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 and UNICEF-UNDP- World Bank – WHO Special Programme for Research and Training in Tropical Diseases (TDR)

10 October – 1 November, 2011

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 17days course consisting of lectures, open discussions, group activity, site visit and practical exercises on specific activities.

Course Directors and Coordinators:

Professor Dr. Kenji Hirayama
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Professor Dr. Kesara Na-Bangchang
Faculty of Allied Health Sciences, Thammasat University
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Venue:

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

Registration deadline: 30 September, 2011

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

Administration Office

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Module 1: Introduction

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

October 10, Monday (Day 1)

09:00-09:15	Welcome address *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
09:15-09:30	Objectives of the course and expectation *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
09:30-10:30	Overview of product research and development *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
10:30-10:45	Tea break
10:45-11:45	Key medical and public health issues, and the need for new products *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
11:45-12:45	Stakeholders in product research and development *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
12:45-13:45	Lunch

Module 2: Discovery and Development

Session 1: Drug Discovery

Objective: To describe the pharmacological process for drug discovery and to identify the process to protect intellectual property.

13:45-14:15	History and overview of drug discovery process *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals,*

	Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.
14:15-15:15	The role of pharmacology in drug discovery *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
15.15-15.30	Tea break
15:30-16:30	Genomics and bioinformatics *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*

October 11, Tuesday (Day 2)

9:00-10:00	High throughput screening *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
10:00-10:15	Tea break
10:15-11:30	The role of chemistry in drug discovery *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
11:30-13:30	Lunch
13:30-14:45	Drug development for neglected tropical diseases *Professor Dr. Kiyoshi Kita, Department of Biomedical Chemistry, Graduate School of Medicine, The University of Tokyo, Japan*
14:45-15:00	Tea break
15:00-16:30	Publications, IRP & patents *Dr. Kenichi Osawa, President, OSAWA IP LAW FIRM, Japan*

October 12, Wednesday (Day 3)

Session 2: Chemistry, Manufacturing and Control (CMC)

Objective: To describe different processes of CMC.

9:00-9:30	Formulation of drug products *Professor Hitoshi Sasaki, Nagasaki University Hospital, Nagasaki, Japan*
9:30-12:45	Overview of CMC, development of specifications, QA/QC, Regulatory, naming the new chemical entity, Stability for drug substance and drug product *Professor Hitoshi Sasaki, Nagasaki University Hospital, Nagasaki, Japan*
12:45-13:45	Lunch

Session 3: Pre-clinical Development

Objective: To describe the process of pharmacological development.

13:45-14:30	Overview, pharmacological data in new drug application *Dr. Hiroyuki Ito, Senior Director, Pharmacology Research Labs. Drug Discoversy Research,Astellas Pharma Inc., Japan*
14:30-15:30	Methods in pharmacological R&D *Dr. Hiroyuki Ito, Senior Director, Pharmacology Research Labs. Drug Discoversy Research,Astellas Pharma Inc., Japan*
15:30-15:45	Tea break
15:45-17:00	The role of pharmacokinetics and drug metabolism *Professor Dr. Eiji Uchida, Showa University, Japan*

October 13, Thursday (Day 4)

Session 4: Toxicology

Objective: To describe the toxicological methods.

9:00-10:00	Overview *Associate Professor Dr. Wongwiwat Tassaneeyakul, Dean, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand*
10:00-11:00	Toxicological tests: *in vitro & in vivo*

	Associate Professor Dr. Wongwiwat Tassaneeyakul, Dean, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand
11:00-13:00	Tea break & Lunch
13:00-14:30	Necessary facility to toxicology Visit animal facility for medical research *Professor Dr. Kazutaka Ohsawa, Laboratory Animal Center for Biomedical research, Nagasaki University*

Session 5: Traditional Medicine

Objective: To underline the importance of traditional medicine in PRD.

14:45-15:45	Introduction of traditional medicine *Professor Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Science, The University of Tokyo, Japan*
15:45-16:00	Tea break
16:00-17:00	Regulation for traditional medicine development *Dr. Ichiro Arai, Manager, Tsumura Drug Information Library, Tsumura & Co., Japan*
17:00-18:00	Guidance on herbal medicine *Professor Dr. Kiichiro Tsutani*

October 14, Friday (Day 5)

Session 6: Clinical Development

Objective: To explain the different phases for clinical trials, explain the critical role of pharmacokinetics/pharmacogenomics and safety monitoring, and explain the regulatory aspects for Clinical Trials

