# Nagasaki-Thammasat University Diploma Course on Research & Development of Products to Meet Public Health Needs

*Organized by*
*Nagasaki Institute of Tropical Medicine, Nagasaki University, Japan*
*and Faculty of Allied Health Sciences, Thammasat University, Thailand*
*in cooperation with*
*Chulalongkorn University, and Khon Kaen University, Thailand*
*Supported by*
*Nagasaki Institute of Tropical Medicine, Nagasaki University, Japan,*
*Japanese Association of Pharmaceutical Medicine (JAPHMED), Japan*
*and*
*UNICEF-UNDP- World Bank - WHO Special Programme for Research and Training in Tropical Diseases (WHO/TDR)*

28 October – 2 December, 2008

**Course Directors:**
*Professor Dr. Kenji Hirayama*
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*Director, Graduate Program in Biomedical Sciences, Thammasat University*
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**Course Coordinators:**
*Associate Professor Dr. Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand*

*Associate Professor Dr. Wichittra Tassneeyakul, Faculty of Medicine, Khon Kaen University, Thailand*

*Assistant Professor Dr. Ratchaneewan Aunpad, Faculty of Allied Health Sciences, Thammasat University, Thailand*

**Course Facilitator:**
*Dr. Wanna Chaijaroenkul, Faculty of Allied Health Sciences, Thammasat University, Thailand*

*Dr. Veerachai Eursitthichai, Faculty of Allied Health Sciences, Thammasat University, Thailand*

**Venue:**
*Faculty of Allied Health Sciences, Thammasat University (Rangsit Campus)*

**Registration Fee :**
*Foreign participants : 1,500 USD for the whole course or 100 USD /day*
*(including 2 tea breaks and lunch)*
*Participants from International Organization in Thailand : 1,200 USD for the whole course or 80 USD/day*
*(including 2 tea breaks and lunch)*
*Thai participants : 23,200 Baht for the whole course (20% discount) or 1,000 Baht /day**
*(including 2 tea breaks and lunch)*

| *No.* | *Participants Category* | *Whole course* | *1 Day* | *Note** |
|---|---|---|---|---|
| *1.* | *Foreign* | *1,500 USD* | *100 USD* | - |
| *2.* | *International Organization in Thailand* | *1,200 USD* | *80 USD* | - |
| *3.* | *Thai* | *23,200 Baht* | - | - |
| *4.* | *Thai (Module 1 or 4 only)* | - | - | *1,000 Baht* |
| *5.* | *Thai (Module 2 only)* | - | - | *14,000 Baht* |
| *6.* | *Thai (Module 3 only)* | - | - | *6,000 Baht* |
| *7.* | *Thai (Module 5 only)* | - | - | *3,000 Baht* |
| *8.* | *Thai (Module 6 or 7 only)* | - | - | *2,000 Baht* |

**Registration deadline : October 10, 2008**
*(We also accept onsite registration however registration kit material including tea breaks and lunch are not guaranteed)*

**Accommodation:** *On-campus accommodation is provided by Thammasat Property Management Office at Asian Games Village and Institute of East Asian Studies. Accommodation charges at Asian Games Village and Institute of East Asian Studies is 500 Baht/day and 600 Baht/day, respectively. 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.*

# Module 1：Course Orientation

**28 October, 2008 Tuesday**

0900-0915 1.1 Welcome address
*Professor Dr. Surapon Nitikraipoj, Rector, Thammasat University,Thailand*
*Professor Dr. Vithoon Viyanant, Dean, Faculty of Allied Health Sciences, Thammasat University*
*Professor Dr. Kenji Hirayama, Dean, Nagasaki Institute of Tropical Medicine Nagasaki University, Nagasaki, Japan*

0915-0930 1.2 Objective of the course and expectation
*Professor Dr. Kesara Na-Bangchang, Course Director & Director, Graduate Program in Biomedical Sciences, Thammasat University*
*Dr. Janis Lazdins, WHO/TDR, Geneva*

