

# **2022 Introductory Training Course for standard practice (GxP) organised by the Global Training Hub for Biomanufacturing (GTH-B) in Seoul, Republic of Korea.**

## **Call for Applications**

***Deadline for applications:*** 17 August 2022 17:00 (GMT)

### **Background**

Low- and Middle-Income Countries (LMICs) face significant inequity in terms of access to vaccines and other biologics and are making efforts to establish biological manufacturing in their regions. Establishing such manufacturing capacity, through bilateral technology transfer or through local R&D efforts is frequently hampered by the lack of a workforce that is trained in biomanufacturing.

To address this gap and to build the biomanufacturing capacity in LMICs, the World Health Organization (WHO) and the Ministry of Health and Welfare of the Republic of South Korea (MOHWK) are working towards establishing the first of a kind Global Training Hub for Biomanufacturing (GTH-B).

The hub is mandated to provide training in 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.

In July 2022, a two-week introductory training programme on biomanufacturing was organized by the International Vaccine Institute (IVI) in Seoul, South Korea for more than 100 participants from 33 LMICs. To complement this course, the Republic of Korea in agreement with WHO is organizing a second course operated by IVI focusing on standards practices (GxP) in biomanufacturing in October 2022 for 200 participants from LMICs.

### **Proposed dates for the upcoming Introductory Training Course for standard practice (GxP)**

Monday, October 31, 2022 – Friday, November 18, 2022 (3 Weeks)

## Scope

The purpose of this introductory course for standard practices is to equip the participants representing the biomanufacturing workforce from LMICs with essential skills required to operate according to good biomanufacturing practices. This course will be conducted in-person over three weeks and will include didactic sessions on Good Laboratory Practice, Good Clinical Practice, Good Clinical Laboratory Practice, Good Manufacturing Practice and biosafety. The course is targeting technicians, engineers or managers employed by a entity formally registered in LMICs and currently involved in the production of bioproducts including vaccines, therapeutics, monoclonal antibodies, etc. The tentative course agenda is attached in the appendix 1.

However, due to the restricted number of attendees (200), priorities will be given to 1) manufacturers identified as recipient of mRNA technology from the technology transfer initiative led by WHO and COVAX and 2) participants from LMICs.

Support awarded are not transferrable from one individual to another or from one session to another. Participants must be committed to return to their home institution after completion of the training. Participants will have to demonstrate in their application how the experience gained during the training programme will be applied upon return to their home organization.

## Expected impact

At the end of the training, all participants will be equipped with the knowledge and skills required to operate in a biomanufacturing facility according to international standards. By investing in workforce development, the hub will support ongoing initiatives in local bioproduction and will strengthen knowledge sharing between manufacturers.

## Eligibility

Applicants are required to have the following qualifications to be considered eligible for the course.

- Have an education background in the field of life science
- Have hold position as technician, engineer, scientist, and manager with up to 6 years of experience in biomanufacturing, or related experience
- Employed by a company registered as a legal entity in LMIC conducting activities in the scope of biomanufacturing
- National or a citizen of, and resident in a LMIC
- Have at least an intermediate level of spoken and written English language
- Demonstrate in the application how the skills and competencies acquired during the training will be applied after the training in the institution the participant is coming from,
- Demonstrate in the application the relevance to professional project,
- Demonstrate in the application the expectations, knowledge, skills and expectations from their own institution

## Application procedure

The online application form is available at the following link: <https://ivionlinecampus.ivi.int/courses/>

The following information must be provided:

1. First and family name
2. Date of birth, gender, and other personal information
3. Copy of information page of passport
4. Name, address, telephone number and e-mail address of institution where the applicant is employed.
5. Educational qualifications and level of English proficiency
6. A description of the applicant's current post
7. A description of the applicant's current work/ interests
8. A description of competencies and skills the applicant would like to acquire during the training.
9. A description of how the applicant, if selected, plans to apply the acquired skills and knowledge after returning to home country/institution.
10. An endorsement from the Director of the applicant's institution testifying the ability of the applicant to successfully undertake the training proposed and certifying the applicant's current employment. The Director also has to indicate how the proposed training will strengthen the institution's capability, to develop bioproducts. (Endorsement letter sample is available at application website)

### **Deadline for submission of proposals**

All applications must be submitted online at <https://ivionlinecampus.ivi.int/courses/> by 17 August 2022 17:00 (GMT)

### **Selection process**

The selection process includes the following steps:

- Eligible applications will be reviewed by the selection committee formed by members recommended by MoHW in South Korea and WHO.
- When the selection process is completed, the selected participant will be informed by e-mail, upon which following administrative arrangements will be made.

### **Financial provisions**

Course is free of charge to participants. Accommodation and breakfast will be provided during the course days and over the weekends. Lunches will be provided during the course days only and will not be included in weekends.

The trip cost to/from Seoul, South Korea will NOT be provided. Applicants must secure the traveling costs at their own expense.

### **Gender**

WHO is committed to Equality, Diversity and Inclusivity in science. Qualified applicants are encouraged to apply irrespective of gender identity, sexual orientation, ethnicity, religious, cultural and social backgrounds, or (dis)ability status.

**For further information**

For questions related to this, please contact [gthb.coordinator@ivi.int](mailto:gthb.coordinator@ivi.int)

The receipt of the applications will be automatically acknowledged via return email from [gthb.coordinator@ivi.int](mailto:gthb.coordinator@ivi.int) . Applicants who do not receive an acknowledgement within the specified time should contact [gthb.coordinator@ivi.int](mailto: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 Agenda: GxP Training

Group	Course	Topic	hrs.	Remarks
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	

\* Course agenda will be more divided and refined.

\* Course content and faculty plan are tentative.