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

20 October – 30 October, 2014

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 10 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: 8 October, 2014

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

Administration Office

For Oversea participants: the information should be sent to

Ms. Sayuri Delaney
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Module 1: Introduction

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

October 20, 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 Patents in Drug Discovery:
- Publication VS Patents
- Patent system
- Type of Patent
Professor Dr. Hiroshi Kato, Nihon University, Japan

October 21, 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	Pharmaceutical Development and CMC *Professor Dr. Hitoshi Sasaki, Nagasaki University Hospital, 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 22, 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 *Ms. Mai Mikawa, 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, ONO Pharmaceutical Company Limited Head Office, Japan*
14:30-15:00	Pharmacokinetics in Clinical Development Extrapolation from animal to human pharmacokinetics *Dr.Shyh-Yuh Liou, ONO 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 medicines *Professor Dr. Kiichiro Tsutani, The University of Tokyo, Japan*
16:10-17:00	Regulation for traditional medicine development *Professor Dr. Ichiro Arai, Nihon Pharmaceutical University, Japan*
17:00-17:45	Rev and Exam 1 (Module 2) *Professor Dr. Hirayama or Professor Dr. Kesara*

October23, Thursday (Day 4)

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

Module 3: Vaccine Development

October 24, 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*

October 25, Saturday (Day 6)

Session 3: Clinical Development

Describe the process of vaccine clinical development

09:00-10:00	Assessment of pre-clinical information *Dr. Daisuke Tsuzuki*
10:00-10:30	Clinical development plan *Dr. Daisuke Tsuzuki*
10:30-10:45	Break
10:45-11:45	Dose selection and regimen *Dr. Daisuke Tsuzuki*
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 2 (Module 3) *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*

Module 4: Post-registration Activities

October 27, Monday (Day 7)

Describe post-registration activities for medicinal products

09:00-10:00	Overview *Professor Emeritus Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
10:00-11:00	How to solve Access to Medicines (ATM) problems in developing countries *Professor Emeritus 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 Emeritus Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
12:15-13:15	Lunch
13:15-14:15	Post-marketing product vigilance *Professor Emeritus 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 Emeritus Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand*
15:15-15:30	Break
15:30-16:30	Intellectual Property Rights Protection in Developing Countries *Professor Emeritus Hiroko Yamane, Teikyo University, Japan*
16:30-17:00	Rev and Exam 3 (Module 4) *Professor Dr. Kenji Hirayama, Nagasaki University, Japan*

Module 5: Good Clinical Practice

October 28, Tuesday (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-Laothavorn, Nagasaki University, Japan*
09:30-10:30	Principles of Research Ethics and Ethics codes and Guidance *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan*
10:30-10:45	Break
10:45-11:45	Responsibilities: Sponsor, Monitors, audit, DSMB *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan*
11:45-12:30	Responsibilities of EC Professor Dr. Juntra Karbwang-*Laothavorn*, Nagasaki University, Japan
12:30-13:30	Lunch
13:30-14:45	Data Management Process *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan* *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
14:45-16:00	Case studies *Professor Juntra Karbwang-Laothavorn,, Nagasaki University, Japan* *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
16:00-16:15	Break
16:15-16:45	Exam 4 (Module 5) *Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan*

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

Module 6: Diagnostic Development

October 29, Wednesdays (Day 9)

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 5 (Module 6) *Professor Dr. Kenji Hirayama and Professor Dr.Kesara Na-Bangchang*

October 30, Thursday (Day 10)

9:00-11:00 **FINAL EVALUATION. COURSE ASSESSMENT**

Professor Dr. Kenji Hirayama, Nagasaki University, Japan

Professor Dr. Juntra Karbwang-Laothavorn, Nagasaki University, Japan, Course Director

11:00-12:00 **CLOSING CEREMONY**