0930-0945 1.3 Introduction of participants

0945-1030 1.4 Overview of product research and development
*Dr. Janis Lazdins, WHO/TDR, Geneva*

1030-1100 1.5 The nature of disease and the purpose of therapy
*Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand*

1100-1115 *Tea break*

1115-1200 1.6 Key medical and public health issues, and the need for new products
*Dr. Janis Lazdins, WHO/TDR, Geneva*

1200-1300 *Lunch*

1300-1400 1.7 Discovery research and product development and the different approaches required for each of them
*Dr. Janis Lazdins, WHO/TDR, Geneva*

1400-1500 1.8 Stakeholders in Product Research and Development
- Large, medium and small pharmaceutical companies
- Academic institutions
- Clinical Research Organization
- Biotech
- Regulatory

*Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand*

1500-1600 1.9 Drug targets identification and validation in TB
*Associate Professor Dr. Prasit Palittapongarnpim, BIOTEC, Thailand*

1600-1630 *Tea break*

1630-1700 1.10 Stakeholders in Product Research and Development (Discussion)
*Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand*

# Module 2：Drug Discovery and Development

# Drug Discovery

**29 October, 2008 Wednesday**

0900-1030 2.1 The drug discovery process: general principles and some case histories

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

1030-1100 *Tea Break*

1100-1230 2.2 The role of genomics and bioinformatics

*Associate Professor Dr. Wasun Chantratita, Ramathibodi Hospital, Mahidol University, Thailand*

1230-1330 *Lunch*

1330-1530 2.3 Pharmacology: The role in drug discovery

*Associate Professor Dr. Krongtong Yoovathaworn, Mahidol University, Thailand*

1530-1545 *Tea break*

1545-1645 2.4 High-throughput screening

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

1645-1745 2.5 The role of chemistry in drug discovery
Hit/lead generation and optimization

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

**30 October, 2008 Thursday**

0900-1030 2.6 Biopharmaceuticals

*Associate Professor Dr. Wacharee Limpanathikul, Faculty of Medicine, Chulalongkorn University*

1030-1100 *Tea break*

1100-1230 2.7 Introduction to pharmacokinetics & issues in drug discovery
*Professor Dr. Kesara Na-Bangchang, Course Director & Director, Graduate Program in Biomedical Sciences, Thammasat University*

1230-1330 *Lunch*

1330-1500 2.8 Drug discovery in CNS diseases

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

1500-1530 *Tea break*

1530-1700 2.9 Publications, IPR and patents in drug discovery

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

# Chemistry, Manufacturing and Control (CMC)

**31 October, 2008 Friday**

0900-1000 2.10 Introduction to CMC
*Associate Professor Dr. Satit Puttipipatkhachorn, Faculty of Pharmacy, Mahidol University*

1000-1100 2.11 Formulations of drug products
*Associate Professor Dr. Satit Puttipipatkhachorn, Faculty of Pharmacy, Mahidol University*

1100-1130 *Tea Break*

1130-1230 2.12 Methods for determination of concentrations in various media by means of spectrometric methods, HPLC, and biological methods
*Associate Professor Dr. Prapin Wilairat, Faculty of Sciences, Mahidol University*

1230-1330 *Lunch*

1330-1430 2.13 Stability for drug substance and drug product
*Associate Professor Dr. Detpon Preechagoon, Faculty of Pharmaceutical Sciences, Khon Kaen University*

1430-1500 *Tea break*

1500-1600 2.14 Examples: Formulations and stability of drugs and health products
*Associate Professor Dr. Satit Puttipipatkhachorn, Faculty of Pharmacy, Mahidol University*

1600-1630 2.14 (Cont.) Examples: Formulations and stability of drugs and health products
*Associate Professor Dr. Detpon Preechagoon, Faculty of Pharmaceutical Sciences, Khon Kaen University*

**1 November, 2008 Saturday (Video Conference from Nagasaki University, Japan)**

0900-1000 2.15 Development of specification
*Professor Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan*

