

Capability Building – Role of Academia in Quality Ecosystem

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Capability Building: Role of Academia in Quality Ecosystem – The context

- Alvin Toffler: accelerating social and technological change and its profound impact on society, the term "**future shock**" and theory of "**three waves**" of civilization.
- **Future Shock 1970** : psychological state of individuals or societies experiencing "too much change in too short a time". Symptoms include disorientation, anxiety, and decision paralysis from "overchoice" or information overload.
- **The Three Waves of Civilization**: Toffler categorized human history into three distinct stages or "waves" based on their primary mode of wealth creation:
 - **First Wave (Agricultural Society)**: Based on farming and land ownership.
 - **Second Wave (Industrial Society)**: Characterized by mass production, mass media, mass consumption, standardization, and bureaucracy.
 - **Third Wave 1980 (Information/Knowledge-Based Society)**: The emerging post-industrial era, knowledge and information are primary drivers of economic and political power.
- Traditional industrial-era education system (focused on rote learning) was obsolete: "The illiterate of the 21st century will not be those who cannot read and write, but those who cannot **learn, unlearn, and relearn**".
- **Need for continuous skill acquisition and the ability to discard outdated information and behaviors – Role of AI?**

WHO Academy, Lyon, France

- Launch of the WHO Academy in December 2024- **WHO Academy Strategy 2024-2026**
 - Lifelong learning for a healthier world, continuous process of acquiring knowledge, skills and competencies- to stay updated with best practices
 - Continuous development of new skills to meet evolving health sector needs, adopt new technologies
- Resource for health and care workers, teachers, students, policy makers and the public
- Create the state-of-the art digital learning hub that will meet the world's needs.
- **Target learners:** health care workers, senior decision makers, national institutes of health training, public, WHO workforce
- **Biomanufacturing** Responding to critical needs revealed by COVID-19, the initiative aims to provide LMICs with the know-how, skills and competencies to manufacture vaccines.
 - Within the framework of a partnership signed in 2023 between WHO and the Republic of Korea, the Academy will support and guide the design and delivery of training programmes aimed at empowering LMICs in biomanufacturing.
 - The Global Training Hub for Biomanufacturing (GTH-B) operated by the Ministry of Health and Wellbeing Welfare of the Republic of Korea and WHO and part of the Global Bio Campus

