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, and Khon Kaen 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)

26 October – 17 November, 2009

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:

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
Email: kesaratmu@yahoo.com
Tel: 662-9869207

Course Coordinator:

Professor Dr. Masayuki Ikeda, Nagasaki University School of Medicine, Japan

Venue:
Institute of Tropical Medicine (NEKKEN), Nagasaki University (Sakamoto Campus)

Registration Fee :
Participants from out side of the allied universities (Thammasat, Chulalongkorn, Khon Kaen, China Military Medical University No 2, Universidad de Antioquia, Univ Tokyo, Nagasaki Univ.) : 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: October 1, 2009
(We also accept onsite registration however registration kit material including tea breaks are not guaranteed)

Accommodation: *Those who wish to book accommodation through us are advised to contact as soon as possible otherwise it may be difficult for us to arrange accommodation at the last moment. For Foreign participants, we will arrange a reasonable rate hotel.*

Administration Office
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Module1: Introduction

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

October 26, Monday (Day 1)

AM

Welcome address

Objectives of the course and expectation
Professor Dr. Kenji Hirayama, Nagasaki University, Japan

Overview of product research and development
Professor Dr. Masayuki Ikeda, Nagasaki University Graduate School of Medical Science, Japan

Tea break

Key medical and public health issues, and the need for new products
Professor Dr.Kenji Hirayama, Nagasaki University, Japan

Stakeholders in Product Research and Development
Dr.Kihito Takahashi, President of Japanese Association of Pharmaceutical Medicine (JAPhMed), Japan

Lunch

Module 2: Discovery and Development

Session 1: Drug Discovery

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

PM

History and overview of drug discovery process
Dr. Nobuhiro Noro, Glaxo Smith Klein K.K. Tokyo, Japan

The role of pharmacology in drug Discovery
Dr. Nobuhiro Noro, Glaxo Smith Klein K.K. Tokyo, Japan

Tea break

Genomics and bioinformatics
Dr. Nobuhiro Noro, Glaxo Smith Klein K.K. Tokyo, Japan

October 27, Tuesday (Day 2)

AM

High throughput screening
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K.Tokyo, Japan

Tea break

The role of Chemistry in Drug Discovery
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K.Tokyo, Japan

Lunch

PM

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

Drug development for Neglected Tropical Diseases
Professor Dr. Kiyoshi Kita, Department of Biomedical Chemistry,
Graduate School of Medicine, The University of Tokyo, Japan

Tea break

Publications, IPR, & Patents
Dr. Kenichi Osawa, Banyu Pharmaceutical Co., LTD, Japan

October 28, Wednesday (Day 3)

Session 2: Chemistry, Manufacturing and Control (CMC)

Describe different processes of CMC

AM

Formulation of drug products
Associate Professor Dr. Rumiko Shimazawa, Tohoku University,
Translational Research Center, Japan

Overview of CMC, development of specifications,
QA/QC, Regulatory, naming the new chemical entity,

Stability for drug substance and drug product
Associate Professor Dr. Rumiko Shimazawa, Tohoku University, Translational Research Center, Japan

Lunch

Session 3: Pre-clinical Development

Describe the process of pharmacological development

PM

Overview, Pharmacological data in new drug application
Dr. Hiroyuki Itoh, Astellas Pharma Inc.Japan

Methods in pharmacological R&D
Dr.Hiroyuki Itoh, Astellas Pharma Inc.Japan

Tea break

The role of pharmacokinetics and drug metabolism
Professor Dr.Eiji Uchida, Showa University, Japan

October. 29, Thursday (Day 4)

Session 4: Toxicology

Describe the toxicological methods

AM

Overview
Associate Professor Dr.Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand

Toxicological tests: *in vitro & in vivo*
Associate Professor Dr.Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand

Tea break & Lunch

PM

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

Underline the importance of traditional medicine in PRD

Introduction of Traditional Medicine
Professor Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Science, The University of Tokyo, Japan

Tea Break

Regulation for traditional medicine development
Dr. Ichiro Arai, Manager, Tsumura Drug Information Library, Tsumura & Co.

Guidance on herbal medicine
Professor Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Science, The The University of Tokyo, Japan

October 30, Friday (Day 5)

Session 6: Clinical Development

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

AM

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

Tea break

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

Lunch

PM

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

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

Tea Break

Safety monitoring and reporting in clinical trials
Dr. Kimihiro Kasamo, UCB Japan Co.Ltd, Japan

November 2, Monday (Day 6)

AM

Human pharmacokinetics
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand
Pharmacogenomics
Dr.Shyh-Yuh Liou, Takeda Pharmaceutical Company Limited Head Office, Japan

Tea Break

Regulatory aspects of clinical development
Dr.Ayako Mikami, Tokai University School of Medicine, Japan

Lunch

PM

Rev and Exam 1 (Module 2)
Prof. Hirayama or Prof. Ikeda

November 3, Tuesday (Day 7)

Module 7: Post-registration Activities

Describe post-registration activities for medicinal products

AM

Overview
Dr.Chitr Sitthi amorn, Chulalongkorn University, Thailand

Post-marketing product vigilance
Dr. Yupin Lawanprasert, Ministry of Public health, Thailand

Tea Break

improving the quality of new products in health systems:
International network of rational use of drugs
Dr.Chitr Sitthi amorn, Chulalongkorn University, Thailand

Lunch

PM

Global spread of health technology assessment (HTA) in healthcare policies
Dr.Mie Kasai, Eisai Co., Ltd., Japan,

Stakeholders to be involved in making product development work for the intended beneficiaries
Dr. Chitr Sitthi Amorn, Chulalongkorn University, Thailand

