swissmedic

World Health Organization

Swissmedic Regulatory Training, Fall 2026
AGENDA

Module 2 QMS

Day 2: Tuesday, 3 November 2026 Room H047

Time	*Topic*	*Speaker / Moderator*
09:15	**Start Day 2** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:30–10:30	Corporate Risk Management	Renato Buchs *Business controller* *Corporate Development*
10:30–11:00	***Coffee break***	
11:00–12:00	Digitization @Swissmedic Challenges, key learnings and solution-oriented tools	Ulrich Vogler *Head of IT Division*
12:00–13:00	**Lunch @ Facility Hallerstrasse**	
13:00–14:00	Submission Formats	Urs Niggli *Head of Division* *Operational Support Services*
14:00–14:30	Questions / Discussion	All
14:30–15:00	**Coffee break**	
15:00–16:30	Optional program: - Participation in Module 3 Authorisations => H 45 - Preparation of country presentation - Individual study time (room H 48)	
16:30	**Social Event (on site)**	
18:00	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 2	

swissmedic

World Health Organization

Module 2 QMS

Day 3: Wednesday, 4 November 2026 F036 @ Lab Facility

Time	*Topic*	*Speaker / Moderator*
08:40 09:00	**Start Day 3** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse ➔ Transfer to Freiburgstrasse 139	Stefania Camerata *Assistant SHE*
09:00–09:15	Welcome	Shkipe Klenja *Quality Management specialist Lab. (OMCL)*
09:15–10:30	Introduction of Swissmedic Laboratory (OMCL) with focus on the QMS (ISO 17025)	Shkipe Klenja *Quality Management specialist Lab. (OMCL)*
10:30–11:00	**Coffee break**	
11:00–11:30	EDQM (Strasbourg) and the GEON Network (OMCL)	Shkipe Klenja *Quality Management specialist Lab. (OMCL)*
11:30–12:00	Questions / Discussion	
12:00–13:00	**Lunch @ Facility Freiburgstrasse**	
13:00–13:50	Establishment licensing system with focus on QMS (ISO 17020)	Georges Meseguer *Head of Unit Certificates and Licenses*
13:50–14:45	Swiss GMP/GDP inspection system	Georges Meseguer *Head of Unit Certificates and Licenses*
14:45–15:00	Questions / Discussion	
15:00–15:15	**Coffee break**	
15:00–15:30	Certificates (GMP/GDP and CPP)	Georges Meseguer *Head of Unit Certificates and Licenses*
15:30–16:00	International cooperation	Georges Meseguer *Head of Unit Certificates and Licenses*
16:00–16:30	Questions / Discussion	
16:30	**Departure Shuttle** from Facility Freiburgstrasse =>Hallerstrasse => Hotel Ibis Styles	
	End of Day 3	

swissmedic

World Health Organization

Module 2: QMS

Day 4: Thursday, 5 November 2026 Lab Tour @ Lab Facility/H048

Time	*Topic*	*Speaker / Moderator*
08:40 09:00	**Start Day 4** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini *Scientific Officer Stakeholder Engagement*
09:00–11:00	Laboratory tour with open Q&A	Michael Gilgen *Head of Unity Laboratory 1* Magali Gobet *Head of Unity Laboratory 2* Daniel Glauser *Head of Unity Laboratory 3*
11:00–12:00	Transfer to Hallerstrasse	Lodovico Paganini *Scientific Officer Stakeholder Engagement*
12:00–13:30	**Lunch @ Facility Hallerstrasse**	
13:30 – 14:30	Regulatory Science / Regulatory Innovation	Andreas Pfenninger *Senior Chief of Office*
14:30 –	Optional program in the afternoon: - Participation in sessions on MD (Modul 4) => H044 - Preparation of country presentation - Individual study time (room H048)	
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 4	