

# **2024 Hands-On Training for Upstream Process in Cell-Based Vaccine Manufacturing**

organized by the Global Training Hub for Biomanufacturing (GTH-B)  
in the Republic of Korea, supported by the World Health Organization

## **Call for Applications**

**Application Deadline: August 23, 2024, 18:00 (KST)**

### **I. Background**

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

To address this gap and build biomanufacturing capacity in LMICs, the World Health Organization (WHO) and the Ministry of Health and Welfare (MoHW) of the Republic of Korea established the Global Training Hub for Biomanufacturing (GTH-B). The hub's mandate is to provide training in the manufacturing of high-quality vaccines and biologics in an industrial setting, aiming to resolve inequality in access to vaccines and biologics worldwide by expanding manufacturing capacity in LMICs.

There is an urgent need for developing countries to improve vaccine access by developing local biomanufacturing capabilities, which are hindered by a shortage of trained personnel. GTH-B is helping these countries by providing essential biomanufacturing training, aiming to expand the technical know-how and capability for sustainable vaccine R&D and manufacture in LMICs by facilitating vaccine manufacturing apprenticeships.

A crucial aspect of such training is the hands-on experience provided at a real biomanufacturing facility. The GTH-B will operate two batches of hands-on training utilizing public biomanufacturing facilities in the Republic of Korea. One is a 5–6-week program (including a pre-online training course) at the International Vaccine Institute (IVI) and the Korea Biopharmaceutical CMO Centre (K-Bio CMO), targeting 20 individuals and focusing on the upstream process in cell-based vaccine manufacturing. The other is a 7-week program (including a pre-online training course) at the Korean National Institute for Bioprocessing Research and Training (K-NIBRT) and the Hwasun site (K-VCAST and JBRC), targeting 20 individuals and focusing on mRNA vaccine manufacturing and regulatory affairs.

These programs not only offer practical training in biomanufacturing and analytical techniques but also prepare participants to meet industry demands. By enhancing the skills of the workforce, this initiative strengthens the healthcare infrastructure of LMICs, fostering self-reliance and contributing to a more equitable global healthcare system.

## II. Training Overview

### 1. Training Objectives

The purpose of the Hands-on Training is to enhance the technical knowledge and capabilities of vaccine and biopharmaceutical manufacturers from LMICs in the processes of vaccine research, development, and manufacturing. The focus is on providing extensive hands-on training in industrial facilities, enabling participants to gain practical experience and a deeper understanding of the intricacies involved in vaccine production.

The training also supports participants in applying newly acquired skills to enhance vaccine production capabilities in their home institutions through strategic collaborations among local biomanufacturers, Korea Biopharmaceutical CMO (K-Bio CMO), and the International Vaccine Institute (IVI), thereby contributing to the ongoing enhancement of LMICs' biomanufacturing capability.

### 2. Training Schedule and Venues

	Didactic Training (Online)	Didactic Training (In Person)	Hands-on Training
Period	October 31, 2024 – November 6, 2024 (1 Week)	November 7, 2024 – November 8, 2024 (2 Days)	November 11, 2024 – December 6, 2024 (4 Weeks)
Venue	Online	International Vaccine Institute (IVI) Seoul, Republic of Korea	Korea Biopharmaceutical CMO Center (K-Bio CMO) Andong, Republic of Korea

### 3. Training Method

The training program utilizes a blend of theoretical instruction through live online and in-person lectures and practical hands-on training, complemented by apprenticeships and mentorship programs. Key components include interactive workshops and seminars, as well as networking opportunities with international biomanufacturers. Direct experience at vaccine manufacturing facilities and regular evaluations ensure a comprehensive learning experience. Pre-online training and follow-ups after the hands-on training will include several sessions of live online (real-time) interactions.

## III. Application Requirements and Selection Process

### 1. Eligibility Criteria

Applicants must meet the following qualifications to be considered eligible for the training:

- Be a citizen of, and resident in, an LMIC.
- Be employed by a company registered as a legal entity in an LMIC conducting activities in the scope of biomanufacturing.
- Hold a position in the company as a technician, engineer, scientist, or manager in biomanufacturing or a related field, with up to 6 years of experience.
- Have an educational background in life sciences.
- Have at least an intermediate level of proficiency in spoken and written English.
- 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.

## 2. Application Submission

All applications must be submitted online at the following link: <https://ivionlinecampus.ivi.int/> by August 23, 2024, 18:00 Korea Standard Time (KST).

