

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

Organized by

Nagasaki University, Japan and

Faculty of Allied Health Sciences, Thammasat University, Thailand

in cooperation with

Graduate School of Pharmaceutical Science, The University of Tokyo, Japan,

Chulalongkorn University, Thailand,

China Second Military Medical University, China,

Universidad de Antioquia, Colombia

Supported by

Nagasaki University Global COE Program

29 October – 10 November, 2012

Objective: To provide basic knowledge and skills of the different steps in the whole process of PRD to research scientists, post-graduate students, medical doctors involved in PRD, regulatory authorities, professionals.

Output: At the end of the course, the participants will be able to: 1. Describe the development activities related in the PRD process. 2. Integrate the various components needed for PRD and 3. Disseminate the knowledge to other scientists and institutions working in any aspect of PRD in order to work together

Outcome: Increase research activity on PRD in DEC (Disease Endemic Countries) institutions

Participants: Research scientists, post-graduate students, medical doctors involved in PRD, regulatory authorities, professionals.

Research scientists/Professionals:

- (1) Diploma degree in science
- (2) Involved as a member of the team in any aspect of PRD
- (3) Good track record- work ethics and ability to work as a team/recommendation letter from supervisor
- (4) Conversant in English

Post-graduate students:

- (1) Accepted in the post-graduate program
- (2) Good track record- work ethics and ability to work as a team/recommendation letter from supervisor
- (3) Conversant in English

Medical doctors:

- (1) Degree in medicine
- (2) Involved as a member of the team in any aspect of PRD
- (3) Good track record- work ethics and ability to work as a team/recommendation letter from supervisor
- (4) Conversant in English

Regulatory authorities:

- (1) Diploma degree
- (2) Member of the regulatory in the country
- (3) Good track record- work ethics and ability to work as a team/recommendation letter from supervisor
- (4) Conversant in English

Course Language: English

Course format: This is 12 days course consisting of lectures, open discussions, group activity, site visit and practical exercises on specific activities.

Course Directors :

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Venue:

*Seminar Room No. 125, Institute of Tropical Medicine (NEKKEN), Nagasaki University
(Sakamoto Campus)*

Registration deadline: 15 October, 2012

(We also accept onsite registration however registration kit materials are not guaranteed)

Administration Office

For Oversea participants: the information should be sent to

Ms. Ikumi Frizt

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Module 1: Introduction

Recognize the concept needs of PRD in medical and global view of health

October 29, Monday (Day 1)

09:30-09:45	Welcome address <i>Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN), Nagasaki University, Japan</i>
09:45-10:00	Objective of the course and expectation, Pre-test <i>Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN), Nagasaki University, Japan</i>
10:00-10:15	Break
10:15-11:15	Overview of product research and development and stakeholders <i>Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan</i>
11:15-12:15	Key medical and public health issues, and the need for new products <i>Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan</i>
12:15-14:00	Lunch

Module 2: Drug Discovery and Development

Session 1: Discovery Phase

Describe the pharmacological process for drug discovery. Identify the process to protect intellectual property.

14:00-14:30	History and overview of drug discovery process <i>Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan</i>
14:30-15:00	The role of Genomics and bioinformatics <i>Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan</i>
15:00-15:30	High throughput screening: Pre-requisite of HITS systems, Assay Development & Validation, Biochemical & Cell-based assay, Assay Readout & Detection <i>Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan</i>
15:30-15:45	Break

- 15:45-16:15 The role of Chemistry in Drug Discovery:-Lead Identification,
-Lead Generation Libraries (Combinatorial Chemistry,
Computational Approches), -Lead Optimization
Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan
- 16:15-16:45 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
Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan

October 30, Tuesday (Day 2)

- 09:00-09:45 The role of Pharmacology
- Pharmacological Evaluations (Selectivity screening,
Pharmacological profiling, Testing in animal models of disease,
Safety pharmacology)
- Examples
Professor Dr. Hiroshi Ueda, Nagasaki University, Japan
- 09:45-10:15 Biopharmaceuticals
- Development of Biopharmaceuticals
- Type of Biopharmaceuticals
- Issues Related to the use of Biopharmaceuticals (Antigenicity,
Stability, Drug delivery)
Dr. Hiroyuki Itoh, Astellas Pharma Inc., Japan
- 10:15-10:30 Break
- 10:30-11:30 Drug Discovery in Academia
Professor Dr. Takayoshi Okabe, University of Tokyo, Japan
- 11:30-12:30 Patents in Drug Discovery:
- Publication VS Patents
- Patent system
- Type of Patent
Professor Dr. Hiroshi Kato, Nihon University, Japan

