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SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin

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Activity Centre:	ISS/CNS-CNT, Zadig ltd
Author(s):	L. Cannata, M. Gentile, A. Palmieri
Contributors	F. Bariani, A. P. Barreiros, C. Carella, R. Daghini, C. Deligant, P. Di Ciaccio, P. Dri, H. Kurz, A. Kurzreiter, U. La Rocca, M. Mareri, S. Masterson, S. Pupella, F. Teskrat, M.R. Valetto, A. Vassanelli
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D.1 Inception report and training planning of Round 1 & 2

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ACRONYMS

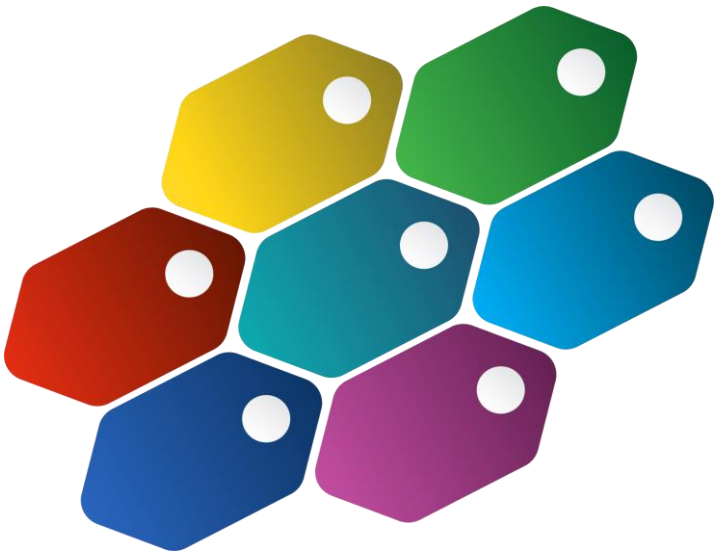
ARTHIQS	Assisted Reproductive Technologies and Haematopoietic stem cells Improvements for Quality and Safety
ATMP	Advanced Therapy Medicinal Products
BTC	Blood, Tissue and Cell
CA(s)	Competent Authority(ies)
CATIE	Competent Authority Training of Inspections in Europe
CESIP	Common European SoHO Inspection Programme
CHESSMEN	Coordination and Harmonization of the Existing Systems against Shortage of Medicine - European Network
CNS	*Centro Nazionale Sangue* (Italian National Blood Centre)
CNT	*Centro Nazionale Trapianti* (Italian National Transplant Centre)
EC	European Commission
EDQM	European Directorate for the Quality of Medicines & HealthCare
EGALiTE'	European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments
EU	European Union
EuBIS	European Blood Inspection System
EURO-GTP	European Good Tissue Practice
EUSTITE	European Union Standards and Training for the Inspection of Tissue Establishments
F2F	Face-To-Face
FACT	Foundation for the Accreditation of Cellular Therapy
GAPP	facilitatinG the Authorisation of Preparation Process for blood and tissues and cells
ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IES	Inspection Experts sub-group
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
ISO	International Organization for Standardization
ISS	*Istituto Superiore di Sanità*
JA	Joint Action
JACIE	Joint Accreditation Committee-ISCT & EBMT
MAR	Medical Assisted Reproduction
MS(s)	Member State(s)
PBM	Patient Blood Management
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PPA	Preparation Process Authorization
QMS	Quality Management System
RAB	Rapid Alert Blood
RATC	Rapid Alert Tissues and Cells
RVI	Remote Virtual Inspection
SoHO	Substances of Human Origin
SOP	Standard Operating Procedure
SPC	Statistical Process Control
SUPPLY	Strengthening voluntary non-remunerated plasma collection capacity in Europe
T&C	Tissues and Cells
TRANSPOSE	TRANSfusion and transplantation: PrOtection and SElection of donors
V&S	Vigilance and Surveillance
VES	Vigilance Expert Sub-group
VISTART	Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation
WHO	World Health Organization
WMDA	World Marrow Donor Association

1 Introduction

The National Institute of Health, through the Italian National Blood and Transplant Centres (ISS/CNS-CNT), together with the Joint Tenderer Zadig and in collaboration with a team of external tutors, have been granted the opportunity to lead the design and organisation of training courses addressed to European inspectors, assessors and vigilance officers.

The initiative is named *SIGHTSoHO* - strengthening overSIGHT through training and networking in the field of Substances of Human Origin - to express the importance of all the o*verSIGHT* activities in the field of SoHO. In particular, the word *SIGHT* stresses the idea to supervise the systems related to *SoHO* providing a wider and harmonised *vision*. Therefore, the title *SIGHTSoHO* also highlights the relevance of strengthening oversight knowledges and competences throughout Europe, providing advanced training to all SoHO CA and Vigilance professionals. A Logo proposal has been created accordingly.
The stylized hexagons recall the area of the project (a Substance of Human Origin) but also the involvement of several professionals, who play an important role in the vigilance and surveillance tasks in this field. The joining of these shapes into a single one underlines the importance of the unity of the system, with a homogenisation across countries, whereas the different colours transfer the concept of existence of various Substances of Human Origin as well as the importance of the different experiences in the individual countries, which are networked and shared with the ultimate goal of a harmonious vision.

Figure 1: SIGHTSoHO logo



Following previous European experiences (EUSTITE, CATIE, VISTART, GAPP etc.), SIGHTSoHO will significantly contribute to further encourage and promote:

- the “formal” recognition of the commonalities among blood and blood components, tissues and cells 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 national CAs to allow mutual recognition of certifications and authorisations of BTC establishments throughout the EU.

2 Objectives

This Inception Report aims to:

- share a detail **timeline** for the overall training service (**tasks, deliverables and meetings**);
- give an aligned snapshot of the **reporting periods** and **deliverables** (along with the evaluation reports);
- better describe the **target groups** general selection criteria and application procedure;
- introduce the **eLearning platform, methodology and tools**;
- present the overall **preliminary training programme**, including timeframe (adjustments could be made, if necessary) for both Round 1 and Round 2 online and F2F courses;
- provide a summary of the **performance indicators** cited in the technical offer;
- offer an overview of the **overall Teams** involved in the Service (see Annex 1).

3 Detailed timeline for the overall training service (tasks, deliverables and meetings)

The overall service will be delivered in two Rounds, starting from February 1st, 2023, until January 31st, 2026. Details regarding timelines of tasks and deliverables are described in the following figures (Fig. 2 and Fig. 3). Table 1 summarises tasks specifications and related activities and outputs for both Round 1 and Round 2.

