



# SIGHTSoHO

strengthening overSIGHT through training and networking on  
Substances of Human Origin

## Overall eLearning programme, including all weekly training modules



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## Week 1 - EU LEGAL PROVISIONS

27/11/23 - 01/12/23

### Tutors and External experts involved:

J. Kurz, S. Pupella, DG SANTE, W. Ecker, S. Masterson, U. La Rocca, R. Barrio

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
27-Nov	<b>Monday</b>	
	Intro message launched in the “Announcements” Live opening event	10:00 - 11:00 14:00 - 15:30
28-Nov	<b>Tuesday</b>	
	Independent asynchronous study	
29-Nov	<b>Wednesday</b>	
	Synchronous live session on <b>Overlaps between SoHO, ATMPs and Medical Devices frameworks</b>	14:00 - 15:30
30-Nov	<b>Thursday</b>	
	Independent asynchronous study	
01-Dec	<b>Friday</b>	
	Forum - discussion on assignment on <b>EU Directives</b>	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>EU current directives</b>	J. Kurz
Assignment on <b>EU current directives</b>	J. Kurz
Presentation on <b>Introduction to the proposal for the new SoHO regulation</b>	DG SANTE
Pre-recorded presentation on <b>Basic info on current Medical Device Regulations relevant for BTC establishments</b>	W. Ecker
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 2 - LICENSING, AUTHORISATION AND ACCREDITATION SYSTEM (INCLUDING OVERVIEW OF INSPECTION TOOLS)

04/12/23 - 07/12/23

Tutors and External experts involved:

S. Pupella, R. Barrio, R. Piteira/J. Tabera Fernandez, J. Kurz, A. Vassanelli, A. Kurzreiter,  
U. La Rocca

### SYNCHRONOUS LIVE APPOINTMENTS

	Monday	When (CET)
04-Dec	Intro message launched in the “Announcements”	10:00 - 11:00
	Tuesday	
05-Dec	Independent asynchronous study	
	Wednesday	When (CET)
06-Dec	Synchronous live session on EuroGTP II risk assessment tool	14:00 - 15:30
	Thursday	When (CET)
07-Dec	Forum - survey results on Mutual recognition tools (e.g., Common European SoHO Inspection Programme - CESIP, Joint inspections)	14:00 - 16:00
	Friday	
08-Dec	Independent asynchronous study/Bank Holiday	

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Inspection Guidelines for EU Competent Authorities responsible for the inspection and authorisation of Blood and Tissue Establishments</b>	S. Pupella
Pre-recorded presentations on <b>GAPP Joint Action and GAPP Guideline for Preparation Process Authorisation (PPA)</b>	R. Barrio
Survey on <b>Mutual recognition tools (e.g., Common European SoHO Inspection Programme - CESIP, Joint inspections)</b>	S. Pupella R. Barrio
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 3 - QUALITY MANAGEMENT SYSTEM - OVERVIEW

11/12/23 - 15/12/23

### Tutors and External experts involved:

S. Masterson, A. Vassanelli, A. Kurzreiter, Expert from EDQM, J. Kurz, S. Pupella, U. La Rocca, F. Teskrat, F. Bariani

### SYNCHRONOUS LIVE APPOINTMENTS

	Monday	When (CET)
11-Dec	Intro message launched in the “Announcements”	10:00 - 11:00
	Tuesday	
12-Dec	Independent asynchronous study	
	Wednesday	When (CET)
13-Dec	Synchronous live session (Intro lecture and breakout rooms) on <b>Classification of real-life non compliances</b>	14:00 - 15:30
	Thursday	
14-Dec	Independent asynchronous study	
	Friday	When (CET)
15-Dec	Forum	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Documentation, Data processing Third parties Management</b>	A. Vassanelli S. Masterson
Pre-recorded presentation on <b>Non-conformance/deviation system/recall (NCs and risk assessment tool)</b>	S. Masterson A. Kurzreiter
Pre-recorded presentation on <b>Self-Inspection/Internal &amp; External Audit</b>	Expert from EDQM
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

## Week 4 - QUALITY MANAGEMENT SYSTEM - GOOD PRACTICES

18/12/23 - 22/12/23

Tutors and External experts involved:

J. Kurz, A. Kurzreiter, S. Masterson, F. Teskrat, A. Vassanelli, S. Pupella, U. La Rocca

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
18-Dec	<b>Monday</b>	
	Intro message launched in the "Announcements"	10:00 - 11:00
19-Dec	<b>Tuesday</b>	
	Independent asynchronous study	
20-Dec	<b>Wednesday</b>	When (CET)
	Synchronous live session - Lecture followed by open discussion on <b>Quality Control and Statistical Process Control</b>	14:00 - 15:30
21-Dec	<b>Thursday</b>	
	Independent asynchronous study	
22-Dec	<b>Friday</b>	When (CET)
	Forum - discussion on assignment on <b>Personnel (Training and competences of the staff)</b>	14:00 - 15:00
	Forum - discussion on assignment on <b>Validation and Change control</b>	15:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Assignment on <b>Personnel (Training and competences of the staff)</b>	S. Masterson S. Pupella
Assignment on <b>Validation and Change control</b>	A. Vassanelli A. Kurzreiter
POST SELF- ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 5 - QUALITY RISK ASSESSMENT (INCLUDING TOOLS)

