EMBASSY OF THE REPUBLIC OF KOREA

KSR/143/2025

The Embassy of the Republic of Korea presents its compliments to the Ministry of Foreign Affairs, Foreign Employment and Tourism of the Democratic Socialist Republic of Sri Lanka and has the honour to transmit hereby the guidelines for the "2025 Introductory Course for Standard Practice" organized by the Global Training Hub for Biomanufacturing.

In this regard, the Embassy would be grateful if the Ministry could kindly forward the guidelines to the Ministry of Health and the participating official could submit the application with the required documents before 18th July 2025.

The Embassy of the Republic of Korea avails itself of this opportunity to renew to the Ministry of Foreign Affairs, Foreign Employment and Tourism of the Democratic Socialist Republic of Sri Lanka the assurance of its highest consideration.

Colombo, 11th June 2025

Enclosure: As Stated

CC:

Ministry of Health

2025 Introductory Course for Standard Practice

organized by the Global Training Hub for Biomanufacturing (GTH-B)

in Seoul, Republic of Korea

Call for Applications

Deadline for applications: Friday, 18 July 2025, 18:00 (KST)

Background

Low- and middle-income countries (LMICs) face significant inequities in access to vaccines and other biologics and are making efforts to establish biological manufacturing in their regions. However, these efforts—whether through bilateral technology transfer or local R&D—are often hindered by the lack of a trained workforce.

To address this gap and to build the biomanufacturing capacity in LMICs, the World Health Organization (WHO) designated the Republic of Korea as the Global Biomanufacturing Training Hub. In 2023, WHO and the Ministry of Health and Welfare (MoHW) of the Republic of Korea signed a Memorandum of Understanding (MOU) to establish the Global Training Hub for Biomanufacturing (GTH-B). In May 2024, the GTH-B Support Foundation was established under the Civil Act with the approval of MoHW, to conduct and coordinate the GTH-B training programs as a non-profit foundation.

The hub is mandated to provide training in the manufacturing of high-quality vaccines and biologics in an industrial setting to resolve inequality in access to vaccines and biologics worldwide by expanding manufacturing capacity in LMICs.

Since 2022, GTH-B, in collaboration with the International Vaccine Institute (IVI), has offered two introductory courses every year: *Introductory Course for Biologics Development and Manufacturing* and *Introductory Course for Standard Practice (GxP)*. These courses have been provided to over 900 participants from 70 different LMICs in total.

For the fourth year, the Republic of Korea, in agreement with WHO, is organizing a new training focusing on the introduction to standard practice (GxP) in biomanufacturing from October to November 2025 for 150 trainees from LMICs.

Course Period

Proposed dates for 2025 Introductory Course for Standard Practice (GxP) are:

- Pre-Online Course: Thursday, October 2, 2025 – Sunday, October 26, 2025
- In Person Course: Monday, October 27, 2025 – Friday, November 14, 2025

Course Objectives

The purpose of this Introductory Course for Standard Practice (GxP) is to equip participants representing the biomanufacturing workforce from LMICs with the essential skills required to operate according to current good practices.
After completing the course, participants will be equipped with the knowledge and skills required to operate in a biomanufacturing facility according to international GxP standards. By investing in workforce development, the hub will support ongoing initiatives in local bioproduction and strengthen knowledge sharing between manufacturers. This includes, but is not limited to, didactic and practice sessions on Good Laboratory Practice, Good Clinical Practice, Good Clinical Laboratory Practice, Good Manufacturing Practice, and Biosafety.

Content and Structure

This course will consist of three weeks of pre-online sessions followed by three weeks of in-person sessions. At the end of each session, participants will be required to test their learning through online or in-person quizzes. Certification will be awarded to participants who achieve 100% completion of the pre-online sessions and 90% completion of all required quizzes of the in-person course.

For the specific areas of sessions being developed for the course, please refer to Appendix 1: Tentative Course Outline.

Eligibility, Limitation, and Selection Criteria

The course targets individuals employed by entities in countries formally registered as LMICs on the OECD DAC list (https://www.oecd.org/en/topics/oda-eligibility-and-conditions/dac-list-of-oda-recipients.html) and currently involved in the production of bioproducts including vaccines, therapeutics, monoclonal antibodies, etc.

Training and services will be provided exclusively to selected individuals and cannot be transferred or shared. Applicants are expected to demonstrate in their application how they will apply the experience gained during the training program and commit to returning to their home institution upon completion.

The priority selection criteria for this course are as follows:

- Have an educational background in the field of life sciences

- Hold a position as a technician, engineer, scientist, or manager with up to 6 years of experience in biomanufacturing or a related field
- Be employed by a company registered as a legal entity in an LMIC conducting activities within the scope of biomanufacturing
- Be a citizen of, and resident in, a LMIC
- Have at least an intermediate level of spoken and written English
- Demonstrate in the application how the acquired knowledge, skills, and competencies during the training will be applied within the applicant's organization after the training
- Explain in the application the relevance to a professional project

Application Procedure

All applications must be submitted via online application form by **18 July 2025, 18:00 (KST)**

The online application form is available at 'Apply' page of the following link: https://ivionlinecampus.ivi.int/

Applicants must provide the following information:

- Personal information including name, gender, date of birth, nationality, country of residence, passport information, contact details, etc.
- Educational background/qualifications and level of English proficiency
- Professional background including description of applicant's current post and work experience
- GTH-B training history

Applicants must upload the following documents:

- A copy of their passport
- A letter of endorsement: A letter from the Director of the applicant's institution confirming the applicant's capability to successfully undertake the training and certifying their current employment status. (Refer to the endorsement letter sample in the online application form of the website.)