Figure 2 Round 1 Timeline

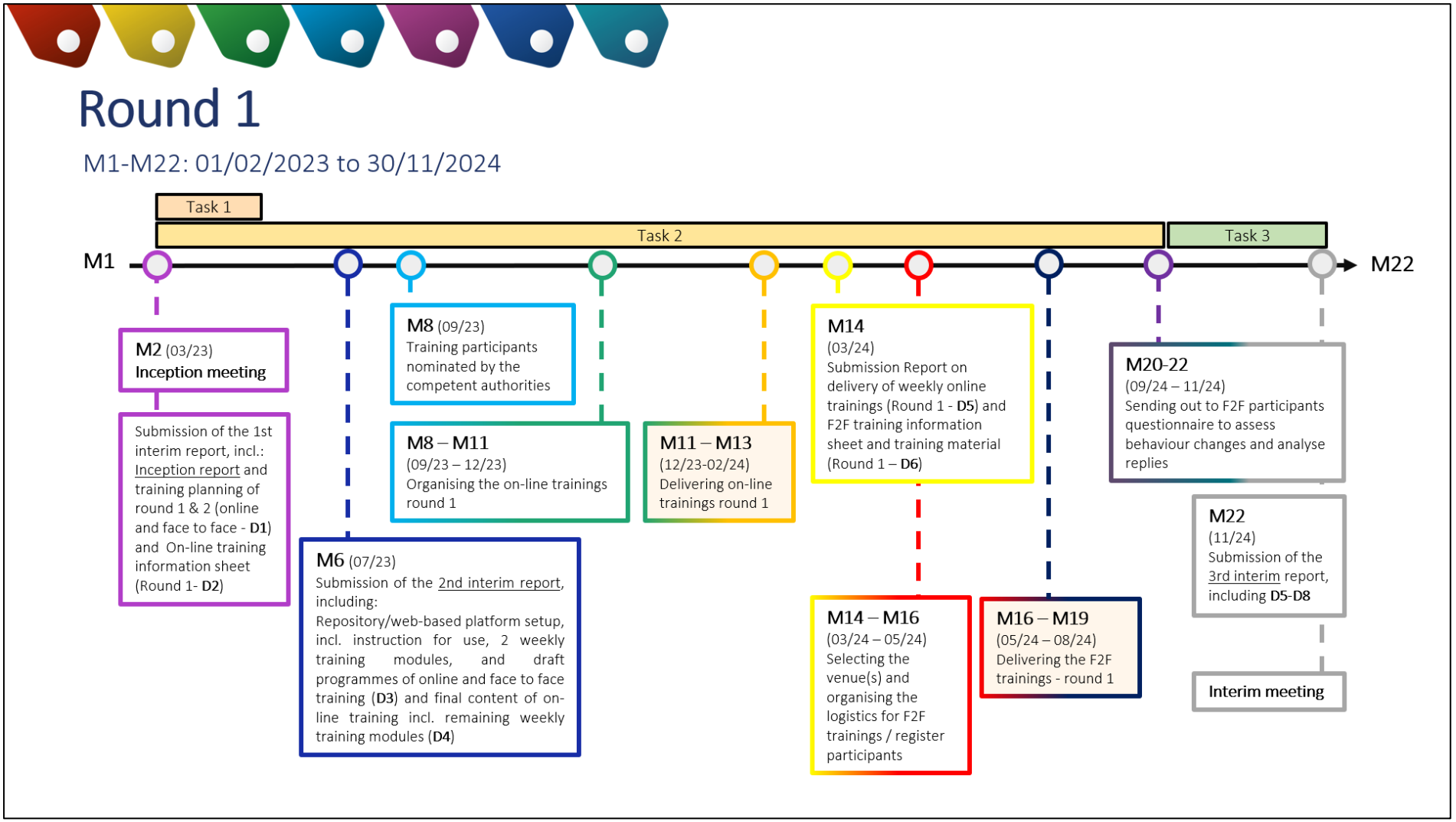


Figure 3 Round 2 Timeline

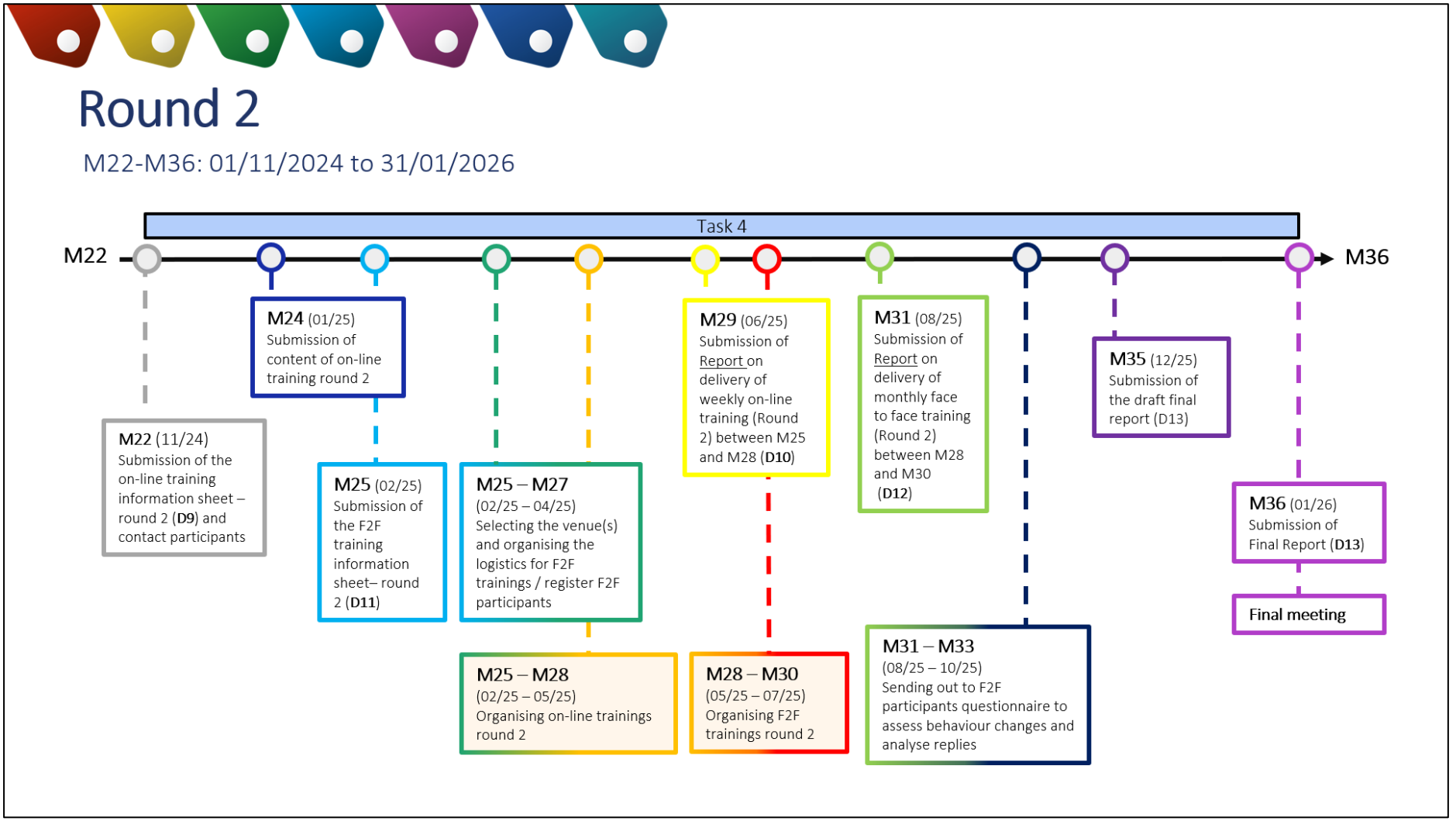


Table 1 Tasks specifications, activities and deliverables

Task	Activities	Deliverables
1. Prepare the first Round of on-line training **M1-M6**	The team designs the overall training programme and sets-up a dedicated repository/web-based platform. Under this task, training activities and technical contents are prepared and detailed for each identified topic area. Two weekly training modules will be uploaded in the platform.	**D1**: Inception report and planning of Round 1 & 2 training (online and face to face) **D2**: On-line training information sheet (Round 1) **D3**: Repository/ web-based platform setup, including instruction for use, 2 weekly training modules, and draft programmes of online and face to face training (Round 1) **D4**: Final content of on-line training incl. remaining weekly training modules (Round 1)
2. Organise and deliver Round 1 of online and F2F training **M1-M20**	The first Round will consist of a mix of plenary sessions and break-out groups to ensure balanced theoretical and practical training, Simulations, case studies, and group exercises will be favoured to gather practical peer experience/benchmarking information.	**D5**: Report on delivery of weekly online trainings (Round 1) between M11 and M13 **D6**: F2F training information sheet and training material (Round 1) **D7**: Report on delivery of the F2F training (Round 1) between M16 and M19

3. Analyse the results and impact from Round 1 training (3rd interim report) and prepare the dissemination kit M20-M22	The team will circulate a survey among participants and will then analyse their answers so to draft and implement the second Round of online training. After that, a course syllabus in electronic form (covering all on-line weekly modules and the different F2F courses) will be provided. It will include glossary of terms and abbreviations used in the course and any additional references for further study. The team will also prepare a dissemination kit, which will be a compendium of all information and materials shared during the eLearning and F2F training courses of the first Round.	D8: Dissemination kit in electronic form
4. Organise and deliver Round 2 online and F2F training M22-M36	The team will revise and update the on-line training materials according to the results of the survey that will be conducted among Round 1 participants. After the revision, the second Round of training activities will be delivered.	D9: on-line training information sheet – Round 2 D10: Report on delivery of weekly on-line training (Round 2) between M25 and M28 D11: F2F training information sheet –Round 2 D12: Report on delivery of monthly face to face training (Round 2) between M28 and M30 D13: Final report of all trainings carried out

4 Snapshot of the reporting periods and related overlapping deliverables

Table 2 Snapshot of reporting periods (in the tender specifications, the second and third reports are not listed as deliverables).

Tasks	Deliverables	Report	Months
Task 1	D1	Inception report and training planning of Round 1 & 2 (first interim report)	M2
		Second interim report	M6
Task 2	D5	Report on delivery of weekly online trainings (Round 1)	M14
	D7	Report on delivery of the F2F training (Round 1)	M20
Task 3		Third interim report	M22
Task 4	D10	Report on delivery of weekly on-line training (Round 2)	M29
	D12	Report on delivery of monthly face to face training (Round 2)	M31
	D13	Final report of all trainings carried out	M35-36

5 Target groups general selection criteria and application procedure

5.1 Selection criteria

The profile of the target groups varies across MSs and depends on different professional backgrounds. Moreover, considering that the ultimate goal of this service is to train an extensive number of SoHO inspectors/assessors/vigilance officers, participants' selection criteria are identified at a general level:

- Be nominated or formally recognised as qualified inspectors/assessors/vigilance officers for one or more than one of the specific fields of blood, organs, T&C and MAR by their CAs;
- Knowledge of EU BTC Directives;
- Good command of the English language.

In addition, in order to access F2F workshops, participants will be requested to have attended specific eLearning modules, which are deemed preparatory for the effectiveness of the activities. These specifications will be provided during the application procedure.

The number of participants in the online training will be between a minimum of 30 to a maximum of 60 per each weekly module, whereas for each F2F workshop, the attendance will be between a minimum of 30 to a maximum of 50.
