2022 Introductory Course for biologics development and manufacturing

The 2022 Introductory Course for Biologics Development and Manufacturing is the first training course under the program Global Training Hub for Biomanufacturing (GTH-B), supported by the South Korean Ministry of Health and Welfare (MoHW) and WHO. It focuses on the training of biomanufacturing workforce not only for Korea but for all Low- and Middle-Income Countries (LMICs) interested in the development of biomanufacturing capacity.

The 2-week course is designed as an introductory training course for the bio manufacturing workforce. It includes basic learnings across various fields related to biologics development and manufacturing. The In-Person course also offers a great chance to network with 150+ vaccine and biomanufacturing professionals worldwide.

Course Information (Offline, Seoul South Korea)

- **Course Content:** Basic vaccinology for the biomedical workforce
- **Course Duration:** 10 working days, (2 calendar weeks)
- **Faculty:** Area-specific experts
- **Hours of Training:** 80 hours including case study, networking workshop and excursions.
- **Excursion Sites:** hospital clinical centers, biomedical product development and research sites, manufacturing sites
- **Target Trainees:** 150 trainees from South Korea and LMICs.
- **Certificate of completion:** Certificates will be issued if trainee participation exceeds 90% of the whole training, which will be assessed through exams during the course.

	Jul 18 Mon	Jul 19 Tue	Jul 20 Wed	Jul 21 Thur	Jul 22 Fri
1st	History & Development of Vaccine Technologies - Jerome Kim (IVI)	Types of Different Vaccine Technologies - Dr. Manki Song (IVI)	Vaccine R&D: Discovery to Early Clinical Phase Development Ravi Ganapathi (HL)	Vaccine Process Development - Upstream and Downstream (purification) operations - Ravi Ganapathi (HL)	Case Study
2nd	Innate and Adaptive Immune system -Prof. Yoo Jeong Lee (SNU)	Pre-clinical evaluation of vaccine immunology using small animal model. - faculty TBD	Vaccine Development from Late Phase Clinical stages to Post-Commercialization--> Workflow in manufacturing - Ravi Ganapathi (HL)	Vaccine Process Development - Formulation, Packaging and Analytical Development, and Delivery Systems - Ravi Ganapathi (HL)	
3rd	Immunity to Pathogens & Vaccination - Prof. Kwangseog Ahn (SNU)	Establishment of animal challenge model for evaluation of protective immune response - faculty TBD	Biomarkers and correlates of protection - Dr. Hazel Dockrell (LSHTM)	Standard clinical development pathway for vaccines - Dr. Anh Wartel (IVI)	
4th	Orientation	Vaccine Adjuvants – What, when and why they are needed? - Dr. Nathalie Garcon	Immunogenicity assessment of vaccines in clinical trials - Dr. Jae Seung Yang (IVI)	Clinical trial for vulnerable population (pregnant women) - Dr. Flor Munoz (Baylor University)	Excursion to Sites
5th	Case study	Vaccine adjuvants-development and challenges - Dr. Nathalie Garcon	Case Study	Integrated Product Development Plan for Vaccines - Dr. Sushant Sahastrabuddhe (IVI)	
6th	welcome dinner	Target Product Profile - Dr. Sushant Sahastrabuddhe (IVI)	Laboratory Tour	Clinical development pathway and regulatory approvals by National Regulatory Agencies and WHO faculty TBD	
7th		Tox study - Faculty TBD		Pharmacovigilance system in resource limited settings - Dr. Deok Ryun Kim (IVI)	
8th		Design of the toxicology study - faculty TBD			

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Session	Jul 25 Mon	Jul 26 Tue	Jul 27 Wed	Jul 28 Thur	Jul 29 Fri
1st	IP strategy for biomedical product development and manufacturing - Dr. DongKuk Kang (KIPO)	(1) Basic concepts of intellectual Property in Biomedical Field - Dr. Soo Jung Lee (KIPO)	Basic Statistics for Clinical Research - Dr. Deok Ryun Kim (IVI)	Case Study Presentation	Quality Assay -Dr. Vikam Pabbati (gMRI)
2nd	case study for IP strategy for biomedical product development and manufacturing - Dr. DongKuk Kim (KIPO)	(2) Emerging intellectual property issues on COVID19 mRNA vaccine - Dr. Soo Jung Lee (KIPO)	Introduction to Clinical Data Management - Dr. Deok Ryun Kim (IVI)		CEPI(Coalition for Epidemic Preparedness Innovations) strategy in preparation to DD emerging infectious diseases - faculty TBD (CEPI supported by Jakob
3rd	Product safety monitoring after marketing authorization and guidelines in managing data - Dr. Albin Rouckenooghe (HL)	Adverse event monitoring, and vaccine safety pertaining to COVID-19 Vaccines - Dr Sonali kochhar	Post licensure vaccine safety and Value of post authorization data - Dr. Bikineh Tadesse (IVI)		Clinical development pathway in emergent situation - TBD (CEPI)
4th	Introduction of the ethical committee's role in the vaccine development -Dr. Sonali kochhar	Adverse event monitoring, and vaccine safety pertaining to COVID-19 Vaccines - faculty Sonali kochhar	Health economics Real-based evidence generation - Dr. Jungseok Lee (IVI)	biological standards and control - Faculty (Mark Page)	Vaccine development for neglected tropical disease - Prof. Florian Mark (IVI)
5th	Ethical consideration for clinical development of vaccines - Mr. Hanif Shaikh(IVI)	KGC special lecture - Dr. Kil Jang (KGC)	Health economics -model-based evidence generation - Dr. Jungseok Lee(IVI)	mRNA Vaccine Process - Faculty TBD (K NIBRT) Prof. JH. Jung	Immunology Laboratories in support of Non-clinical Development: Regulatory Requirements, Animal Management and Facility Overview Mr. Yohannes Lemaco (IVI)
6th	Recombinant Protein vaccine - Dr. SH Park	Quality by Design - Dr. SH Park	Epidemiology activities and examples of surveillance study - Dr. Bikineh Tadesse (IVI)	Development of conjugate vaccines for enteric fever - Dr. So Jung An (IVI)	Vaccine effectiveness study - Dr. Bikineh Tadesse (IVI)
7th	Killed Vaccine - Dr. SH Park	Common Technical Document - Dr. SH Park	Why disease burden matters in vaccine development - Dr. Bikineh Tadesse (IVI)	mRNA vaccine research and development in Korea Prof. Kilong Hong (Gachon Univ)	closing ceremony
8th		Industry Presentation & mini convention	Introductory GCP - Dr. Tarun Sekara (IVI)		

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