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

Organized by
Institute of Tropical Medicine (NEKKEN),
Center for International Collaborative Research (CICORN), 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 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
Dean, Institute of Tropical Medicine (NEKKEN)
Nagasaki University, Nagasaki, Japan
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Professor Dr. Kesara Na-Bangchang
Director, Graduate Program in Biomedical Sciences, Thammasat University
Deputy Dean, Faculty of Allied Health Sciences, Thammasat University
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Venue:
Institute of Tropical Medicine (NEKKEN), Nagasaki University (Sakamoto Campus)

Registration Fee:

Participants of the allied universities (Thammasat University, Chulalongkorn University, China Military Medical University, Universidad de Antioquia, University of Tokyo, Nagasaki University): Free of charge

Participants from International Organization or private sector: 1,000 USD for the whole course or 100 USD/day.

Student participants: 800 USD for the whole course (20% discount).

No.	*Participants Category*	*Whole course*	*1 Day*	*Note**
1.	*Ordinary*	*1,000 USD*	*100 USD*	-
2.	*International Organization/Private Sector*	*1,000 USD*	*100 USD*	-
3.	*Student*	*800 USD*	*80-USD*	-
4.	*Partial(Module 1 or 6 only)*	-	-	*100 USD*
5.	*Partial (Module 2 only)*	-	-	*400 USD*
6.	*Partial (Module 3 only)*	-	-	*300 USD*
7.	*Partial (Module 5 only)*	-	-	*200 USD*
8.	*Partial (Module 4 or 7 only)*	-	-	*100 USD*

Registration deadline: 31 August, 2011

(We also accept onsite registration however registration kit material including tea breaks are not guaranteed)

Administration Office

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Module1: 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, Dean, Institute of Tropical Medicine, Nagasaki University, Japan*
09:15-09:30	Objectives of the course and expectation *Professor Dr. Kenji Hirayama, Institute of tropical Medicine, Nagasaki University, Japan*
09:30-10:30	Overview of product research and development *Professor Dr. Juntra Karbwang, Quality management, WHO/TDR, Geneva, 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, Nagasaki University, Japan*
11:45-12:45	Stakeholders in Product Research and Development *Dr. Kihito Takahashi, R&D Department, GSK Japan, Japan*
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, Vaccine Clinical Development, Glaxo Smith Kline, Japan*
14:15-15:15	The role of pharmacology in drug Discovery

Dr. Nobuhiro Noro, Head,Vaccine Clinical Development, GlaxoSmith Kline, Japan

15.15-15.30 Tea break

15:30-16:30 Genomics and bioinformatics
Dr. Nobuhiro Noro, Head,Vaccine Clinical Development, GlaxoSmith Kline, Japan

October 11, Tuesday (Day 2)

9:00-10:00 High throughput screening
Dr. Nobuhiro Noro, Head,Vaccine Clinical Development, GlaxoSmith Kline, Japan

10:00-10:15 Tea break

10:15-11:30 The role of Chemistry in Drug Discovery
Dr. Nobuhiro Noro, Head,Vaccine Clinical Development, *GlaxoSmith Kline, Japan*

11:30-12:30 Lunch

12:30-13:30 Novel Anti-TB drug development
Dr. Hiroshi Ishikawa, Otsuka Pharmaceutical Co.,Ltd. Japan

13:30-13:45 Tea break

13:45-15:00 Drug development for Neglected Tropical Diseases
Professor Dr. Kiyoshi Kita, Department of Biomedical Chemistry, Graduate School of Medicine, The University of Tokyo, Japan

15:00-16:30 Publications, IPR, & Patents
Dr. Kenichi Osawa, Banyu Pharmaceutical Co., LTD, 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
Dr. Rumiko Shimazawa, Clinical Pharmacology, Faculty of Medicine, 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 *Dr. Rumiko Shimazawa, Clinical Pharmacology, Faculty of Medicine, Nagasaki, Japan, 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 Itoh, Astellas Pharma Inc., Japan*
14:30-15:30	Methods in pharmacological R&D *Dr. Hiroyuki Itoh, 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 Osawa, 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, Graduate School of Pharmaceutical Science, The University of Tokyo, Japan*

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, Cancer Information Services and Surveillance Division, Center for Cancer Control and Information Services National Cancer Center, Japan*
10:00-10:15	Tea break
10:15-11:45	Investigational phases of clinical research (Phases I-IV) *Dr. Hanako Mihara, Cancer Information Services and Surveillance Division, Center for Cancer Control and Information Services National Cancer Center, Japan*
11:45-12:45	Lunch
12:45-13:45	Study design (ethical aspects, control, patient population, design techniques to avoid bias) *Dr. Hanako Mihara, Cancer Information Services and Surveillance Division, Center for Cancer Control and Information Services National Cancer Center, Japan*

13:45-14:45 Statistical consideration

Dr. Hanako Mihara, Cancer Information Services and Surveillance Division, Center for Cancer Control and Information Services National Cancer Center, Japan

14:45-15:00 Tea Break

15:00-16:00 Safety monitoring and reporting in clinical trials

Dr. Kimihiro Kasamo, UCB Japan Co.Ltd, Japan

October 17, Monday (Day 6)

9:00-10:00 Human pharmacokinetics

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

10:00-11:00 Pharmacogenomics

Dr. Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan

11:00-11:15 Tea Break

11:15-12:15 Regulatory aspects of clinical development

Dr. Ayako Mikami, Tokai University, Japan

12:15-13:15 Lunch

13:15-14:15 Effective Use of Microdosing and PET Studies in the New Drug Development

Professor Dr.Yuichi Sugiyama, Dean, The University of Tokyo Graduate School of Pharmaceutical Science, Department of Pharmaceutical Technology, Japan

