

SIGHTSoHO

**strengthening overSIGHT through training and
networking on Substances of Human Origin**

Final Version

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D2. ONLINE TRAINING INFORMATION SHEET (ROUND 1)

Context

SIGHTSoHO 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). 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.

The 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 systems. Information relating to application and registration will be shared in due course.

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 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 general requirements

- 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 by their CAs;
- Knowledge of EU BTC Directives;
- Good command of the English language.

Digital tool

The digital tool (www.sightsoho.eu) foresees a repository accessible to both tutors and participants; a real-time chat; forum and interactive tools, as well as synchronous live sessions, through which participants can liaise with tutors, post questions, share information and experience of mutual interest. The overall online training will provide effective 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. Tutorials to become familiar with the IT platform will be available.

Modules and overall calendar

Online training course will be delivered weekly starting from November 27th 2023 to March 1st 2024, as described in the following figure.

Weekly training benefits from the use of blended learning methods with synchronous (one live session each week) and asynchronous activities. A detailed time schedule and training programme, including methodology and activities, are available at www.sightsoho.eu.

