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

Time	*Topic*	*Speaker / Moderator*
08:45	***Start Day 1***	
08:45	Welcome and registration at Facility Hallerstrasse 7	All
09:00–09:15	Opening remarks	Hiiti Sillo *Unit Head, Regulation and Safety, WHO*
09:15–09:45	General information and presentation of agenda Context on RSS engagement Group introduction	Lodovico Paganini *Scientific Officer Stakeholder Engagement* All
09:45–10:30	Introduction Swissmedic • Context and figures • Role and Responsibility	Jörg Schläpfer *Head of Sector Staff and external Relations*
10:30–10:45	***Group photo and coffee break***	
10:45–11:15	Overview Swissmedic: National and International cooperation	Gabriela Zenhäusern *Head of Division Stakeholder Engagement*
11:15-12:00	Introduction to Swissmedic's Horizon Scanning	Daniel Hürlimann *Scientific Officer Stakeholder Engagement*
12:00–13:00	***Lunch @ Cafeteria Swissmedic Hallerstrasse 7***	
13:00–13:45	Overview of WHO Regulatory Systems Strengthening Programme • Capacity building activities • WHO Role during the pandemic	Razieh Ostad Ali *Scientist, Regulatory Systems Strengthening Team, Regulation and Safety Unit, WHO*
13:45–14:30	Good reliance practices in regulatory decision-making high-level principles and recommendations	Sunday Kisoma *Technical Officer, Facilitated Product Introduction, Regulation and Safety, WHO*
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 *Team Lead, Regulatory Systems Strengthening Team, WHO*
16:15-17.00	WHO Global Global Model Regulatory Framework for Medical Devices and GBT+	Agnes Kijo, *Technical Officer, Regulation and Safety Unit, WHO*
17:00-17:30	Q&A	
	End of Day 1	

Module 3 Authorisations

Day 2: Tuesday, 3 June 2025 — Room H046

Time	*Topic*	*Speaker / Moderator*
09:30	**Start Day 2**	
09:30–10:30	**Marketing Authorisation and Regulatory Management** • Introduction Marketing Authorisation • Processes incl. risk-based approaches and reliance • Swiss Medical Expert committee • Benchmarking	Eveline Trachsel *Head of Sector Medicinal product authorisation and vigilance* Rosa Stebler *Deputy Head of Division, Regulatory Operations and Development*
10:30–11:00	***Coffee break***	
11:00–12:00	**Marketing Authorisation and Regulatory Management** (continued) Questions / Discussion	
12:00–13:00	***Lunch***	
13:00–14:30	Introduction **Regulatory Assessment**	Chantal Walther *Head of Unit Regulatory Assessment 4*
14:30–15:00	***Coffee break***	
15:00–16:30	Introduction **Quality Assessment** MA Procedures for **Biosimilar Applications** in Switzerland	Bernhard Spörri *Head of Unit Quality Assessment Synthetics* Pascal Crottet *Quality Assessor*
16:30	**End of Day 2**	
TBD	**Social Event at external venue (10 min walking distance)**	

swissmedic

World Health Organization

Module 3 Authorisations

Day 3: Wednesday, 4 June 2025 Room H047

Time	*Topic*	*Speaker / Moderator*
09:00	**Start Day 3**	
09:00–10:30	Introduction **Non-Clinical Assessment**	Elisabeth Klenke *Head of Division Non-Clinical Assessment*
10:30–10:45	***Coffee break***	
10:45–12:30	Introduction **Clinical Assessment** (Part 1) Generics	Arno Nolting *Senior Clinical Pharmacology Assessor*
12:30–13:30	***Lunch***	
13:30–15:00	Introduction **Clinical Assessment** (Part 2) Case study: Step-by-step assessment report template	Jan Wagner *Senior Clinical Assessor* Thomas Kleppisch *Clinical Assessor*
15:00–15:30	***Coffee break***	
15:30–16:30	**Introduction to Clinical Study Assessment**	Kirsten Leidreiter *Head Clinical Study Assessment*
16:30	**End of Day 3**	

Module 3 Authorisations

Day 4: Thursday, 5 June 2025 Room H046

Time	*Topic*	*Speaker / Moderator*
09:00	**Start Day 4**	
09:00–10:00	Introduction to **Advanced Therapeutic Medicinal Products** - General information ATMPs - Requirements on documentation for MA	Julia Djonova *Head of Division Advanced Therapy Medicinal Products*
10:00–10:30	***Coffee break***	
10:30–11:30	Swissmedic collaborative **Marketing Authorisation and Scientific Advice Procedure** for Global Health products (MAGHP/SAGHP)	Lodovico Paganini *Scientific Officer Stakeholder Engagement*
11:30-12:00	Free time / Preparation Country Presentation	All
12:00–13:30	***Lunch @ Facility Hallerstrasse***	
	Optional program in the afternoon: - Participation in session on MD (Modul 4) - Preparation of country presentation - Individual study time (room H046)	
	End of Day 4	

Module 5: End module (All groups)

Day 5, Friday, 25 October 2024 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***	
TBD	**City Tour**	
	End of Day 5 / End of Training	