9:00-10:00	Overview of clinical development *Dr. Hanako Mihara, Medical Director, Health Economics and Outcomes Research (HEOR), Division of Medical Affairs, Japan/Asia-Pacific, Abbott Diagnostics. Co., Ltd.*
10:00-10:15	Tea break
10:15-11:45	Investigational phases of clinical research (Phases I-IV)

	Dr. Hanako Mihara, Medical Director, Health Economics and Outcomes Research (HEOR), Division of Medical Affairs, Japan/Asia-Pacific, Abbott Diagnostics. Co., Ltd.
11:45-12:45	Lunch
12:45-13:45	Study design (ethical aspects, control, patient population, design techniques to avoid bias) *Dr. Hanako Mihara, Medical Director, Health Economics and Outcomes Research (HEOR), Division of Medical Affairs, Japan/Asia-Pacific, Abbott Diagnostics. Co., Ltd.*
13:45-14:45	Statistical consideration *Dr. Hanako Mihara, Medical Director, Health Economics and Outcomes Research (HEOR), Division of Medical Affairs, Japan/Asia-Pacific, Abbott Diagnostics. Co., Ltd.*
14:45-15:00	Tea break
15:00-16:00	Safety monitoring and reporting in clinical trials *Dr. Mitsuyoshi Hara, Senior Research Fellow, Pharmacovigilance Area, Japan Development, MSD KK*

October 17, Monday (Day 6)

9:00-10:00	Human pharmacokinetics *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
10:00-11:30	Pharmacogenomics *Dr. Shyh-Yuh Liou, Director, Takeda Pharmaceutical Company Limited Head Office, Japan*
12:00-13:00	Lunch
13:00-14:30	Regulatory aspects of clinical development *Mr. Kenichi Mikami, Division Director, Coordination Division Office of Planning and Coordination Pharmaceuticals and Medical Devices Agency*
15:30~17:00	Drug discovery in academia *Professor Dr. Takayoshi Okabe, Open Innovation Center for Drug Discovery, University of Tokyo, Japan*
17:00-18:00	Review and exam (Module 2)

Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang

October 18, Tuesday (Day 7)

10:00-17:00	Field trip to Hisamitsu Pharmaceutical Co., Inc *Mr. Hideyuki Nakano, Manager, Clinical Development Dpt., Hisamitsu Pharmaceutical Co., Inc, Japan*

October 19, Wednesday (Day 8)

Module 4: Diagnostic Development

Objective: To describe the process of discovery and development of diagnostic tools

9:00-10:00	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	Tea break
10:45-12:45	Scale-up, manufacture and control *Dr. Masato Sasaki, QIAGEN, Japan*
12:45-13:45	Lunch
13:45-14:45	Development of kits *Dr. Masato Sasaki, QIAGEN, Japan*
14:45-15:00	Tea break
15:00-16:00	Quality assurance/quality control: evaluation of efficacy after application *Dr. Masato Sasaki, QIAGEN, Japan*
16:00-16:30	Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial *Dr. Masato Sasaki, QIAGEN, Japan*
16:30-17:00	Clinical development: supply chain logistics and production, Statistical consideration, regulatory issues *Dr. Masato Sasaki, QIAGEN, Japan*
17:00～	Review and exam (Module 4)

Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang

October 20, Thursday (Day 9)

Module 3: Vaccine Development

Session 1: Discovery

Objective: To describe the principles of basic immunology and the process of vaccine discovery

9:00-10:00	*What is immune system?* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
11:15-10:15	Tea break
10:15-11:15	*Innate Immunity* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, (NEKKEN) Nagasaki University, Japan*
11:15-12:15	*Adaptive Immunity 1* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
12:15-14:00	Lunch
14:00-15:00	*Adaptive Immunity 2* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
15:00-15:15	Tea break
15:15-16:30	Vaccine platform technology and adjuvant development *Associate Professor, Dr. Takeshi Arakawa, Tropical Biosphere Research Center, University of the Ryukyus*
16:40-17:10	*Presentation subjects* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*

October 21, Friday (Day 10)

Session 2: Pre-Clinical Development

Objective: To describe the process of pre-clinical development of vaccine

9:00-10:00	CMC *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
10:00-10:15	Tea break
10:15-12:15	Immunogenicity and protect activity assessment *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
12:15-13:15	Lunch
13:15-14:15	Safety assessment: toxicity test in animals: regional complications, systemic toxicity *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*
14:15-14:30	Tea break
14:30-15:30	Examples of pre-clinical development *Dr. Nobuhiro Noro, Head, Clinical Research/Biologicals, Alliance and Rare Diseases, Development & Medical Affairs Division, GlaxoSmith Kline, K.K.*

