

# **2024 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:*** 23 February 2024 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) and the Ministry of Health and Welfare of the Republic of South Korea (MoHWK) established the 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.

Since 2022, the GTH-B has run through the International Vaccine Institute (IVI) two editions of 'Introductory Course for Biologics Development and Manufacturing', and 'Introductory Course for Standard Practice (GxP)' to provide GTH-B training to about 500 people in more than 40 low- and middle-income countries (LMICs).

For the third year, the Republic of Korea in agreement with WHO is organizing a new training operated by IVI focusing on introduction to biologics development & manufacturing in June 2024 for 130 trainees from LMICs.

## **Proposed dates for Introductory Course for Biologics Development and Manufacturing**

Monday, June 3, 2024 – Friday, June 14, 2024 (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**

Course content is being developed and applicants can refer the appendix 1.

This course will be consisted of pre-online courses for a week followed by and in-person course for two weeks. At the end of every session, participants will be asked to test their learning through online or in-person quizzes for completion of each session. Certification will be awarded to participants who have 90% completion of all requested quizzes and 100% completion of pre-online sessions.

### **Eligibility, Limitation, and Selection Criteria**

The course is targeting people 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 the appendix 1.

Priority will be given to manufacturers identified as recipients of mRNA technology from the technology transfer initiative led by WHO and COVAX.

All training and service will be provided to the individual who are selected for training only and it cannot be transferred or shared. Participants are expected to demonstrate in their application how the experience gained during the training program will be applied and are required to commit to returning to their home institution upon the completion of the training.

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

- Have an educational background in the field of life science
- 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 LMIC conducting activities in the scope of biomanufacturing
- Be resident in a LMIC
- Have at least an intermediate level of spoken and written English language

- Demonstrate in the application how the acquired knowledge, skills and competencies during the training will be applied after the training in the institution the participant is coming from
- Explain in the application the relevance to a professional project

## 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 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 and work / interests
7. A description of how the applicant, if selected, plans to apply the acquired skills and knowledge after returning to home country/institution
8. A letter of endorsement from the Director of the applicant's institution confirming his/her capability to successfully undertake the proposed training and certifying the applicant's current employment status (Endorsement letter sample is available at the application page on the website)

## Deadline for applications submission

All applications must be submitted online at <https://ivionlinecampus.ivi.int/> by **23 February 2024 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 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 decision for the selection will be made by the selection committee in collaboration with the home institution.
- 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. 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 South 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.

## **For further information**

For further questions related to this, please contact the course Coordinator at [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). 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 about 10 hours and in-person course for 80 hours

Session	Area	Hours
Pre-online course	Some of the areas from in-person course	10
<b>Total</b>		<b>10</b>

Session	Area	Hours
Didactic sessions	Immunology	3
	Product Development	4
	Vaccine Technology	4
	Clinical immunology	3
	Vaccine Development	4
	Adjuvant	2
	Clinical Development	2
	Data Management	2
	Epidemiology	2
	Health Economy	2
	Intellectual Property	3
	Pre-Clinical	2
	Post Market Authorization	3
	Regulatory Affairs	4
	Special Lecture	2
Group Activity	Case Study (Group work)	20
Course Orientation	Course Orientation	2
Interactive sessions	Networking session	4
	Mini Convention	4
	Excursion to Korean manufacturing sites and research centres	8
<b>Total</b>		<b>80</b>