Tea Break

Intellectual Property Rights Protection in Developing Countries
Dr. Hiroko Yamane, National Graduate Institute for Policy Studies, Japan

Rev and Exam 2 (Module 7)
Dr. Hirayama or Dr. Ikeda

November 4, Wednesday (Day 8)

Field Trip to Hisamitsu Pharmaceutical Co., Inc
Mr, Hideyuki Nakano, Manager, Clinical Development Dpt., Hisamitsu Pharmaceutical Co., Inc

November 5, Thursday (Day 9)

Module 3: Vaccine Development

Session 1: Discovery

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

AM Historical overview of vaccine Discovery
Lecturer is not finalized

PM Basic Immunology
Lecturer is not finalized

November 6, Friday (Day 10)

AM Basic Immunology
Lecturer is not finalized

PM Overview of modern vaccine development
Lecturer is not finalized

AM Selection of candidate and back-ups
Lecturer is not finalized

November 9, Monday (Day 11)

Session 2: Pre-Clinical Development

Describe the process of pre-clinical development of vaccine

AM

CMC
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K.Tokyo, Japan

Tea Break

Immunogenicity and protect activity assessment
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K.Tokyo, Japan

Lunch

PM

Safety assessment: Toxicity test in animals: regional complications,

systemic toxicity
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K.Tokyo, Japan

Regulatory
Dr. Daisuke Tsuzuki, sanofi pasteur, Vaccines Division of sanofi-aventis KK. Tokyo, Japan

Tea Break

Topics
Dr. Nobuhiro Noro, GlaxoSmith Klein K.K. Tokyo, Japan

November 10, Tuesday (Day 12)

Session 3: Clinical Development

Describe the process of vaccine clinical development

AM

Assessment of pre-clinical information
Dr. Daisuke Tsuzuki, sanofi pasteur, Vaccines Division of sanofi-aventis KK. Tokyo, Japan

Tea Break

Clinical development plan
Dr. Daisuke Tsuzuki, sanofi pasteur, Vaccines Division of sanofi-aventis KK. Tokyo, Japan

Lunch

PM

Dose selection and regimen
Dr. Daisuke Tsuzuki, sanofi pasteur, Vaccines Division of sanofi-aventis KK. Tokyo, Japan

Tea Break

Topics Examples clinical trials
Dr. Hirayama or Dr. Ikeda

Rev and Exam 3 (Module 3)
Dr. Hirayama or Dr. Ikeda

November 11, Wednesday (Day 13)

Module 4: Diagnostic Development

Describe the process of discovery and development of diagnostic tools

AM

Discovery and development of diagnostic tools
Dr. Masato Sasaki, QIAGEN in Japan

Prototype production and assessment
Dr. Masato Sasaki, QIAGEN in Japan

Tea Break

Scale-up, manufacture and control
Dr. Masato Sasaki, QIAGEN in Japan

Lunch

PM

Development of kits
Dr. Masato Sasaki, QIAGEN in Japan

Tea Break

Quality assurance/quality control: evaluation of efficacy after Application
Dr. Masato Sasaki, QIAGEN in Japan

Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial
Dr. Masato Sasaki, QIAGEN in Japan

Clinical development: Supply chain logistics and production, Statistical consideration, regulatory issues
Dr. Masato Sasaki, QIAGEN in Japan

Rev and Exam 4 (Module 4)

November 12, Thursday (Day 14)

Module 5 Good Clinical Practice

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

AM

Good Clinical Practice and Quality Management in Clinical Research
Dr. Juntra Karbwang-Laothavorn, TDR, Switzerland

Tea Break

Responsibilities: Sponsor, Investigators, IRB, Monitors, DSMB
Dr. Allan Johansen, Roche Products Pty limited, Australia

Lunch

PM

Ethics codes and Guidelines
Professor Dr. Cristina Torres, UP, Manila and FERCUP

Tea Break

Principles of Research Ethics
Project Senior Lecturer Dr. Kenji Matsui & Assistant Professor Dr. Shimon Tashiro, The University of Tokyo, Japan

Case studies (Mock IRB)

November 13, Friday (Day 15)

AM

Case study presentation (Group work)
Project Senior Lecturer Dr. Kenji Matsui & Assistant Professor Dr. Shimon Tashiro, The University of Tokyo, Japan

Tea Break

Human Subject Protection and Ethics Committees
Dr. Cristina Torres UP, Manila and FERCUP

Monitoring and auditing Ethics Committee
Dr. Cristina Torres and Allan Johansen

Lunch

PM

Data and Safety Monitoring Board DSMB
Dr. Juntra Karbwang-Laothavorn, TDR, Switzerland

Tea Break

Audit and Inspection
Dr.Allan Johansen

Rev and Exam 5 (Module 5)
Prof.Hirayama or Prof.Ikeda

November 16, Monday (Day 16)

Module 6: Clinical Data Management

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

AM

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

Protocols and CRF
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

Standard Operating Procedures (SOPs)
Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand

Data management
Ms. Panida Kongjam & Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand (Practical Session)

Lunch

PM

Data management (Practice)

Ms. Panida Kongjam & Professor Dr. Kesara Na-Bangchang,
Thammasat University, Thailand (Practical Session)

Rev and Exam 6 (Module 6)
Prof.Hirayama or Prof.Ikeda

November 17, Tuesday (Day 17)

FINAL EVALUATION. COURSE ASSESMENT

Dr. Juntra Karbwang-Laothavorn, TDR, Switzerland

CLOSING CEREMONY