Global Training Hub for Biomanufacturing (GTH-B): progress and future plans

April. 2023

Ministry of Health and Welfare
Republic of Korea
COVID-19 and Vaccine Equity

COVID-19 vaccine doses administered per 100 people, by income group

All doses, including boosters, are counted individually.

Source: Official data collated by Our World in Data, World Bank
Note: Country income groups are based on the World Bank classification.

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Note: Country income groups are based on the World Bank classification.
WHO, Designated Korea as the Global Training Hub for Biomanufacturing

“Moving forward on goal to boost local pharmaceutical production, WHO establishes ‘Global Biomanufacturing Training Hub’ in Republic of Korea” (2022.2.23, WHO DG)
Korea, serving as the Global Training Hub for LMICs

“By sharing these lessons we’ve learnt from our own experience in the past, we will strive to support the low- and middle-income countries in strengthening their biomanufacturing capabilities so that we could pave the way together towards a safer world during the next pandemic.”

(2022.2.23, Minister of Health and Welfare, Korea)
What is GTH-B (Global Training Hub for Biomanufacturing)?

**Vision**

**Resolving Inequality**
In access to vaccines and biologics worldwide by expanding manufacturing capacity in LMICs

**Mission**

**Training the global workforce**
in high quality manufacturing of biologics

**As-is**

**With WHO,**
- biologics development and manufacturing
- Standard practice

**With ADB,**
- Vaccine manufacturing and processing with hands-on training

**With IDB, (in planning)**
- Standard practice with hands-on training
Training courses in 2022

1. Vaccine Manufacturing Training for Asia Pacific Countries (KOR-ADB)

2. Introductory course for biologics development and manufacturing (KOR-WHO)

3. Introductory course for standard practice (KOR-WHO)

4. On-site Training and Consulting
1 Vaccine Manufacturing Training for Asia Pacific Countries (KOR-ADB)

**Date**
- 1st Batch: 2022. 6. 6 ~ 7.29 (8 weeks)
- 2nd Batch: 2022. 9.26 ~ 11.18 (8 weeks)

**Contents**
Vaccine processing and manufacturing training
- **(Didactic, 3 weeks)**
  Biopharmaceutical basics, Principles of Bioprocesses, Vaccine manufacturing process
- **(Hands-on, 5 weeks)**
  Fermentation, Purification, Finalization, Analysis, Utilities and Packaging

**Participants**
59 trainees from 13 Asian countries

**Funding**
ADB
E-Asia and Knowledge Partnership Fund of Korea

**Operator**
K-NIBRT (Korea- National Institute for Bioprocessing Research and Training)
Vaccine Manufacturing Training for Asia Pacific Countries (KOR-ADB)
PHOTOS

“Vaccine Manufacturing Training for Asia Pacific Countries”

Opening Ceremony

Hands-on training

Lecture

Study Trip
Program Evaluation and Feedback
“Vaccine Manufacturing Training for Asia Pacific Countries”

**Satisfaction Survey**

| Professional knowledge and skills were acquired | 4.6 | 4.7 |
| To improve work performance and provide positive outcome | 4.5 | 4.6 |
| The curriculum was organized appropriately | 4.2 | 4.3 |
| The person was effective and helpful | 4.5 | 4.7 |
| Prior guidance and orientation were appropriate | 4.4 | 4.4 |

**Overall Handson Training:** 4.5 out of 5  
**Overall Didactic Training:** 4.6 out of 5  
⇒ High satisfaction rate for majority of trainees

