Module1: Introduction					Time	
Day 1					**14-Oct-15**	
Recognize the concept needs of PRD in medical and global view of health	Welcome address		0.25	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	13:00-13:45	D1−1
	Objective of the course and expectation, Pre-test	Lecture	0.25		13:45-14:00	D1−2
	Overview of product research and development and stakeholders	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:00-15:00	D1−3
	Key medical and public health issues, and the need for new products	Lecture	1.00	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	15:00-16:00	D1−4
Day 2					**15-Oct-15**	
Module 2: Drug Discovery and Development						
Session 1: Discovery Phase						
Describe the pharmacological process for drug discovery. Identify the process to protect intellectual property	History and overview of drug discovery process	Lecture	0.50	Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan	09:00-09:30	D2−1
	The role of Genomics and bioinformatics	Lecture	0.50		09:30-10:00	D2−2
	High throughput screening: Pre-requisite of HITS systems, Assay Development & Validation, Biochemical & Cell-based assay, Assay Readout & Detection	Lecture	0.50		10:00-10:30	D2−3
	The role of Chemistry in Drug Discovery: -Lead Identification, -Lead Generation Libraries (Combinatiorial Chemistry, Computational Approches), -Lead Optimization	Lecture	0.75		10:30-11:15	D2−4
	Pharmacokinetic Issues in Drug Discovery: - Designs and Purposes of DMPK Profiles of Lead & Drug Candidates - DMPK studies in Drug Discovery (Late lead identification & Early lead optimization, Mid lead optimization, Late lead optimization) - Prediction of DMPK and PKPD Correlation - Prediction of Toxicity	Lecture	0.75		11:15-12:00	D2−5
	Lunch					
Session 2: Pre-clinical Development						
	Patents in Drug Discovery: - Publication VS Patents - Patent system - Type of Patent	Lecture	1.00	Professor Dr. Hiroshi Kato, Nihon University, Japan	13:00-14:00	D2−6
	The role of Pharmacology - Pharmacological Evaluations (Selectivity screening, Pharmacological profiling, Testing in animal models of disease, Safety pharmacology) - Examples	Lecture	0.75	TBA	14:00-14:45	D2−7
Session 3: Traditional Medicine						

Underline the importance of traditional medicine in PRD	Introduction of Traditional Medicine and guidance on herbal medicines	Lecture	0.75	Professor Dr. Kiichiro Tsutani, The University of Tokyo, Japan	14:45-15:30	D2−8
	Regulation for traditional medicine development	Lecture	0.75	Dr. Ichiro Arai, Tsumura & Co., Japan	15:30-16:15	D2−9
	Pharmaceutical Development and CMC	Lecture	1.00	Professor Dr. Hiroshi Sasaki, Nagasaki University, Japan	16:15-17:15	D2−10
Day3					**16-Oct-15**	
Describe the process of pharmacological development	Overview: Pre-clinical study requiments for human clinical studies	Lecture	0.50	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	09:00-09:30	D3−1
	Assessing of Drug Safety: the role of toxicology - Objective and Type of Toxicology - Exploratory Toxicology - Regulatory Toxicology - Toxicity Measures and Toxicity Test	Lecture	1.00	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	09:30-10:30	D3−2
	Pharmacokinetics	Lecture	1.00	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	10:30-11:30	D3−3
Session 4: Clinical Development						
	Overview of clinical development	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	11:30-12:00	D3−4
	Lunch					
	Regulatory Framework	Lecture	1.00	Dr. Mai Mikawa, Coordination Division Office of Planning and Coordination Pharmaceuticals and Medical Devices Agency	13:00-14:00	D3−5
	Investigational Phases of Clinical Research (I-IV) and Study Design	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:00-14:30	D3−6
	Clinical Development Plan	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:30-15:00	D3−7
	Exercise	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	15:00-16:30	D3−8
Day4					**17-Oct-15**	
	Pharmacogenomics - Anticipated Benefits - Polymorphisms in Drug Targets - Polymorphisms in ADME - Pharmacogenomics Testing - Pharmacogenomics in Clinical Trials - Examples	Lecture	1.50	Dr.Shyh-Yuh Liou, Ono Pharmaceutical Company Limited Head Office, Japan	09:00-10:30	D4−1
	Pharmacokinetics in Clinical Development - Extrapolation from animal to human pharmacokinetics	Lecture	0.50		10:30-11:00	D4−2

