

# **2025 Introductory Course for Biologics Development and Manufacturing organised by the Global Training Hub for Biomanufacturing (GTH-B)**

## **in Seoul, Republic of Korea**

### **Call for Applications**

***Deadline for applications:*** 28 February 2025 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 often hindered by the lack of a trained workforce in biomanufacturing.

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

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.

Since 2022, the GTH-B, in collaboration with the International Vaccine Institute (IVI), has offered two introductory courses: '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 low- and middle-income countries (LMICs).

For the fourth year, the Republic of Korea, in agreement with WHO, is organizing a new training focusing on introduction to biologics development & manufacturing in June 2025 for 120 trainees from LMICs. GTH-B will be collaborating with IVI for this training.

## **Course Period**

Proposed dates for 2025 Introductory Course for Biologics Development and Manufacturing are:

Monday, June 16, 2025 – Friday, June 27, 2025 (2 Weeks)

## **Course Objectives**

After completing the course, participants will have basic and primary knowledge about various areas that are related to biologics manufacturing.

It includes but not limited to pre-clinical & clinical trials, the biologics manufacturing process, quality control & quality assessment, and regulatory affairs to develop and produce vaccines and biologics.

## **Content and Structure**

This course will consist of pre- and post-online courses followed by a two-week in-person course. 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.

Refer to Appendix 1 (Tentative Course Outline) for the specific areas of sessions being developed for the course.

## **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, an 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 **18:00 Korea Standard Time (KST), 28 February 2025**.

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 and level of English proficiency
- Professional background
- GTH-B training history
- Course preparation information

### **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 in 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 should be addressed to the GTH-B with a statement regarding an institutional plan to expand its scope to human vaccine.

## Financial Provisions

The course is offered free of charge to participants. Accommodation and breakfast will be provided during the course days and over the weekends. Lunch will be provided on weekdays only and is not included on weekends.

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

## Equality, Diversity, and Inclusivity

The Ministry of Health and Welfare (MoHW) in 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](mailto:gthb@gthbsf.org)

The receipt of the applications will be automatically acknowledged. An acknowledgement of the application receipt does not imply that the application is complete and eligible for review.

## Appendix 1. Tentative Course Outline

Current course is tentatively planned as follows: a 10-hour pre-online course, an 80-hour in-person course, and a 5-hour post-online course.

Course	Area	Hours
Pre-online	Course that maximizes the learning effectiveness of the in-person course	10
In-person	Immunology	3
	Vaccine Technology Platform	4
	Process development	5
	Technology Transfer	4
	Quality Management	6
	Technology Discovery	2
	Clinical Development	5
	Product Lifecycle	3
	Data Management	2
	Epidemiology	2
	Project Management	3
	Intellectual Property	2
	Pre-Clinical	4
	Vaccine Safety	2
	Regulatory Affairs	5
	Special Lecture	4
	Facility Management	2
	Quality Assay	4
	Course Orientation	2
	Mini Convention	4
	Interactive Session	4
	Excursion	8
Post-online	Course that maximizes the utilization of in-person learning outcomes	5
<b>Total</b>		<b>95</b>