**Comments from the Participants**

- Training curriculum were well organized, it will improve our knowledge and skill greatly.
- Many great distinguished speakers with invaluable experiences to share, informative details provided on slides.
- The topics are complete and essentials for biologics product manufacturing touching from basics to GMP compliance.
- The course content provided comprehensive information in 8 weeks allotted and delivered the necessary knowledge.
- The knowledge and skills I have learned from the course help strengthen the vaccine manufacturing in my country.
- K-NIBRT people including all professors, assistant and staffs are well educated, skilled and experienced in their own field. They have given their best effort to teach us almost everything needed to build and operate a bio-manufacturing company.
- I, especially, liked the program as it is production oriented and practical: giving us the opportunity to conduct hands-on training to cover all the stage of vaccine manufacturing.
<table>
<thead>
<tr>
<th>Date</th>
<th>2022. 7. 18 ~ 7.29 (2weeks)</th>
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</thead>
<tbody>
<tr>
<td>Contents</td>
<td>Basic knowledge on vaccine development and production, vaccine – related policies, patents, intellectual properties</td>
</tr>
<tr>
<td>Participants</td>
<td>106 trainees from 24 LMICs</td>
</tr>
<tr>
<td>Expenses</td>
<td>Covered by Korea, except traveling costs</td>
</tr>
<tr>
<td>Operator</td>
<td>International Vaccine Institute (IVI)</td>
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</table>
Introductory course for biologics development and manufacturing (KOR-WHO)
PHOTOS

“Introductory course for biologics development and manufacturing”
Overall, how would you rate the contents of the course?

Overall **Average rating: 4.5 out of 5**

⇒ Generally satisfied with the course
⇒ Case study, visit to Korean industry received good feedback

**Comments from the Participants**

- Topics were broad and comprehensive, and the case study was also useful
- Interact with experts in the vaccine field and finally be able to understand the Korea success in the development of vaccines
- Learning new things and meeting amazing people. The cultural experience was very valuable
- Meeting people from diverse disciplines in this field. Learnt number of new things. Coverage of the topics is wide.
- The importance for this program can not be overemphasized especially for us in Africa. Vaccine used is now a gold standard in treatment of disease burden in the world
- Very informative and very updated information from top scientists. I have understood certain concepts that I will use back in my home country Kenya and train others
- Having the chance to attend this training in one of the best training center in the world by prominent scientists
# Introductory course for standard practice (KOR-WHO)

## Date
2022. 10. 31 ~ 11.18 (3 weeks)

## Contents
**Specific knowledge on GxP and Biosafety**
- GLP (Good Laboratory Practice)
- GCP (Good Clinical Practice)
- GMP (Good Manufacturing Practice)
- GCLP (Good Clinical Laboratory Practice)
- BioSafety
- Quality Management Principle

## Participants
151 trainees from 31 LMICs

## Expenses
Covered by Korea, except traveling costs

## Operator
International Vaccine Institute (IVI)
“Introductory course for standard practice”
Program Evaluation and Feedback

“Introductory course for standard practice”

Average Satisfaction Level On Features of GxP Course

- Quality of Lecture Materials: 4.59
- Learnings from Case Studies: 4.54
- Lecturer’s Facilitation: 4.54
- Learnings from Industry Examples: 4.45
- Networking / interactive Sessions: 4.53
- Staff / Coordinators: 4.72
- Accommodation: 4.57
- Good Learning Facilities: 4.61
- Cultural Experiences: 4.44
- Food including Snacks: 4.44
- Overall Satisfaction: 4.54

Overall Average rating: **4.54** out of 5

⇒ Generally satisfied with the course
⇒ All lecture-based features were above average in their satisfaction level

Comments from the Participants

“The training 100% met expectations. It was planned very well: from the organization, to the case studies, to the excellent mentors...in my role in quality management, the training is important and will be crucial in applying to the design of a vaccine manufacturing facility. It is a roadmap on how to start planning.” Tanzania.

