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

28 October – 9 November, 2013

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, 2013

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

Administration Office

The information should be sent to
Ms. Ikumi Frizt
secretary, Diploma Course Office,
Institute of Tropical Medicine, Nagasaki University
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Module 1: Introduction

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

October 28, Monday (Day 1)

09:30-09:45 Welcome address
Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN), Nagasaki University, Japan

09:45-10:00 Objective of the course and expectation, Pre-test
Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN), Nagasaki University, Japan

10:00-10:15 Break

10:15-11:15 Overview of product research and development and stakeholders
Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan

11:15-12:15 Key medical and public health issues, and the need for new products
Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan

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
Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan

14:30-15:00 The role of Genomics and bioinformatics
Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan

15:00-15:30 High throughput screening:
Pre-requisite of HITS systems, Assay Development & Validation, Biochemical & Cell-based assay, Assay Readout & Detection
Dr. Nobuhiro Noro, GlaxoSmith Kline, K.K., Japan

15:30-15:45 Break

15:45-16:15 The role of Chemistry in Drug Discovery:-Lead Identification,

-Lead Generation Libraries (Combinatiorial 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

Session 2: Pre-clinical Development
Describe the process of pharmacological development

16:45-17:45 Pharmaceutical Development and CMC
Professor Dr. Hitoshi Sasaki,
Nagasaki University Hospital, Japan

October 29, 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. Yoshimasa Tanaka, 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)
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

10:15-10:30 Break

10:30-11:30 Drug Discovery in Academia

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

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 requiments for human clinical studies
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

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

October 30, Wednesday (Day 3)

Session 3: Clinical Development

09:00-09:30 Overview of clinical development

	Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan
09:30-11:00	Investigational Phases of Clinical Research (I-IV) and Study Design *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, 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 *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan*
14:00-14:30	Pharmacogenomics - Anticipated Benefits - Polymorphisms in Drug Targets - Polymorphisms in ADME - Pharmacogenomics Testing - Pharmacogenomics in Clinical Trials - Examples *Dr.Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan*
14:30-15:00	Pharmacokinetics in Clinical Development Extrapolation from animal to human pharmacokinetics *Dr.Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan*
15:00-15:15	Break

Session 4: Traditional Medicine

Underline the importance of traditional medicine in PRD

15:15-16:10	Introduction of Traditional Medicine and Guidance on herbal medicine *Professor Dr. Kiichiro Tsutani, The University of Tokyo, Japan*
16:10-17:00	Regulation for traditional medicine development *Dr. Ichiro Arai, Tsumura & Co., Japan*
17:00-17:45	Rev and Exam 1 (Module 2) *Professor Dr. Hirayama or Professor Dr. Kesara*

October 31, Thursday (Day 4)

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

Module 3: Vaccine Development

November 1, 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 *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*
09:30-10:30	Vaccines for infection control *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*
10:30-10:45	Break
10:45-12:15	Vaccines for infection control *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*
12:15-13:30	Lunch
13:30-14:30	Vaccine Platform Technology and Adjuvant Development *Dr. Takeshi Arakawa, University of the Ryukyus, Japan*

Session 2: Pre-Clinical Development

Describe the process of pre-clinical development of vaccine

14:30-15:00	CMC *Dr. Takeshi Arakawa, University of the Ryukyus, Japan*
15:00-15:15	Break
15:15-15:45	Immunogenicity and protect activity assessment

	Dr. Takeshi Arakawa, University of the Ryukyus, Japan
15:45-16:30	Safety assessment:Toxicity test in animals: regional complications, systemic toxicity
	Dr. Takeshi Arakawa, University of the Ryukyus, Japan

November 4, Monday (Day 6)

Session 3: Clinical Development

Describe the process of vaccine clinical development

09:00-10:00	Assessment of pre-clinical information
	TBD
10:00-10:30	Clinical development plan
	TBD
10:30-10:45	Break
10:45-11:45	Dose selection and regimen
	TBD
11:45-13:30	Lunch
13:30-15:45	Case studies
	Professor Dr. Kenji Hirayama, Nagasaki University, Japan
15:45-16:00	Break
16:00-17:00	Rev and Exam 3 (Module 3)
	Professor Dr. Kenji Hirayama, Nagasaki University, Japan

Module 4: Diagnostic Development

November 5, Tuesday (Day 7)

Describe the process of discovery and development of diagnostic tools

09:00-10:00	Discovery and development of diagnostic tools
	Dr. Masato Sasaki, QIAGEN, Japan
10:00-10:30	Prototype production and assessment
	Dr. Masato Sasaki, QIAGEN, Japan

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

Module 5: Good Clinical Practice

November 6, 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 *Professor Dr. Juntra Karbwang, Nagasaki University, Japan*
09:30-10:30	Principles of Research Ethics and Ethics codes and Guidance *Professor Dr. Juntra Karbwang, Nagasaki University, Japan*
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 *Professor Dr. Juntra Karbwang, Nagasaki University, Japan* *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
16:00-16:30	Break
16:30-17:00	Review and Exam *Professor Dr. Juntra Karbwang, Nagasaki University, Japan* *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*

Module 6: Clinical Data Management

November 7, 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 *Professor Dr. Kesara Na-Bangchang, Thammasat University*
10:00-11:00	Data management process I *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
11:00-11:15	Break
11:15-11:45	Data management process I (Demo) *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
11:45-12:15	Data management process II *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
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 8, 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 *Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
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 *Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
14:15-15:15	Stakeholders to be involved in making product development work for the intended beneficiaries *Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
15:15-15:30	Break
15:30-16:30	Intellectual Property Rights Protection in Developing Countries *Professor Hiroko Yamane, Teikyo University, Japan*
16:30-17:00	Rev and Exam 2 (Module 7) *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*

November 9, Saturday (Day 11)

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