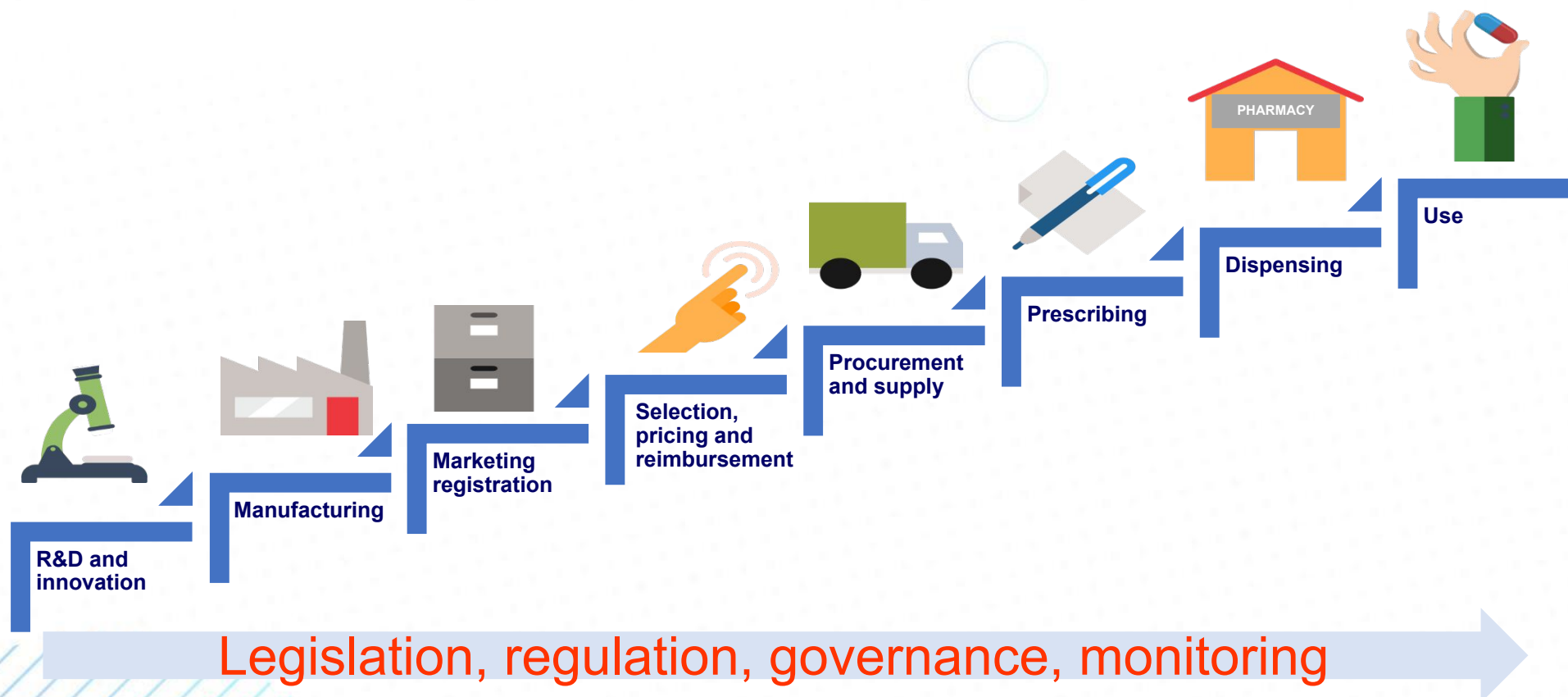
WHO Academy: Priority areas of interest

Priority area	Definition with inclusion/exclusion criteria
Physical and mental health	
Behavioural and mental health	• Courses related to behavioural health topics such as eating disorders, gambling addiction, self-injury, and substance abuse • Courses related to mental health topics such as bipolar disorder, depression, schizophrenia
Infectious, neglected tropical, and non-communicable diseases	• Course topics related to infectious diseases that are caused by pathogenic microorganisms such as bacteria, viruses, parasites, or fungi that can be spread from one person to another including HIV, TB, malaria; excludes sexually transmitted infections which fall under sexual health and reproductive rights • Course topics related to neglected tropical diseases such as Chagas, dengue, and leprosy • Course topics related to non-communicable disease including: ◦ Chronic diseases such as cardiovascular disease, such as asthma and COPD ◦ Health promotion topics such as exercise, nutrition, alcohol and tobacco which aligns closely with urban health ◦ Cancer surveillance, prevention and early detection, control, and research infrastructures and methods
Sexual and reproductive health	• Course topics related to reproductive systems including contraception, abortion, maternal health (pregnancy/antenatal health, childbirth, postpartum health), as well as sexually transmitted infections (excluding HIV, which falls under infectious diseases)
Health systems strengthening	Topics related to the six essential building blocks of a well-functioning health system
Health emergencies and emergency care	• Course topics related to strengthening global preparedness and response to health emergencies • Course topics related to strengthening management and delivery of emergency medicine
Health financing	• Course topics related to strengthening policies and management of health financing to promote financial risk protection
Health information systems	• Course topics related to health information systems, including the process of producing, analysing, visualizing, and using data to inform health system management
Health workforce	• Course topics related to the production, licensing, and management of the health workforce
Leadership and governance	• Course topics related to the processes, structures, and institutions that oversee and manage health systems at the country, regional, and global levels
Medical products, vaccines, and technologies	• Course topics related to the research, development, production, supply chain, and regulation of medicines and technologies, especially in LMICs
Primary health care and universal health coverage	• Course topics related to promoting PHC and UHC in regions and countries