14:15~ Review and Exam 1 (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 3: Vaccine Development

Session 1: Discovery

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

9:00-10:00	Historical overview of vaccine Discovery *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
10:00-11:00	Basic immunology *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
11:00-11:15	Tea break
11:15-12:15	Basic immunology (continued) *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
12:15-13:15	Lunch
13:15-15:00	Basic immunology (continued) *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
15:00-15:15	Tea break
15:15-16:30	Basic immunology (continued) *Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*

October 20, Thursday (Day 9)

9:00-10:30	Basic immunology (continued) *Professor Dr. Kenji Hirayama, Dean, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
10:30-10:45	Tea break

11:45-12:30	Basic immunology (continued) *Professor Dr. Kenji Hirayama, Dean, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
12:30-13:30	Lunch
13:30-15:00	Overview of modern vaccine development *Professor Dr. Kenji Hirayama, Dean, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan*
15:00-15:15	Tea break
15:15-16:30	Mucosal Immunity *Dr. Takeshi Arakawa, Faculty of Medicine, Ryukyu 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,Vaccine Clinical Development, GlaxoSmith Kline, Japan*
10:00-10:15	Tea break
10:15-12:15	Immunogenicity and protect activity assessment *Dr. Nobuhiro Noro, Head, Vaccine Clinical Development, GlaxoSmith Kline, Japan*
12:15-13:15	Lunch
13:15-14:15	Safety assessment: Toxicity test in animals: regional complications, systemic toxicity *Dr. Nobuhiro Noro, Head, Vaccine Clinical Development, GlaxoSmith Kline, Japan*
14:15-15:15	Regulatory *Dr. Shoji Ikeda, sanofi pasteur vaccine division, sanofi-aventis KK. Tokyo, Japan*

15:15-15:30	Tea Break
15:30-17:30	Examples of pre-clinical development *Dr. Nobuhiro Noro, Head, Vaccine Clinical Development, GlaxoSmith Kline, Japan*

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 Vaccine Division, Sanofi-Aventis KK. Tokyo, Japan*
10:00-10:15	Tea break
10:15-12:15	Clinical development plan *Dr. Daisuke Tsuzuki, Sanofi Pasteur Vaccine Division, Sanofi-Aventis KK. Tokyo, Japan*
12:15-13:15	Lunch
13:15-14:15	Dose selection and regimen *Dr. Daisuke Tsuzuki, Sanofi Pasteur, Vaccines Division, Sanofi-Aventis KK. Tokyo, Japan*
14:15-14:30	Tea break
14:30-16:30	Examples of clinical trials *Professor Dr. Kenji Hirayama*
16:30 ~	Review and Exam 3 (Module 3) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

October 25, Tuesday (Day 12)

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 4 (Module 4) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

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, 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. Cristina Torres, Thammasat University , FERCAP Coordinator, Thailand*
14:15-14:30	Tea break
14:30-15:30	Principles of research ethics *Dr. Kenji Matsui, Project Senior Lecturer* *Assistant Professor Dr. Shimon Tashiro, University of Tokyo, Japan*
15:30-16:30	Case studies

October 27, Thursday (Day 14)

9:00-10:00	Case study presentation (Group work) *Dr. Kenji Matsui, Project Senior Lecturer* *Assistant Professor Dr. Shimon Tashiro, University of Tokyo, Japan*
10:00-10:15	Tea break
10:15-11:15	Human subject protection and ethics committees *Professor Dr.Young-Moo Koo, Korea*
11:15-12:15	Monitoring and auditing Ethics Committee *Professor Dr. Cristina Torres, Thammasat University , FERCAP Coordinator, Thailand*
12:15-13:15	Lunch
13:15-14:15	Data and Safety Monitoring Board DSMB *Professor Dr. Cristina Torres, Thammasat University, FERCAP Coordinator, Thailand*
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 5 (Module 5) *Professor Dr. Kenji Hirayama and Professor Dr. Juntra Karbwang-Laothavorn, TDR, Switzerland*

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, Director, Graduate program in Biomedical Sciences, and Director Clinical Coordination and Training center, WHO-TDR Collaborating Center, Thammasat University, Thailand*
10:00-11:00	Protocols, Case Report Form (CRF), Standard Operating Procedures (SOPs) *Professor Dr. Kesara Na-Bangchang, Director, Graduate program in Biomedical Sciences, and Director Clinical Coordination and Training center, WHO-TDR Collaborating Center, 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 6 (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.Chitr Sitthi amorn, Chulalongkorn University, Thailand*
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 *Professor Dr.Chitr Sitthi amorn, Chulalongkorn University, Thailand*
12:15-13:15	Lunch
13:15-14:15	Global spread of health technology assessment (HTA) in healthcare policies *Ms.Mie Kasai, Eisai Co., Ltd., Japan*
14:15-15:15	Stakeholders to be involved in making product development work for the intended beneficiaries *Professor Dr. Chitr Sitthi Amorn, Chulalongkorn University, Thailand*
15:15-15:30	Tea Break
15:30-16:30	Protection of intellectual property rights in developing countries *Dr. Hiroko Yamane, National Graduate Institute for Policy Studies, Japan*
16:30 ~	Review and Exam 2 (Module 7) *Professor Dr. Kenji Hirayama and Professor Dr. Kesara Na-Bangchang*

November 1, Tuesday (Day 17)

FINAL EVALUATION. COURSE ASSESMENT

Professor Dr. Juntra Karbwang-Laothavorn, TDR, Switzerland

CLOSING CEREMONY

Professor Dr. Kenji Hirayama, Institute of Tropical Medicine, Nagasaki University, Japan