08/01/24 - 12/01/24

Tutors and External experts involved:

S. Masterson, F. Bariani, R. Barrio, External expert (IES), S. Pupella

### SYNCHRONOUS LIVE APPOINTMENTS

08-Jan	<b>Monday</b>	<b>When (CET)</b>
	Intro message launched in the “Announcements”	10:00 - 11:00
09-Jan	<b>Tuesday</b>	
	Independent asynchronous study	
10-Jan	<b>Wednesday</b>	<b>When (CET)</b>
	Synchronous live session - Frontal lesson followed by discussion and Q&A on <b>Risk Assessment Methods</b> (e.g., HACCP, FMEA, FTA, Root Cause Analysis, Risk Mitigation Strategies, Risk register etc.)	14:00 - 15:30
11-Jan	<b>Thursday</b>	
	Independent asynchronous study	
12-Jan	<b>Friday</b>	<b>When (CET)</b>
	Forum - discussion on assignment on <b>Management of non-compliances: follow-up activities</b>	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Quality risk management</b>	S. Masterson
Assignment on <b>Management of non-compliances: follow-up activities</b>	F. Bariani
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 6 - BTC PREPARATION PROCESS AUTHORISATION

15/01/24 - 19/01/24

### Tutors and External experts involved:

R. Barrio, External Expert (IES), A. Vassanelli, U. La Rocca, J. Kurz, A. Kurzreiter, S. Pupella

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
15-Jan	<b>Monday</b>	
	Intro message launched in the “Announcements”	10:00 - 11:00
16-Jan	<b>Tuesday</b>	
	Independent asynchronous study	
17-Jan	<b>Wednesday</b>	<b>When (CET)</b>
	Synchronous live session - Lecture followed by breakout sessions on <b>Quality and safety assessment (product/process)</b>	14:00 - 15:30
18-Jan	<b>Thursday</b>	
	Independent asynchronous study	
19-Jan	<b>Friday</b>	<b>When (CET)</b>
	Forum - discussion on selected documents on <b>Clinical assessment as part of PPA (risk-based)</b>	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
<b>PRE SELF-ASSESSMENT QUIZ</b>	
Pre-recorded presentation on <b>A common approach on PPA (a focus on Technical Annexes of the GAPP Guideline for PPA)</b>	R. Barrio
Assignment on <b>Clinical assessment as part of PPA (risk-based)</b>	S. Pupella External Expert (IES)
<b>POST SELF-ASSESSMENT QUIZ</b>	
<b>EMOJI SATISFACTION SURVEY</b>	
<b>EVALUATION TEST</b>	

## Week 7 - SoHO VIGILANCE AND BIOVIGILANCE

22/01/24 - 26/01/24

### Tutors and External experts involved:

A. P. Barreiros, F. Bariani, A. Vassanelli, S. Pupella, A. Kurzreiter, R. Barrio, External Expert (VES), U. La Rocca

### SYNCHRONOUS LIVE APPOINTMENTS

	Monday	When (CET)
22-Jan	Intro message launched in the “Announcements”	10:00 - 11:00
	Tuesday	
23-Jan	Independent asynchronous study	
	Wednesday	When (CET)
24-Jan	Synchronous live session - Webinar followed by Q&A on <b>Biovigilance: organs</b>	14:00 - 15:30
	Thursday	
25-Jan	Independent asynchronous study	
	Friday	When (CET)
26-Jan	Forum	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentations on <b>Donor selection and donor and recipient protection: Blood, T&amp;C, MAR</b>	F. Bariani A. Vassanelli S. Pupella
Pre-recorded presentations on <b>Biovigilance: Blood, T&amp;C, MAR</b>	A. Kurzreiter R. Barrio
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 8 - SERIOUS ADVERSE OUTCOMES/ RAPID ALERTS AND HARMONIZING DATA COLLECTION

29/01/24 - 02/02/24

### Tutors and External experts involved:

A. P. Barreiros, F. Bariani, R. Barrio, J. Kurz, S. Pupella, U. La Rocca, A. Vassanelli, External Expert (VES), Notify Expert

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
29-Jan	<b>Monday</b>	
	Intro message launched in the “Announcements”	10:00 - 11:00
30-Jan	<b>Tuesday</b>	
	Independent asynchronous study	
31-Jan	<b>Wednesday</b>	When (CET)
	Synchronous live session - Intro lecture followed by simulation on <b>WHO/CNT Global Notify Library</b> , simulation of evaluation of examples of medical records through cases study, followed by comparison of the results in plenary	14:00 - 15:30
01-Feb	<b>Thursday</b>	
	Independent asynchronous study	
02-Feb	<b>Friday</b>	When (CET)
	Forum - discussion on assignment on <b>Harmonising data collection, Common approach and definitions, Denominators</b>	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentations on <b>Severe adverse reactions/Events (SARE) Reporting: Blood, T&amp;C, Organs</b>	External Expert (EDQM) A.P. Barreiros
Assignment on <b>Harmonising data collection, Common approach and definitions, Denominators</b>	F. Bariani R. Barrio
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

