

# 2023 Hands-on Training for Upstream Process in Vaccine Manufacturing organized by KWTRP and IVI in Republic of Korea.

## Call for Applications

***Deadline for applications:*** 8 September 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.

With funding from the Bill and Melinda Gates Foundation, the KEMRI-Wellcome Trust Research Programme (KWTRP) in Kenya aims to expand the technical knowhow and capability for sustainable end-to-end vaccine R&D and manufacture in Africa by facilitating vaccine manufacturing apprenticeships for African scientists in collaboration with IVI (International Vaccine Institute). IVI has been providing training on vaccines and biologics development and manufacturing and standard practices for biopharmaceutical through IVI Learning Platform. The intended outcome is an increase in the number of scientists in Africa with the knowhow and experience of working in a human Good Manufacturing Practice vaccine manufacturing environment.

IVI is committed to unlocking the potential of the LMICs' vaccine industry competitiveness by identifying key unmet needs for local talents, developing LMICs-customized & phased trainings, and leveraging IVI's broad experience in capacity building and its global network. In order to become a world-class global training & education platform for fostering biopharmaceutical talents in LMICs, IVI is developing educational programs with long-term goals and focused objectives.

Upstream Process development is the first hands-on training module to be developed by IVI and Korea Bio Pharmaceutical CMO Center (K-Bio CMO), in consideration of above challenges and solutions.

## **Dates and venue for the upcoming Hands-on Training for Upstream Process Development in Vaccine Manufacturing**

Monday, October 30, 2023 – Friday, December 08, 2023 (6 Weeks) in Republic of Korea

### **Scope**

This hands-on training for upstream process development in vaccine manufacturing is to equip 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 six weeks and will include two weeks of didactic sessions and four weeks of hands-on adenovirus vaccine upstream process development. The course is targeting technicians, scientists, engineers, or managers employed by an entity formally registered in Africa and currently involved in the production of vaccines. The tentative course agenda is attached in appendix 1.

However, due to the restricted number of attendees (20), priority will be given to manufacturers operating in Africa and members of the Africa Vaccine Manufacturing Initiative (AVMI).

Support awarded is not transferable from one individual 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 returning to their home organization.

### **Expected impact.**

At the end of the training, all participants will be equipped with the knowledge and skills required to develop upstream process in vaccine manufacturing in a biomanufacturing facility according to international standards. By investing in workforce development, KWTRP and IVI will support ongoing initiatives in local bioproduction and will strengthen knowledgesharing 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.
- 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 Africa conducting activities in the scope of biomanufacturing.
- National or a citizen of an African country
- 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 role.

## **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 or similar authorized official 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 8 September 2023 18:00(KST)

## **Selection process**

The selection process includes the following steps:

- Eligible applications will be reviewed by a Program Steering Committee appointed by KWTRP, composed of KWTRP scientists, an IVI representative, and other stakeholders. IVI will make the final decision on which apprentices to host at their facility.
- When the selection process is completed, the selected participant will be informed by e-mail, upon which the following administrative arrangements will be made.

## **Financial provisions**

The course is free of charge for successful participants. Accommodation, meals, travel, and related travel expenses will be covered.

## **Gender**

IVI and KWTRP 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 [IVILearningPlatform@ivi.int](mailto:IVILearningPlatform@ivi.int)

The receipt of the applications will be automatically acknowledged via return email from [IVILearningPlatform@ivi.int](mailto:IVILearningPlatform@ivi.int). Applicants who do not receive an acknowledgement within the specified time should contact [IVILearningPlatform@ivi.int](mailto:IVILearningPlatform@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: Hands-on Training for Upstream Process Development in Vaccine Manufacturing**

Coordinator	Period	Agenda
Apprentice	Pre-requisite session	Attend online Introductory course for biologics development and manufacturing
IVI (Didactic)	2 weeks (Oct 30-Nov 10)	Discovery and Early Development
		Target Product Profile
		Vaccine development Quality by Design
		Good Laboratory Practices
		Vaccine Upstream Process (USP) development
		Basics of Vaccine Downstream Process (DSP) development
		Analytical methods for characterization and quality evaluation of vaccines
		Key Analytical Assays for evaluation of vaccines by different techniques
		Process Validation
		Pharmaceutical Quality System (PQS)
		Good Manufacturing Practice (GMP)
		Document control and SOP development
		Contamination control and cleanroom behavior
		Technology Transfer
Biosafety		
K-Bio CMO Center (Andong), facilitated by IVI	4 weeks (Nov 13-Dec 08)	<p>Standard Operating Procedure (SOP) practice</p> <ul style="list-style-type: none"> <li>• Culture medium preparation</li> <li>• 1st Seed Cell Culture                             <ul style="list-style-type: none"> <li>- Cell Thawing &amp; Cell counting</li> </ul> </li> <li>• 2nd Seed Cell Culture                             <ul style="list-style-type: none"> <li>- Sub-culture &amp; Cell counting</li> </ul> </li> <li>• 3rd Seed Cell Culture                             <ul style="list-style-type: none"> <li>- Sub-culture &amp; Cell counting</li> </ul> </li> <li>• Main culture (Wave bioreactor) &amp; Cell counting</li> <li>• Virus Infection</li> <li>• Harvest &amp; Clarification                             <ul style="list-style-type: none"> <li>- Freezing &amp; Thawing</li> <li>- Bottle top filter</li> </ul> </li> <li>• In Process Control                             <ul style="list-style-type: none"> <li>- Hexon staining</li> </ul> </li> </ul>
		<p>USP hands-on training</p> <ul style="list-style-type: none"> <li>• Gowning Procedure</li> <li>• Culture medium preparation</li> <li>• Cell Culture                             <ul style="list-style-type: none"> <li>- Cell Thawing &amp; Cell counting</li> <li>- Sub-culture &amp; Cell counting</li> <li>- Wave bioreactor &amp; Cell counting</li> </ul> </li> <li>• Virus Infection</li> <li>• Harvest &amp; Clarification                             <ul style="list-style-type: none"> <li>- Freezing &amp; Thawing</li> <li>- Bottle top filter</li> </ul> </li> <li>• In Process Control                             <ul style="list-style-type: none"> <li>- Hexon staining</li> </ul> </li> </ul>
		<p>Virtual Reality (VR) training (frequently)</p> <ul style="list-style-type: none"> <li>• Gowning Procedure</li> <li>• GMP Facility Tour</li> <li>• GMP Process Training (Upstream Process)</li> </ul>