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국제보건기술연구기금

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Request for Proposals 2023

/ TRAINING AWARD
FOR VACCINE MANUFACTURING

Request for Proposals: TA

Training Award for Vaccine Manufacturing

Executive Summary

The COVID-19 pandemic highlighted inequity in access to essential medical countermeasures including vaccines. Among the key factors underlying the inequity in access to vaccines is the concentration of vaccine manufacturing capabilities in the wealthiest nations, which leaves the low- and middle-income countries (LMICs) dependent on others for the supply of vaccines [1]. In response, there is a growing effort globally to support strengthening of regionalized vaccine manufacturing that can enable timely supply of vaccines to stop epidemics when and where they occur [2].

Last year, the government of the Republic of Korea and WHO established a global training hub in biomanufacturing (GTH-B), which will train work force from LMICs in manufacturing vaccines and biologics, including insulin and monoclonal antibodies [3]. As part of the Korea's GTH-B initiative, RIGHT Foundation is launching Training Award, which will be on vaccine manufacturing during this funding call. Through the Training Award, RIGHT Foundation aspires to contribute toward strengthening regionalized vaccine manufacturing by drawing upon Korea's strengths in biomanufacturing.

The goal of the Training Award (TA) is to **train participants from LMICs in vaccine and biomanufacturing knowledge and practical skills**. To achieve this goal, the Training Award will provide funding for 8-week vaccine manufacturing training course to be delivered by the Korea National Institute for Bioprocessing Research and Training (K-NIBRT) in Incheon, Korea. The course content focuses on the foundational principles of vaccine manufacturing involved in major vaccine platforms including mRNA, GMP requirements and quality control.

1. About RIGHT Foundation

The RIGHT Foundation is a Korean non-profit organization supported by the Korean Ministry of Health and Welfare, Korean life science companies, and the Bill & Melinda Gates Foundation. RIGHT Foundation aims to alleviate the burden of infectious diseases that disproportionately affect the people in low and middle-income countries.

2. Overview of Training

Key training objectives

- Enhanced knowledge of biopharmaceutical manufacturing processes
- Practical, hands-on skills in how to operate specialized equipment used in vaccine manufacturing
- Knowledge of Good Manufacturing Practices
- Enhanced knowledge of regulatory process and key aspect of regulatory requirements in general including WHO Prequalification procedure related to biomanufacturing

Duration of training

Eight weeks (On-line: 3 weeks / Off-line: 5 weeks) in May to July 2024

Training institution

Korea National Institute for Bioprocessing Research and Training (K-NIBRT)

K-NIBRT is the premier vaccine industry training institution located at Yonsei University Songdo Campus in the Republic of Korea, and it combines the expertise of government, academia, and industry. K-NIBRT is also equipped with a GMP-compliant public training center for hands-on training through the entire cycle of biopharmaceutical production.

Constructed in 2021, the K-NIBRT facility includes a fermentation room, an animal cell culture room, a purification room, a drug substance room with aseptic techniques of clean system, and the full range of bioprocessing equipment.

Training format

- **Online learning:** All participants will attend the didactic training online (15 days, 3 weeks). The online learning will consist of recorded lectures, followed by an additional one-week period reserved for live Q&A sessions conducted through Zoom meetings.

- **Hands-on training:** Trainees will participate in interactive and hands-on training in groups of up to 10 trainees (25 days, 5 weeks). After the online lectures, the hands-on practical training will be conducted off-line for 5 weeks at the K-NIBRT campus in Incheon, Korea. The 5-week off-line training course runs from Monday to Friday.

Training content

The online learning (didactic) portion of the training aims to provide participants with an understanding of the fundamental principles of manufacturing major vaccine types: inactivated vaccines, live attenuated vaccines, protein subunit vaccines, nanoparticle vaccines, vectored vaccines, mRNA vaccines, and DNA vaccines.

The hands-on training will focus on the capacity necessary for mRNA vaccine production process while it will include most of the processes for other major vaccine types.

Course details are below and available in Appendix 1.

Didactic training	Hands-on training for vaccine bioprocess
• Basics for biopharmaceuticals and bioprocessing • Vaccine manufacturing bioprocessing • Regulatory process for biopharmaceuticals	• Fermentation • Purification • Finalization • Analysis • Utilities and packaging

Assessment of the trainees

- All participants are expected to attend and actively participate in all training sessions, and complete daily quizzes.
- There are no post-training or "homework" assignments. However, depending on participants' backgrounds and knowledge, self-study may be necessary during the course.
- All trainees who successfully complete the training (based on the attendance, quiz performance, participation) will receive a K-NIBRT certification signed by the President of Yonsei University.

3. Eligibility

Applicants must be individuals from LMICs who currently hold positions directly related to vaccine manufacturing, including but not limited to technicians, engineers, scientists, managers in the private or public sectors, and have the potential to serve as trainers in their home countries.

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

- Nationality and Residency: Nationals or citizens of LMICs who reside in an LMIC.
- Educational Background: Hold either an associate's degree from a two-year college or a bachelor's degree from a university in a field related to the biopharmaceutical industry, such as biology, biological science, biochemistry, chemistry, or an equivalent qualification.
- Work Experience: A minimum of five years of work experience in the vaccine and biopharmaceutical industry or equivalent experience in another relevant sector. Intermediate or higher-level experience in vaccine and biomanufacturing processes is considered an asset.

