

Swissmedic Regulatory Training, Spring 2026 AGENDA

Module 1 Introduction (all groups)

Day 1: Monday, 8 June 2026

Room H044

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
08:45	Start Day 1	
08:45	Arrival and Registration at Facility Hallerstrasse 7	All
09:00–09:05	Welcome address	Vincenza Trivigno <i>Executive Director, Swissmedic</i>
09:05–09:15	Opening remarks	Hiiti Sillo <i>Unit Head, Regulation and Safety, WHO</i>
09:15–09:45	General information and presentation of agenda Group introduction	Lodovico Paganini <i>Deputy Head Stakeholder Engagement</i> All
09:45–10:30	Introduction Swissmedic <ul style="list-style-type: none"> Context and figures Role and Responsibility 	Jörg Schläpfer <i>Head of Sector Staff and External Relations</i>
10:30–10:45	Group photo and coffee break	
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 Innovation Management, Corporate Development</i>
12:00–13:00	Lunch @ Cafeteria Swissmedic Hallerstrasse 7	
13:00–13:45	Overview of WHO Regulatory Systems Strengthening Programme <ul style="list-style-type: none"> Capacity building activities WHO Role during the pandemic 	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	Coffee break	
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	
	End of Day 1	

Module 2 QMS

Day 2: Tuesday, 9 June 2026

Room H047

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
	Day 2	
09:30–10:30	Corporate Risk Management	TBD <i>Corporate Development</i>
10:30–11:15	Coffee break	
11:15–12:00	Regulatory Science / Regulatory Innovation	Andreas Pfenninger <i>Senior Chief of Office</i>
12:00–13:00	Lunch	
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	Coffee break	
15:00–16:30	Digitization @Swissmedic Challenges, key learnings and solution-oriented tools	Nicolás Pérez González <i>Data Scientist</i>
16:30	End of Day 2	
16:30	Social Event (on site)	

Module 2 QMS

Day 3: Wednesday, 10 June 2026

F032 @ Lab Facility

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
	Day 3, Part 1: OMCL with focus on QMS (ISO 17025)	
08:45 09:00	Meeting at Hallerstrasse 7 ➔ Transfer to Freiburgstrasse 139	Stefania Camerata <i>Assistant SHE</i>
09:00–09:15	Welcome	Shkipe Klenja <i>Quality Management specialist Lab. (OMCL)</i>
09:15–10:30	Introduction of Swissmedic Laboratory (OMCL) with focus on the QMS	Shkipe Klenja <i>Quality Management specialist Lab. (OMCL)</i>
10:30–11:00	Coffee break	
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	Lunch @ Facility Freiburgstrasse	
	Day 3, Part 2: Establishment licenses and Swiss GMP/GDP inspection system with focus on QMS (ISO 17020)	
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	Coffee break	
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>
16:00–16:30	Questions / Discussion	
16:30	End of Day 3	

Module 2: QMS

Day 4: Thursday, 11 June 2026

Lab Tour @ Lab Facility

<i>Time</i>	<i>Topic</i>	<i>Speaker / Moderator</i>
	Start Day 4	
08:45 09:00	Meeting at Hallerstrasse ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini <i>Scientific Officer Stakeholder Engagement</i>
09:00–11:00	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	Join Module 3 in F032	Lodovico Paganini <i>Scientific Officer Stakeholder Engagement</i>
12:00–13:30	Lunch @ Facility Freiburgstrasse	
	Optional program in the afternoon: <ul style="list-style-type: none"> - Participation in session on MD (Modul 4) - Preparation of country presentation - Individual study time (room F032) 	
	End of Day 4	

Module 5: End module (All groups)

Day 5, Friday, 12 June 2026

Room EU137

09:00	Start Day 5	
9:00–10:30	NRAs country presentation of Lessons Learned (10 min presentation plus 10 min discussion)	All
10:45–11:00	Coffee break	
11:00–12:00	Wrap-up and closing remarks	Swissmedic and WHO representatives
12:00–13:30	Lunch @ Facility Hallerstrasse	
	End of Day 5 / End of Training	