Given the limited maximum number of participants in each of the F2F workshops, priority will be given to those who have attended at least the specific eLearning modules indicated as preparatory for the F2F workshops. If a higher number than the maximum will express interest in joining the F2F courses, the approach "first come, first served" will be adopted. Eventually, where there are places unfilled, these may be offered to other applicants according to the needs expressed by CAs, or upon recommendations from the Contracting Authority.

5.2 Application procedure

As per the tender, the European Commission will provide the list of contact points in the MSs to allow the ISS/CNS-CNT Team to disseminate the information of the training activities and collect the participants nominated by the CAs.
For both Round 1 & 2 online and F2F training, an application form will be drafted. The main personal data of the trainees will be collected, including information related to the field of competence (BTC including area of professional activity – authorisation, inspection and vigilance), years of experience, previous participation in other European courses. In addition, with regard to eLearning training, it will be possible to select the online weekly modules that the participant would like to attend (as above-mentioned, participants will be informed that a few specific eLearning weekly modules are recommended given that are preparatory for the F2F workshops). The same possibility to point out the preferred workshop/s will be given for the F2F training.

With particular reference to Round 1 online courses, within M6 (July 2023) and once the platform is available, the Online information sheet together with the application form will be circulated among CAs. The detailed programme will be available for consultation at www.sightsoho.eu. By the end of September 2023 (mid-October at latest), the application process will be concluded.
If the maximum number of participants per weekly module is exceeded (max 60 attendees per week module for a total of max 840 trainees), two selection approaches will be adopted: representation of at least 10 MSs (agreed performance indicator) and "first come, first served.
The final list of attendees of each weekly module will be communicated in secure mode to the Joint Tenderer Zadig. The latter will provide the participants with the credentials to register on the platform and become familiar with the tool and training programme, at least one month before the start of the online courses.

As for Round 1 F2F workshops, as per the contract, announcement and application will be managed between March – April 2024.

For Round 2 online and F2F training, circulation of information and the application procedure will be specifically discussed and agreed with the Contracting authority on the occasion of the third interim meeting (November 2024).

6 ELearning platform, methodology and tools

SIGHTSoHO training activities will be delivered using the open-source Moodle platform for all asynchronous activities and real-time chats among participants; a plugin to embed in Moodle the Zoom platform for real-time webinars will be implemented.
The technological platforms will be accessible from different platforms (desktops, laptops, mobile devices, e.g., tablets and smartphones) and with any up-to-date operating system.
The dedicated Moodle platform will be implemented and customised by the Joint Tenderer Zadig, in accordance with the training objectives of the contract. The platform will be in English, but users can set their own language for the service texts. Tutorials to facilitate the use of the platform will be available for participants as well as for tutors, with dedicated didactical tools.
It will allow tutors to share and store contents, materials, case studies and best practices, so to create a professional community that can fruitfully benefit from the networking activity.
On the platform, virtual classrooms will be available through the following activities:

- Webinar recordings;
- Practice cases;
- Other teaching materials (pdf files, video animations, audios, take-home messages);
- SoHO materials (rules, laws, guidance documents…);
- Evaluation questionnaires;
- Forums (available at any time on the platform and will be moderated by one or more tutors in dedicated time slots);
- Real time chat;
- Training calendar;
- Certificates of attendance.

Each of the 11 eLearning weeks, whose contents and activities are constantly available asynchronously, is dedicated to one or more of the 14 topics indicated in the tender (see table 4).