WHO Academy Priority areas - 2

Priority area	Definition with inclusion/exclusion criteria
Transversal priorities	
Climate change	• Courses topics related to climate-related hazards including extreme weather events, heat, sea level rise, air pollution, water scarcity, and reduced food production and their effect on climate-sensitive health outcomes including heat-related illness • Cross-cutting topic, aligns closely with health emergencies, One Health, and urban health
Digital health and AI	• Course topics related to digital health and AI, including policies, implementation, and use of digital health and AI products • Cross-cutting topic, aligns closely with health systems strengthening especially health information systems
Gender and human rights	• Course topics related to identifying, monitoring, and addressing gender and human rights issues • Cross-cutting topic across all thematic areas, aligns closely with health systems strengthening/primary health care, sexual and reproductive health, population-specific health, and urban health
One Health	• Courses related to One Health including AMR, laboratory capacity for diagnosis and surveillance, food and water safety, zoonoses, and field epidemiology • Cross-cutting topic, aligns closely with climate change, health emergencies, and urban health
Urban health	• Cross-cutting topics that focus on improving health at the city-level, including social determinants of health such as the built environment (e.g., housing, transportation, sanitation and waste management), pollution, and heat. Also includes health literacy and education
Population-specific health	• Course topics related to specific WHOA priority populations, including: ◦ Indigenous groups ◦ Refugees and migrants ◦ Newborns, children, and adolescents ◦ Elders/healthy aging • Course topics related to maternal health covered under sexual and reproductive health and gender and human rights

Academia – Industry partnership for the entire technology value chain (adapted from WHO)



World Health Assembly resolutions and TRS

- WHA74.6 (May 2021), World Health Organization (WHO) Member States committed to **“Strengthening local production of medicines and other health technologies to improve access.”**
- WHA75.8 (2022) -strengthening clinical trials
- WHA76.5 (2023)- strengthening diagnostics capacity, - diagnostic services are vital for the prevention, diagnosis, case management
- **Engage in public consultations**
- Publication of the First WHO Model List of Essential In Vitro Diagnostics (2019 (WHO Technical Report Series -TRS, No. 1017)
- Second (2020 (WHO TRS, No. 1022) and third edition (2021 (WHO TRS, No. 1031) - guidance on selection of essential in vitro diagnostics at country level and for procurement of in vitro diagnostics and related laboratory items and equipment;
- India: In February 2025, representatives from the WHO Health Technology Access Programme **(HTAP)**, the WHO Regional Office for South-East Asia, and the WHO Country Office for India convened at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) in Trivandrum, Kerala.

Key roles of academia in quality ecosystem

Human Resource Development: Universities produce qualified professionals equipped with the technical, managerial, and entrepreneurial skills required by the modern workforce. This includes:

- **Skill Upgradation:** Integrating new technologies and global best practices into curricula to ensure graduates are job-ready – **course content 'A point' - fit for purpose and do not require retraining**
- **Lifelong Learning:** Offering professional development, short courses, and certifications to upskill existing employees in the workforce, addressing rapidly changing skill demands (e.g., in digital literacy), **upgradation of content**
- **Mentorship:** Establishing mentorship programs where senior academics and industry experts guide junior professionals- **possible if Academia itself is on a learning curve**
- **Knowledge Production and Research:** Academic institutions primary drivers of (R&D), generating new knowledge, ideas, and technologies that form the basis for innovation in the wider ecosystem.
 - **Applied Research:** Conducting applied research informed by real-world community and industry needs to solve practical problems.
 - **Data Repositories:** Initiating and managing reliable data and information repositories for a common knowledge base for all stakeholders.
- **Industry-Academia Linkages:** strategic partnerships and co-creation models with industry through joint research centers, incubators, and internship programs to bridge the gap between theory and practice. **Role in clinical trials?**
 - **Entrepreneurship and Start up Ecosystems:** Cultivating an entrepreneurial mindset among students and researchers to translate academic knowledge into marketable products, spin-offs, and services.
- **Quality Assurance and Governance:** Academic institutions contribute to the overall quality of the ecosystem through:
 - **Curriculum Alignment:** Ensuring that educational programs align with national and global development goals, such as the Sustainable Development Goals (SDGs).
 - **Policy Support:** Providing expert advice and research findings to policymakers to develop effective regulations and standards.

- Vibrant industry –academia collaboration- the choice in Ethics?

Academic institutions -primary source of talent for pharmaceutical industry

• **Training a Skilled Workforce:**

- Develop and update curricula (e.g., M.Pharm in Quality Assurance) to align with evolving industry and regulatory demands, such as Good Manufacturing Practices (GMP), Quality by Design (QbD), and regulatory affairs.
- Provide hands-on experience through advanced laboratories, simulation labs, and industry internships, which help students develop practical skills in areas like analytical methods (HPLC, mass spectrometry) and quality management systems
- Promote interdisciplinary thinking and problem-solving approaches including new emerging technologies such as AI , essential for navigating the complexities of modern drug development and quality control.

