

2022 Introductory Course for Biologics Development and manufacturing (Online course)

The 2022 Introductory Course for Biologics Development and Manufacturing (Online Course) is a 20-hour online course for vaccine and biomanufacturing professionals who wish to learn from a distance. Compared with the 2022 Introductory Course for Biologics Development and Manufacturing offline course, this course boasts a compact training curriculum with the most essential biologics development topics covered in 20 hours.

Course Information (Online, IVI Online Campus)

- **Course Content:** Basic vaccinology for the biomedical workforce
- **Course Duration:** 5 working days, (1 calendar week)
- **Faculty:** Area-specific experts
- **Hours of Training:** 20 hours online
- **Target Trainees:** Number of trainees unlimited.

Agenda	Mon 26th	Tue 27th	Wed 28th	Thur 29th	Fri 30th
1st Lecture (14:00 ~ 15:00 KST)	Introduction to GMP <i>Dr. Ruchir Pansuriya (IVI)</i>	Types of Vaccines <i>Dr. Jae-Duk Kim (IVI)</i>	Ethical consideration for clinical development of vaccines <i>Dr. Hanif Shalkh(IVI)</i>	Introduction to Good Clinical Practice (GCP) <i>Dr. Tarun Saluja (IVI)</i>	Vaccine Effectiveness Study <i>Dr. Birkenh Tadesse (IVI)</i>
2nd Lecture (15:00 ~ 16:00 KST)	Document control and SOP development <i>Dr. Tobin Guarnacci (IVI)</i>	Immunogenicity assessment of vaccines in clinical trials <i>Dr. Jae Seung Yang (IVI)</i>	Establishment of animal challenge model <i>Dr. Jung-ah Choi (IVI)</i>	Seamless/adaptive study design in vaccine development <i>Dr. Anh Warfel (IVI)</i>	Basic Statistics for Clinical Research <i>Dr. Deok Ryun Kim (IVI)</i>
3rd Lecture (16:00 ~ 17:00 KST)	Pre-clinical Vaccine Development <i>Dr. Raphael Zellweger (IVI)</i>	Regulator's perspective including inspection when reviewing the dossier <i>Dr. Gustavo Santos (IVI)</i>	Preclinical development of conjugate vaccine <i>Dr. So Jung An (IVI)</i>	Toxicology facilities in Support of Biologics Development: Regulatory Requirements, Animal Management and Facility Overview <i>Dr. Tobin Guarnacci (IVI)</i>	Post licensure vaccine safety and Value of post authorization data. <i>Dr. Mohamedou Siribie (IVI)</i>
4th Lecture (17:00 ~ 18:00 KST)	Epidemiology activities and examples of surveillance study <i>Dr. Asma Bintu Aziz (IVI)</i>	Target Product Profile <i>Dr. Sushant Sahastrabudhe (IVI)</i>	Integrated Product Development Plan for Vaccines <i>Dr. Sushant Sahastrabudhe (IVI)</i>	Introduction to Clinical Data Management <i>Dr. Deok Ryun Kim (IVI)</i>	Why disease burden matters in introducing new vaccines <i>Dr. Asma Bintu Aziz (IVI)</i>