Weekly training will benefit from the use of blended learning methods with synchronous and asynchronous activities (e.g., a mixture of recorded and live presentations, power point presentations).

Specifically, a launch of the training week with a dedicated asynchronous message in the Forum will be made by the lead tutor in order to:

- give an intro to the topic, sub-topic/s, learning objectives of the weekly module;
- share information on the timing of the organisation of the week (including independent asynchronous study), assigned tutors, self-assessment quizzes and evaluation tests;
- present the training material (documents, literature, ppt, publications, guidelines, videos, tutorials etc.) available in the repository of the weekly module.
- Anticipate the topic, duration and methodology of the live synchronous session.

With specific reference to:

- independent asynchronous study, participants will autonomously manage their time and effort in using/consulting/studying the training materials identified and developed for each weekly module;
- the live synchronous session, it will be designed to have a duration between a minimum of 45 minutes and to a maximum of 90 minutes, according to the chosen methodology;
- pre and post self-assessment quizzes, they will be submitted right before the beginning and at the end (post) of each week;
- Emoji satisfaction survey, it will be optional and issued at the end of each week for a rapid and user-friendly online compilation;
- Evaluation test, it will be one for each weekly eLearning module. The compilation will be available at any time until February 29th, 2024.

As per the tender, in collaboration with all training team, an opening live session will be organised on Monday November 27th, 2023, as well as a closing live session that will be held on Friday March 1st, 2024. In occasion of the latter, a brief recap will be made, including take home messages, and information about the upcoming F2F will be given.

A proposal of weekly module structure follows in the table below (schedule adjustments could be made, if necessary).

Table 3 Proposal of Module weekly schedule

Monday	Asynchronous launch of the training week in the Forum with practical info about topic, available didactical material, calendar. A link to pre self-assessment quiz will be included in the message.
Tuesday	Independent asynchronous study.
Wednesday	Live synchronous session from 45 to 90 minutes with tutors and specific activities (case studies, working groups, etc.) related to the topic.
Thursday	Independent asynchronous study.
Friday	Forum with 2 hours live chat: tutors available to synchronously answer to questions, discuss possible arisen issues with trainees and animate debate. In addition, a short summary of the online weekly module (take-home messages) will be provided. Post self-assessment quiz, emoji satisfaction survey and evaluation tests will be made available for compilation.

Wednesday and Friday activities will be delivered on the SIGHTSoHO Moodle platform in the early afternoon, approximately between 2 p.m. and 5 p.m. (CET).

Training Material and recorded version of the synchronous weekly live sessions will be available on the platform at any time so to let registered participants manage the eLearning autonomously, if needed. The possibility to join the overall online training in an asynchronous manner after the live closing session (March 1st, 2024) will be discussed with the Contracting authority and DG SANTE according to specific needs that may arise from CAs (e.g., newly recruited as inspectors).

7 Training Programme

7.1 Preliminary overall Round 1[1] online training Programme

Table 4 Preliminary overall Round 1 training programme

Topic* *14 topics cited in the tender are numbered	**Timing**	**Lead Tutor**	**Other tutors and external experts involved**
EU legal provisions (1)	Week 1 27/11/23 - 01/12/23	S. Pupella H. Kurz	DG SANTE, external experts
Certification authorisation system (4)	Week 2 04/12/23 – 07/12/23* *December 8 is bank holiday in some Countries, therefore, the Forum session is anticipated on the 7th Dec.	S. Pupella R. Barrio	H. Kurz, F. Teskrat, A. Vassanelli, A. Kurzreiter, U. La Rocca, External expert
Quality Management System (2) – overview	Week 3 11/12/23 – 15/12/23	H. Kurz A. Kurzreiter	F. Bariani, S. Masterson, F. Teskrat, S. Pupella, U. La Rocca, A. Vassanelli, EDQM QMS working group invited
Quality Management System (2) - good practices	Week 4 18/12/23 – 22/12/23	H. Kurz A. Kurzreiter	S. Masterson, F. Bariani, F. Teskrat, S. Pupella, U. La Rocca, A. Vassanelli, EDQM QMS working group invited
Quality Risk Assessment (3)	Week 5 08/01/24 – 12/01/24	S. Masterson R. Barrio	S. Masterson, F. Bariani, R. Barrio, external experts
BTC Preparation Process Authorisation (14)	Week 6 15/01/24 – 19/01/24	R. Barrio A. Vassanelli	S. Masterson, S. Pupella, U. La Rocca, F. Teskrat, external experts
SoHO Vigilance (6) and Biovigilance (11)	Week 7 22/01/24 – 26/01/24	A. P. Barreiros F. Bariani	A. Kurzreiter, R. Barrio, VES sub-group invited
Serious Adverse Outcomes/Rapid Alerts (12) and Harmonizing data collection (13)	Week 8 29/01/24 – 02/02/24	F. Bariani A. P. Barreiros	S. Pupella, H. Kurz, A. Vassanelli, R. Barrio, U. La Rocca, Notify expert, VES sub-group invited
Stock and critical supplies (8), Import/export (7), Single coding (5)	Week 9 05/02/24 – 09/02/24	S. Masterson S. Pupella	H. Kurz, A. Kurzreiter, A. Vassanelli, F. Bariani
Inspection practice, inspection report and post inspection activities (9)	Week 10 12/02/24 – 16/02/24	S. Pupella S. Masterson	U. La Rocca, F. Bariani, F. Teskrat, A. Vassanelli, H. Kurz, A. Kurzreiter
Risk for inspectorate (10)	Week 11 19/02/24 – 23/02/24	S. Pupella S. Masterson	U. La Rocca, F. Bariani, R. Barrio, A Vassanelli

[1] M11/M13 (Dec. 2023 – Feb. 2024)

7.2 Preliminary detailed Round 1 Online Training Programme

Each training week includes the following:

General topic

Timing

Tutors, teachers and external experts involved

Sub-topic/s

Methodology

Activity (asynchronous independent study, synchronous live session)

Learning objectives

Bibliography (chapters/pages will be selected by the tutors)

7.2.1 EU legal provisions

WEEK 1 27/11/23 - 01/12/23	TOPIC EU LEGAL PROVISIONS		LEAD TUTOR/S S. Pupella - H. Kurz
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
EU current directives	Pre-recorded presentation and reading of selected parts of the directives followed by discussion in the Forum	Asynchronous independent study	H. Kurz
Intro to the new regulation	Pre-recorded presentation	Asynchronous independent study	DG SANTE
Basic info on current Medical Device Regulations relevant for BTC establishments defining the borderlines for novel BTC with other regulatory frameworks, in particular where medicinal products and medical devices are concerned	Pre-recorded presentations	Asynchronous independent study	External Experts
Overlaps between SoHO, ATMPs and Medical Devices frameworks	Discussion (Q&A session, breakout rooms) in synchronous live session	Synchronous live session	H. Kurz, S. Pupella, DG SANTE, External Experts
LEARNING OBJECTIVES To facilitate a harmonised interpretation of the EU legislative framework 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 of novel processes			
BIBLIOGRAPHY EU BTC Directives; Regulation EU 2017/746 Invitro diagnostic medical devices; Regulation EU 2017/745 on medical devices amending Directive 2001/83/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 on medicinal products; Regulation (EC) No 1394/2007 on advanced therapy medicinal products			

