F2F TRAINING INFORMATION SHEET

Context

SIGHTSoHO (strengthening overSIGHT through training and networking on Substances of Human Origin) Service provides 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) and organs. The initiative aims to strengthen the national Competent Authorities (CA) oversight activities in order to contribute to the improvement of the inspection, preparation process authorisation and vigilance of the EU Member States (MS) and increase mutual trust among them.

As for the eLearning, 11 online training modules have been successfully delivered from November 27th, 2023, to March 1st, 2024, through the web platform www.sightsoho.eu
As foreseen, the online modules will be followed by three Face-To-Face (F2F) workshops dedicated to Inspection practice, Preparation Process Authorization and Biovigilance and Hemovigilance, respectively.

Participants

F2F workshops are mainly addressed to eLearning course participants. In addition, SIGHTSoHO staff reached out applicants who had been selected for Round 1 eLearning but could not participate due to constraints related to the maximum number of places available.

F2F training objectives and overall methodology

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 held in **Rome**, at the **Scout Center** (Largo dello Scautismo, 1, 00162).

Face-to-Face training aims to enabling participants:

- To deepen relevant topics and items presented during the eLearning modules;
- To specifically address open issues and training needs arose during the synchronous live appointments;
- To exchange experiences related to all the fields of competence and professional activities in view of the harmonisation and standardisation of some key minimum competencies/knowledge of SoHO inspectors, assessors and vigilance officers.

The training contents will be delivered in order to encourage and stimulate a benchmarking approach mainly using practical methods, which will help simulating daily life situations where inspectors, assessors and vigilance officers are involved.

Funded by
the European Union

Workshops and overall programmes

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, S. Tomljenovic (IES Rapporteur), B. Marquez Garrido/M. Ambrosio (DG SANTE).

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.

Agenda

Day 0. Tuesday 14/05/2024

Time	Session	Title
14:00 - 17:00	Briefing	Briefing session for Facilitators

Day 1. Wednesday 15/05/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 9:15		Welcome message (Training Coordinator – S. Pupella, DG SANTE – B. Marquez Garrido/M. Ambrosio)
9:15 – 9:45		Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 1 expectations and scope
9:45 – 10:45	**Topic 1**	**Ongoing EU Legal Provisions towards the new forthcoming Regulation**
9:45 – 10:30		Frontal lecture (DG SANTE – B. Marquez Garrido/M. Ambrosio) Inspection Expert Sub-Group (IES Rapporteur - S. Tomljenovic)
10:30 – 10:45		Plenary discussion with facilitators J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat, Observers: S. Tomljenovic, B. Marquez Garrido/M. Ambrosio
10:45 – 11:00		**Coffee break**

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

11:00 – 17:00	**Topic 2**	**Performance of an inspection**
11:00 – 11:15	**Exercise 1**	Case studies on performance of an inspection
11:15 – 12:15		Working groups (4) J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat Observers: S. Tomljenovic, B. Marquez Garrido/M. Ambrosio
12:15 – 13:15		Working group rapporteurs presentation, plenary discussion and take-home messages
13:15 – 14:15		**Lunch break**
14:15 – 14:30	**Exercise 2**	Brief intro and presentation of case study on Clarity of non-compliances in the Inspection report
14:30 – 15:30		Working groups (4) J. Kurz, F. Bariani, S. Pupella, R. Barrio, S. Masterson, A. Kurzreiter, U. La Rocca, F. Teskrat Observers: S. Tomljenovic, B. Marquez Garrido/M. Ambrosio
15:30 – 15:45		**Coffee break**
15:45 – 16:45		Working group rapporteurs presentation, plenary discussion and take-home messages
16:45 – 17:00		Recap of the day and closing remarks
20.00		**Social dinner** at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome

Day 2. Thursday 16/05/2024

Time	**Session**	**Title**
8:30 - 9:00		Registration
9:00 – 15:00	**Topic 3**	**Mock inspections at: processing Lab of the BE, collection site of the BE, HSC processing lab, HSC cryopreservation room, MAR centre**
9:00 – 9:20	**Exercise 3**	Introduction and group divisions (7) for mock inspections
9:20 – 10:00		Transfer to Centres
10:00 – 11:30		Start of mock inspections
11:30 – 12:00		Transfer to Scout Centre
12:00 – 13:00		**Lunch break**
13:00 – 14:00		Inspection report elaboration in working groups
14:00 – 15:00		Working group rapporteur presentation, plenary discussion and take-home messages
15:00 – 15:15		**Coffee break**

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

15:15 – 17:00	**Topic 4**	**Assessment of non-compliances and classification of non-conformances**
15:15 – 15:30	**Exercise 4**	Intro lecture and presentation of different non-conformances to be discussed in plenary for shared classification
15:30 – 16:30		Plenary discussion
16:30 – 17:00		Recap of the day and closing remarks

Day 3. Friday 17/05/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 9:30	**Topic 5**	**EU Joint Inspections**
9:00 – 9:15		Presentation on EU Joint Inspections code of practice (S. Tomljenovic)
9:15 – 9:30		Q&A
9:30 – 10:30		Final Examination (Multiple choice)
10:30 – 10:45		**Coffee break**
10:45 – 15:00	**Topic 6**	**Illegal Fraudulent Activities**
10:45 – 11:00		Brief presentation on **Illegal Fraudulent Activities (IFA)**
11:00 – 11:15		Introduction and indications for Role play on IFA
11:15 – 13:00		Role play
13:00 – 14:00		**Lunch break**
14:00 – 14:30		Plenary discussion on Role play outcomes
14:30 – 15:00		Recap of the day and closing remarks

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

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, A. Vassanelli, R. Piteira/J. Tabera Fernandez (Euro-GTP expert), B. Marquez Garrido/M. Ambrosio (DG SANTE).

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.

Agenda

Day 0. Tuesday 04/06/2024

Time	Session	Title
14:00 - 17:00	Briefing	Briefing session for Facilitators

Day 1. Wednesday 5/06/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 9:15		Welcome message (Training Coordinator – S. Pupella, DG SANTE - B. Marquez Garrido/M. Ambrosio, HaDEA - A. Binder)
9:15 – 9:45		Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 2 expectations and scope
9:45 – 11:00	**Topic 1**	**Ongoing EU Legal Provisions towards the new forthcoming Regulation**
9:45 – 10:10		Frontal lecture (B. Marquez Garrido/M. Ambrosio) - (CAs obligations, conditional authorisation)
10:10 – 10:30		Frontal lecture how to build a bridge between Medical Devices/ATMPs sectors/CA
10:30 – 11:00		Plenary discussion with facilitators S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli, Observers: B. Marquez Garrido/M. Ambrosio

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

11:00 – 11:15		**Coffee break**
11:15 – 13:00	**Topic 2**	**Preparation Process Dossier**
11:15 – 11:40	**Exercise 1**	Brief intro on the PPD and presentation of cases study (substantial change control assessment)
11:40 – 13:00		Working groups (6) – (each WG on substantial changes applied in different processes using a different risk assessment tool) – collection/procurement – processing – testing laboratories – facilities (environmental control) – storage – transport, S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli Observers: B. Marquez Garrido/M. Ambrosio
13:00 – 14:00		**Lunch break**
14:00 – 15:15		Working group rapporteurs presentation, plenary discussion and take-home messages
15:15 – 15:45		Lecture on the role of assessors, how the inspector may play the role of assessor too (training, inspector curriculum)
15:45 – 16:00		**Coffee break**
16:00 – 16:30		Plenary discussion and take-home messages
16:30 – 16:45		Recap of the day and closing remarks
20.00		**Social dinner** at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome

