ONLINE TRAINING INFORMATION SHEET
- ROUND 2 -

Context

SIGHTSoHO (strengthening overSIGHT through training and networking on Substances of Human Origin) Service will provide blended training activities (eLearning and Face-to-Face) addressed to European inspectors, assessors and vigilance officers in the field of blood and blood components, tissues and cells (BTC), MAR and organs. In particular, SIGHTSoHO will significantly contribute to further encourage and promote:

- the "formal" recognition of the commonalities among BTC oversight processes and the adoption of a common approach for the evaluation and inspection of SoHO;
- the harmonisation and standardisation of some key minimum competencies/knowledge of SoHO inspectors, assessors and vigilance officers;
- the strengthening of the existing network to foster trust between EU inspectorates and competent authorities (CA) to allow mutual recognition of certifications and authorisations of BTC establishments.

Round 2 online training will be opened to all EU CAs working in the SoHO fields. The CAs are kindly invited to circulate this initiative among their local/regional/national networks.

Online training objectives

eLearning training aims to enabling participants:

- to perform oversight activities with a common methodology at both national and European level (e.g., joint inspections, inter-Member State audits);
- to keep up-to-date and/or receive training to undertake their duties also according to the new EU regulation on SoHO;
- to enhance their technical and organisational skills by familiarising with the best practices in the field and to provide harmonised approach in the accreditation/designation/authorisation/ licensing processes;
- to become proficient in surveillance and reporting procedures relating to serious adverse reactions/events;
- to be part of a network of trained CA staff as well as European professionals community.

Participants' selection criteria and approach

a. Be nominated or formally recognised as qualified inspectors/assessors/vigilance officers for one or more than one of the specific fields of blood, T&C, MAR and organs (in this latter case, only for the modules dedicated to Vigilance) by their CAs;
b. Knowledge of EU BTC relevant legislation;
c. Good command of the English language;
d. Applicants who did not join Round 1 training;
e. Round 1 priority list applicants will be preferred;
f. >1 year experience;
g. Priority to those applicants who showed interest in joining all the modules;
h. for each Country, a proper both SoHO and professional activity coverage (inspector, vigilance officer and assessor);
i. «first come, first served» principle.

Application procedure

Application procedure to join Round 2 eLearning weekly modules is now open. Please, fill in the dedicated form at the following link *https://forms.office.com/e/hWZGTXzPAe* within **December 20th, 2024 (23:59 CET).**

IMPORTANT: In order to finalise your application, please bear in mind that you are required to provide a **formal commitment** to attend the training modules for which you have expressed interest.
The note will have to be **signed** also by the Competent Authority or your direct responsible person in order to allow your participation without restrictions.

Once the application is submitted, please send the Note of Commitment to *application.sightsoho@iss.it*
If you do not share the Note of Commitment **within one week from the submission of the application**, your place will be reallocated to another applicant.

In addition, please, take into consideration that if you are accepted and, once the eLearning training starts, you do not attend, you will be promptly contacted by SIGHTSoHO staff. If no answer is received, the DG SANTE team will inform your CA.
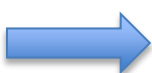
SIGHTSoHO Platform

The web platform SIGHTSoHO foresees sections dedicated to each weekly training module and it includes: a repository of the most relevant reference documents; pre-recorded presentations, links to join the synchronous live appointments, self-assessment and evaluation tests, as well as forum and interactive tools through which participants can liaise with tutors, post questions, share information and experience of mutual interest.
The overall online training will offer effective and dynamic instructional methods such as practicing breakout rooms, combining collaboration activities with simulation, case studies, problem solving and group exercises always supported and facilitate by tutors.
In order to become familiar with the eLearning platform, enrolled participants will receive credentials to access the IT tool where, once logged in, they can find Video Tutorials.

www.sightsoho.eu

The overall structure and contents of the eLearning training will be the same as the one of SIGHTSoHO Round 1 online training. Nevertheless, given the recent adoption of the new European regulation on SoHO, during Wednesday and Friday live appointments, specific insights relating to the topic of the weekly online module will be shared.

Modules and overall calendar

ONLINE TRAINING

The online training course will be delivered weekly starting from **January 27th 2025** to **April 11th 2025**, as described in the figure.

The 11 weekly modules will be preceded by a Live Opening event on **January 22nd, 2025** and followed by a Live Closing event that will be held on **April 30th, 2025.**

Weekly training benefits from the use of both synchronous (two live appointments each week) and asynchronous activities. A detailed **time schedule** and **training programme**, including methodology and activities, will be made **available at www.sightsoho.eu**.

RESIDENTIAL COURSE

The online training will be followed by a residential course, which consists of 3 face-to-face workshops of 3 days each in Rome:

- Inspection practice **May 7 – 8 - 9, 2025**
- Vigilance **June 11- 12- 13, 2025**
- Preparation process authorisation **July 2 - 3 - 4, 2025**

SAVE THE DATE ON YOUR CALENDAR!

Live Opening Event
22/01/25

WEEK 1
EU Legal Provisions
27/01/25 - 31/01/25

WEEK 2
Licensing, Authorisation and Accreditation System
03/02/25 - 07/02/25

WEEK 3
Quality Management System – Overview
10/02/25 – 14/02/25

WEEK 4
Quality Management System - Good Practices
17/02/25 – 21/02/25

WEEK 5
Quality Risk Assessment (including tools)
24/02/25 - 28/02/25

WEEK 6
BTC Preparation Process Authorisation
03/03/25 - 07/03/25

WEEK 7
SoHO Vigilance and Biovigilance
10/03/25 - 14/03/25

WEEK 8
Serious Adverse Outcomes/Rapid Alerts and Harmonizing Data Collection
17/03/25 - 21/03/25

WEEK 9
Stock and Critical Supplies, Import/Export, Single Coding
24/03/25 – 28/03/25

WEEK 10
Inspection Practice, Inspection Report and Post Inspection Activities
31/03/25 – 04/04/25

WEEK 11
Risk for Inspectorate
07/04/25 – 11/04/25

Live Closing Event
30/04/25

Funded by the European Union