to access the F2F workshops. Further information will follow in due course.

Public area of the platform will be accessible with the overall training Programmes (eLearning and F2F)

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Forthcoming appointments for CAs (2/2)

Within the end of Sept. 2023:
List from CAs and application forms filled in by participants.

Within Oct. 2023:
Participants Registration to the platform

Weekly online trainings will start in **December 2023** and end in early **March 2024**
30 to 60 participants for each weekly training module

3 workshops of 3 days in Rome:

- Preparation Process Authorisation - **May 2024**
- Inspection - **June 2024**
- Vigilance - **July 2024**

30 to 50 participants for each workshop

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Overall Training Contents

Online

1. EU legal provisions;
2. Certification/authorisation system;
3. Quality management system - overview;
4. Quality management system – good practices;
5. Quality risk assessment;
6. BTC preparation processes authorisation;
7. SoHO vigilance and Biovigilance;
8. Serious Adverse Outcomes/Rapid Alerts and Harmonising data collection;
9. Stock and critical supplies; Imports and exports; Single Coding of tissues and cells;
10. Inspection practice, inspection report and post inspection activities;
11. Risk for inspectorate.

F2F

1. EU legal provisions;
2. Preparation Process Authorisation;
3. State-of-the-art of processing, testing laboratories, facilities, storage, transport, transplantation/transfusion;
4. Preparation and performance of inspection;
5. Practical on-site inspection;
6. Assessment of non-compliances and classification of deficiencies;
7. Joint inspections;
8. Vigilance protocols, follow-up, activities and serious adverse reactions and events reporting using common denominators, annual vigilance data analysis.

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Thank you!

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