



# EMPOWER

## SCHOOL OF HEALTH

Geneva | New Delhi | Nairobi | Addis Ababa | Dakar | Bangkok | New York

# STRENGTHENING HUMAN RESOURCES CAPACITY OF NATIONAL MEDICINES REGULATORY AUTHORITIES

by establishing State-of-the-Art Learning Systems,  
Digital Centres of Excellence and Training Academies



### Key Partners:



Ethiopian Pharmaceutical Association



# ENHANCING REGULATORY WORKFORCE TALENT — A SUSTAINABLE APPROACH TO ML3 AND WLA STATUS

National Medicines Regulatory Authorities (NMRAs) play a pivotal role in ensuring access to safe and effective medical products, including medicines, medical devices, and diagnostics.

A competent workforce is one of the foundational components for the NMRAs to operate effectively. Therefore, systematic and continuous regulatory workforce development is critical to address the gaps in regulatory capacity for medical products. The [WHO Global Competency Framework](#) for regulators of medicines offers a roadmap for harmonizing workforce development efforts by establishing an internationally accepted set of best practice competencies.

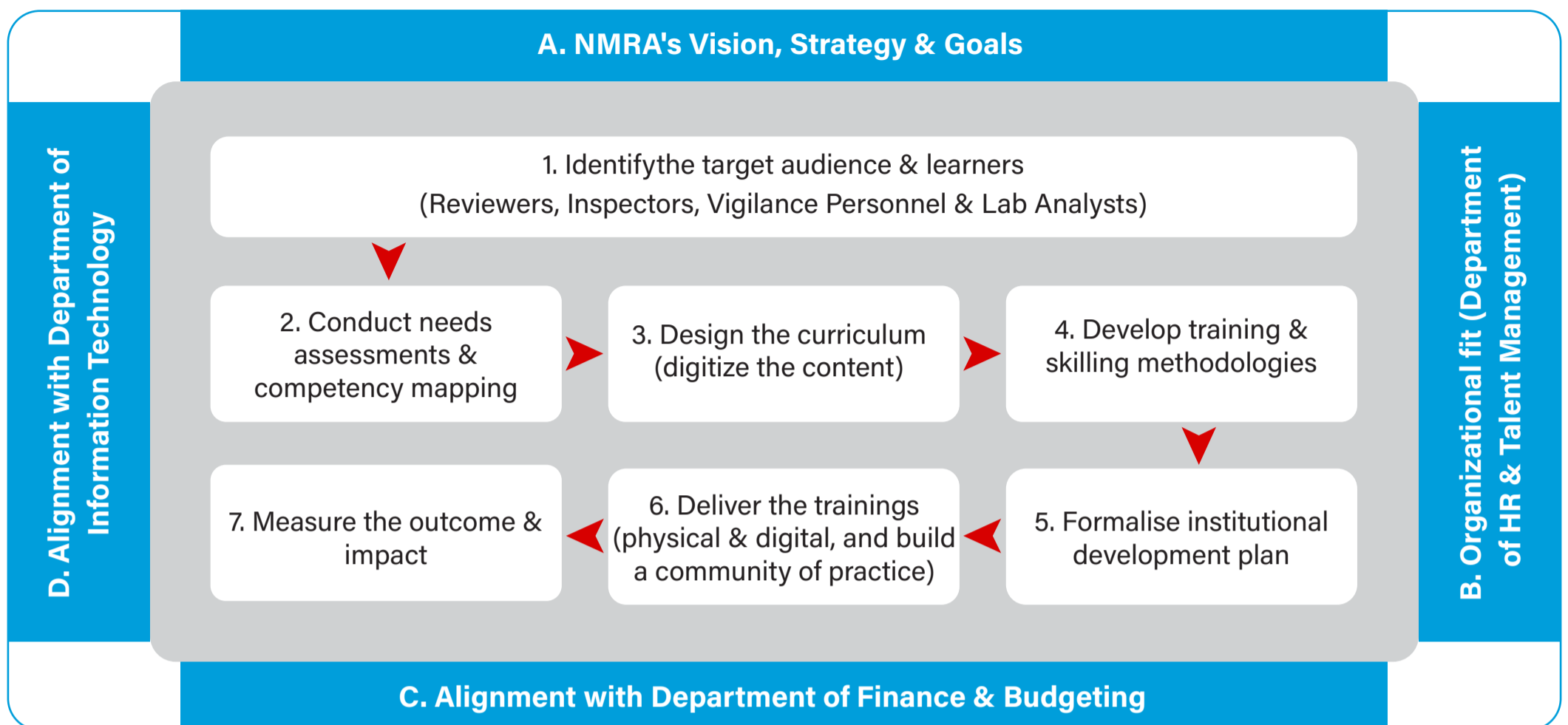
Working with an [array of partners](#) and leveraging state-of-the-art digital learning technologies, Empower School of Health offers a wide range of solutions to effectively implement the Framework. By applying evidence-based learning approaches and continuously integrating the latest open-source digital tools and AI systems, Empower works with Ministries of Health to build comprehensive, cost-effective and impactful training solutions. Specifically:

