

Information sheet

Swissmedic Training Concept in Support of Capacity Building for National Regulatory Authorities in LMICs

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1 Abbreviations

GBT	WHO Global Benchmarking Tool
GMP	Good manufacturing practices
LMIC	Low- and middle-income countries
NRA	National Regulatory Authority
REC	Regional Economic Communities
SDC	Swiss Development Cooperation Agency
SRA	Stringent Regulatory Authorities
TC	Technical Committee
WHA	World Health Assembly
WHO	World Health Organisation
WLA	WHO Listed Authorities

2 Introduction

Swissmedic's training offer, in close collaboration with the World Health Organization (WHO), focuses on building the capacity of national regulatory authorities (NRAs), as well as regional regulatory initiatives particularly in low- and middle-income countries (LMICs). Through tailored workshops, practical training sessions, and collaborative initiatives, Swissmedic addresses key regulatory challenges throughout the life cycle of medicinal products. These efforts support sustainable improvements in regulatory practices, aligning with international standards and fostering global public health.

3 Background and rationale

Regulators are a crucial component of the health workforce. Effective regulatory systems are key to strengthening health systems and improving public health outcomes. On the other hand, inefficient regulatory systems can pose significant barriers to accessing safe, effective, and high-quality medical products. Limited resources and capacity within both the manufacturers and the NRAs greatly contribute to prolonged timelines in the approval of essential medicines. Particularly in African nations, which often bear the greatest burden of disease, NRAs are typically the most resource-limited (Deloitte, 2023). In addition, a lack of an efficient reliance mechanism also significantly hampers the regulatory approval process in many regions. NRAs often conduct redundant assessments of quality, safety, and efficacy for medical products, despite these evaluations having already been performed by SRAs/WLAs¹ or through the WHO pathways (McAuslane, et al., 2023).

WHO plays a central role in assisting countries to enhance their regulatory frameworks and promote equitable access to safe, effective, high-quality and affordable therapeutic products. In 2014, World Health Assembly's (WHA) Resolution *WHA67.20* on regulatory system strengthening highlighted WHO's mandate in this area, urging both WHO and Member States to dedicate more resources to strengthening regulatory systems and to address all health products and technologies (World Health Assembly, 2014). As part of its support to Member States in bolstering their regulatory systems, WHO encourages training courses and exchanges between NRAs. These initiatives provide valuable learning opportunities for both the visiting and host NRAs, facilitating the exchange of best practices and experiences.

It is in this spirit that Swissmedic has developed its contribution to strengthening regulatory systems through activities supporting existing regional harmonisation initiatives, improving access to medicines

¹ See definition: [WHO-Listed Authority \(WLA\)](#)

and, indeed, fostering capacity building and exchange amongst regulators. In the latter field, Swissmedic runs a training offer for other regulators that is constantly evolving and expanding.

4 Aim of training programmes

Swissmedic's training program aims to address the above-mentioned capacity gaps and thus to strengthen the capacity of NRAs in LMICs by offering hands-on trainings and workshops, in alignment with WHO's role and mandate. Regional regulatory systems/initiatives and their respective harmonisation schemes and joint assessment mechanisms, which play an increasingly important role especially in the African context, are also in the focus of capacity-strengthening efforts.

The current training offer addresses regulatory gaps especially in marketing authorisation processes, licensing, market control, pharmacovigilance, quality management, and good manufacturing practices (GMP). It has been demonstrated that training opportunities for health product regulators promote peer learning, international collaboration, and practical application of regulatory skills (Dehaghi, Broojerdi, Paganini, & Sillo, 2023). With the support of the WHO, participating NRAs, RECs and continental Technical Committees (TCs) are encouraged to develop action plans for implementing collected knowledge and learned strategies, ensuring long-term impact.

Swissmedic's training programmes align with the WHO Global Benchmarking Tool² (GBT) by addressing critical gaps in the maturity of regulatory systems in LMICs. Through practical capacity-building efforts, structured on various levels of competence and fields of expertise, Swissmedic supports countries in achieving higher GBT maturity levels, promoting safe and effective regulation of medicinal products. This collaboration reinforces WHO's vision of strengthening NRAs and regional regulatory systems for sustainable public health improvements globally.

5 Resources and partners

Under the 2014 Memorandum of Understanding between the Gates Foundation, the Federal Department of Home Affairs (represented by Swissmedic) and the Federal Department of Foreign Affairs (represented by the Swiss Agency for Development and Cooperation, SDC), Swissmedic is committed to strengthening regulatory systems in LMICs with the aim of supplying people with high-quality, life-saving medicinal products as quickly as possible. Work in this area focuses on dialogue, exchange, and training courses for regulatory authorities from these countries.

Within this context, Swissmedic conducts trainings by leveraging and coordinating resources through cooperation with the other parties to the MoU and the WHO, provided that the funding of the activities

² [Global Benchmarking Tools](#)

(at full cost) is guaranteed through third-party resources. In addition, the independence and functioning of Swissmedic must not be put at risk by these activities.

The main financial contribution towards the implementation of the training opportunities is covered through 3-year recurring grant agreements with the Gates Foundation as well as through the core voluntary contributions operated by SDC to WHO. The technical, functional, and logistical aspects are devised and implemented in close cooperation between Swissmedic and WHO.

The commitment of Swissmedic to strengthen regulatory systems in LMICs has been consolidated in recent years and is carried on as part of operational activities. The support is aligned with the Swiss Health Foreign Policy and contributes to the implementation of the priority action area “Access to medicine”. With its engagement Swissmedic is also actively addressing one of Switzerland’s health foreign policy goals.

