

The Diploma Course on Research & Development of Products to meet Public Health Needs

Day 1					20-Aug-18	
Module1: Introduction					Time	
Recognize the concept needs of PRD in medical and global view of health	Welcome address		0.25	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	09:00-09:15	D1-1
	Objective of the course and expectation, Pre-test	Lecture	0.25		09:15-09:30	D1-2
	Overview of product research and development and stakeholders	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	09:30-10:30	D1-3
	Break				1030:-10:45	
	Key medical and public health issues, and the need for new products	Lecture	1.00	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	10:45-11:45	D1-4
Lunch					11:45-13:00	
Module 2: Drug Discovery and Development						
Session 1: Discovery						
Describe the pharmacological process for drug discovery. Identify the process to protect intellectual property	History and overview of drug discovery process	Lecture	2.50	Professor Dr.Yoshimasa Tanaka, Nagasaki University, Japan	13:00-15:30	D1-5
	The role of Genomics and bioinformatics					D1-6
	High throughput screening: Pre-requisite of HITS systems, Assay Development & Validation, Biochemical & Cell-based assay, Assay Readout & Detection					D1-7
	The role of Chemistry in Drug Discovery: -Lead Identification, -Lead Generation Libraries (Combinatorial Chemistry, Computational Approaches), -Lead Optimization					D1-8
Break					15:30-15:45	
	Drug Discovery in Academia 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) - Examples	Lecture	1.25	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	15:45-17:00	D1-9
Day 2					21-Aug-18	

	The role of Pharmacology - Pharmacological Evaluations (Selectivity screening, Pharmacological profiling, Testing in animal models of disease, Safety pharmacology) - Examples	Lecture	0.75	Professor Dr.Yoshimasa Tanaka, Nagasaki University, Japan	09:00-09:45	D2-1
Session 2 : Pre-clinical Development						
Describe the process of pharmacological development	Overview: Pre-clinical study requirements for human clinical studies	Lecture	0.50	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	09:45-10:15	D2-2
	Assessing of Drug Safety: the role of toxicology - Objective and Type of Toxicology - Exploratory Toxicology - Regulatory Toxicology - Toxicity Measures and Toxicity Test	Lecture	0.75	Assit Prof. Supatra Porasuphatana, Khon Kaen University, Thailand	10:15-11:00	D2-3
Break					11:00-11:15	
	Pharmaceutical Development and CMC	Lecture	1.00	Professor Dr. Hitoshi Sasaki, Nagasaki University, Japan	11:15-12:15	D2-4
Lunch					12:15-13:15	
	Patents in Drug Discovery: - Publication VS Patents - Patent system - Type of Patent	Lecture	1.00	Professor Dr. Hiroshi Kato, Nihon University, Japan	13:15-14:15	D2-6
Session 3: Clinical Development						
	Overview of clinical development	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:15-15:15	D2-7
Break					15:15-15:30	
	Regulatory Framework	Lecture	1.00	Dr. Hiroshi Yamamoto Nagasaki University, Japan	15:30-16:30	D2-8
Day3					22-Aug-18	
	Investigational Phases of Clinical Research (I-IV) and Study Design	Lecture	0.50	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	09:00-09:30	D3-1
	Clinical Development Plan	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	09:30-10:30	D3-2
Break					10:30-10:45	
	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	10:45-12:15	D3-3
Lunch					12:15-13:00	
	Pharmacokinetics (Non-clinical & Clinical)	Lecture	1.25	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	13:00-14:15	D3-4
Break					14:15-14:30	
	Case studies - Group Exercise	Group Work	2.50	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	14:30-16:30	D3-5
	Biopharmaceuticals	Lecture	0.50	Assit Prof. Supatra Porasuphatana, Khon Kaen University, Thailand	16:30-17:00	D3-6