Day 2. Thursday 06/06/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 13:00	**Topic 3**	**Euro-GTP II risk assessment tool application**
9:00 – 9:20		Brief overview of Euro-GTP tool contents given in the dedicated eLearning module and brief intro to future development (Euro-GTP expert - R. Piteira/J. Tabera Fernandez)
9:20 – 09:40	**Exercise 2**	Presentation of cases study: blood, T&C, MAR
09:00 – 10:30		Working groups (6) – (3 cases per substance – 2 groups on the same case) S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli Observer: R. Piteira/J. Tabera Fernandez, B. Marquez Garrido/M. Ambrosio
10:30 – 10:45		**Coffee Break**

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

10:45 – 12:00		Working group rapporteurs presentation, plenary discussion and take-home messages
12:00 – 17:00	**Topic 4**	**Novelties: scientific state-of-the-art (the expert point of view), preparation process authorisation (CA approach)**
12:00 – 12:30		Lecture on faecal microbiota (scientific background, consolidated application, future development) Scientific expert (CNT)
12:30 – 13:00		Q&A and plenary discussion
13:00 – 14:00		**Lunch break**
14:00 – 14:30		Lecture on serum eye drop (scientific background, consolidated application, future development) Scientific expert (CNS)
14:30 – 15:00		Q&A and plenary discussion
15:00 – 15:20		Presentation on regulatory approach to the novelties (faecal microbiota)
15:20 – 15:35		**Coffee break**
15:35 – 16:05		Presentation on regulatory approach to the novelties (serum eye drop)
16:05 – 16:40		Q&A and plenary discussion
16:40 – 17:00		Recap of the day and closing remarks

Day 3. Friday 07/06/2024

Time	Session	Title
8:30 - 9:00		Registration
09:00 – 10:00		Final Examination (Multiple choice)
10:00 – 10:15		**Coffee break**
10:15 – 13:00	**Topic 5**	**Assessing/inspecting products and processes**
10:15 – 10:40		Presentation on critical process parameters and the critical product attributes in a quality risk assessment
10:40 – 11:00		Q&A
11:00 – 11:15		Introduction and indications for Role play
11:15 – 12:30		Role play
12:30 – 13:00		Plenary discussion on Role play outcomes
13:00 – 14:00		**Lunch break**
14:00 – 15:30	**Topic 6**	**EU ongoing initiatives**
14:00 – 14:20		Presentation on **EGALITE** R. Piteira/J. Tabera Fernandez

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

14:20 – 14:40		Presentation on GAPP PRO
14:40 – 15:00		Q&A
15:00 – 15:30		Recap of the day and closing remarks

Funded by
the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

Workshop 3 - BIOVIGILANCE AND HEMOVIGILANCE

3, 4, 5 July 2024

Tutors and External experts involved:

A. P. Barreiros, R. Barrio, S. Pupella, F. Teskrat, U. La Rocca, J. Kurz, J. Weirsum/S. Lucas-Samuel (VES - Vigilance Expert Sub-group), A. Navarro and E. Petrisli (Notify expert).

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.

Agenda

Day 0. Tuesday 02/07/2024

Time	Session	Title
14:00 - 17:00	Briefing	Briefing session for Facilitators

Day 1. Wednesday 3/07/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 9:15		Welcome message (Training Coordinator – S. Pupella, VES - J. Weirsum/S. Lucas-Samuel)
9:15 – 9:45		Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 3 expectations and scope
9:45 – 11:15	**Topic 1**	**Ongoing EU Legal Provisions towards the new forthcoming Regulation**
9:45 – 10:15		Frontal lecture (J. Weirsum/S. Lucas-Samuel) - (CAs and establishments obligations)
10:15 – 10:45		Frontal lecture (J. Weirsum/S. Lucas-Samuel) – (common approach)
10:45 – 11:00		Q&A and plenary discussion
11:00 – 11:15		**Coffee break**
11:15 – 15:15	**Topic 2**	**Biovigilance in organs with interactions with other fields**
11:15 – 11:40	**Exercise 1**	Brief intro with presentation of the cases study

