

## Swissmedic Regulatory Training, Spring 2025

02 to 06 June 2025, Swissmedic, Berne, Switzerland

### Agenda

#### Module 1 Introduction (all groups)

Day 1: Monday, 2 June 2025

Room H044

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
08:45	<b>Start Day 1</b>	
08:45	Welcome and registration at Facility Hallerstrasse 7	All
09:00–09:15	Opening remarks	Hiiti Sillo <i>Unit Head, Regulation and Safety, WHO</i>
09:15–09:45	General information and presentation of agenda Context on RSS engagement	Lodovico Paganini <i>Scientific Officer Stakeholder Engagement</i>
	Group introduction	All
09:45–10:30	Introduction Swissmedic <ul style="list-style-type: none"> <li>Context and figures</li> <li>Role and Responsibility</li> </ul>	Jörg Schläpfer <i>Head of Sector Staff and external Relations</i>
10:30–10:45	<b>Group photo and coffee break</b>	
10:45–11:15	Overview Swissmedic: National and International cooperation	Gabriela Zenhäusern <i>Head of Division Stakeholder Engagement</i>
11:15–12:00	Introduction to Swissmedic's Horizon Scanning	Daniel Hürlimann <i>Scientific Officer Stakeholder Engagement</i>
12:00–13:00	<b>Lunch @ Cafeteria Swissmedic Hallerstrasse 7</b>	
13:00–13:45	Overview of WHO Regulatory Systems Strengthening Programme <ul style="list-style-type: none"> <li>Capacity building activities</li> <li>WHO Role during the pandemic</li> </ul>	Razieh Ostad Ali <i>Scientist, Regulatory Systems Strengthening Team, Regulation and Safety Unit, WHO</i>
13:45–14:30	Good reliance practices in regulatory decision-making high-level principles and recommendations	Sunday Kisoma <i>Technical Officer, Facilitated Product Introduction, Regulation and Safety, WHO</i>
14:30–15:00	<b>Coffee break</b>	
15:00–16:15	Good regulatory practices and QMS guidelines for national regulatory authorities for medical products	Alireza Khadem <i>Team Lead, Regulatory Systems Strengthening Team, WHO</i>
16:15–17:00	WHO Global Model Regulatory Framework for Medical Devices and GBT+	Agnes Kijo, <i>Technical Officer, Regulation and Safety Unit, WHO</i>
17:00–17:30	Q&A	
	<b>End of Day 1</b>	

## Module 2 QMS

Day 2: Tuesday, 3 June 2025

Room H048

<i><b>Time</b></i>	<i><b>Topic</b></i>	<i><b>Speaker / Moderator</b></i>
	<b>Day 2</b>	
09:30–10:30	Corporate Risk Management	Vikran Sellappah <i>Junior Business Controller</i>
10:30–11:00	<b>Coffee break</b>	
11:00–11:45	Swissmedic approach to QMS – benefits and challenges	Urs Niggli <i>Head of Division Operational Support Services</i>
11:45–12:00	Exchange on national approaches to QMS	All
12:00–13:00	<b>Lunch</b>	
13:00–14:00	Submission Formats	Urs Niggli <i>Head of Division Operational Support Services</i>
14:00–14:30	Questions / Discussion	All
14:30–15:00	<b>Coffee break</b>	
15:00–16:30	Digitization @ Swissmedic Challenges, key learnings and solution-oriented tools	Michael Renaudin <i>Division Swissmedic 4.0</i>
16:30	<b>End of Day 2</b>	
TBD	<b>Social Event</b>	

## Module 2 QMS

Day 3: Wednesday, 4 June 2025

Room F032 @ Lab Facility

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
09:00	<b>Day 3, Part 1: OMCL with focus on QMS (ISO 17025)</b>	
09:00 09:00–09:15	Meeting at Hallerstrasse 7 ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini <i>Scientific Officer Stakeholder Engagement</i>
09:15–09:30	Welcome	Shkipe Klenja <i>Quality Management specialist Lab. (OMCL)</i>
09:30–10:30	Introduction of Swissmedic Laboratory (OMCL) with focus on the QMS	Shkipe Klenja <i>Quality Management specialist Lab. (OMCL)</i>
10:30–11:00	<b>Coffee break</b>	
11:00–11:30	EDQM (Strasbourg) and the GEON Network (OMCL)	Shkipe Klenja <i>Quality Management specialist Lab. (OMCL)</i>
11:30–12:00	Questions / Discussion	
12:00–13:00	<b>Lunch</b>	
	<b>Day 3, Part 2: Establishment licenses and Swiss GMP/GDP inspection system with focus on QMS (ISO 17020)</b>	
13:00–13:50	Establishment licensing system	Georges Meseguer <i>Head of Unit Certificates and Licenses</i>
13:50–14:45	Swiss GMP/GDP inspection system	Christian Schärer <i>Head of Unit Inspection Management and Blood Safety</i>
14:45–15:00	Questions / Discussion	
15:00–15:15	<b>Coffee break</b>	
15:00–15:30	Certificates (GMP/GDP and CPP)	Georges Meseguer <i>Head of Unit Certificates and Licenses</i>
15:30–16:00	International cooperation	Christian Schärer <i>Head of Unit Inspection Management and Blood Safety</i>
16:00–16:15	Questions / Discussion	
16:15	<b>End of Day 3</b>	

## Module 2: QMS

Day 4: Thursday, 5 June 2025

@ Lab Facility

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
	<b>Start Day 4</b>	
09:00 09:00–09:15	Meeting at Hallerstrasse ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini <i>Scientific Officer Stakeholder Engagement</i>
09:15–10:45	Laboratory tour with open Q&A	Michael Gilgen <i>Head of Unity Laboratory 1</i>  Magali Gobet <i>Head of Unity Laboratory 2</i>  Daniel Glauser <i>Head of Unity Laboratory 3</i>
11:00–12:00	Transfer to Erlachstrasse	All
12:00–13:30	<b>Lunch @ Facility Hallerstrasse</b>	
	Optional program in the afternoon: <ul style="list-style-type: none"> <li>- Participation in session on MD (Modul 4)</li> <li>- Preparation of country presentation</li> <li>- Individual study time (room H046)</li> </ul>	
	<b>End of Day 4</b>	

## Module 5: End module (All groups)

Day 5, Friday, 6 June 2025

Room EU137

09:00	<b>Start Day 5</b>	
09:00–10:30	NRAs country presentation of Lessons Learned (10 min presentation plus 10 min discussion)	All
10:45–11:00	<b>Coffee break</b>	
11:00–12:00	Wrap-up and closing remarks	Swissmedic and WHO representatives
12:00–13:30	<b>Lunch @ Facility Hallerstrasse</b>	
<b>TBD</b>	<b>City Tour</b>	
	<b>End of Day 5 / End of Training</b>	