1000-1100 2.16 Quality assurance/quality control
*Professor Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan*

1100-1115 *Tea break*

1115-1230 2.17 Regulatory (with an example of a drug CMC requirement)
*Professor Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan*

1230-1330 *Lunch*

1330-1400 2.18 Naming the New Chemical Entity (NCE)
*Professor Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan*

1400-1530 2.19 Synthesis of active pharmaceutical ingredient
*Professor Dr. Hiroaki Nagaoka, Faculty of Health Management, Nagasaki International University, Japan*

**3 November, 2008 Monday**

900-1000 Participants' Report on Drug Discovery

1300-1600 2.20 Visit Clinical Site (Dr. Yupin Lawanprasert)

# Pre-clinical Development

## *Pharmacological development*

**4 November, 2008 Tuesday**

0900-1100 2.21 Pharmacological data in new drug application
*Associate Professor Dr. Nongluck Sookvanichsilp, Faculty of Pharmacy, Mahidol University*

1100-1130 *Tea break*

1130-1230 2.22 Methods in pharmacological R&D-I
*Associate Professor Dr. Chuthamanee Suthisisang, Faculty of Pharmacy, Mahidol University*

1230-1330 *Lunch*

1330-1430 2.23 Methods in pharmacological R&D-II
*Associate Professor Dr. Chuthamanee Suthisisang, Faculty of Pharmacy, Mahidol University*

1430-1530 2.24 The role of drug metabolism in R&D
*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

1530-1600 *Tea break*

1600-1730 2.25 Discussion

*Dr. John Cashman, Director, Human BioMolecular Research Institute (HBRI), San Diego, California, USA.*

## *Toxicology*

**5 November, 2008 Wednesday**

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|---|---|
| 0900-1000 | 2.26 Principles of toxicology<br>*Professor Dr. Amnuay Thithapandha, Mahidol University, Thailand* |
| 1000-1100 | 2.27 Toxicological tests: *in vitro & in vivo:* acute, subacute, chronic, special organ toxicology, reproduction toxicology, teratogenicity, mutagenicity, carcinogenicity and toxicokinetic studies<br>*Associate Professor Dr. Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand* |
| 1100-1130 | *Tea break* |
| 1130-1300 | 2.28 Scheduling of toxicological studies in the development plan, the registration requirements, human & animal pharmacology, the proposed clinical application and the forms of administration.<br>*Associate Professor Dr. Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand* |
| 1330-1400 | *Lunch* |
| 1400-1500 | 2.29 Continuous monitoring of the correlation between new toxicological findings and the unwanted events observed in humans up till now.<br>*Associate Professor Dr. Wongwiwat Tassaneeyakul, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand* |
| 1500-1530 | *Tea break* |
| 1530-1630 | 2.30 Transferability of the pharmacokinetic findings in animals to humans Investigating toxicological problems - practices and pitfalls<br>*Associate Professor Dr. Krongtong Yoovathaworn, Mahidol University, Thailand* |
| 1630-1700 | Video: Animal facility from Nagasaki Institute of Tropical Medicine, Nagasaki University, Japan<br>*Prof. Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan* |

**6 November, 2008 Thursday**

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|---|---|
| 900-1200 | 2.31 Visit Siam Pharmaceutical Company (Dr. Yupin Lawanprasert) |
| 1330-1630 | 2.32 Visit animal facility for medical research (Mahidol University, Salaya) |

# Clinical Development

## *Study design*

**7 November, 2008 Friday**

0900-1030 2.33 Study design

- Possible study designs taking into account ethical aspects, indication, controls, patient population, location of the trial centers
- Trial design (parallel group design, cross over design, factorial design, group sequential design)
- Design techniques to avoid bias (blinding, randomization)

*Associate Professor Dr. Jaranit Kaewkungwal, Faculty of Tropical Medicine, Mahidol University*

1030-1100 *Tea break*

1100-1230 2.33 Study design (Cont.)

