Swissmedic Regulatory Training, Spring 2025

2 to 6 June 2025, Swissmedic, Berne, Switzerland

BACKGROUND

The World Health Organization (WHO) plays a pivotal role in supporting countries in strengthening their regulatory systems and promoting equitable access to high quality, safe, efficacious and affordable medical products and health technologies. The WHO Constitution affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. Towards the achievement of such an ambitious objective, the WHO Constitution states the functions of WHO, which include among others, assisting Governments, upon request, in strengthening health services.[1] Various World Health Assembly (WHA) Resolutions encompass aspects of the need to promote the aforementioned WHO role.[2] It should be noted that regulators are an essential part of the health workforce and effective regulatory systems are an essential component of health systems and contribute to better public health outcomes. In contrast, inefficient regulatory systems themselves can be a barrier to access safe, effective and quality medical products.[3]

In the light of these WHO mandates, the Regulatory Systems Strengthening (RSS) programme within the Regulation and Prequalification (RPQ) Department is based on a five-step capacity building strategy. Starting with the development of tools used for the assessment of the regulatory system in Member States, followed by the actual benchmarking (assessment) of the National Regulatory Authority (NRA) to identify strengths as well as areas for improvement and finishing by the development of an Institutional Development Plan (IDP) to build on strengths and address areas for improvement. Subsequently, WHO provides technical support in the implementation of the IDP along with continued monitoring of progress and outcome. The WHO RSS programme covers all medical products and health technologies including medicines, vaccines, medical devices and diagnostics. In 2014, a WHA Resolution (WHA67.20) on regulatory system strengthening emphasized the WHO's mandate and requested both WHO and Member States to invest more in this area and to address all health products and technologies.

In the context of WHO`s support to Member States in strengthening their regulatory systems, training courses and placements between NRAs are encouraged in order to share good practices and experience. A training course is a learning opportunity both for the experts from the visiting NRA and the host NRA. All participants are therefore, encouraged to present and share the experiences of their country, disseminate to their peers the knowledge and information acquired during the visits and placements and establish professional contacts that would facilitate follow-up activities and the exchange of information. It is encouraged to allocate time for discussions and exchange of information as well as informal talks and exchange of views.

SWISSMEDIC ENGAGEMENT IN REGULATORY SYSTEMS STRENGTHENING ACTIVITIES

In 2013, the Federal Council issued a revised mandate to the Swissmedic to conduct projects in the area of development cooperation, in conjunction with the Swiss Agency for Development Cooperation (SDC) and/or non-profit organizations.
In view of the above, the Gates Foundation, the Federal Department of Home Affairs (FDHA) and the Federal Department of Foreign Affairs (FDFA) agreed in January 2014 on a Memorandum of Understanding (MoU) to improve and accelerate access to health interventions and therapeutic products in resource-constrained countries by strengthening regulatory systems. This is to be achieved by leveraging and coordinating resources through cooperation between the three parties of the MoU and the WHO. Various projects have been implemented under this cooperation since 2016. The regulatory training courses complement the range of projects and the first one was conducted successfully in November 2018 as a pilot project in close cooperation between WHO and Swissmedic. This document serves as the Terms of Reference (ToR) for the 14th training week planned to take place from 2 to 6 June 2025.

[1] World Health Organization Constitution, Chapter II – Functions, Article 2 (c).
[2] World Health Assembly (WHA) Resolutions WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, WHA65.19 and WHA67.20.
[3] World Health Assembly (WHA) Resolution WHA67.20.

AIM AND OBJECTIVES OF THE REGULATORY TRAINING

The Pandemic Influenza Preparedness (PIP) Framework is a WHA Resolution 64.8 for the sharing of influenza viruses through a network of public health laboratories and promoting access to vaccines and other benefits (the PIP Framework) to improve global pandemic influenza preparedness and response. The Framework established a PIP benefit sharing system that includes annual Partnership Contributions (PC) to WHO from manufacturers of influenza medical products. In 2012, the PIP Advisory Group (AG) recommended the WHO Director General to invest PIP PC on regulatory capacity building in priority countries to address gaps in regulatory systems as well as marketing authorization and pharmacovigilance functions. The PIP PC funding would therefore support capacity building in the target NRAs. This would enable the NRAs to undertake their major responsibility of safeguarding public health in an expedient manner under both normal and public health emergency situations by ensuring quality, safety and efficacy of medical products available on the national market.