7.2.2 Certification and authorisation system

WEEK 2 04/12/23 – 07/12/23* *December 8 is bank holiday in some Countries; therefore, the Forum session is anticipated on the 7th Dec.	TOPIC CERTIFICATION AND AUTHORISATION SYSTEM (INCLUDING OVERVIEW OF INSPECTION TOOLS)		LEAD TUTOR/S S. Pupella – R. Barrio
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments	Pre-recorded presentation	Asynchronous independent study	S. Pupella
Remote Virtual Inspection guidance document versus desk-based inspection	Pre-recorded presentation followed by a video	Asynchronous independent study	F. Teskrat
EuroGTP II risk assessment tool	Webinar in synchronous live session Introduction on the tool in plenary followed by break-out sessions for simulated application of the tool and feedback in plenary	Synchronous live session	S. Pupella, H. Kurz, F. Teskrat, A. Vassanelli, A. Kurzreiter, R. Barrio, U. La Rocca, External expert
Overall Guide for PPA	Pre-recorded presentations	Asynchronous independent study	R. Barrio
Mutual recognition: tools (e.g., CESIP, Joint inspections – Code of practice)	Forum on a survey launched in the platform at the start of the week	Asynchronous independent study	S. Pupella, R. Barrio

LEARNING OBJECTIVES
To improve knowledge of the new inspection tools in order to harmonize the inspection methodology To understand the common approach for authorising new product/process and activities
BIBLIOGRAPHY
Main deliverables of the EU projects/JAs (VISTART, GAPP, RVI), Euro-GTP Guide.

7.2.3 Quality Management System - overview

WEEK 3 11/12/23 – 15/12/23	TOPIC QUALITY MANAGEMENT SYSTEM - OVERVIEW		LEAD TUTOR H. Kurz - A. Kurzreiter
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Documentation, Data processing Third parties Management	Pre-recorded presentations	Asynchronous independent study	S. Masterson, A. Vassanelli
Non-conformance/deviation system/recall	Pre-recorded presentation on NCs and risk assessment tool	Asynchronous independent study	S. Masterson, A. Kurzreiter
Non-conformance/deviation system/recall	Intro lecture and working groups on classification of real-life non compliances	Synchronous live session	A. Kurzreiter, S. Masterson, F. Bariani, A. Vassanelli, F. Teskrat, S. Pupella, U. La Rocca
Self-Inspection/Internal & External Audit	Pre-recoded presentation from EDQM	Asynchronous independent study	Expert from EDQM
LEARNING OBJECTIVES To establish a common understanding of how to inspect various/assorted components of a quality system Examples of difficulties, issues that arise on inspection relating to QMS Inspection will be requested from participants and a common approach agreed and noted			
BIBLIOGRAPHY General principles of document on quality management, quoted in EU Directives General principles of technical and non-technical skills and training, quoted in EU Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments National and International Standards: ISO, EDQM, JACIE-FACT, WMDA, PIC/S QM			

7.2.4 Quality Management System – good practices

WEEK 4 18/12/23 – 22/12/23	TOPIC QUALITY MANAGEMENT SYSTEM – GOOD PRACTICES		LEAD TUTOR H. Kurz - A. Kurzreiter
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Qualification of premises, equipment and materials	Reading selected documents and SOPs	Asynchronous independent study	H. Kurz, A. Kurzreiter
Validation and Change control	Reading of a SOP identified by the Tutor followed by discussion in the Forum	Asynchronous independent study	S. Masterson, F. Teskrat
Quality Control (QC and SPC)	Lecture followed by open discussion	Synchronous live session	S. Masterson, F. Teskrat, S. Pupella, U. La Rocca, A. Vassanelli, F. Bariani, EDQM QMS working group
Personnel (Training and competences of the staff)	Reading of a SOP identified by the Tutor followed by discussion in the Forum	Asynchronous independent study	A. Vassanelli, A. Kurzreiter

LEARNING OBJECTIVES

To establish a common understanding of how to inspect various/assorted components of a quality system
Examples of difficulties, issues that arise on inspection relating to QMS Inspection will be requested from participants and a common approach agreed and noted

BIBLIOGRAPHY

General principles of document on quality management, quoted in EU Directives
General principles of technical and non-technical skills and training, quoted in EU
Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments
National and International Standards: ISO, EDQM, JACIE-FACT, WMDA, PIC/S QM

7.2.5 Quality risk assessment

WEEK 5 08/01/24 – 12/01/24	TOPIC QUALITY RISK ASSESSMENT (INCLUDING TOOLS)		LEAD TUTOR S. Masterson - R. Barrio
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Quality risk management	Pre-recorded presentation	Asynchronous independent study	S. Masterson, external expert
Risk Assessment Methods (e.g., HACCP, FMEA, FTA, Root Cause Analysis, Risk Mitigation Strategies, Risk register etc.)	Frontal lesson followed by discussion and Q&A	Synchronous live session	R. Barrio, external experts
Management of non-compliances: follow-up activities	Assignment followed by discussion in the Forum	Asynchronous independent study	F. Bariani
LEARNING OBJECTIVES How to select the most appropriate and effective tools to perform quality risk management, including mitigation			
BIBLIOGRAPHY EURO-GTP Guide, including Blood components specific chapter GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes (specific pages will be selected)			

7.2.6 BTC preparation process authorisation

WEEK 6 15/01/24 – 19/01/24	TOPIC BTC PREPARATION PROCESS AUTHORISATION		LEAD TUTOR R. Barrio - A. Vassanelli
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
A common approach on PPA (GAPP Guideline)	Pre-recorded presentation	Asynchronous independent study	R. Barrio
Quality and safety assessment (product/process)	Lectures followed by breakout sessions	Synchronous live session	R. Barrio, A. Vassanelli, S. Pupella, U. La Rocca, External experts
Clinical assessment as part of PPA (risk-based)	Reading of selected documents followed by discussion in the Forum	Asynchronous independent study	F. Teskrat, external experts
LEARNING OBJECTIVES To gain awareness on quality, safety and clinical efficacy of new preparation processes			
BIBLIOGRAPHY EURO-GTP Guide, including Blood components specific chapter GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes (specific pages will be selected) VISTART D5.4: Principles for Competent Authorities for the evaluation and approval of clinical follow-up protocols for blood, tissues and cells prepared with newly developed and validated processing methodologies			

7.2.7 SoHO Vigilance and Biovigilance

WEEK 7 22/01/24 – 26/01/24	TOPIC SoHO VIGILANCE AND BIOVIGILANCE		LEAD TUTOR A. P. Barreiros - F. Bariani
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER/EXTERNAL EXPERT INVOLVED**
Donor selection and donor and recipient protection: Blood, T&C, MAR	Pre-recorded presentations	Asynchronous independent study	F. Bariani, A. Vassanelli
Biovigilance: Blood, T&C, MAR	Pre-recorded presentations	Asynchronous independent study	A. Kurzreiter, R. Barrio, VES experts
Biovigilance: organs	Webinar followed by Q&A	Synchronous live session	A. P. Barreiros
LEARNING OBJECTIVES To gain awareness on Vigilance principles applied on BTC and organs To know the common approach to assess the compliance with vigilance requirements (scientifically evidence-based tools for fostering patient safety within the competence of inspectorates and inspectors, methodology for donor selection evaluation and living donor protection)			
BIBLIOGRAPHY WHO/CNT Global Notify Library EU directives EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition			