- Multi centers trials
- Type of comparison
- Outcome measurements

*Associate Professor Dr. Jaranit Kaewkungwal, Faculty of Tropical Medicine, Mahidol University*

1230-1330 *Lunch*

1330-1500 2.34 Statistical considerations

- Biostatistics in the planning phase (estimate of number of cases, randomization, statistical models, definition of end-points, planning of the subsequent evaluation)
- Statistical analysis plan
- Analysis sets: full analysis set, per protocol set, missing values and outliers

*Associate Professor Dr. Jaranit Kaewkungwal, Faculty of Tropical Medicine, Mahidol University*

1500-1530 *Tea break*

1530-1700 2.35 Statistical considerations (Cont.)

- Data transformation
- Method of statistical analysis (estimation, confidence intervals, hypothesis testing, evaluation of safety and tolerability)
- Statistical analysis report

*Associate Professor Dr. Jaranit Kaewkungwal, Faculty of Tropical Medicine, Mahidol University*

## *Clinical Trial*

**10 November, 2008 Monday**

0900-1100 2.36 Overview of clinical development

- Assessment of pre-clinical information
- Clinical development plan
- Application of pharmacokinetics and pharmacodynamics in drug development
- Dose selection and regimen

*Professor Dr. Juntra Karbwang, TDR, World Health Organization, Switzerland*

1100-1130 *Tea break*

1130-1200 2.37 The various investigational phases of clinical research (Phases I-IV)
*Professor Dr. Juntra Karbwang, TDR, World Health Organization, Switzerland*

1200-1300 *Lunch*

1500-1530 *Tea break*

1530-1630 2.38 Pharmacogenomics
*Associate Professor Dr. Wichittra Tassneeyakul, Faculty of Medicine, Khon Kaen Univerity, Thailand*

**11 November, 2008 Tuesday**

0900-1030 2.39 Therapeutic exploratory (with example)

*Professor Dr. Juntra Karbwang, TDR, World Health Organization, Switzerland*

1030-1100 *Tea Break*

1100-1230 2.40 Safety monitoring and reporting in clinical trials

- Basic principles and evaluation of investigational results (Phase-I and early Phase-II), with a view to further Development
- Basic principles for decisions regarding further development or discontinuation of a development project

*Dr. Kitima Yuthavong, PRIMA, Thailand*

1230-1330 *Lunch*

1330-1500 2.41 Role of CRO in global drug development

1500-1530 *Tea Break*

1530-1700 2.42 Human pharmacokinetics:

- Clinical Application of PKs
- Special human-pharmacokinetic studies e.g. bioavailability studies of multiple-dose, interaction studies, pregnancy, liver disease *etc*.

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

## *Regulatory Issues*

**12 November, 2008 Wednesday**

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| 0900-1030 | 2.43 Regulatory aspects of clinical development<br>*Professor Dr. Masayuki Ikeda, Nagasaki University Graduate School of Medical Sciences , Nagasaki, Japan* |
| 1030-1100 | *Tea break* |
| 1100-1230 | 2.44 Special topics:<br>*Professor Dr. Masayuki Ikeda, Nagasaki University Graduate School of Medical Sciences , Nagasaki, Japan* |
| 1230-1300 | *Lunch* |
| 1330-1630 | 2.45 Visit Government Pharmaceutical Organization of Thailand (Dr.Vichai Chokevivat) |