6 Implemented Training Programmes

6.1 General

6.2 Basic Regulatory Training

In partnership with the WHO, Swissmedic devised a comprehensive regulatory training course for regulatory authorities. Such courses are part of the WHO’s programme to improve its member states’ regulatory systems. The regulatory training is structured as a “peer learning” event, i.e., learning goals are achieved primarily through interaction with other specialists and colleagues. In this four-day workshop, participants gain a better understanding and acquire new skills for developing and implementing their knowledge of regulatory processes and approaches. The presentations and discussions enable the participants to better understand the processes, approaches, and strengths of both Swissmedic and visiting NRAs as well as the challenges facing them.

In addition to a general section, the workshop is conducted in three parallel modules:

- Marketing authorisation
- Market surveillance / pharmacovigilance / materiovigilance
- Quality management system / Quality Control Laboratories / GMP licenses and inspections

Swissmedic holds this regulatory training in partnership with the WHO twice a year. Seven authorities are invited to nominate up to four experts to each course. The selection process is conducted by WHO in consultation with Swissmedic and is based on the NRAs voluntary participation to and corresponding progress within the framework of the GBT. The selected NRA are invited by the WHO to nominate suitable experts.

To ensure the long-term sustainability of the project, the foreign authorities are required to submit an action plan to the WHO, setting out how they intend to implement the knowledge acquired by participants.

6.3 Advanced Training

In addition to the general training outlined above, Swissmedic intends to conduct trainings on specific topics. This type of advanced training is targeted to senior assessors/regulators, who ideally already participated in the Regulatory Training and perform a function at supranational level, such as in regional or continental regulatory systems. The topic shall be determined on a case-by-case basis in consultation with the relevant partners and WHO, based on concrete needs as outlined in the work plans of the concerned partner organisations.

An example of such a course, which has already been run in collaboration with the WHO, is a training session on the assessment of inhalation products. The main target group of this type of specialized training course were members of the regional Expert working group on medical products evaluation and NRAs senior assessors with senior experience in dossier evaluation and registration. Based on the experience gained and the feedback gathered during the execution of this in-depth training, Swissmedic plans to organize a face-to-face advanced training workshop with a specific focus on a particular type of assessment or in-depth regulatory aspect every two years.

6.4 GMP Training

Swissmedic organises a regular GMP Training workshop for GMP inspectors from foreign authorities once a year. The training has a specific thematic focus each year, which is determined within the division Inspectorates and Licences at Swissmedic, responsible for the organization of the training. In the context of its collaboration with the WHO and the SDC, Swissmedic supports inspectors from African RECs and the continental GMP TC in attending this training workshop.

6.5 Guided inspections

At the WHO's request and based on needs on the ground and the available capacities, Swissmedic offers the opportunity for inspectors from foreign authorities in LMICs to shadow a team of Swissmedic inspectors during a GMP inspection. Swissmedic organises a simultaneous interpreting service and ensures that all aspects of security and confidentiality are complied with.

Targeted audience for this activity are inspectors who are members of the respective regional GMP Working Groups and/or of the continental GMP TC.

This activity requires great financial, coordination and logistical resources and is therefore conducted on an ad-hoc basis, depending on need and opportunity.

6.6 Ad-hoc training opportunities

Swissmedic remains committed to supporting capacity building by sharing its expertise and best practices through tailored training initiatives. In addition to structured training programs, Swissmedic is open to evaluating ad-hoc training requests in collaboration with WHO to support NRAs in strengthening their regulatory capacities.

As part of this commitment, Swissmedic is planning a dedicated webinar on the application of reliance in quality assessment and Post-Approval Changes (PACs) protocols. The webinar is aimed at providing a platform for regulatory professionals to learn from Swissmedic's experiences in implementing reliance mechanisms within its regulatory framework, specifically within the context of quality assessment and post-approval changes. The session will delve into Swissmedic's PACs Protocols, which act as a regulatory tool to expedite the handling of PACs. Participants will also gain insights into how reliance can enhance regulatory efficiency. This event is designed as an advanced training session, building upon previously discussed concepts in the [Swissmedic Regulatory Training](#) program.

Moving forward, Swissmedic will continue to explore opportunities for similar knowledge-sharing initiatives, reinforcing its role as a key partner in global regulatory strengthening efforts.

7 Conclusions

Swissmedic has been actively engaged in supporting NRAs through structured training programs and knowledge-sharing initiatives since 2018. As a recognised WLA, Swissmedic is dedicated to strengthening regulatory systems, particularly in LMICs, through close collaboration with WHO and key partners on site. By working alongside regional regulatory authorities and harmonisation initiative, Swissmedic ensures that its capacity-building initiatives are tailored to local needs, supporting sustainable improvements in regulatory practices and facilitating access to high-quality medicinal products. Its extensive experience, advanced regulatory performance, and international recognition make it a key contributor to global capacity-building efforts.

Through ongoing partnerships and tailored training opportunities, Swissmedic is committed to play a key role in advancing global regulatory capacity and convergence, strengthening NRAs, and contributing to a more efficient and collaborative international regulatory landscape.

8 Other related documents

Memorandum of Understanding

[MoU between The Bill & Melinda Gates Foundation, The Federal Department of Home Affairs and The Federal Department of Foreign Affairs of the Swiss Confederation](#)

Study on the impact of Swissmedic regulatory training:

[Frontiers | Collaborative training of regulators as an approach for strengthening regulatory systems in LMICs: experiences of the WHO and Swissmedic \(frontiersin.org\)](#)

9 References

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