7.2.8 Serious adverse outcomes/rapid alerts and Harmonizing data collection

WEEK 8 29/01/24 – 02/02/24	TOPICs SERIOUS ADVERSE OUTCOMES/RAPID ALERTS AND HARMONIZING DATA COLLECTION		LEAD TUTOR F. Bariani - A. P. Barreiros
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Adverse reactions and events	Pre-recorded presentations	Asynchronous independent study	S. Pupella, H. Kurz, A. P. Barreiros, F. Bariani, VES expert
WHO/CNT Global Notify Library	Intro lecture followed by simulation on WHO/CNT Global Notify Library, simulation of evaluation of examples of medical records through cases study in working groups, followed by comparison of the results in plenary	Synchronous live session	H. Kurz, Notify Expert
Harmonising data collection, Common approach and definitions, Denominators	Reading of selected documents followed by discussion in the Forum	Asynchronous independent study	F. Bariani, R. Barrio

LEARNING OBJECTIVES

To deepen the awareness of the positive impact on donor and patient safety by implementing and utilising:

- an efficient and effective upstream and downstream harmonised reporting system,
- a harmonised definitions and agreed denominators all supporting continuous improvement feeding into an appropriate data management system,
- the WHO/CNT Global Notify Library

BIBLIOGRAPHY

ISBT-IHN working party
WHO/CNT Global Notify Library
EU directives
EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition
EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition

7.2.9 Stock and critical supplies, Import/export, Single coding

WEEK 9 05/02/24 – 09/02/24	TOPICs STOCK AND CRITICAL SUPPLIES, IMPORT/EXPORT, SINGLE CODING		LEAD TUTOR S. Masterson - S. Pupella
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Stock and critical supplies (reagents, etc)	Intro lecture and problem-solving exercise in working groups (contingency planning)	Synchronous live session	S. Masterson, S. Pupella, H. Kurz
Imports and exports	Pre-recorded presentation followed by discussion in the Forum	Asynchronous independent study	S. Masterson, H. Kurz
Single Coding of tissues and cells	Reading of selected documents followed by assignment and discussion in the Forum	Asynchronous independent study	A. Kurzreiter, A. Vassanelli
Traceability	Pre-recorded presentation	Asynchronous independent study	F. Bariani

LEARNING OBJECTIVES

To deepen the awareness of:

- possible challenges critical for the SoHO in a logistic chain,
- the impact of epidemic or pandemic outbreaks as well as preparation breakdown on the donor safety and the supply for patients, respectively,
- limitations and advantages of Single Coding in the distribution of TC,
- the system in place for traceability of all the process from donor – donation – preservation/storage- distribution and application is under control and managed according to the minimum requirements defined in the EU BTC Directives and matching the current EDQM BTC guides

BIBLIOGRAPHY

EU BTC directives
EU directive on Single European Coding (SEC)
EDQM Guide to the preparation, use and quality assurance of blood component 21st Edition
EDQM Guide to the quality and safety of tissues and cells for human application 5th Edition
PBM Implementation Guide for Hospitals (selected items)

7.2.10 Inspection practice, inspection report and post inspection activities

WEEK 10 12/02/24 – 16/02/24	TOPIC INSPECTION PRACTICE, INSPECTION REPORT AND POST INSPECTION ACTIVITIES		LEAD TUTOR S. Pupella - S. Masterson
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Inspection practices (pre and post inspection activities)	Pre-recorded presentation	Asynchronous independent study	S. Pupella
Inspection report	Intro lecture followed by practical exercise in breakout sessions	Synchronous live session	S. Pupella, S. Masterson, F. Teskrat
Illegal and fraudulent activities	Pre-recorded presentation	Asynchronous independent study	F. Teskrat
Common approach for distance assessment (hybrid, remote, documentary)	Reading of selected material followed by discussion in the Forum	Asynchronous independent study	A. Vassanelli
Special requirements and protocol for initiating and performing joint inspections upon justified request of an EU MS	Pre-recorded presentation, Reading of selected material followed by discussion in the Forum	Asynchronous independent study	H. Kurz, A. Kurzreiter
LEARNING OBJECTIVES To harmonise interpretation of inspection methodology To strengthen cooperation of inspectorates			
BIBLIOGRAPHY Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments Remote Virtual Inspection guidance document for EU Competent Authorities responsible for the inspection and authorisation of blood and tissue establishments Code of practice for the Joint Inspections			

7.2.11 Risk for inspectorate

WEEK 11 19/02/24 – 23/02/24	TOPIC RISK FOR INSPECTORATE		LEAD TUTOR S. Pupella - S. Masterson
SUB-TOPIC	**METHODOLOGY**	**ACTIVITY**	**TEACHER EXTERNAL EXPERT INVOLVED**
Quality management system (including risk management)	Pre-recorded presentation	Asynchronous independent study	S. Masterson
Inspectors management (skills, competences, responsibilities, independence and conflict of interest/impartiality)	Frontal lesson followed by discussion	Synchronous live session	R. Barrio, S. Pupella, U. La Rocca, A Vassanelli
Procedure for products sampling for analysis purposes by independent laboratories on the request of the CAs	Reading of selected material	Asynchronous independent study	S. Masterson, S. Pupella
LEARNING OBJECTIVES To exchange experiences for effective and efficient quality management in the inspectorates To raise awareness of risks for inspectorates			
BIBLIOGRAPHY Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments			

7.3 F2F Round 1 – M16/19 (May 2024 – Aug. 2024)

The F2F training will consist of three workshops on inspection, preparation process and vigilance of three days each according to the areas of competence.

The training initiatives will be organised in Rome in order to facilitate contacts, optimize costs and smoothly carry out all the organisational procedures to provide the services (e.g., catering, rent of venues…).

Workshops will be a mix of plenary sessions and break-out groups to ensure balanced theoretical and practical sessions with emphasis on the practical sessions, including simulations, case studies, role playing and group exercise to gather practical experience on oversight activities.