Objectives of National Institute of Pharmaceutical Education and Research (NIPER) Institutions in India

- Need for more pharmaceutical scientists, from lab to the clinic, from basic sciences drug discovery to drug development, manufacturing and quality assurance
- NIPER
 - nurture and promote quality and excellence in pharmaceutical education and research.
 - Courses leading to master's degrees, doctoral and postdoctoral courses, and research in pharmaceutical education.
 - Act as a nucleus for interaction between academics and industry by encouraging the exchange of scientists and other technical staff between the Institutes and the industry and by undertaking sponsored and funded research as well as consultancy projects

ICH – effective communication of guidelines

- International Council for Harmonization – A product of WHO ICDRS in 1989
 - joint regulatory – industry initiative on international harmonization
 - Technical guidelines implemented by Regulatory agencies
- Quality Guidelines- Harmonisation achievements include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.
- **Engaging in consultative processes – communication of updated guidelines**
- Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin Q5A(R2)
 - The revision provides additional recommendations on established and complementary approaches to control potential viral contamination of biotechnology products and describes the evaluation of the viral safety of biotechnology products including viral clearance and testing, and **outlines what data should be submitted in marketing applications for those products.**
 - Guideline training materials finalised in May 2025: The ICH Q5A(R2) “Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- From Batch manufacturing to Continuous manufacturing- describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of CM.
- **ICH - Industry and regulators, stakeholders –Academia ?**

Pursuing Quality

- WHO GMP 1967
- GBT - 1997 – Regulatory strengthening for quality – 9 functions
 1. National regulatory system
 2. Registration and market authorization
 3. Vigilance
 4. Market surveillance and control
 5. Licensing premises
 6. Regulatory inspection
 7. Lab access and testing
 8. Clinical trials oversight
 9. Lot release
- Role of Academia in quality and control of data on clinical trials
 - Protection of human subjects
 - Adverse reactions - voluntary reporting of problems associated with medical products (US MedWatch 1993) - FDA program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

WHO-India Initiative for Quality Local Production 2020-2024

Virtual Workshops on Current Good Manufacturing Practices (cGMP) for Access to Quality-assured Medical Products (Medicines, Vaccines, Diagnostics, Devices) WHO-JSS Mysuru – IPA

Workshop	Category	Dates 2020–2021	Number of Participating Units	Number of Participants	Duration (in days)
Pilot	Formulation	1–14 December	33	101	12
1.	Formulation	5–18 May	40	143	12
2.	APIs	24 May–5 June	35	139	12
3.	APIs	14–26 June	49	166	12
4.	Medical Devices	5–9 July	51	165	05
5.	APIs	19–30 July	115	310	12
Total			323	1115	
Pilot Mentorship programme		August 2021–December 2021	33 units		
Mentorship programme	All	March–August 2022	Completed		

The story of Current Good Manufacturing Practices (cGMP) Online Workshops for Pharmaceutical Units is published on both South-East Asia Region and Headquarters websites:

1. South-East Asia Region (SEAR)
<https://www.who.int/southeastasia/health-topics/universal-health-coverage>
2. WHO HQ.
[https://www.who.int/southeastasia/news/detail/10-12-2021-current-good-manufacturing-practices-\(cgm\)-online-workshops-for-pharmaceutical-units](https://www.who.int/southeastasia/news/detail/10-12-2021-current-good-manufacturing-practices-(cgm)-online-workshops-for-pharmaceutical-units)

WHO mRNA Technology Transfer Programme

Number of partners for mRNA Hub

WHO,
Medicines Patent Pool(MPP),
Funders: France, Belgium, Germany,
Norway, Canada, Switzerland,
South Africa, EC/EU, Alma
Foundation
AU and Africa CDC (PAVM),
SAMRC and
SAMVAC consortium,
Biovac,
Civil Society Groups,
mRNA Hub Steering and Scientific Advisory
Committee,
PATH,
NIH/VRC,
Curapath,
Quantoom
Syngoi
Evaxion
Enselitech
Equipment and technology
suppliers,
University of the Witwatersrand, NICD,
CeBER-UCT, PCDDP NWU, and other SA
Universities.
Afrigen Team and Supporting
Stakeholders and Shareholders.

DIVERSE UNIQUE GLOBAL PARTNERSHIPS



AND DEDICATED COMPETENT PEOPLE...

Established in 2021 to improve health security in LMICs by strengthening future pandemic preparedness through sustainable regional production of mRNA products

Thank you