



# SIGHTSoHO

strengthening overSIGHT through training and networking on  
Substances of Human Origin

## Overall eLearning programme, including all weekly training modules



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the European Union**

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Live Opening Event on January 22<sup>nd</sup> from 14:00 to 15:30 (CET)

## Week 1 - EU LEGAL PROVISIONS

27/01/25 - 31/01/25

### Tutors and External experts involved:

J. Kurz, S. Pupella, S. Masterson, R. Barrio, DG SANTE, W. Ecker (MD external expert), R. Bauer (MD external expert)

### SYNCHRONOUS LIVE APPOINTMENTS

27-Jan	<b>Monday</b> Intro message launched in the “Announcements”	<b>When (CET)</b> 10:00 - 11:00
28-Jan	<b>Tuesday</b> Independent asynchronous study	
29-Jan	<b>Wednesday</b> Synchronous live session on <b>Bridges between SoHO, ATMPs and Medical Devices frameworks</b>	<b>When (CET)</b> 14:00 - 15:30
30-Jan	<b>Thursday</b> Independent asynchronous study	
31-Jan	<b>Friday</b> Forum on <b>Criticalities/ applicability of the new SoHO regulation as per the oversight aspects/obligations</b>	<b>When (CET)</b> 14:00 - 15:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>EU current directives</b>	J. Kurz
Assignment on <b>Criticalities/applicability of the new SoHO regulation as per the oversight aspects/obligations</b>	J. Kurz
Presentation on <b>Introduction to 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 (MD external expert)
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

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

03/02/25 - 07/02/25

Tutors and External experts involved:

S. Pupella, R. Barrio; J. Kurz, A. Vassanelli, A. Kurzreiter, U. La Rocca, J. Tabera Fernandez  
(Euro-GTP external expert)

### SYNCHRONOUS LIVE APPOINTMENTS

03-Feb	<b>Monday</b> Intro message launched in the "Announcements"	<b>When (CET)</b> 10:00 - 11:00
04-Feb	<b>Tuesday</b> Independent asynchronous study	
05-Feb	<b>Wednesday</b> Synchronous live session on EuroGTP II risk assessment tool	<b>When (CET)</b> 14:00 - 15:30
06-Feb	<b>Thursday</b> Independent asynchronous study	
07-Feb	<b>Friday</b> Webinar on GAPP Guideline	<b>When (CET)</b> 14:00 - 15:00

### 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
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

## Week 3 - QUALITY MANAGEMENT SYSTEM - OVERVIEW

10/02/25 - 14/02/25

Tutors and External experts involved:

S. Masterson, A. Vassanelli, A. Kurzreiter, J. Kurz, S. Pupella, U. La Rocca, F. Bariani, M. Emery (EDQM external expert)

### SYNCHRONOUS LIVE APPOINTMENTS

10-Feb	<b>Monday</b>	<b>When (CET)</b>
	Intro message launched in the “Announcements”	10:00 - 11:00
11-Feb	<b>Tuesday</b>	
	Independent asynchronous study	
12-Feb	<b>Wednesday</b>	<b>When (CET)</b>
	Synchronous live session on <b>Classification of real-life non compliances</b>	14:00 - 15:30
13-Feb	<b>Thursday</b>	
	Independent asynchronous study	
14-Feb	<b>Friday</b>	<b>When (CET)</b>
	Webinar on <b>key definitions of quality management</b>	14:00 - 15:00

### 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</b> (NCs and risk assessment tool)	S. Masterson - A. Kurzreiter
Pre-recorded presentation on <b>Self-Inspection/Internal &amp; External Audit</b>	M. Emery (EDQM external expert)
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	



## Week 4 - QUALITY MANAGEMENT SYSTEM - GOOD PRACTICES

17/02/25 - 21/02/25

Tutors and External experts involved:

J. Kurz, A. Kurzreiter, S. Masterson, A. Vassanelli, U. La Rocca, EDQM external expert

### SYNCHRONOUS LIVE APPOINTMENTS

17-Feb	<b>Monday</b> Intro message launched in the “Announcements”	<b>When (CET)</b> 10:00 - 11:00
18-Feb	<b>Tuesday</b> Independent asynchronous study	
19-Feb	<b>Wednesday</b> Synchronous live session on <b>Quality Control and Statistical Process Control</b>	<b>When (CET)</b> 14:00 - 15:30
20-Feb	<b>Thursday</b> Independent asynchronous study	
21-Feb	<b>Friday</b> Webinar on <b>Validation and Change control</b>	<b>When (CET)</b> 14:00 - 15:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
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)

24/02/25 - 28/02/25

Tutors and External experts involved:

S. Masterson, F. Bariani, R. Barrio, S. Pupella, F. Teskrat, IES Sub-group Rapporteur

### SYNCHRONOUS LIVE APPOINTMENTS

24-Feb	Monday	When (CET)
	Intro message launched in the “Announcements”	10:00 - 11:00
25-Feb	Tuesday	
	Independent asynchronous study	
26-Feb	Wednesday	When (CET)
	Synchronous live session on Risk Assessment Methods (e.g., HACCP, FMEA, FTA, Root Cause Analysis, Risk Mitigation Strategies, Risk register etc.)	14:00 - 15:30
27-Feb	Thursday	
	Independent asynchronous study	
28-Feb	Friday	When (CET)
	Synchronous live session on Management of non-compliances: follow-up activities	14:00 - 15:00

### INDEPENDENT ASYNCHRONOUS STUDY

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

## Week 6 - BTC PREPARATION PROCESS AUTHORISATION

03/03/25 - 07/03/25

Tutors and External experts involved:

R. Barrio, A. Vassanelli, U. La Rocca, J. Kurz, S. Pupella, F. Teskrat, IES Sub-group  
Rapporteur

### SYNCHRONOUS LIVE APPOINTMENTS

03-Mar	Monday	When (CET)
	Intro message launched in the "Announcements"	10:00 - 11:00
04-Mar	Tuesday	
	Independent asynchronous study	
05-Mar	Wednesday	When (CET)
	Synchronous live session on <b>Quality and safety assessment (product/process)</b>	14:00 - 15:30
06-Mar	Thursday	
	Independent asynchronous study	
07-Mar	Friday	When (CET)
	Webinar on <b>Quality and safety assessment</b>	14:00 - 15:00

### INDEPENDENT ASYNCHRONOUS STUDY

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

## Week 7 - SoHO VIGILANCE AND BIOVIGILANCE

10/03/25 - 14/03/25

Tutors and External experts involved:

A. P. Barreiros, F. Bariani, A. Vassanelli, S. Pupella, R. Barrio, U. La Rocca, VES Rapporteur

### SYNCHRONOUS LIVE APPOINTMENTS

10-Mar	Monday	When (CET)
	Intro message launched in the “Announcements”	10:00 - 11:00
11-Mar	Tuesday	
	Independent asynchronous study	
12-Mar	Wednesday	When (CET)
	Synchronous live session on <b>Biovigilance: organs and Biovigilance updates according to the new Regulation</b>	14:00 - 15:30
13-Mar	Thursday	
	Independent asynchronous study	
14-Mar	Friday	When (CET)
	Forum on <b>SoHO Vigilance and Biovigilance</b>	14:00 - 15:00

### 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	



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

17/03/25 - 21/03/25

Tutors and External experts involved:

A. P. Barreiros, F. Bariani, R. Barrio, J. Kurz, S. Pupella, U. La Rocca, A. Vassanelli, G. Bodea (EDQM external expert), Notify Library external experts, VES Rapporteur