## *Traditional Medicine*

**13 November, 2008 Thursday**

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| 0900-1030 | 2.46 Introduction of Traditional Medicine: Alternative but rational approach<br>*Dr. Vichai Chokevivat, Chair, FERCAP*<br>*Prof. Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan* |
| 1030-1100 | *Tea break* |
| 1100-1200 | 2.47 Guidance on herbal medicine<br>*Dr. Vichai Chokevivat, Chair, FERCAP*<br>*Prof. Dr. Kiichiro Tsutani, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan* |
| 1200-1300 | *Lunch* |
| 1300-1400 | 2.48 Regulation for traditional medicine development<br>*Dr. Vichai Chokevivat, Chair, FERCAP*<br>*Associate Professor Dr. Pleumchitt Rojanapanthu, Faculty of Pharmacy, Mahidol University, Thailand* |
| 1400-1500 | 2.49 Example: Herbal medicine to modern medicine<br>*Associate Professor Dr. Pleumchitt Rojanapanthu, Faculty of Pharmacy, Mahidol University, Thailand* |
| 1500-1530 | *Tea break* |
| 1530-1700 | 2.50 Example of Clinical Drug development<br>*Associate Professor Dr. Pleumchitt Rojanapanthu, Faculty of Pharmacy, Mahidol University, Thailand* |

# Module 3: Vaccine Development

# Vaccine Discovery

**14 November, 2008 Friday**

0900-0930 3.1 Historical of vaccine Discovery
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

0930-1030 3.2 Overview of modern vaccine discovery
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

1030-1100 *Tea break*

1100-1200 3.3 Screening for antigens
*Professor Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan*

1200-1330 *Lunch*

1330-1430 3.4 Evaluating antigens
*Professor Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan*

1430-1500 *Tea break*

1500-1700 3.5 Vaccine discovery: Malaria
*Professor Dr. Kenji Hirayama, Director of the course, Institute of Tropical Medicine, Nagasaki University, Japan*

**15 November, 2008 Saturday**

0900-1030 3.6 Adjuvant
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

1030-1100 *Tea break*

1100-1200 3.7 Alternatives to antigens: DNA vaccine, Live or attenuated pathogen
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

1200-1330 *Lunch*

1330-1430 3.8 Selection of development candidate and back-ups
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

1430-1500 *Tea break*

1500-1630 3.9 Efficacy, toxicity, route if immunization, price, stability, cold chain,
*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia*

**17 November, 2008 Monday**

900-1200 3.10 Vaccine discovery: Liver flukes
*Dr. Hans Rudi Grams, Faculty of Allied Health Sciences, Thammasat University*

1200-1300 *Lunch*

1300-1400 3.11 Visit Vaccine Discovery laboratory (Dr. Hans Rudi Grams and Dr. Veerachai Eurshittichai)

# Antigen Development

**18 November, 2008 Tuesday**

0900-1100 3.12 Antigen development
- History of vaccine development
- Down period –Try and error period
- The second period –Toxoid vaccine
- The 3rd period – Virus vaccine period
- The 4th period – Genetic engineering period

*Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan*

1100-1115 *Tea break*

1115-1300 3.13 Process of vaccine production

*Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan*

1300-1400 *Lunch*

1400-1500 3.13 Process of vaccine production (continued)

*Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan*

1500-1600 3.14 Quality Assurance of Vaccine

*Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan*

1600-1615 *Tea break*

1615-1700 3.14 Quality Assurance of Vaccine (Continued)

*Dr. Nobuhiro Noro, Glaxo SmithKlein KK, Tokyo, Japan*

# Pre-Clinical Development

**19 November, 2008 Wednesday**

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| 0900-1030 | 3.15 Safety assessment<br>Toxicity test in animals: regional complications, systemic toxicity<br>*Dr. Nobuhira Noro, GSK, Tokyo, Japan* |
| 1030-1100 | *Tea break* |
| 1100-1230 | 3.16 Immunogenicity assessment<br>*Dr. Nobuhira Noro, GSK, Tokyo, Japan* |
| 1230-1330 | *Lunch* |
| 1330-1430 | 3.17 Regulatory<br>*Dr. Nobuhira Noro, GSK, Tokyo, Japan* |
| 1430-1445 | *Tea break* |
| 1445-1600 | 3.18 Example: Animal model used in pre-clinical studies<br>*Dr. Nobuhira Noro, GSK, Tokyo, Japan* |