- Relevant Position: Currently holds a position relevant to the training program, such as a technician, engineer, scientist, manager, or another relevant role in biomanufacturing or a related field.
- Employment: Currently employed by a biomanufacturing company or a related institution registered as a legal entity in an LMIC.
- English Proficiency: Proficiency in spoken and written English, sufficient for interactions with English speakers, or equivalent to IELTS score of 4.0-5.0 and a TOEIC score of 550-780.

4. Application Guidelines

- All required documents must be submitted in PDF format on the Grant Management System by **10:00AM KST on January 3, 2024**.
- Only successful applicants will be notified via email.

Required Documents

- Completed application
- **Link to a recorded video** (max. 2 minutes) as part of application which should include:
  - A brief personal introduction and the purpose for applying for the Training Award
- **Curriculum vitae** (CV)
- **Letter of employment** from the employer to verify the current employment status, including the employment start date, current position title, and the name of the unit/department to which the applicant is affiliated.
- **Letter of recommendation** from the applicant's supervisor or another relevant reporting authority, addressing the following points:
  - The applicant's ability to successfully undertake the proposed training and the potential to contribute to the manufacturing capacity at the institution
  - Acknowledgement of the time requirement for the course and a commitment to allow educational leave during the training period for the applicant if selected. (i.e., the applicant's participation in the course will not adversely affect the applicant's employment upon his/her return)
  - The referee's position and relationship to the applicant

5. Evaluation Criteria

- Educational background (relevance, degree, caliber, achievements)
- Professional background (quality, relevance, duration)

- Potential to enhance the training's impact within the home institute, country, and the region

6. Scope of Support

Up to 40 qualified personnel from LMICs will receive the 8-week training by K-NIBRT in May to July 2024 and the course is free of charge. During the offline, hands-on training at K-NIBRT, participants will be accommodated in single rooms at the dormitory on the Songdo Campus of Yonsei University in Incheon, Korea.

The Training Award will be fully covered by the RIGHT Foundation including round-trip airfare to Korea, visa application fees, course fees, accommodation, and meals for the duration of the course.

7. References

[1] Global Vaccine Market Report 2022. 2022, WHO

[2] Expanding sustainable vaccine manufacturing in Africa. Delivered by Gavi and partners in response to a call from the African Union and G7 Development Ministers. 2022, GAVI.

[3] WHO and Republic of Korea sign landmark agreement to boost biomanufacturing capacity May 26, 2023, News release, WHO

Appendix 1. Tentative Course Agenda

Didactic Training for three weeks

Module	Hours	Topic
Basics for biopharmaceuticals and bioprocessing	30	• Introduction to biopharma industry • Biologics regulation • Cell and enzyme • Core technologies of therapeutics • Production of recombinant proteins in prokaryotic hosts • Production of recombinant proteins in eukaryotic cells • Cell growth • How vaccines work • Vaccine registration and international cooperation • GMP for biopharmaceuticals • QC and analysis of biopharmaceuticals
Vaccine manufacturing bioprocessing	30	• Upstream processing; downstream processing • DNA and mRNA vaccines • Vaccine manufacturing process: mRNA and LNP • Aseptic process simulation • Formulation (stability and quality control, quality issues for advanced products) • Lyophilization (freeze-drying, unit operation, cycle development, understanding and monitoring process) • PQ and process validation for vaccine • Vaccine manufacturing process: DP (fill and finish) • Latest trends in biomanufacturing
Regulatory process for biopharmaceuticals	30	• Regulation guidelines of biopharmaceuticals • ICH guidelines • Management of pharmaceuticals in USA and EU • Introduction of GMP in Korea, USA, EU • CMC (Chemistry, Manufacturing and Control) • Safety and efficacy test; clinical test • Approval and international cooperation of biopharmaceuticals • Approval and patent linkage system • Post marketing surveillance of Pharmaceuticals

Hands-on training for five weeks

Module	Hours	Topic
Fermentation	30	• Introduction of gene transformation (chemical- transformation, electro- transformation) • Microbial subculture (liquid, solid media); Transformation (E.coli+plasmid); stock - Media preparation • Equipment preparation (reactor assembly, sensor calibration) • Microbiome assessment • Single use operation • Pilot-scale bioreactor operation (50L) • Harvest preparation • Cell disruption and centrifuge (lab scale, pilot scale)
Purification	30	• Technical background and basic protocols for pDNA purification and in vitro transcription • Chromatography column packing system • Chromatography and TFF with Cytiva • Filter integrity test with MERCK

Finalization	30	• Formulation process development • Basal buffer system, buffer exchange • Protein concentration and quantification • Protein purification and concentration • Protein stability • Lipid preparation for LNPs • Lyophilization process (critical temperature, Lyo- cycle development) and quality evaluation • Lipid nanoparticle (LNP) process: preparation and characterization • Fill and finish • Compatibility with injection device
Analysis	30	• Introduction of compendia method • Microbiological test (Sterility, bioburden) with SARTORIUS • UV/Vis Spectroscopy, HPLC method with DAD, ELSD • TOF- MS Analysis • Capillary electrophoresis • Endotoxin • PCR, Real Time- PCR • Gel Electrophoresis (horizontal) • Image analysis of PCR product • Protein analysis: SDS-PAGE, Gel image analysis
Utilities and packing	30	• Overview of utilities • Utilities facility plant visit 1 (Janssen) • Utilities facility field training 2 • Utilities facility field training 3 • Utilities facility field training 4 • Utilities and hospital visit

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