### SYNCHRONOUS LIVE APPOINTMENTS

17-Mar	Monday	When (CET)
	Intro message launched in the “Announcements”	10:00 - 11:00
18-Mar	Tuesday	
	Independent asynchronous study	
19-Mar	Wednesday	When (CET)
	Synchronous live session on WHO/CNT Global Notify Library	14:00 - 15:30
20-Mar	Thursday	
	Independent asynchronous study	
21-Mar	Friday	When (CET)
	Webinar on Common approach for data collection, and harmonised definitions, Denominators	14:00 - 15:00

### 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>	G. Bodea (EDQM external expert) A. P. Barreiros
Assignment on <b>Common approach for data collection, and harmonised 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

24/03/25 - 28/03/25

Tutors and External experts involved:

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

### SYNCHRONOUS LIVE APPOINTMENTS

24-Mar	Monday	When (CET)
	Intro message launched in the “Announcements”	10:00 - 11:00
25-Mar	Tuesday	
	Independent asynchronous study	
26-Mar	Wednesday	When (CET)
	Synchronous live session on <b>Stock and critical supplies (reagents, etc)</b>	14:00 - 15:30
27-Mar	Thursday	
	Independent asynchronous study	
28-Mar	Friday	When (CET)
	Webinar on <b>Single Coding of tissues and cells, EU platform and compendium of SoHO preparation</b>	14:00 - 15:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Imports and exports</b>	S. Masterson - J. Kurz
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

31/03/25 - 04/04/25

Tutors and External experts involved:

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

### SYNCHRONOUS LIVE APPOINTMENTS

31-Mar	Monday	When (CET)
	Intro message launched in the “Announcements”	10:00 - 11:00
01-Apr	Tuesday	
	Independent asynchronous study	
02-Apr	Wednesday	When (CET)
	Synchronous live session on <b>Harmonisation of Inspection report</b>	14:00 - 15:30
03-Apr	Thursday	
	Independent asynchronous study	
04-Apr	Friday	When (CET)
	Webinar on <b>Keys requirements and agreed protocol for initiating and performing EU MS joint inspections between two or more CA</b>	14:00 - 15:00

### 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
Presentation on <b>Remote Virtual Inspection guidance document</b>	F. Teskrat
Pre-recorded presentation on <b>Keys requirements and agreed protocol for initiating and performing EU MS joint inspections between two or more CA</b>	A. Kurzreiter - J. Kurz
Assignment on <b>Keys requirements and agreed protocol for initiating and performing EU MS joint inspections between two or more CA</b>	J. Kurz - A. Kurzreiter
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

## Week 11 - RISK FOR INSPECTORATE

07/04/25 - 11/04/25

Tutors and External experts involved:

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

### SYNCHRONOUS LIVE APPOINTMENTS

07-Apr	<b>Monday</b> Intro message launched in the "Announcements"	<b>When (CET)</b> 10:00 - 11:00
08-Apr	<b>Tuesday</b> Independent asynchronous study	
09-Apr	<b>Wednesday</b> Synchronous live session on <b>Inspectors management (skills required, qualification, responsibilities, independence and impartiality, management of conflict of interest)</b>	<b>When (CET)</b> 14:00 - 15:30
10-Apr	<b>Thursday</b> Independent asynchronous study	
11-Apr	<b>Friday</b> Forum on <b>Empowerment of Inspectors</b>	<b>When (CET)</b> 14:00 -15:00

### INDEPENDENT ASYNCHRONOUS STUDY

ACTIVITY	Who
PRE SELF-ASSESSMENT QUIZ	
Pre-recorded presentation on <b>Quality Management System &amp; Quality Risk Management for Inspectorates</b>	S. Masterson
Assignment on <b>Empowerment of Inspectors</b>	S. Masterson - S. Pupella
POST SELF-ASSESSMENT QUIZ	
EMOJI SATISFACTION SURVEY	
EVALUATION TEST	

**Live Closing Event on April 30<sup>th</sup> from 14:00 to 15:30 (CET)**