- We develop [digital competency assessments](#) and mapping that not only serve as a baseline but also provide ongoing insight as the training progresses
- We design [digital learning management systems](#) for Ministries of Health, and build centres for digital learning to deliver and measure the impact of training
- We develop and [curate tailored courses](#) (in 16+ languages) and build and [manage communities-of-practice](#) to sustain continuous professional development
- We offer consultancy services to support [setting up regulatory training academies](#) that can operate sustainably under the purview of the Department of Human Resources and Talent Management





# FRAMEWORK FOR ESTABLISHING A CENTRE OF EXCELLENCE FOR NMRA WORKFORCE STRENGTHENING



The framework for establishing a Centre of Excellence (COE) for NMRA workforce strengthening has 4 foundational elements and 7 key steps.

## The four Foundational Elements include:

1. *NMRA's vision, strategy, and goals:* Understanding the country's vision, goals and timeline.
2. *Organizational fit:* Support in setting up divisions for capacity building (& capable teams) under NMRAs for sustainability measures.
3. *Alignment with the Department of Finance and Budgeting:* Activities will require human, financial and technology-related resources to achieve their goals.
4. *Alignment with the Department of Information Technology:* Training & skilling deployment through digital technologies, while pre-assessing the desired hardware, software & connectivity.

## The seven steps to establishing a Centre of Excellence for workforce strengthening:

1. *Identify the target audience:* Segmentation of four main NMRA cadres, in terms of tenure, seniority, learning styles, etc. will be assessed.
2. *Conduct needs assessment and workforce competency assessment:* Developing a Competency Assessment Tool for NMRA based on WHO Global Competency Framework (covering core competencies, meta competencies and core activities).
3. *Design the curriculum (and digitize the content):* Develop a standardized curriculum that covers essential regulatory topics while collaborating and leveraging existing content with international partners (AMRH, WHO, USP, etc). *\*more details on next page*
4. *Design and develop training and skilling methodologies, including a digital learning platform (if required):* Empower works with an open-source digital learning platform which is user-friendly, multi-linguistic, highly accessible & designed to support on-the-job upskilling. Training programmes will include hands-on secondments at a more mature NRA. *\*\*more details on next page*
5. *Formalize the institutional development plan:* To prioritize areas of improvement, based on an assessment carried out through use of WHO's Global Benchmarking Tool.
6. *Deliver the trainings (physical and digital) and build a community-of-practice:* Roll out the digital learning academy to all NMRA staff, ensuring adequate support and resources are available for successful adoption.
7. *Measure the outcome and impact:* Continuously monitor usage, engagement, and performance to assess the impact and identify areas for improvement.