12:30-13:30 Lunch

Session 2: Pre-clinical Development

Describe the process of pharmacological development

13:30-14:00 Overview: Pre-clinical study requirements for human clinical studies

Dr. Hiroyuki Itoh, Astellas Pharma Inc. Japan

14:00-15:00 Assessing of Drug Safety: the role of toxicology

- Objective and Type of Toxicology

- Exploratory Toxicology

- Regulatory Toxicology

- Toxicity Measures and Toxicity Test

Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

15:00-15:15 Break

15:15-16:15 Pharmacokinetics

Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

16:15-17:15 Pharmaceutical Development and CMC

Professor Dr. Hitoshi Sasaki, Nagasaki University Hospital, Japan

October 31, Wednesday (Day 3)

Session 3: Clinical Development

09:00-09:30 Overview of clinical development

Dr. Hanako Mihara, Abbott Diagnostics. Co., Ltd., Japan

09:30-11:00 Investigational Phases of Clinical Research (I-IV) and Study Design

Dr. Hanako Mihara, Abbott Diagnostics. Co., Ltd., Japan

11:00-11:15 Break

11:15-12:15 Regulatory Framework

Dr. Shimokawa Masafumi, Coordination Division Office of Planning and Coordination Pharmaceuticals and Medical

Devices Agency

12:15-13:30	Lunch
13:30-14:00	Clinical Development Plan <i>Dr. Hanako Mihara, Abbott Diagnostics. Co., Ltd., Japan</i>
14:00-14:30	Pharmacogenomics - Anticipated Benefits - Polymorphisms in Drug Targets - Polymorphisms in ADME - Pharmacogenomics Testing - Pharmacogenomics in Clinical Trials - Examples <i>Dr. Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan</i>
14:30-15:00	Pharmacokinetics in Clinical Development Extrapolation from animal to human pharmacokinetics <i>Dr. Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan</i>
15:00-15:15	Break

Session 4: Traditional Medicine

Underline the importance of traditional medicine in PRD

15:15-15:45	Introduction of Traditional Medicine <i>Professor Dr. Kiichiro Tsutani, The University of Tokyo, Japan</i>
15:45-16:30	Regulation for traditional medicine development <i>Dr. Ichiro Arai, Tsumura & Co., Japan</i>
16:30-17:00	Guidance on herbal medicine Professor Dr. Kiichiro Tsutani, The University of Tokyo, Japan
17:00-17:45	Rev and Exam 1 (Module 2) <i>Professor Dr. Hirayama or Professor Dr. Kesara</i>

November 1, Thursday (Day 4)

10:00-17:00	Field Trip to Hisamitsu Pharmaceutical Co., Inc Mr. Hiroyuki Hidaka, Hisamitsu Pharmaceutical Co., Inc
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Module 3: Vaccine Development

November 2, Friday (Day 5)

Session 1: Discovery

Describe the principles of basic immunology. Describe the process of vaccine discovery

09:00-09:30	Historical overview of vaccine Discovery <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>
09:30-10:30	Vaccines for infection control <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>
10:30-10:45	Break
10:45-12:15	Vaccines for infection control <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>
12:15-13:30	Lunch
13:30-14:30	Vaccine Platform Technology and Adjuvant Development (Dr.Arakawa) <i>Dr. Takeshi Arakawa, University of the Ryukyus, Japan</i>

Session 2: Pre-Clinical Development

Describe the process of pre-clinical development of vaccine

14:30-15:00	CMC <i>Dr. Takeshi Arakawa, University of the Ryukyus, Japan</i>
15:00-15:15	Break
15:15-15:45	Immunogenicity and protect activity assessment <i>Dr. Takeshi Arakawa, University of the Ryukyus, Japan</i>
15:45-16:30	Safety assessment: Toxicity test in animals: regional complications, systemic toxicity <i>Dr. Takeshi Arakawa, University of the Ryukyus, Japan</i>

Module 4: Diagnostic Development

November 5, Monday (Day 6)