In particular, for each F2F workshop specifications are given relating to:

General topic

Timing

Tutors, teachers and external experts involved (tbc)

Sub-topic/s

Methodology

Learning objectives

Bibliography

7.3.1 F2F Workshop on Preparation Process Authorisation

WOKRSHOP 1 May 2024	TOPIC PREPARATION PROCESS AUTHORISATION	LEAD TUTOR S. Pupella
SUB-TOPIC	**METHODOLOGY**	**TEACHER EXTERNAL EXPERT INVOLVED**
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	S. Pupella, H. Kurz, R. Barrio
Taking into account the best current practice according to scientific development, assessment of the state-of-the-art of: o collection/procurement o processing o testing laboratories o facilities o storage o transport, transplantation/transfusion	Intro lecture, expert talk and working group's exercises	U. La Rocca, R. Barrio, S. Pupella, H. Kurz, F. Bariani, A. Vassanelli
EuroGTP II risk assessment tool application	Intro lecture, plenary exercise with simulation and discussion	Euro-GTP expert, U. La Rocca, A. Vassanelli, R. Barrio, S. Pupella, H. Kurz, S. Masterson, F. Bariani
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		
BIBLIOGRAPHY EU BTC Directives; Regulation EU 2017/746 Invitro diagnostic medical devices; Regulation EU 2017/745 on medical devices amending Directive 2001/83/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 on medicinal products; Regulation (EC) No 1394/2007 on advanced therapy medicinal products EURO-GTP Guide, including Blood components specific chapter; GAPP Guideline to authorisation on preparation processes in blood, tissue and cells establishments, including Technical Annexes (specific pages will be selected)		

7.3.2 F2F Workshop on Inspection Practice

WOKRSHOP 2 June 2024	TOPIC INSPECTION PRACTICE	LEAD TUTOR H. Kurz
SUB-TOPIC	**METHODOLOGY**	**TUTOR EXTERNAL EXPERTS INVOLVED**
EU legal provisions	Frontal lectures followed by plenary discussion with facilitators	H. Kurz, F. Bariani, S. Pupella, R. Barrio
Preparation and performance of inspection	Intro presentation, working groups' exercises followed by plenary discussion	S. Masterson, H. Kurz, A. Kurzreiter, F. Bariani, S. Pupella, U. La Rocca, F. Teskrat, R. Barrio
Assessment of non-compliances and classification of deficiencies	Intro lecture with case studies to be discussed in plenary	S. Masterson, H. Kurz, A. Kurzreiter, F. Bariani, S. Pupella, U. La Rocca, F. Teskrat, R. Barrio
Joint inspections	Frontal lecture and role play	S. Masterson, H. Kurz, A. Kurzreiter, F. Bariani, S. Pupella, U. La Rocca, F. Teskrat, R. Barrio
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 MS in case of joint inspections		
BIBLIOGRAPHY Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments Code of practice for the Joint Inspections Remote Virtual Inspection guidance document for EU Competent Authorities responsible for the inspection and authorisation of blood and tissue establishments		

7.3.3 F2F Workshop on Biovigilance and Hemovigilance

WOKRSHOP 3 July 2024	TOPIC BIOVIGILANCE AND HEMOVIGILANCE	LEAD TUTOR A. P. Barreiros, S. Pupella
SUB-TOPIC	**METHODOLOGY**	**TUTOR** **EXTERNAL EXPERTS INVITED**
EU legal provisions	Frontal lectures followed by plenary discussion with facilitators	A. P. Barreiros, R. Barrio, S. Pupella
Principles of donor and patient protection in the different SoHO fields	Intro lecture, lecture by expert, followed by discussion	A. P. Barreiros, VES and IHN experts
Serious adverse events and reactions reporting	Intro lecture, RAB/RATC platforms, role play	F. Teskrat, A. P. Barreiros, R. Barrio, S. Pupella, DG SANTE
Vigilance data reporting, analysis and follow-up actions	Intro lecture, working group exercises	F. Teskrat, A. P. Barreiros, R. Barrio, S. Pupella, 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		
BIBLIOGRAPHY Key deliverables from TRANSPOSE Project (donor protection) WHO/CNT Global Notify Library ISBT-IHN working party WHO Guide Common approach document		

7.4 Round 2 organisation

As for Round 2, adjustments and update may be made with regard to:

- Participants registration criteria;
- Online and F2F training contents, methodology and material (revision and update according to the results of the survey that will be circulated among Round 1 participants);
- Timing.

With particular reference to online Round 2 courses, recorded weekly modules from Round 1 will be mainly used except for the opening and closing session that will be presented live.

8 Summary of the performance indicators cited in the technical offer

During the overall activities requested and implemented for this service, data will regularly be collected relating to the specific performance indicators identified in accordance with tasks requirements. Moreover, meta-data will be disseminated in compliance with confidentiality and data protection rules.
In the following tables lists of specific performance indicators for each task are presented. After the first Round, these indicators may be discussed with the contracting authority and, if necessary, amended accordingly.

Table 5 Task 1 Performance Indicators

Task 1 – Prepare the first Round of online training
a. Set-up of 1 web-based platform with the features and functionalities requested (e.g., Forum, chat, tutorials); **b.** Compatibility with the main updated following browsers: Google Chrome, Safari, Mozilla Firefox, Microsoft Edge; **c.** Usability with the main available devices (e.g., tablet, smartphone, notebook); **d.** Number of online weekly defined: at least 4 online weeks; **e.** Number of online weekly modules uploaded: 2 online weekly modules; **f.** Number of tutorials prepared for participants and tutors/trainers/facilitators: at least 2.

Table 6 Task 2 Performance Indicators

Task 2 – Organise and deliver a first Round of online and F2F trainings
Online training
Delivery **a.** Number of total online weekly modules prepared: 11 online weekly modules; **b.** Number of online synchronous live sessions delivered: at least 11 online synchronous live sessions; **c.** Number of at least 30 participants for each online session so to calculate the rate of participation (effective number of participants vs expected number of participants); **d.** Rate of participants at the beginning and at the end of each online synchronous live session (monitor attendance): minimum 60%; **e.** Number of countries covered in the EU (list of countries and CAs attending each session): at least 10 MSs.

Evaluation f. Pre and post self-assessment quiz: an average acknowledgment improvement of at least 30%; g. Emoji satisfaction survey: at least 70% of positive feedbacks; h. Successfully passed evaluation tests: at least 70% of the participants.
F2F training
Delivery a. Number of total workshops organised: 3 workshops; b. Number of at least 30 participants for each F2F workshop so to calculate the rate of participation (effective number of participants vs expected number of participants); c. Rate of participants at the beginning and at the end of each daily workshop (monitor attendance): minimum 60%; d. Number of countries covered in the EU (list of countries and CAs attending each session): at least 10 MSs. Evaluation e. Pre and post group-assessment quiz: an average acknowledgment improvement of at least 30%; f. Successfully passed final tests: at least 70% of the participants; g. Satisfaction survey: at least 70% of positive feedbacks; h. Lessons learned questionnaire: percentage of participants declaring to have introduced changes in their activity after the course, minimum 30%.

Table 7 Task 3 Performance Indicators

Task 3 – Analyse the results and impact from the first Round of training (3rd interim report) and prepare the dissemination kit
a. Percentage of competent authority staff successfully trained: at least 70% for online training and at least 70% for F2F training; b. Number of changes/improvements indicated by the external independent experts' peer review (qualitative indicator); c. Number of changes/improvements suggested by the contractor vs number of changes/improvements approved by the contracting authority.