“We have learned a lot of good practices and we can incorporate these into our work. The knowledge is invaluable for implementation. We will take the materials, experiences, and practices back, share the knowledge and contribute to management and policy. These will help to improve current systems. The knowledge sharing will be beneficial for both company and country.” Indonesia

“We need new knowledge, new connections, exchange of knowledge, networking with countries, and companies. The interaction with different colleagues, cultures, experts, experiences was vital: in terms of building a facility to manufacture vaccines next year.” Uzbekistan

“I was keen to take part in the closing ceremony to show Tunisia’s commitment to training and technology transfer in the field of biotechnology. Korea, host country of the GTH-B training center, is playing a key role in this domain together with IVI. I am very happy that the Tunisian delegation is among the largest in number in this training and I hope that we will have more participants next year.” Embassy of the Republic of Tunisia in Seoul.
4 On-site Training and Consulting

Customized On-Site Consultation

Customized on-site training based on the need of the targeted manufacturer

Number of Entities

Two companies were consulted in the year of 2022
- Bangladesh (Incepta, Jul. 2022)
- South Africa (Afrigen, Dec. 2022)
- US Pharmacopeia workshop support (South Africa, Dec. 2022)

Areas of training and consulting

Facility readiness, production process, quality management, quality assays, clinical development, regulatory affair, etc.
Future plans

1. 2023 Program Snapshot
2. Establishing Global Bio Campus in Korea as a main training site
3. Strengthening Cooperation with entities including mRNA Tech Hub
## 2023 program snapshot

<table>
<thead>
<tr>
<th>Month</th>
<th>Training for Asia-Pacific Countries</th>
<th>Training for Latin American Countries</th>
<th>Training for biologics development and manufacturing</th>
<th>Training for Standard Practice</th>
<th>On-site training and consulting</th>
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<tbody>
<tr>
<td>May 2023</td>
<td></td>
<td></td>
<td>In person 40 trainees</td>
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<tr>
<td>Jun 2023</td>
<td></td>
<td></td>
<td>In person 20 trainees</td>
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<tr>
<td>Jul 2023</td>
<td></td>
<td></td>
<td>In person 20 trainees</td>
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<td>Aug 2023</td>
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<tr>
<td>Sep 2023</td>
<td>In person 200 trainees</td>
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<tr>
<td>Oct 2023</td>
<td>In person 20 trainees</td>
<td>In person 20 trainees</td>
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<td>Nov 2023</td>
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<tr>
<td>Dec 2023</td>
<td>In person 150 trainees</td>
<td>On-line</td>
<td></td>
<td></td>
<td>Senegal, Kenya, To be decided</td>
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</tbody>
</table>


Establishing Global Bio Campus

World-class Bio Manufacturing Training Facilities of GTH-B

Concept
Main training site for GTH-B

Facilities
Hands-on training facilities, lecture rooms, meeting rooms, and so on.

Curriculum
Comprehensive curriculum on bio-processing of hands-on training, lecture-based training, and training for trainers

Schedule
Deciding location (‘23), setting up facilities (‘24, 1H), Pilot programmes operation (‘24, 2H), Opening ceremony (‘25)
Network Campus

Based on training demands expanding network campus

SEOU L | International Vaccine Institute

SONGDO | K-NIBRT

OSONG | K-BIO

ANDONG | Vaccine CDMO Training Center('25)

HWASUN | Analytical Assay Institution Training Center('26)
Strengthening cooperation

1. Strengthening cooperation with mRNA Tech Transfer Hub and Spokes

   1. Meet the training needs in mRNA Tech Transfer Hub and Spokes
      - Establishing strategic partnership for training
      - Providing tailored training based on stakeholders’ needs

   2. Catalyze cooperation based on Korea’s strength
      - Knowledge-sharing with the Korean government entities including MOHW, KCDA, KFDS, Patent Office
      - Expanding partnership with Korean bio companies holding mRNA related technology and others
Strengthening cooperation

2 Strengthening cooperation with IOs, GOs and NGOs
“The Global Training Hub for Biomanufacturing (GTH-B) can support LMICs to develop and strengthen their biomanufacturing capacity.

The Hub can contribute to resolving vaccine inequality and enhancing global preparedness for future pandemics.”

Thank you