Day4					23-Aug-18	
Session 4 : Traditional Medicine						
Underline the importance of traditional medicine in PRD	Introduction of Traditional Medicine and guidance on herbal medicines	Lecture	1.00	Professor Dr. Kiichiro Tsutani, Tokyo Ariake university of medical and health ,Japan	09:00-10:00	D4-1
	Regulation for traditional medicine development	Lecture	1.00	Professor Dr. Ichiro Arai, Nihon Pharmaceutical University, Japan	10:00-11:00	D4-2
	Rev and Exam 2 (Module 2)		1.00	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	11:00-12:00	D4-3
Lunch					12:00-13:00	
Module 5: 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	13:00-13:30	D4-4
	Principles of Research Ethics and Ethics codes and Guidance	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	13:30-14:30	D4-5
	Break				14:30-14:45	
	Responsibilities: Sponsor, Monitors, audit, DSMP	Lecture	1.00	Professor Dr. Juntra Karbwang, Nagasaki University, Japan	14:45-15:45	D4-6
	Clinical Data Management	Lecture	0.75	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	15:45-16:30	D4-7
	Exam 3 Module 4		0.50	Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand	16:30-17:00	D4-8
Day5					24-Aug-18	
Module 3: Vaccine Discovery and Development						
Session 1: Discovery						
Describe the principles of basic immunology. Describe the process of vaccine discovery	Historical overview of vaccine Discovery	Lecture	0.50	Assistant Professor Dr. Shusaku Mizukami, Nagasaki University, Japan	09:00-09:30	D5-1
	Vaccines for infection control	Lecture	1.00		09:30-10:30	D5-2
Session 2: Pre-Clinical Development						
Describe the principles of basic immunology. Describe the process of vaccine discovery	Vaccine Platform Technology and Adjuvant Development	Lecture	1.00	Professor Dr. Takeshi Arakawa, University of the Ryukyu, Japan	10:30-11:30	D5-3
Describe the process of pre-clinical development of vaccine	CMC	Lecture	0.50	Professor Dr. Takeshi Arakawa, University of the Ryukyu, Japan	11:30-12:00	D5-4
	Lunch				12:00-13:00	
	Immunogenicity and protect activity assessment	Lecture	1.00		13:00-14:00	D5-5
	Break				14:00-14:30	
	Safety assessment:Toxicity test in animals: regional complications, systemic toxicity	Lecture	1.50		14:30-16:00	D5-6
Day6					27-Aug-18	
Session 3: Clinical Development						
Describe the process of vaccine clinical development	Assessment of pre-clinical information	Lecture	1.00	Dr.Daisuke Tsuzuki	09:00-10:00	D6-1
	Clinical development plan	Lecture	0.50		10:00-10:30	D6-2
	Dose selection and regimen	Lecture	1.00		10:30-11:30	D6-3
	Rev and Exam 4 (Module 3)		1.00	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	11:30-12:30	D6-4
Lunch					12:30-13:30	
Visit Immunology lab			Assistant Professor Dr. Shusaku Mizukami and Dr. Shym Dumre, Nagasaki University, Japan		13:30-16:00	D6-5
Day7					28-Aug-18	

Field Trip to Hisamitsu Pharmaceutical Co.,Inc				site visit	Mr,Hisashi Yamada,Hisamitsu Pharmaceutical Co.,Inc	10:00-17:30	D7
Day8						29-Aug-18	
Module 4: Diagnostic Development							
Describe the process of discovery and development of diagnostic tools	Development of molecular diagnostic tests for emerging infectious diseases.			Assistant Professor Dr,Yohei Kurosaki, Nagasaki University, Japan		9:00-10:00	D8-1-7
	Development of diagnostic tests for arbovirus.			Associate Professor Dr,Shingo Inoue, Nagasaki University, Japan		10:00-12:00	
	Rev and Exam 5 (Module 4)		1.00	Professor Dr. Kenji Hirayama and Professor Dr.Kesara Na-Bangchang		14:00-15:00	D8-8
Day 9						30-Aug-18	
Module 6: Post-registration Activities							
Describe post-registration activities for medicinal products	Overview	Lecture	0.75	Professor Dr, Chitr Sitthi-amorn, Chulalongkorn University, Thailand		09:00-09:45	D9-1
	How to solve Access to Medicines (ATM) problems in developing countries	Lecture/Discussion	0.50			09:45-10:15	D9-2
	Improving the quality of new products in health systems: International network of rational use of drugs	Lecture	1.00			10:15-11:15	D9-3
	Post-marketing product vigilance	Lecture	1.00			11:15-12:15	D9-4
	Lunch					12:15-13:00	
	Stakeholders to be involved in making product development work for the intended beneficiaries	Lecture/Discussion	1.00			13:00-14:00	D9-5
	Rev and Exam 6 (Module 6)		0.50	Professor Dr. Kenji Hirayama, Nagasaki University, Japan	14:00-14:30	D9-6	
Day 10						31-Aug-18	
FINAL EVALUATION. COURSE ASSESSMENT				Professor Dr. Kenji Hirayama, Nagasaki University, Japan		09:00-11:00	D10-1
				Professor Dr. Juntra Karbwang, Nagasaki University, Japan, Course Director			
CLOSING CEREMONY						11:00-12:00	D10-2