Swissmedic Regulatory Training, Spring 2025

02 to 06 October 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	

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Module 4 Surveillance and Vigilance

Day 2, Tuesday, 3 June 2025 Room H044

Time	*Topic*	*Speaker / Moderator*
09:30	**Start Day 2**	
09:30–10:00	Welcome and Introduction to Market surveillance	Susanne Wegenast *Head of Division Market Monitoring of Medicines*
10:00–10:30	Market control of Medicines (quality deficiencies handling) Control of Illegal Medicines on the Swiss market	Susanne Wegenast *Head of Division Market Monitoring of Medicines* Myrtha Näf *Scientific Officer Unit Control of Illegal Medicines*
10:30–11:00	***Coffee break***	
11:00–12:30	Market control continued Q&A / Discussion	Susanne Wegenast *Head of Division Market Monitoring of Medicines* Myrtha Näf *Scientific Officer Unit Control of Illegal Medicines*
12:30–13:30	***Lunch***	
13:30–14:00	Introduction Safety of Medicines / Pharmacovigilance	Christoph Küng *Head of Division Safety of Medicines*
14:00–15:00	The Swiss Reporting System	Thomas Stammschulte *Deputy Head Division Safety of Medicines*
15:00–15:30	***Coffee break***	
15:30–16:30	Swiss National Database: Medango	Irene Scholz *Senior Vigilance Assessor*
16:30	**End of Day 2**	
TBD	**Social Event at external venue (10 min walking distance)**	

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Module 4 Surveillance and Vigilance

Day 3: Wednesday, 4 June 2025 Room H044

Time	*Topic*	*Speaker / Moderator*
09:00	**Start Day 3**	
09:00–10:30	Risk Management • Signal Management • PSUR Evaluation • RMP Evaluation	Oliver Würstlin *Senior Vigilance Assessor, Unit Risk Management*
10:30–10:45	***Coffee break***	
10:45–11:30	Risk Management, cont.	Oliver Würstlin *Senior Vigilance Assessor, Unit Risk Management*
11:30–12:30	Signal detection and management in VOU	Valeriu Toma *Vigilance Assessor / Deputy Head Unit Pharmacovigilance*
12:30–13:30	***Lunch***	
13:30–14:30	Pharmacovigilance Inspections	Adisa Cokoja *Senior GCP/GVP Inspector, Unit GCP/GVP Inspectorate*
14:30–15:00	Q/A on PV and Risk Management	All
15:00–15:15	***Coffee break***	
15:15–16:30	Blood Surveillance incl. Q/A	Julia Engels *Vigilance Assessor*
16:30	**End of Day 3**	

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Module 4 Medical Devices - Surveillance and Vigilance

Day 4: Thursday, 5 June 2025 Room H044

Time	*Topic*	*Speaker / Moderator*
9:00	**Start Day 4**	
9:00–9:30	General Introduction to Market Surveillance of **Medical Devices**	Karoline Mathys *Head of Sector Medical Devices Surveillance*
9:30–10:00	International networking and collaboration	Matthias Gautschi *Scientific Officer Stakeholder Engagement*
10:00–10:30	***Coffee break***	
10:30- 11:30	Clinical Trials of MDs	Eva Brombacher *Scientific Officer MD Clinical Investigations*
11:30–12:15	MD Operations & Development	Sébastian Lerch *Head of Unit MD Operations & Development 1*
12:15–13:30	***Lunch @ Facility Hallerstrasse***	
13:30 – 14:30	MD Vigilance	Sandra Tanner *Scientific Officer MD Vigilance* Erminio Di Renzo *Scientific Officer MD Vigilance*
14:30 – 15:30	Market Surveillance of MDs	Elly Gysels *Inspector MD Surveillance*
15:30 – 16:30	Hospital Inspections	Rafael Moreno *Senior Inspector MD Hospitals*
	End of Day 4	

Module 5: End module (All groups)

Day 5, Friday, 6 June 2025 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	