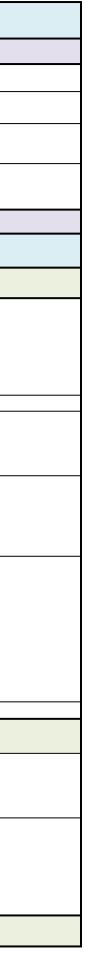
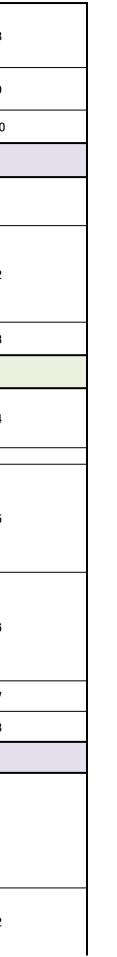
	Module1: Intro	duction			Time	
Day 1					14-Oct-15	
Recognize the concept needs of PRD in	Welcome address		0.25	Professor Dr. Kenji Hirayama, Nagasaki	13:00-13:45	D1-1
	Objective of the course and expectation, Pre-test	Lecture	0.25	University, Japan	13:45-14:00	D1-2
	Overview of product research and 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	
		Mod	ule 2: Dr	ug Discovery and Development		
			Sess	ion 1: Discovery Phase		
	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
Describe the	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
pharmacological process for drug discovery. Identify the process to protect intellectual property	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					
	Patents in Drug Discovery: - Publication VS Patents - Patent system - Type of Patent	Lecture	1.00	Session 2: Pre-clinical Developmen Professor Dr. Hiroshi Kato, Nihon University, Japan	t 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	ТВА	14:00-14:45	D2-7
	Sessi	on 3: Tradit	tional Me	edicine		



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	
	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
Describe the process of pharmacological development	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
		L	Sessio	n 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	a 3: Vaccine Development		
			S	ession 1: Discovery		
Describe the principles of basic immunology. Describe the process	Historical overview of vaccine Discovery	Lecture	0.50	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	15:00-15:30	D4-6
of vaccine discovery	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
		S	Session 2	2: Pre-Clinical Development		
Describe the process	СМС	Lecture	0.50	Dr. Takeshi Arakawa, University of the Ryukyus, Japan	10:00-10:30	D5-2
of pre-clinical development of	Immunogenicity and protect activity assessment	Lecture	0.50		10:30-11:00	D5-3
vaccine	Safety assessment:Toxicity test in animals: regional complications, systemic toxicity	Lecture	0.75		11:00-11:45	D5-4
	Lunch					
			Sessio	n3: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	l: Diagnostic Development		
	Discovery and development of diagnostic tools	Lecture	0.50		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
Describe the process of discovery and	Development of kits	Lecture	0.50		10:30-11:00	D7-4
development of diagnostic tools	Quality assurance/quality control: evaluation of efficacy after application	Lecture	0.50	Dr. Masato Sasaki, QIAGEN, Japan	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
	Mod	ule5: Goo	d Clinica	al Practice		
Discribe the concepts	Concept of Good Clinical Practice	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:00-14:30	D7-9
of GCP, Recognise the principles of Ethics in research and the	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
functions of Ethics Committee	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	
		Ν	lodule6:	Date Management Process		
	Data Management Process	Lecture	0.50	Professor Dr. Kesara Na-Bangchang,	09:00-09:30	D8-1
Discribe the concepts of GCP, Recognise the			Thammasat University, Thailand		22.	
		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-regist	ration Activi	ties			
	Overview	Lecture	0.75		13:00-13:45	D8-4
	How to solve Access to Medicines (ATM) problems in developing countries	Lecture/Dis cussion	0.50	 Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand 	13:45-15:15	D8-5
for medicinal products	Improving the quality of new products in health systems: International network of rational use of drugs	Lecture	1.00	University, Bangkok, Thananu	15:15-16:00	D8-6
Day 9					22-Oct-15	
Describe post-	Post-marketing product vigilance	Lecture	1.00	Professor Chitr Sitthi-amorn, Chulalongkorn	09:00-10:00	D9-1
registration activities	Stakeholders to be involved in making product development work for the intended beneficiaries	Lecture/Dis cussion	1.00	University, Bangkok, Thailand	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 CEF	15:00-16:00				

