2023 Introductory 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: 30 June 2023 18:00 (KST)

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 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 its 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 2022, two training courses, Introductory course for biologics development & manufacturing and Introductory course for global standards practice (GxP) were organized by the International Vaccine Institute (IVI) in Seoul, South Korea for about 325 participants from more than 30 LMICs.

For the second year in a row, the Republic of Korea in agreement with WHO organized a new training operated by IVI focusing on introduction to biologics development & manufacturing in June 2023 for more than 150 trainees from LMICs. The 2nd GxP course for the year 2023 is being launched in October as per the details below:

Proposed dates for the upcoming Introductory Course for Standard Practice (GxP)

Monday, October 30, 2023 – Friday, November 17, 2023 (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 current good practices. This course will be conducted in-person over three weeks and will include didactic and practice 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 an 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 appendix 1.

However, due to the restricted number of attendees (120), priorities will be given to 1) manufacturers identified as recipients 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 program 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, manager with up to 6 years of experience in biomanufacturing or any other relevant functions
- 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/

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 must 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/ by 30 June 2023 18:00 (KST)

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 the following administrative arrangements will be made.
- Due to limited capacity, up to **5 participants maximum** from each organization will be allowed to participate. The decision for the selection will be made by the selection committee.
- For the institutions involved in animal vaccine production only and wishing to send participants to the training, a letter from the institution should be addressed to the GTH-B with a statement regarding an institutional plan to expand its scope to human vaccine.

Financial provisions

Course is free of charge to participants. Accommodation and breakfast will be provided during the course days and over the weekends. Lunch and light dinner will be provided during the course days only and will not be provided on the weekends.

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

Gender

MoHW in South Korea and WHO are 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

The receipt of the applications will be automatically acknowledged via return email from gthb.coordinator@ivi.int . Applicants who do not receive an acknowledgement within the specified time should contact 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.