October 24, Monday (Day 11)

Session 3: Clinical Development

Objective: To describe the process of vaccine clinical development

9:00-10:00	Assessment of pre-clinical information *Dr. Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan*
10:00-10:15	Tea break
10:15-12:15	Clinical development plan *Dr. Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan*
12:15-13:15	Lunch
13:15-14:15	Dose selection and regimen *Dr. Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan*

14:15-14:30	Tea break
14:30-15:30	Regulatory *Dr. Daisuke Tsuzuki, Sanofi Pasteur KK. Tokyo, Japan*
15:30-17:00	Review and Exam (Module 3) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

October 25, Tuesday (Day 12)

10:00-12:00	*Presentation 15min + 5min* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
12:00-13:00	Lunch
13:00-15:00	*Presentation 15min + 5min* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
15:00-15:15	Tea break
15:15-16:30	*Allergy autoimmune immune evasion* *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan*
16:30-17:30	*Review Exam*

October 26, Wednesday (Day 13)

Module 5 Good Clinical Practice

Objective: To describe the concepts of GCP, Recognise the principles of Ethics in research and the functions of Ethics Committee

9:00-10:00	Good clinical practice and quality management in clinical research *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
10:00-10:15	Tea break

10:15-12:15	Responsibilities: sponsor, investigators, IRB, monitors, DSMB *Dr. Allan Johansen, Roche Products Pty limited, Australia*
12:15-13:15	Lunch
13:15-14:15	Ethics codes and guidelines *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
14:15-14:30	Tea break
14:30-15:30	Principles of research ethics *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
15:30-16:30	Protection of intellectual property rights in developing countries *Professor Hiroko Yamane, Faculty of Law, Teikyo University*
16:30-17:30	Case studies *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland Professor*

October 27, Thursday (Day 14)

9:00-10:00	Case study presentation (Group work) *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
10:00-10:15	Tea break
10:15-11:15	Human subject protection and ethics committees *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
11:15-12:15	Monitoring and auditing ethics committee *Dr. Allan Johansen, Roche Products Pty limited, Australia*
12:15-13:15	Lunch
13:15-14:15	Data and Safety Monitoring Board: DSMB *Dr. Allan Johansen, Roche Products Pty limited, Australia*
14:15-14:30	Tea break
14:30-15:30	Audit and inspection *Dr. Allan Johansen, Roche Products Pty limited, Australia*
15:30～	Review and exam (Module 5) *Professor Dr. Kenji Hirayama and Professor Dr. Juntra Karbwang-Laothavorn*

October 28, Friday (Day 15)

Module 6: Clinical Data Management

Objective: To describe clinical data management processes; describe how to write a good SOP for CDM

9:00-10:00	Overview of clinical data management *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
10:00-11:00	Protocols, Case Report Form (CRF), Standard Operating Procedures (SOPs) *Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand*
11:00-11:15	Tea break
11:15-12:30	Data management (practical session) *Ms. Panida Kongjam, System Manager, Thammasat University Clinical Data Management Center, Thailand*
12:30-13:30	Lunch
13:15-16:15	Data management (practice) *Ms. Panida Kongjam, System Manager, Thammasat University Clinical Data Management Center, Thailand*
16:30～	Review and exam (Module 6) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

October 31, Monday (Day 16)

Module 7: Post-registration Activities

Objective: To describe post-registration activities for medicinal products

9:00-10:00	Overview *Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland*
10:00-11:00	Post-marketing product vigilance *Dr. Yupin Lawanprasert, Ministry of Public health, Thailand*

11:00-11:15	Tea break
11:15-12:15	Improving the quality of new products in health systems: International network of rational use of drugs *Mr. Kenji Toda, Senior director, The Health Care Science Institute, Japan*
12:15-13:15	Lunch
13:15-14:15	The Japanese pharmaceutical industry's growing contribution to health in developing countries *Mr. Simon Collier, Director, Government Relations, Eisai Co., Ltd. Chairman, IFPMA/International Cooperation Sub-Committee, Japan*
14:15-15:15	Stakeholders to be involved in making product development work for the intended beneficiaries *Dr. Yupin Lawanprasert, Ministry of Public health, Thailand*
15:15-15:30	Tea break
15:30～	Review and exam (Module 7) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

November 1, Tuesday (Day 17)

9:00- **FINAL EVALUATION, COURSE ASSESSMENT**
Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO, Switzerland

CLOSING CEREMONY
Professor Dr. Kenji Hirayama, Institute of Tropical Medicine (NEKKEN) Nagasaki University, Japan