In this context, the training offer at Swissmedic aims to contribute to the regulatory capacity building according to the goals of the PIP. The main objective of this regulatory training course at Swissmedic is to strengthen the capacity of the participating NRAs through experience and knowledge exchange in applying up-to-date methods and procedures for the day-to-day processes in Quality Management System (QMS), Registration and Marketing Authorization (MA) and Vigilance (PVL) in accordance with the WHO and other international standards and good practices.

For this purpose, the participants will engage in a peer learning experience and will be able to use the practical application of methods and procedures for the above mentioned regulatory functions. More specifically the regulatory training course will lead to an increased capacity to interpret and apply the WHO and other international standards in their day-to-day activities in developing and implementing the good practices for the quality management system, marketing authorization and vigilance functions in their own NRAs.
Swissmedic has agreed to host this regulatory training course within its development co-operation framework and cooperation with WHO to improve and accelerate access to health interventions and therapeutic products in resource-constrained countries by strengthening regulatory systems.

The specific objectives of the regulatory training course are:

Quality management system

1. Improve the regulators knowledge, skills and competences on a quality management system (QMS) for Inspectorates and Laboratory.
2. Understand the minimum requirements for establishing, implementing and maintaining the QMS in the NRAs.
3. Be able to transfer knowledge to other staff, upon return.

Authorisations

1. Improve the assessors' knowledge, skills and competences regarding assessment of the CTD Modules 3, 4 and 5.
2. Acquire a better understanding of the assessment of the scientific content of the dossiers to facilitate overall assessment process.
3. Acquire knowledge on process engineering (i.e. designing processes end-to-end) and case management as applied by Swissmedic to ensure the quality of the assessment outcomes: consistency, reliability and transparency.
4. Improve management and review of variations by applying international best practices, including timelines and resources.
5. Enhance the abilities to decide on the depth of assessment when there is prior assessment and approval done by an WHO Listed Authority (WLA) or WHO Prequalification Procedure (PQP).
6. Understand the importance of the risk based approach to assessment and quality risk management (QRM) principles in reviewing of new applications and variations by developing practical skills.
7. Identify potential problematic areas through practical questions, issues and real-life case studies; and
8. Be able to transfer knowledge to other staff, upon return.

Surveillance and Vigilance

1. Acquire knowledge, skills and competences on ADRs, AEFIs and safety reports from clinical trials (SUSARs and Safety data analysis) to achieve fully efficient pharmacovigilance system.
2. Improve the understanding of the organization of pharmacovigilance activities in an efficient manner considering limited human and financial resources.
3. Improve the skills to assess PSURs and RMPs along with implementation of subsequent additional risk minimization measures, including risk-based approach in vigilance activities.
4. Become familiar with different reporting methods.
5. Acquire knowledge on surveillance of medical devices
6. Develop new contacts and explore opportunities of cooperation.
7. Be able to transfer knowledge to other staff, upon return.

DELIVERABLES

1. Identified areas of improvement for each function by participating NRAs.
2. Acquired new skills and best practices for QMS, marketing authorization and pharmacovigilance.
3. Participating NRAs to draft a roadmap to implement lessons from the regulatory training course.

METHODOLOGY

The Training is devised as a five-day workshop in the format of hands-on training and Q&A to get a better understanding and acquire new skills for developing and implementing the standard practices to the country specifics of the participants. The discussions will enable the different expert teams to better understand and see on-site the current capacities, strengths and challenges of both Swissmedic and visiting NRAs.

The programme will include certain defined modules as standard and yield efficiency gains by repeating content. All participants will attend the introductory and final modules (modules 1 and 5, respectively). Between these two fixed points, three different modules addressing operational areas of Swissmedic's work will take place simultaneously.