Describe the process of discovery and development of diagnostic tools

09:00-10:00	Discovery and development of diagnostic tools <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
10:00-10:30	Prototype production and assessment <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
10:30-10:45	Break
10:45-11:45	Scale-up, manufacture and control <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
11:45-12:30	Development of kits <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
12:30-13:45	Lunch
13:45-14:45	Quality assurance/quality control: evaluation of efficacy after application <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
14:45-15:45	Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
15:45-16:00	Break
16:00-16:30	Clinical development: Supply chain logistics and production, Statistical <i>Dr. Masato Sasaki, QIAGEN, Japan</i>
16:30-17:00	Rev and Exam 4 (Module 4) <i>Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang</i>

Module 3: Vaccine Development

November 6, Tuesday (Day 7)

Session 3: Clinical Development

Describe the process of vaccine clinical development

09:00-10:00	Assessment of pre-clinical information <i>Dr.Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan</i>
10:00-10:30	Clinical development plan <i>Dr.Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan</i>
10:30-10:45	Break
10:45-11:45	Dose selection and regimen <i>Dr.Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan</i>
11:45-13:30	Lunch
13:30-15:45	Case studies <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>
15:45-16:00	Break
16:00-17:00	Rev and Exam 3 (Module 3) <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>

Module 5: Good Clinical Practice

November 7, Wednesday (Day 8)

Describe the concepts of GCP, Recognise the principles of Ethics in research and the functions of Ethics Committee

09:00-09:30	Concept of Good Clinical Practice <i>Professor Dr. Juntra Karbwang, Nagasaki University, Japan</i>
09:30-10:30	Principles of Research Ethics and Ethics codes and Guidance <i>Professor Dr. Juntra Karbwang, Nagasaki University, Japan</i>
10:30-10:45	Break
10:45-11:45	Responsibilities: Sponsor, Monitors, audit, DSMB

Professor Dr. Juntra Karbwang, Nagasaki University, Japan

11:45-12:30	Responsibilities of EC Professor Dr. Juntra Karbwang, Nagasaki University, Japan
12:30-13:30	Lunch
13:30-16:00	Case studies <i>Professor Dr. Juntra Karbwang, Nagasaki University, Japan</i> <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>
16:00-16:30	Break
16:30-17:00	Review and Exam <i>Professor Dr. Juntra Karbwang, Nagasaki University, Japan</i> <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>

Module 6: Clinical Data Management

November 8, Thursday (Day 9)

Describe clinical data management processes, Describe how to write a good SOP for CDM

09:00-10:00	Overview, Protocol, CRF, SOPs <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>
10:00-11:00	Data management process I <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>
11:00-11:15	Break
11:15-11:45	Data management process I (Demo) <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>
11:45-12:15	Data management process II <i>Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand</i>
12:15-13:15	Lunch
13:15-13:45	Data management II (Demo)

Ms. Panida Kongjam, Thammasat University Clinical Data Management Center, Thailand

- 13:45-14:15 Data management process III
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand
- 14:15-15:15 Data management process III (Practice)
Ms. Panida Kongjam, Thammasat University Clinical Data Management Center, Thailand
- 15:15-16:15 Statistical analysis and sample size estimation
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand
- 16:15-16:45 Rev and Exam 6 (Module 6)
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

Module 7: Post-registration Activities

November 9, Friday (Day 10)

Describe post-registration activities for medicinal products

- 09:00-10:00 Overview
Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand
- 10:00-11:00 How to solve Access to Medicines (ATM) problems in developing countries
Mr. Kenji Toda, The Health Care Science Institute, Japan
- 11:00-11:15 Break
- 11:15-12:15 Improving the quality of new products in health systems: International network of rational use of drugs
Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand
- 12:15-13:15 Lunch
- 13:15-14:15 Post-marketing product vigilance

	<i>Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand</i>
14:15-15:15	Stakeholders to be involved in making product development work for the intended beneficiaries <i>Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand</i>
15:15-15:30	Break
15:30-16:30	Intellectual Property Rights Protection in Developing Countries <i>Professor Hiroko Yamane, Teikyo University, Japan</i>
16:30-17:00	Rev and Exam 2 (Module 7) <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i>

November 10, Saturday (Day 11)

9:00-11:00	FINAL EVALUATION. COURSE ASSESSMENT <i>Professor Dr. Kenji Hirayama, Nagasaki University, Japan</i> <i>Professor Dr. Juntra Karbwang, Nagasaki University, Japan,</i> <i>Course Director</i>
11:00-12:00	CLOSING CEREMONY <i>Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan</i>