Appendix 1. Tentative Course Outline

Pre-online course for approximately 19 hours and in-person course for 120 hours.

Group	Course	Topic	Hours	Remarks
Pre-online course			19	Some areas from in-person course
QA, QC, and GMP		Program overview and introduction	3	Introduction of GxP and Quality Management
GLP	Introduction & Fundamentals of GLP		8	Understanding basic concepts and history of GLP (e.g., as per OECD)
	Resources			Organization, facilities, personnel, equipment needs for GLP
	Characterization			Test items and systems
	Rules for Performing Studies			Protocols, SOPs, etc.
	Results - Raw Data & Collection			Raw data, final reporting, archival, etc.
	Quality Assurance			Independent monitoring of research processes and outcomes
	Stepwise Implementation			Planning, structuring and implementing GLP and its maintenance in an organization
GMP	Module 1	Introduction of GMP	16	Understanding basic concepts of GMP and its importance for vaccines mfg.
		Building design and construction		Understanding the location, design, construction, maintenance, and operations appropriate for the stage of manufacture and the product
		Sanitary facilities and control		Requirements for water system, containment facilities, waste disposal, cleaning-sanitation & maintenance, etc.
		Equipment and utensils		Understanding the equipment need, size, capacity, calibration/maintenance/ cleaning needs, automation systems, etc.
	Module 2	Personal Hygiene	24	Concepts of clothing, personal hygiene practices/monitoring, health status/ monitoring, etc.
		Product and Process control		Sampling/testing needs identification, methods evaluation, control limits, procedural controls, etc.
		Raw Material, Ingredients and Storage		Identification of raw material sources, quality parameters, vendor evaluation/ selection, evaluation/management of supply risks, storage facilities needed for inventory control, etc.
		Personnel Training and Competency		Personnel requirements, right selection of personnel for meeting the needs, identification of training needs and their periodicity, etc.
	Module 3	Risk Management	12	Overall risk assessment/management practices and their importance while designing facilities, processes, etc. and ICH-Q9 (Quality RM) concepts
		Management Commitment and Continual Improvement		Importance of commitment of the organization's management to quality aspects and continual improvement of quality, productivity, etc.
		Holding and Distribution		Storage requirements for different product stages, their distribution practices, records maintenance, etc.
		Pest Control		Control/management of pests in/around facilities
		Self-inspection		Need for self-inspection/quality audits, guideline requirements, different types of SI, etc.
	GDP	Documentation and Records	4	Good practices to be followed while recording operations before/during/after execution, guideline requirements for maintenance of records, etc.

GCP		Good Clinical Practice	4	GCP guidelines
		Test for certificate	2	online test for GCP certificate
GCLP and Biorepository		GCLP guideline	2	What is GCLP and why it is needed
		GCLP premise and equipment		Tour of IVI GCLP
		Biorepository guideline	2	Basic guidelines and systems in handling bio-samples
		Biorepository system and equipment		Tour of IVI Biorepository
Biosafety	Overview	Principles of Biosafety	2	From the principles, guideline and hands-on training
		Biohazard risk assessment	2	
	Practice	Biosafety Program	1	
		Biosecurity into Biorisk Management	1	
		Biological Materials & Biological Waste Management	2	
		Biosafety Facility & Equipment	2	
		Personal protective equipment	3	
		Emergency Response	3	
Exam		Test (MCQ) / SOP group work	3	
Excursion		Minimum three times	24	e.g., one GCP site, 1~2 GMP sites, KDCA or KMFDS
Total			120	