Swissmedic Regulatory Training, Fall 2026

2 to 6 November 2026, 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 existing range of projects, with the first successfully conducted as a pilot in November 2018 through close collaboration between WHO and Swissmedic.

This document serves as the Terms of Reference (ToR) for the 17th training week planned to take place from 2 to 6 November 2026.

[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), as well as and surveillance and vigilance of medical devices 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 Armenia, Cambodia, El Salvador, Guyana, Malawi, Sri Lanka and Türkiye 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 in **spring 2027.**

VENUE & CONTACT:

Venue:
Swissmedic, Swiss Agency for Therapeutic Products
Hallerstrasse 7
3012 Berne
Switzerland

Points of contact:

Training content and programme
Lodovico Paganini
Deputy Head of Division / Scientific Officer
Division Stakeholder Engagement
Phone +41 58 414 06 49
Mobile +41 79 309 77 47
networking@swissmedic.ch

Support and logistics on site
Stefania Camerata
Assistant
Stakeholder Engagement
Phone +41 58 414 06 21
Mobile +41 79 269 54 77
networking@swissmedic.ch

Registration, Travel and Accommodation
Laura Di Trapani
Technical Officer
World Health Organization
Regulation & Prequalification Department (RPQ)
DITRAPANIL@who.int

AGENDA

Module 1 Introduction (all groups)

Day 1: Monday, 2 November 2026 Room H044

Time	*Topic*	*Speaker / Moderator*
08:15	**Start Day 1** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	
09:00–09:15	Welcome address	Jörg Schläpfer *Member of the Management Board*
09:15–09:30	Opening remarks	Hiiti Sillo *Unit Head, Regulation and Safety, WHO*
09:30–09:45	General information and presentation of agenda Group introduction	Lodovico Paganini *Deputy Head Stakeholder Engagement* All
09:45–10:30	Introduction Swissmedic • Context and figures • Role and Responsibility	Lodovico Paganini *Deputy Head Stakeholder Engagement*
10:30–11:00	**Group photo and coffee break**	
11:00–12:00	Overview Swissmedic: National and International cooperation	Lodovico Paganini *Deputy Head 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	Djamila Reis *Technical Officer, RSS 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	Djamila Reis *Technical Officer, RSS Team, Regulation and Safety Unit, 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	
17:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 1	

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	

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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	

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	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	

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Module 3 Authorisations

Day 2: Tuesday, 3 November 2026 Room H044

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	**Marketing Authorisation and Regulatory Management** • Introduction Marketing Authorisation • Processes incl. risk-based approaches and reliance • Swiss Medical Expert committee • Benchmarking	Rosa Stebler *Deputy Head of Division, Regulatory Operations and Development* Gierin Thomi *Responsible for Expert Affairs*
10:30–11:00	**Coffee break**	
11:00–12:00	**Marketing Authorisation and Regulatory Management** (continued) Q&A / Discussion	
12:00–13:00	**Lunch @ Facility Hallerstrasse**	
13:00–14:30	Introduction **Regulatory Assessment**	Sandra Zaugg *Head of Division Regulatory Assessment*
14:30–15:00	**Coffee break**	
15:00–16:00	**Introduction to Clinical Study Assessment**	Kirsten Leidreiter *Head Clinical Study Assessment*
16:30	**Social Event (on site)**	
18:00	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 2	

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Module 3 Authorisations

Day 3: Wednesday, 4 November 2026 Room H047

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 3** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
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* Andrea Villiger *Clinical Pharmacology Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–15:00	Introduction **Clinical Assessment** (Part 2) Case study: Step-by-step assessment report template	Jan Wagner *Senior Clinical Assessor* Alain Bizzini *Clinical Assessor*
15:00–15:15	**Coffee break**	
15:15–16:30	Introduction **Quality Assessment** MA Procedures for **Biosimilar Applications** in Switzerland	Lisa Eisenbeiss *Senior Quality Assessor* Pascal Crottet *Quality Assessor*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 3	

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Module 3 Authorisations

Day 4: Thursday, 5 November 2026 Room H045

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 4** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:00–10:00	Introduction to **Advanced Therapeutic Medicinal Products** - General information ATMPs - Requirements on documentation for MA	Andreas Marti *Senior Nonclinical Assessor*
10:00–10:30	**Coffee break**	
10:30–12:00	Swissmedic collaborative **Marketing Authorisation and Scientific Advice Procedure** for Global Health products (MAGHP/SAGHP)	Lodovico Paganini *Deputy Head Stakeholder Engagement*
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 F036)	
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 4	

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Module 4 Surveillance and Vigilance

Day 2, Tuesday, 3 November 2026 Room H046

Time	*Topic*	*Speaker / Moderator*
09:15	**Start Day 2** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:30–09:45	Welcome and Introduction to Market surveillance	Christoph Küng *Head of Division Safety of Medicines*
09:45–10:15	Introduction Safety of Medicines / Pharmacovigilance	Christoph Küng *Head of Division Safety of Medicines*
10:15–10:30	**Coffee break**	
10:30–11:30	The Swiss Reporting System	Thomas Stammschulte *Deputy Head Division Safety of Medicines*
11:30–12:30	Swiss National Database: Medango	Irene Scholz *Senior Vigilance Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–15:00	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*
15:00–15:30	**Coffee break**	
15:30–16:30	Market control continued Q&A / Discussion	Susanne Wegenast *Head of Division Market Monitoring of Medicines* Myrtha Näf *Scientific Officer Unit Control of Illegal Medicines*
16:30	**Social Event (on site)**	
18:00	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 2	

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Module 4 Surveillance and Vigilance

Day 3: Wednesday, 4 November 2026 Room H046

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 3** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:00–10:30	Risk Management • RMP Evaluation • PSUR Evaluation	Stephanie Storre *Head of Unit Risk Management* Nora Ruef *Senior Vigilance Assessor, Risk Management*
10:30–10:45	**Coffee break**	
10:45–11:30	Signal management	Giulia Paternoster *Vigilance Assessor, Risk Management*
11:30–12:30	Blood Surveillance incl. Q/A	Julia Engels *Vigilance Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–14:30	Pharmacovigilance Inspections	Adisa Cokoja *Senior inspector GCP/GVP Inspectorate, Division Clinical Trials*
14:30–15:00	Q/A on PV and Risk Management	All
15:00–15:15	**Coffee break**	
15:15–16:30	Signal detection and management in pharmacovigilance	Valeriu Toma *Vigilance Assessor / Deputy Head Unit Pharmacovigilance*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 3	

Module 4 Medical Devices - Surveillance and Vigilance

Day 4: Thursday, 5 November 2026 Room H044

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 4** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
9:00–9:30	General Introduction to Market Surveillance of **Medical Devices**	Markus Wälti *Head of Division Medical Devices Vigilance*
9:30–10:00	International networking and collaboration	Markus Wälti *Head of Division Medical Devices Vigilance*
10:00–10:30	**Coffee break**	
10:30- 11:30	Clinical Trials of MDs	Yvonne Naegelin *Head 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*
14:30 – 15:30	Market Surveillance of MDs	Elly Gysels *Inspector MD Surveillance*
15:30 – 16:30	Hospital Inspections	Yannick Bohren *Inspector MD Hospitals*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 4	

Module 5: End module (All groups)

Day 5, Friday, 6 November 2026 Room H 44

08:40	**Start Day 5** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Lodovico Paganini *Deputy Head Stakeholder Engagement*
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	