	Biopharmaceuticals - Development of Biopharmaceuticals - Type of Biopharmaceuticals - Issues Related to the use of Biopharmaceuticals (Antigenicity, Stability, Drug delivery)	Lecture	0.75	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	11:00-12:00	D4−3
	Lunch					
	Drug Discovery in Academia	Lecture	0.75	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	13:00-14:00	D4−4
	Rev and Exam 1 (Module 2)		0.75	Profeesor Dr. Hirayama or Professor Dr. Kesara	14:00-14:45	D4−5
Module 3: Vaccine Development						
Session 1: Discovery						
Describe the principles of basic immunology. Describe the process of vaccine discovery	Historical overview of vaccine Discovery	Lecture	0.50	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	15:00-15:30	D4−6
	Vaccines for infection control	Lecture	1.00		15:30-16:30	D4−7
Day5					**18-Oct-15**	
Describe the principles of basic immunology. Describe the process of vaccine discovery	Vaccine Platform Technology and Adjuvant Development (Dr.Arakawa)	Lecture	1.00	Dr. Takeshi Arakawa, University of the Ryukyus, Japan	09:00-10:00	D5−1
Session 2: Pre-Clinical Development						
Describe the process of pre-clinical development of vaccine	CMC	Lecture	0.50	Dr. Takeshi Arakawa, University of the Ryukyus, Japan	10:00-10:30	D5−2
	Immunogenicity and protect activity assessment	Lecture	0.50		10:30-11:00	D5−3
	Safety assessment:Toxicity test in animals: regional complications, systemic toxicity	Lecture	0.75		11:00-11:45	D5−4
	Lunch					
Session3:Clinical Development						
Describe the process of vaccine clinical development	Assessment of pre-clinical information	Lecture	1.00	Dr.daisuke tsuzuki	13:00-14:00	D5−5
	Clinical development plan	Lecture	0.50		14:00-14:30	D5−6
	Dose selection and regimen	Lecture	1.00		14:30-15:30	D5−7
	Case studies		1.00	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	15:30-16:30	D5−8
	Rev and Exam 3 (Module 3)		1.00	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	16:30-17:30	D5−9

Day6					**19-Oct-15**	
	Field Trip to Hisamitsu Pharmaceutical Co.,Inc		site visit	Mr.Hideyuki Nakano,Hisamitsu Pharmaceutical Co.,Inc	10:00-17:00	
Day7					**20-Oct-15**	
Module4: Diagnostic Development						
Describe the process of discovery and development of diagnostic tools	Discovery and development of diagnostic tools	Lecture	0.50	Dr. Masato Sasaki, QIAGEN, Japan	09:00-09:30	D7−1
	Prototype production and assessment	Lecture	0.50		09:30-10:00	D7−2
	Scale-up, manufacture and control	Lecture	0.50		10:00-10:30	D7−3
	Development of kits	Lecture	0.50		10:30-11:00	D7−4
	Quality assurance/quality control: evaluation of efficacy after application	Lecture	0.50		11:00-11:30	D7−5
	Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial	Lecture	0.50		11:30-12:00	D7−6
	Clinical development: Supply chain logistics and production, Statistical	Lecture	0.50		12:00-12:30	D7−7
	Lunch					
	Rev and Exam 4 (Module 4)		0.50	Professor Dr. Kenji Hirayama and Professor Dr.Kesara Na-Bangchang	13:30-14:00	D7−8
Module5： Good Clinical Practice						
Discribe the concepts of GCP, Recognise the principles of Ethics in research and the functions of Ethics Committee	Concept of Good Clinical Practice	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:00-14:30	D7−9
	Principles of Research Ethics and Ethics codes and Guidance	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:30-15:00	D7−10
	Responsibilities: Sponsor, Monitors, audit, DSMB	Lecture	1.00	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	15:00-15:30	D7−11
	Responsibilities of EC	Lecture	0.75	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	15:30-16:00	D7−12
Day8					**21-Oct-15**	
Module6: Date Management Process						
Discribe the concepts of GCP, Recognise the principles of Ethics in research and the functions of Ethics Committee	Data Management Process	Lecture	0.50	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	09:00-09:30	D8−1
	Case studies	Group Work	2.00	Professor Juntra Karbwang, Nagasaki University, Japan Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	09:30-11:30	D8−2

	Exam		0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	11:30-12:00	D8−3
	Lunch					
Module 7: Post-registration Activities						
Describe post-registration activities for medicinal products	Overview	Lecture	0.75	Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand	13:00-13:45	D8−4
	How to solve Access to Medicines (ATM) problems in developing countries	Lecture/Discussion	0.50		13:45-15:15	D8−5
	Improving the quality of new products in health systems: International network of rational use of drugs	Lecture	1.00		15:15-16:00	D8−6
Day 9					**22-Oct-15**	
Describe post-registration activities for medicinal products	Post-marketing product vigilance	Lecture	1.00	Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand	09:00-10:00	D9−1
	Stakeholders to be involved in making product development work for the intended beneficiaries	Lecture/Discussion	1.00		10:00-11:00	D9−2
	Rev and Exam 2 (Module 7)		0.50	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	11:00-12:00	D9−3
FINAL EVALUATION. COURSE ASSESSMENT				Professor Dr. Kenji Hirayama, Nagasaki University, Japan Professor Dr. Juntra Karbwang, Nagasaki University, Japan, Course Director	13:00-15:00	
CLOSING CEREMONY					15:00-16:00	