Table 8 Task 4 Performance Indicators

Task 4 – Organise and deliver a second Round of online and F2F trainings
Online training
Delivery a. Number of total online weekly modules prepared: 11 online weekly modules; b. Number of synchronous live sessions delivered: at least 11 synchronous live sessions; c. Number of at least 30 participants for each online session so to calculate the rate of participation (effective number of participants vs expected number of participants); d. Rate of participants at the beginning and at the end of each session (monitor attendance): minimum 60%; e. Number of countries covered in the EU (list of countries and CAs attending each session): at least 10 MSs. Evaluation f. Pre and post self-assessment quiz: an average acknowledgment improvement of at least 30%; g. Emoji satisfaction survey: at least 70% of positive feedbacks; h. Successfully passed evaluation tests: at least 70% of the participants.
F2F training
Delivery a. Number of total workshops organised: 3 workshops; b. Number of at least 30 participants for each F2F workshop so to calculate the rate of participation (effective number of participants vs expected number of participants); c. Rate of participants at the beginning and at the end of each daily workshop (monitor attendance): minimum 60%; d. Number of countries covered in the EU (list of countries and CAs attending each session): at least 10 MSs. Evaluation e. Pre and post group-assessment quiz: an average acknowledgment improvement of at least 30%; f. Successfully passed final tests: at least 70% of the participants; g. Satisfaction survey: at least 70% of positive feedbacks; h. Lessons learned questionnaire: percentage of participants declaring to have introduced changes in their activity after the course, minimum 30%.

Annex 1: Overall Teams involved in the Service

ISS and External tutors TRAINING TEAM			
Name	*Role*	*Activity – TASKs*	*SoHO competences*
Simonetta Pupella (ISS)	*Training coordinator* *Teacher* *Tutor*	➢ Responsible for the overall planning of the training sessions (on-line and on-site) ➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A ➢ coordination of the work of the tutors' activity ➢ ensuring the coherence of lectures' content and training methodology and the peer-review of the training material	BLOOD
Sinead Masterson	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	TISSUE and CELLS
Johann Kurz	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	BLOOD, TISSUE and CELLS
Fiorenza Bariani (ISS)	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	TISSUE
Aurora Vassanelli (ISS)	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	CELLS

Ruth Barrio	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	*BLOOD, TISSUE and CELLS*
Anna Kurzreiter	*Tutor*	➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	*TISSUE and CELLS*
Fewzi Teskrat	*Tutor*	➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	*BLOOD, TISSUE and CELLS*
Ursula La Rocca (ISS)	*Tutor*	➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	*BLOOD*
Ana Paula Barreiros	*Teacher* *Tutor*	➢ Teaching lessons ➢ Develop, elaborate and provide didactical and training material (exercises, case studies, lecture, assignments) ➢ Perform the role of the facilitator or moderator in plenary sessions, Live Forum and Q&A sessions ➢ Reply to Chat and Forum Question and Discussion	*ORGANS* *BIOVIGILANCE*
Margherita Gentile (ISS)	*Senior Educational Tutor*	➢ Developing learning methodology ➢ Assure coherence to training needs and learning objects ➢ Coordination of learning activity and Tutors panel ➢ Contact point for Zadig (Joint Tenderer) ➢ Facilitate networking among participants ➢ Preparing documents and training material	
Livia Cannata (ISS)	*Senior Educational Tutor*	➢ Developing learning methodology ➢ Assure coherence to training needs and learning objects ➢ Coordination of learning activity and Tutors panel ➢ Facilitate networking among participants ➢ Preparing documents and training material	
Anna Palmieri (ISS)	*Junior Educational Tutor*	➢ Preparing documents and training material ➢ Coordination of learning activity and Tutors panel ➢ Managing participants registration and trainee community	

		➢ Facilitate networking among participants	
Alfonso Mazzaccara (ISS)	*ISS Training expert*	➢ Overseeing learning methodology ➢ Overseeing and eventually contributing for didactical materials and tools ➢ Quality control on eLearning platform	
Ughetta Maria Favazzi (ISS)	*ISS Training expert*	➢ Methodological support ➢ Quality control on eLearning platform	
Stefania Bocci (ISS)	*ISS Training expert*	➢ Methodological support ➢ Quality control on eLearning platform	

ISS PROJECT MANAGEMENT and COORDINATION TEAM		
Name	*Role*	*Activity – TASKs*
Paola di Ciaccio	*Project Manager* *Translator*	➢ Project management and Event management ➢ Overseeing project delivery ➢ Quality control of delivered service ➢ Coordination of all Service's Teams ➢ Main contact for ISS ➢ Supervision of learning activity and Tutors activity
Livia Cannata	*Project Manager*	➢ Project management and Event management ➢ Main contact for HaDEA and DG Santè ➢ Supervision of learning activity and Tutors activity ➢ Facilitate networking among all Service Teams
Maura Mareri	*Project assistant*	➢ Project management assistance ➢ Event management ➢ Organisation and management of workshops and meetings across EU cities
Claudia Carella	*Project assistant* *Tutor*	➢ Project management and Event management assistance ➢ Organisation and management of workshops and meetings across EU cities ➢ Working in liaison with healthcare professionals, healthcare managers, high-ranking governmental officials ➢ Managing multidisciplinary teams
Anna Palmieri	*Project and event assistant*	➢ Project management and Event management assistance ➢ Organisation and management of workshops and meetings across EU cities

Valentina Caramia	*Translator*	➢ Supervision of English language of training materials ➢ Translate training documents and materials – if needed

ISS ADMINISTRATIVE TEAM **This personnel is employed at the ISS and is not paid with Service's funds**		
Name	*Role*	*Activity – TASKs*
Andrea Aguzzi	Administrative supervision and business management (ISS)	➢ Support and monitor administrative procedures related to the Service ➢ Support to internal communication among different administrative offices involved in project activities
Maria Francesca Arrivi	Administrative support Administrative secretariat (ISS)	➢ Administration of due payment and reimbursement ➢ Support and monitor administrative procedures related to the Service

ISS DPO TEAM		
Name	*Role*	*Activity – TASKs*
Carlo Villanacci	Data Protection Officer	➢ Supervision *of* compliance with the requirements of the GDPR ➢ Provide highly specialized GDPR consultancy where necessary
Teresa Vermiglio	Expert EU Data Protection	➢ Assess the compliance of the Service activities with the requirements of the GDPR ➢ Providing information and support both to the preparation of the information on the processing of personal data and to the implementation of the appropriate technical and organizational measures necessary to guarantee the effective data protection in carrying out its administrative and scientific activities
Stefano Maria D'Ottavi	Expert EU Data Protection	➢ Assess the compliance of the Service activities with the requirements of the GDPR ➢ Providing information and support both to the preparation of the information on the processing of personal data and to the implementation of the appropriate technical and organizational measures

		necessary to guarantee the effective data protection in carrying out its administrative and scientific activities

ZADIG Platform TEAM		
Name	*Role*	*Activity – TASKs*
Pietro Dri	eLearning coordinator	Platform editor in chief: coordination of the technology platform development, the construction of eLearning materials and the implementation of eLearning modules
Maria Rosa Valetto	Project Manager	Project management, contacts with partners, definition of eLearning activities, quality control of eLearning materials
Raffaella Daghini	Web Editor	Study and teaching solutions for e-learning activities, online structuring of modules, uploading of training materials, platform operation checks
Christian Deligant	IT Manager	Server management, platform implementation, IT management of the platform, technical troubleshooting
Nicoletta Scarpa	Contents editor	Editing training materials and uploading them to the platform
Silvia Emendi	Web Editor	Technical management of online webinars