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

11:40 – 13:00		Working groups (4) – each WG on different items (root cause analysis) A. P. Barreiros, R. Barrio, S. Pupella, F. Teskrat, U. La Rocca, J. Kurz Observers: J. Weirsum/S. Lucas-Samuel, A. Navarro and E. Petrisli
13:00 – 14:00		**Lunch break**
14:00 – 15:15		Working group rapporteurs presentation, plenary discussion and take-home messages
15:15 – 16:45	**Topic 3**	**Organ Donation and allocation**
15:15 – 15:45		Lecture on process donation and allocation with focus on donor selection criteria and derogations
15:45 – 16:00		**Coffee Break**
16:00- 16:30		Plenary discussion and take-home messages
16:30 – 16:45		Recap of the day and closing remarks
20.00		**Social dinner** at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome

Day 2. Thursday 04/07/2024

Time	Session	Title
8:30 - 9:00		Registration
9:00 – 12:00	**Topic 4**	**Investigations, evaluation and SAR/E classifications**
9:00 – 9:20		Brief overview of Notify Library tool contents given in the dedicated eLearning module and brief intro to future development (A. Navarro and E. Petrisli)
9:20 – xxx	**Exercise 2**	Presentation of biovigilance cases study: blood, T&C, MAR, Organs
09:20 – 10:40		Working groups (4) – (4 different cases per substance) A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, F. Teskrat, J. Kurz Observers: J. Weirsum/S. Lucas-Samuel, A. Navarro and E. Petrisli
10:40 – 11:00		**Coffee Break**
11:00 – 12:00		Working group rapporteurs presentation, plenary discussion and take-home messages
12:00 – 17:15	**Topic 5**	Serious adverse events and reactions reporting
12:00 – 12:30		Lecture on RAB/RATC platforms (J. Weirsum/S. Lucas-Samuel) (The use of the Rapid Alert System in the case of cross-border implications)

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

12:30 – 13:00		Q&A and plenary discussion
13:00 – 14:00		**Lunch break**
14:00 – 14:30		Brief intro and case study presentation on Recall, quarantine, collection of samples for analysis, of products
14:30 – 15:45		Working groups (4) – 1 case study A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, F. Teskrat, J. Kurz Observers: J. Weirsum/S. Lucas-Samuel, A. Navarro and E. Petrisli
15:45 – 16:00		**Coffee break**
16:00 – 17:00		Working group rapporteurs presentation, plenary discussion and take-home messages
17:00 – 17:15		Recap of the day and closing remarks

Day 3. Friday 05/07/2024

Time	Session	Title
8:30 - 9:00		Registration
09:00 – 10:00		Final Examination (Multiple choice)
10:00 – 12:30	**Topic 6**	**Vigilance data reporting, analysis and follow-up actions**
10:00 – 10:15		Brief Presentation on CA's follow-up actions in response to critical vigilance notifications
10:15 – 10:30		Brief intro and case study presentation on RATC
10:30 – 10:45		**Coffee break**
10:45 – 11:45		Working groups (4) – 1 case study A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, F. Teskrat, J. Kurz Observers: J. Weirsum/S. Lucas-Samuel, A. Navarro and E. Petrisli
11:45– 12:30		Working group rapporteurs presentation, plenary discussion and take-home messages
12:30 – 15:00	**Topic 7**	**Biovigilance in the MAR sector**
12:30 – 13:00		Lecture on protection of offspring from medically assisted reproduction and follow-up procedures
13:00 – 13:30		Q&A and plenary discussion
13:30 – 14:30		**Lunch break**
14:30 – 15:00		Recap of the day and closing remarks

Funded by the European Union

This document was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this document are those of the author(s) and do not necessarily reflect the official opinion of the Commission/Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this document. Neither the Commission/Executive Agency nor any person acting on the Commission's/Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.