# Clinical Development

## *Overview*

**20 November 2008 Thursday**

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| 0900-1030 | 3.19 Assessment of pre-clinical information<br>*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia* |
| 1030-1100 | *Tea break* |
| 1100-1200 | 3.20 Clinical development plan<br>*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia* |
| 1200-1300 | *Lunch* |
| 1300-1430 | 3.21 Application of immunogenicity for vaccine development<br>*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia* |
| 1430-1500 | *Tea break* |
| 1500-1600 | 3.22 Dose selection and regimen<br>*Dr. Howard Engers, Armauer Hansen Research Institute (AHRI), Ethiopia* |
| 1600-1700 | Participants' report on vaccine R&D |

# Module 4: Diagnostic Development

**21 November, 2008 Friday**

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|---|---|
| 0900-1000 | 4.1 Discovery and development of diagnostic tools: Necessity assessment, Principles and technology selection<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1000-1030 | 4.2 Prototype production and assessment<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1030-1100 | *Tea break* |
| 1100-1200 | 4.3 Scale-up, manufacture and control<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1200-1300 | *Lunch* |
| 1300-1400 | 4.4 Scale-up, manufacture and control (Cont.)<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1400-1500 | 4.5 Development of kits<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1500-1530 | *Tea break* |
| 1530-1630 | 4.6 Quality assurance/quality control: evaluation of efficacy after application<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1630-1700 | 4.7 Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |
| 1700-1730 | 4.8 Clinical development: Supply chain logistics and production, Statistical consideration, regulatory issues<br>*Dr. Masato Sasaki, Roche Diagnostics KK, Tokyo, Japan* |

# Module 5: Post-registration Activities

**24 November, 2008 Monday**

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| 0900-1200 | 5.1 Stakeholders to be involved in making product development work for the intended beneficiaries<br>*Prof. Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand*<br>*Dr. Kihito Takahashi, Japanese Association of Pharmaceutical Medicine (JAPHMED), Merck Banyu Pharma, Japan* |
| 1200-1300 | *Lunch* |
| 1300-1400 | 5.2 Public private partnership<br>*Professor Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand* |
| 1400-1430 | *Tea break* |

1430-1530 5.3 Medicine access Problems and PPP
*Professor Dr. Chitr Sitthi-amorn, Chulalongkorn University, Thailand*
*Mr. Kenji Toda, Senior Vice President, Government Relations, Tokyo, Eisai Co., Ltd,*

**25 November, 2008 Tuesday**

0900-1030 5.4 Improving the quality of new products in health systems: International network of rational use of drugs
*Professor Dr. Chitr Sitthi-amorn, Chulalongkorn University*

1030-1045 *Tea break*

1045-1230 5.5 Post-marketing product vigilance
*Dr. Yupin Lawanprasert, Principal Scientific Advisor on Safety, Efficacy and Use of Medicines and Health Products, Thailand*

1230-1330 *Lunch*

1330-1500 5.6 Intellectual Property Rights Protection in Developing Countries
*Dr. Yupin Lawanprasert, Principal Scientific Advisor on Safety, Efficacy and Use of Medicines and Health Products, Thailand*

1500-1515 *Tea Break*

1515-1630 Parcipants's report on post registration activities

# Module 6: Good Clinical Practice

## *Ethics in research and Ethics Committee*

**26 November, 2008 Wednesday**

0900-1000 6.1 Ethics Codes and Guidelines
*Professor Dr. Christina Torres, FERCAP*

1000-1100 6.2 Principles of Research Ethics
*Professor Dr. Christina Torres, FERCAP*

1100-1115 *Tea Break*

1115-1230 6.3 Principles of Research Ethics - case studies
*Professor Dr. Christina Torres, FERCAP*

1230-1400 *Lunch*

1400-1500 6.4 Research Methodologies and Ethical Issues in Traditional and Alternative Medicine
*Dr. Vichai Chokevivat, Chair, FERCAP*

1500-1630 6.5 Research methodology and ethical issues, International study -Case studies
*Dr. Vichai Chokevivat, Chair, FERCAP*