## Week 9 - STOCK AND CRITICAL SUPPLIES, IMPORT/EXPORT, SINGLE CODING

05/02/24 - 09/02/24

Tutors and External experts involved:

S. Masterson, S. Pupella, J. Kurz, A. Kurzreiter, A. Vassanelli, F. Bariani, U. La Rocca

### SYNCHRONOUS LIVE APPOINTMENTS

05-Feb	<b>Monday</b>	<b>When (CET)</b>
	Intro message launched in the “Announcements”	10:00 - 11:00
06-Feb	<b>Tuesday</b>	
	Independent asynchronous study	
07-Feb	<b>Wednesday</b>	<b>When (CET)</b>
	Synchronous live session - Intro lecture and problem-solving exercise in breakout rooms (contingency planning) on <b>Stock and critical supplies (reagents, etc)</b>	14:00 - 15:30
08-Feb	<b>Thursday</b>	
	Independent asynchronous study	
09-Feb	<b>Friday</b>	<b>When (CET)</b>
	Forum - discussion on assignment on <b>Single Coding of tissues and cells</b>	14:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Imports and exports</b>	S. Masterson J. Kurz
Assignment on <b>Single Coding of tissues and cells</b>	A. Kurzreiter A. Vassanelli
Pre-recorded presentation on <b>Traceability</b>	F. Bariani
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 10 - INSPECTION PRACTICE, INSPECTION REPORT AND POST INSPECTION ACTIVITIES

12/02/24 - 16/02/24

Tutors and External experts involved:

S. Pupella, S. Masterson, F. Teskrat, A. Vassanelli, J. Kurz, A. Kurzreiter, U. La Rocca

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
12-Feb	<b>Monday</b>	
	Intro message launched in the “Announcements”	10:00 - 11:00
13-Feb	<b>Tuesday</b>	
	Independent asynchronous study	
14-Feb	<b>Wednesday</b>	When (CET)
	Synchronous live session on <b>Inspection report</b>	14:00 - 15:30
15-Feb	<b>Thursday</b>	
	Independent asynchronous study	
16-Feb	<b>Friday</b>	When (CET)
	Forum - discussion on assignment on <b>Common approach for distance assessment (hybrid, remote, documentary)</b>	14:00 - 15:00
	Forum - discussion on assignment and ppt on <b>Special requirements and protocol for initiating and performing joint inspections upon justified request of a EU MS</b>	15:00 - 16:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Inspection practices (pre and post inspection activities)</b>	S. Pupella
Pre-recorded presentation on <b>Illegal and fraudulent activities</b>	F. Teskrat
Pre-recorded presentation on <b>Remote Virtual Inspection guidance document</b>	F. Teskrat
Assignment on <b>Common approach for distance assessment (hybrid, remote, documentary)</b>	A. Vassanelli
Pre-recorded presentation on <b>Special requirements and protocol for initiating and performing joint inspections upon justified request of an EU MS</b>	J. Kurz A. Kurzreiter
Assignment on <b>Special requirements and protocol for initiating and performing joint inspections upon justified request of an EU MS</b>	J. Kurz A. Kurzreiter
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 11 - RISK FOR INSPECTORATE

19/02/24 - 23/02/24

### Tutors and External experts involved:

S. Masterson, S. Pupella, R. Barrio, U. La Rocca, A. Vassanelli, F. Bariani

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
19-Feb	<b>Monday</b>	10:00 - 11:00
	Intro message launched in the “Announcements”	
20-Feb	<b>Tuesday</b>	
	Independent asynchronous study	
21-Feb	<b>Wednesday</b>	14:00 - 15:30
	Synchronous live session - Frontal lesson followed by discussion on <b>Inspectors management (skills, competences, responsibilities, independence and conflict of interest/impartiality)</b>	
22-Feb	<b>Thursday</b>	
	Independent asynchronous study	
23-Feb	<b>Friday</b>	14:00 -16:00
	Forum - discussion on assignment on <b>Procedure for products sampling for analysis purposes by independent laboratories on the request of the CAs</b>	

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
<b>PRE SELF-ASSESSMENT QUIZ</b>	
Pre-recorded presentation on <b>Quality management system (including risk management)</b>	S. Masterson
Assignment preparation: selection of documents on <b>Procedure for products sampling for analysis purposes by independent laboratories on the request of the Cas</b> to be discussed in the Forum	S. Masterson S. Pupella
<b>POST SELF-ASSESSMENT QUIZ</b>	
<b>EMOJI SATISFACTION SURVEY</b>	
<b>EVALUATION TEST</b>	

### SYNCHRONOUS LIVE APPOINTMENTS

		When (CET)
01-Mar	<b>Friday</b>	14:00 - 15:30
	Live closing event	