Applicants must provide the following information:

- Personal information including nationality, country of residence, passport number, name, date of birth, gender, contact details, and others.
- Information about the institution.
- Information about educational background.
- Information about work experience.
- Information about English proficiency.

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. (A sample endorsement letter is available on the application page 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 institution'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.

## 3. Selection Process

The selection process involves the following steps:

- Eligible applications will be reviewed by a selection committee composed of members recommended by the MoHW of the Republic of Korea and WHO.
- Once the selection process is completed, selected participants will be notified of the next steps and required information via email.
- Due to limited capacity, a maximum of 5 participants from each country will be selected. The decision will be made by the selection committee in collaboration with the home institution.
- Institutions involved solely in animal vaccine production must provide a letter to GTH-B stating their institutional plan to expand into human vaccine production if they wish to send participants for training.

Priority will be given to trainees with certificates from completing the following GTH-B training programs:

- Introductory Course for Biologics Development and Manufacturing
- Introductory Course for Standard Practice (GxP)

## 4. Equality, Diversity, and Inclusivity

The MoHW of the Republic of Korea and WHO are dedicated to promoting equality, diversity, and inclusivity in science. Women are particularly encouraged to apply, and all qualified applicants are welcomed regardless of sexual orientation, ethnicity, religious beliefs, cultural background, social status, or (dis)ability status.

#### **IV. Financial Provisions**

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

The cost of travel to/from Seoul, Republic of Korea will **NOT** be covered. Applicants must secure travel costs at their own expense. Selected applicants will be responsible for obtaining any necessary vaccinations and visas for travel.

#### **V. Contact Information**

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

An automatic email acknowledging receipt of the application will be sent from [gthb.coordinator@ivi.int](mailto:gthb.coordinator@ivi.int). This acknowledgment does not confirm that the application is eligible for review.

## Appendix I. Tentative Training Agenda

### 1. Didactic Training (Online, 1 Week)

- Pre-Requisite Session: Attend online *Introductory Course for Biologics Development and Manufacturing*
- Pre-Online Session:

	<b>Agenda</b>
<b>Online (Recorded)</b>	Types of Vaccines
	Fundamentals of Biological Products
	Target Product Profile
	Intellectual Property
	Adjuvants
	Key Analytical Assays for Evaluation of Vaccines by Different Techniques
	Statistical Process Control
	Analytical Methods for Characterization and Quality Evaluation of Vaccines
	Vaccine Platform Technologies (mRNA, Adeno-vectored, VSV, DNA, etc.)
	Introduction to GxP
	Good QC Laboratory Practices
	Introductory Good Manufacturing Practices
	Overview of Biosafety Part 1
	<b>Online (Real-time)</b>
Vaccine History and Types	
Discovery and Early Development	
Quality Risk Management	
Technology Transfer	
Principles of Regulatory Affairs	
Quality Control and In-process Control	
Analytical Method Validation	
Process Validation	
Manufacturing Facility Management	
Facility Management	
Aseptic Processing	

### 2. Didactic Training at IVI (In Person, 2 Days)

	<b>Agenda</b>
<b>In Person</b>	Vaccine Development Quality by Design
	Project Management
	Vaccine Upstream Process (USP) Development
	Basics of Vaccine Downstream Process (DSP) Development
	Manufacturing Scale up
	Pharmaceutical Quality System
	Process Control
	Contamination Control
	Aseptic Processing
	Good Documentation Practices
	Data Integrity
	Biosafety and Bio Risk Assessment
	Development and Writing of SOP

### 3. Hands-on Training at K-Bio CMO Center (4 Weeks)

Agenda		
<b>Hands-on</b>	Standard Operating Procedure (SOP) Practice	Culture Medium Preparation
		1st Seed Cell Culture - Cell Thawing & Cell Counting
		2nd Seed Cell Culture - Sub-culture & Cell Counting
		3rd Seed Cell Culture - Sub-culture & Cell Counting - Main Culture (Wave Bioreactor) & Cell Counting
		Virus Infection
		Harvest & Clarification - Freezing & Thawing - Bottle Top Filter
		In Process Control - Hexon Staining
		Gowning Procedure
	USP Hands-on Training	Culture Medium Preparation
		Cell Culture - Cell Thawing & Cell Counting - Sub-culture & Cell Counting - Wave Bioreactor & Cell Counting
		Virus Infection
		Harvest & Clarification - Freezing & Thawing - Bottle Top Filter
		In Process Control - Hexon staining
		Gowning Procedure
	Virtual Reality (VR) Training	GMP Facility Tour
		GMP Process Training (Upstream Process)