**The first phase of the NMRA Academy can be launched within 6 months of project kick-off and become fully operational within 3 years**

# OUTLINE OF TOPICS FOR NATIONAL MEDICINES REGULATORY AUTHORITY PROFESSIONALS:

## 1. Regulatory Science and Practice

- Regulatory framework and compliance
- Good Regulatory Practices (GRP)
- Clinical trial oversight

## 2. Pharmaceutical Quality Assurance

- Good Manufacturing Practices (GMP)
- Quality control and quality assurance
- Good Laboratory Practices (GLP)

## 3. Pharmacovigilance and Drug Safety

- Adverse drug reaction reporting
- Risk management and communication
- Post-market surveillance

## 4. Inspection and Enforcement

- Regulatory inspections
- Enforcement actions and compliance management
- Counterfeit medicines detection

## 5. Health Technology Assessment

- Evaluation of medical devices
- Cost-effectiveness analysis
- Health economics

## 6. Digital Tools and Innovations in Regulation

- Use of digital tools in regulatory processes
- Data management and cybersecurity
- E-submissions and electronic health records

## 7. Leadership and Management

- Diagnosis of leadership styles of leaders, managers and team members
- Performance and team management
- Decision-making and risk mitigation

## 8. Cross-Cutting and Meta-Competency Training

- Collaboration and coordination
- Communication, effective board management, and partner engagement
- Computer skills, including project management tools

# SOME COMMON STYLES OF TRAINING DELIVERY THAT EMPOWER USES:

## 1. Classroom-Based Training:

Traditional instructor-led training conducted in a physical classroom setting. It's ideal for foundational knowledge and skills that benefit from hands-on demonstrations and group activities.

## 2. On-the-Job Training (OJT) and Peer-to-Peer Learning:

Practical training conducted in the actual work environment. Trainees learn by doing, under the supervision of experienced colleagues.

## 3. Mentoring and Coaching:

Personalized training through one-on-one interactions between a trainee and a more experienced mentor or coach. This method provides tailored guidance, feedback, and support, facilitating personal and professional growth.

## 4. Self-Directed Learning:

Encourages trainees to take control of their learning journey by providing resources such as books, articles, and online modules. This style promotes autonomy and caters to individual learning paces and interests.

## 5. Webinars and Virtual Classrooms:

Live, online sessions that mimic traditional classroom settings.

## 6. Workshops and Seminars:

Short-term, intensive training sessions focused on specific topics. These formats are ideal for skill development and deep dives into particular subjects.

## 7. E-Learning:

Digital courses accessible online, allowing trainees to learn at their own pace and convenience. This method is flexible and scalable, making it suitable for large organizations with geographically dispersed staff. It often includes interactive elements such as quizzes, videos, and simulations to enhance engagement.

## 8. Industry Tours:

This approach provides a different and unique perspective by observing how the industry is operating, including introduction to best practices and identification of areas of risk.



# OUTCOME AND IMPACT

The main outcome of our support is the *creation of a competent workforce*. We do this by establishing or strengthening the development of a national COE or training academy that can reliably deliver quality-assured and certified training to its workforce.

Other outcomes include increased cross-border collaboration and relationship building with regional NRMAs and greater exposure to global best practices in learning, training and skilling.

*The ultimate impact will be to improve access to safe, effective and quality-assured medicines.*

## ABOUT EMPOWER & OUR TEAM

*Empower School of Health* is a specialized public health training organization with broad experience in workforce development in the health and life-science sectors. Empower has been working in partnership with the United Nations Institute for Training and Research (UNITAR), Africa CDC, West African Health Organization (WAHO), and the International Federation of Pharmacists (FIP, a WHO-Collaborating Center). *We design, develop and deliver scalable and sustainable learning solutions* to doctors, nurses, pharmacists, lab technicians and national medicines regulators in more than 40 countries using all the major languages (English, French, Portuguese, Arabic, Spanish, Russian).

Within the regulatory space, *Empower and its team members have experience and expertise in regulatory sciences, good manufacturing practices, pharmacovigilance and quality assurance across Africa, Asia, and the Middle-East.*

Empower's work has been sponsored by the Bill and Melinda Gates Foundation, Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH (GIZ), the Global Fund, USAID, UNICEF, WHO, the World Bank, and national governments.

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