Applicants must demonstrate the following:

- A description of their current position and justification for their selection.
- A description of the relevance of the training to their professional project.
- A description of the knowledge and skills they wish to acquire during the training.
- A description of their organization's needs related to the training and the anticipated impact on their institution.
- A description of the plan to apply and share the acquired knowledge and skills after returning to their home institution upon completion of the training.
- Agreement to the GTH-B code of conduct.

Selection Process

The selection process includes the following steps:

- Eligible applications will be reviewed by the selection committee formed by members recommended by MoHW of the Republic of Korea and WHO.
- When the selection process is completed, the selected participant will be informed of the next steps and necessary information by e-mail.
- Due to limited capacity, up to **5 participants maximum** from each organization will be allowed to participate.
- The Selection Committee may apply a limit of 10% of the total training participants accepted from any single LMIC if the number of applications exceeds the limit.
- For the institutions involved in animal vaccine production only and wishing to send participants to the training, a letter from the institution must be addressed to the GTH-B with a statement regarding an institutional plan to expand its scope to human vaccine.
- The selection process will be based solely on the eligibility and merits of the applicants. **Personal connections or informal recommendations will not be considered under any circumstances.**

Financial Provisions

The course is offered free of charge to participants. Accommodation will be provided during the entire course days and weekends. On weekdays, breakfast and lunch will be provided. On weekends, only breakfast will be provided.

The trip cost to/from Seoul, South Korea will **NOT** be covered. Applicants must secure the traveling costs at their own expense, and it is recommended to schedule the return flight within 3 days following the course. Selected participants will be responsible for obtaining any vaccinations and visas which may be necessary for the travel.

Equality, Diversity, and Inclusivity

The Ministry of Health and Welfare (MoHW) of the Republic of Korea and the World Health Organization (WHO), are dedicated to promoting equality, diversity, and inclusivity in science. We particularly encourage women to apply, and encourage any qualified applicants regardless of sexual orientation, ethnicity, religious, cultural, and social backgrounds, or (dis)ability status.

Further Information

For any questions regarding the application, please contact the GTH-B Support Foundation at gthb@gthbsf.org

The receipt of the applications will be automatically acknowledged via return email from gthb.coordinator@ivi.int. An acknowledgement of the application receipt does not imply that the application is complete and eligible for review.

Appendix 1. Tentative Course Outline

Pre-online course for approximately 19 hours and in-person course for 120 hours

Group	Course	Topic	Hours	Remarks
Pre-online course			19	Some areas from in-person course
QA, QC, and GMP		Program overview and introduction	3	Introduction of GxP and Quality Management
GLP	Introduction & Fundamentals of GLP		8	Understanding basic concepts and history of GLP (e.g., as per OECD)
	Resources			Organization, facilities, personnel, equipment needs for GLP
	Characterization			Test items and systems
	Rules for Performing Studies			Protocols, SOPs, etc.
	Results - Raw Data & Collection			Raw data, final reporting, archival, etc.
	Quality Assurance			Independent monitoring of research processes and outcomes
	Stepwise Implementation			Planning, structuring and implementing GLP and its maintenance in an organization
GMP	Module 1	Introduction of GMP	16	Understanding basic concepts of GMP and its importance for vaccines mfg.
		Building design and construction		Understanding the location, design, construction, maintenance, and operations appropriate for the stage of manufacture and the product
		Sanitary facilities and control		Requirements for water system, containment facilities, waste disposal, cleaning-sanitation & maintenance, etc.
		Equipment and utensils		Understanding the equipment need, size, capacity, calibration/maintenance/ cleaning needs, automation systems, etc.
	Module 2	Personal Hygiene	24	Concepts of clothing, personal hygiene practices/monitoring, health status/ monitoring, etc.
		Product and Process control		Sampling/testing needs identification, methods evaluation, control limits, procedural controls, etc.
		Raw Material, Ingredients and Storage		Identification of raw material sources, quality parameters, vendor evaluation/ selection, evaluation/management of supply risks, storage facilities needed for inventory control, etc.
		Personnel Training and Competency		Personnel requirements, right selection of personnel for meeting the needs, identification of training needs and their periodicity, etc.
	Module 3	Risk Management	12	Overall risk assessment/management practices and their importance while designing facilities, processes, etc. and ICH-Q9 (Quality RM) concepts
		Management Commitment and Continual Improvement		Importance of commitment of the organization's management to quality aspects and continual improvement of quality, productivity, etc.
		Holding and Distribution		Storage requirements for different product stages, their distribution practices, records maintenance, etc.
		Pest Control		Control/management of pests in/around facilities
		Self-inspection		Need for self-inspection/quality audits, guideline requirements, different types of SI, etc.
	GDP	Documentation and Records	4	Good practices to be followed while recording operations before/during/after execution, guideline requirements for maintenance of records, etc.

GCP		Good Clinical Practice	4	GCP guidelines
		Test for certificate	2	online test for GCP certificate
GCLP and Biorepository		GCLP guideline	2	What is GCLP and why it is needed
		GCLP premise and equipment		Tour of IVI GCLP
		Biorepository guideline	2	Basic guidelines and systems in handling bio-samples
		Biorepository system and equipment		Tour of IVI Biorepository
Biosafety	Overview	Principles of Biosafety	2	From the principles, guideline and hands-on training
		Biohazard risk assessment	2	
	Practice	Biosafety Program	1	
		Biosecurity into Biorisk Management	1	
		Biological Materials & Biological Waste Management	2	
		Biosafety Facility & Equipment	2	
		Personal protective equipment	3	
		Emergency Response	3	
Exam		Test (MCQ) / SOP group work	3	
Excursion		Minimum three times	24	e.g., one GCP site, 1~2 GMP sites, KDCA or KMFDS
Total			120	