- Module 1 "Introduction" (introduction to Swissmedic, WHO and their roles and responsibilities)
- Module 2 "Quality Management Systems" (document management system, QMS within licensing system, GMP/GCP inspections and laboratory)
- Module 3 "Authorisations" (reviewing applications, authorisation processes, regulatory assessment, non-clinical assessment, clinical assessment, quality assessment, ATMPs, clinical trial assessment)
- Module 4 "Surveillance and Vigilance" (pharmacovigilance, market monitoring/illegal activities, surveillance and vigilance of medical devices, hospital inspections)
- Module 5 "End Module" (Lessons learned and closing remarks)

Requirements for participants

Good command of English, as the presentations and training sessions will be held in English.
Training is intended for subject experts who already have several years' experience (at least 5 – 7 years) in their particular field of work. Invited NRAs are requested to nominate 4 experts, one each with the required expertise in the field of QMS (1), registration and marketing authorisation (1), surveillance and vigilance of medicines (1) and surveillance and vigilance of medical devices (1). The aim is to give them a general overview of Swissmedic's tasks and activities and to demonstrate and explain the actual procedure and underlying processes using, where possible, examples or case studies.

The number of participants is limited to a maximum of four (4) per NRA to ensure that each NRA can send one expert for each regulatory function. For the upcoming course, authorities from **The Gambia, India, Kazakhstan, Mexico, Morocco, Tunisia, and Ukraine** will be invited by the WHO.

Attendance is free of charge. WHO will cover the costs of travel and accommodation. Swissmedic will organize group lunches at their premises, arrange for a transfer service from/to the Hotel and provide information on public transport in Switzerland.

Before the training begins, or at the latest on the first training day, Swissmedic will require participants to sign a confidentiality agreement. Training documents will be made available to participants in advance of the training through a dedicated SharePoint platform.

DATES OF NEXT REGULATORY TRAINING

The next Regulatory Training at Swissmedic will take place from **20 to 24 October 2025.**

VENUE & CONTACT:

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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 2 QMS

Day 2: Tuesday, 3 June 2025 Room H048

Time	*Topic*	*Speaker / Moderator*
	Day 2	
09:30–10:30	Corporate Risk Management	Vikran Sellappah *Junior Business Controller*
10:30–11:00	***Coffee break***	
11:00–11:45	Swissmedic approach to QMS – benefits and challenges	Urs Niggli *Head of Division* *Operational Support Services*
11:45–12:00	Exchange on national approaches to QMS	All
12:00–13:00	***Lunch***	
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	Digitization @ Swissmedic Challenges, key learnings and solution-oriented tools	Michael Renaudin *Division Swissmedic 4.0*
16:30	**End of Day 2**	
17:00	**Social Event at external venue (10 min walking distance)**	

Module 2 QMS

Day 3: Wednesday, 4 June 2025 F032 @ Lab Facility

Time	*Topic*	*Speaker / Moderator*
09:00	**Day 3, Part 1: OMCL with focus on QMS (ISO 17025)**	
09:00 09:00–09:15	Meeting at Hallerstrasse 7 ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini *Scientific Officer Stakeholder Engagement*
09:15–09:30	Welcome	Shkipe Klenja *Quality Management specialist Lab. (OMCL)*
09:30–10:30	Introduction of Swissmedic Laboratory (OMCL) with focus on the QMS	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***	
	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 *Head of Unit Certificates and Licenses*
13:50–14:45	Swiss GMP/GDP inspection system	Christian Schärer *Head of Unit Inspection Management and Blood Safety*
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	Christian Schärer *Head of Unit Inspection Management and Blood Safety*
16:00–16:15	Questions / Discussion	
16:15	**End of Day 3**	

Module 2: QMS

Day 4: Thursday, 5 June 2025 Lab Tour @ Lab Facility

Time	*Topic*	*Speaker / Moderator*
	Start Day 4	
09:00 09:00–09:15	Meeting at Hallerstrasse ➔ Transfer to Freiburgstrasse 139	Lodovico Paganini *Scientific Officer Stakeholder Engagement*
09:15–10:45	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 Erlachstrasse	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	

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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) Q&A / 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**	
17:00	**Social Event at external venue (10 min walking distance)**	

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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	

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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**	
17:00	**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**	

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*
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	