**27 November, 2008 Thursday**

0900-1030 6.6 Human Subject Protection and Ethics Committees
*Professor Dr. Christina Torres, FERCAP*

1030-1100 *Tea break*

1100-1230 6.7 Human Subject Protection and Ethics Committees (Cont.)
*Professor Dr. Christina Torres, FERCAP*

1230-1330 *Lunch*

1330-1430 6.8 Monitoring and Auditing Ethics Committee
*Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO*
*Dr. Allan Johansen, Roche Products Pty limited, Australia*

1430-1530 6.9 Data and Safety Monitoring Board (DSMB)
*Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO*
*Dr. Allan Johansen, Roche Products Pty limited, Australia*

1530-1545 *Tea Break*

1545-1630 6.10 Case studies
*Dr. Allan Johansen, Roche Products Pty limited, Australia*
*Professor Dr. Juntra Karbwang-Laothavorn, TDR/WHO*

## *Quality Standards*

**28 November, 2008 Friday**

0900-0930 6.11 Concept of Good Clinical Practice
*Professor Dr. Juntra Karbwang, WHO/TDR, Geneva, Switzerland*

0930-1230 6.12 Responsibilities: Sponsor, Investigators, IRB, Monitors, DSMB
*Professor Dr. Juntra Karbwang, WHO/TDR, Geneva, Switzerland*
*Dr. Allan Johansen, Roche Products Pty limited, Australia*

1230-1330 *Lunch*

1330-1530 6.13 Audit and Inspection
*Dr. Allan Johansen, Roche Products Pty limited, Australia*

# Module 7: Clinical Data Management

**1 December, 2008 Monday**

0900-1000 7.1 Overview of clinical data management
Data management plan
*Dr. Chacrin Na-Bangchangj, TU-CDMC, Thailand*

1000-1030 7.2 Protocol and CRF
*Professor Dr. Kesara Na-Bangchang, TU-CDMC, Thailand*

1030-1100 *Tea break*

1100-1230 7.3 Statistical Analysis Plan (SAP)
Data: primary & secondary data
*Professor Dr. Jia He, Clinical Data Management Centre, Department of Health Sciences, Faculty of Health Service, Second Military Medical University, China*

1230-1330 *Lunch*

1330-1430 7.4 Data capture, development of database
Data entry, data verification, data validation, audit trail
Data clarification process
Data query and resolution
*Mr.A.Rajagopal, Clinical Data Management Centre, Biostatistic Resource and Training Centre, Christian Medical College, Vellore, India*
*Mr. Kasin Issaranucheap, TU-CDMC, Thailand*

1430-1445 *Tea Break*

1445-1700 7.4 Continued

**2 December, 2008 Tuesday**

0900-1200 7.5 Practical session on data entry, verification, validation
*Mr.A.Rajagopal, Clinical Data Management Centre, Biostatistic Resource and Training Centre, Christian Medical College, Vellore, India*
*Mr. Kasin Issaranucheap, TU-CDMC, Thailand*
*Ms. Panida Kongjam, TU-CDMC, Thailand*

1200-1300 *Lunch*

1300-1400 7.6 Data transform process (demonstration)
- Adverse Event Dictionary
- Drug Dictionary

*Associate Professor Dr. Sangkae Chamnanvanakij, TU-CDMC, Thailand*
*Mr. Kasin Issaranucheap, TU-CDMC, Thailand*
*Mr. A.Rajagopal, Clinical Data Management Centre, Biostatistic Resource and Training Centre, Christian Medical College, Vellore, India*

1400-1530 7.7 Quality Control & Assurance (QC & QA)
*Dr. L.Jeyaseelan, Clinical Data Management Centre, Biostatistic Resource and Training Centre, Christian Medical College, Vellore, India*

1530-1545 *Tea Break*

1545-1700 7.8 Standard Operating Procedures (SOPs)
*Professor Dr. Kesara Na-Bangchang, TU-CDMC, Thailand*

1700-1710 Closing Ceremony

1800-2000 Farewell party