

| <b>Day 1</b>  |   |         |      |   |                    | <b>21-Aug-17</b>   |  |
|---|---|---------|------|---|--------------------|--------------------|--|
| <b>Module1: Introduction</b>  |   |         |      |   |                    | <b>Time</b>        |  |
| Recognize the concept needs of PRD in medical and global view of health   | Welcome address   |         | 0.25 | Professor Dr. Kenji Hirayama, Nagasaki University, Japan          | 09:00-09:15        | D1-1               |  |
|   | Objective of the course and expectation, Pre-test   | Lecture | 0.25 |   | 09:15-09:30        | D1-2               |  |
|   | Overview of product research and development and stakeholders   | Lecture | 1.00 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan         | 09:30-10:30        | D1-3               |  |
|   | <b>Break</b>  |         |      |   | <b>1030:-10:45</b> |                    |  |
|   | Key medical and public health issues, and the need for new products   | Lecture | 1.00 | Professor Dr. Kenji Hirayama, Nagasaki University, Japan          | 10:45-11:45        | D1-4               |  |
| <b>Lunch</b>  |   |         |      |   |                    | <b>11:45-13:00</b> |  |
| <b>Module 2: Drug Discovery and Development</b>   |   |         |      |   |                    |                    |  |
| <b>Session 1: Discovery</b>   |   |         |      |   |                    |                    |  |
| Describe the pharmacological process for drug discovery.<br>Identify the process to protect intellectual property | History and overview of drug discovery process  | Lecture |      | Professor Dr. Yoshimasa Tanaka, Nagasaki University, Japan        | 13:00-15:30        | D1-5               |  |
|   | The role of Genomics and bioinformatics   |         |      |   |                    | D1-6               |  |
|   | High throughput screening:<br>Pre-requisite of HITS systems, Assay Development & Validation, Biochemical & Cell-based assay, Assay Readout & Detection                                    |         |      |   |                    | D1-7               |  |
|   | The role of Chemistry in Drug Discovery:<br>-Lead Identification,<br>-Lead Generation Libraries (Combinatorial Chemistry, Computational Approches),<br>-Lead Optimization                 |         |      |   |                    | D1-8               |  |
| <b>Break</b>  |   |         |      |   |                    | <b>15:30-15:45</b> |  |
|   | Drug Discovery in Academia  | Lecture | 0.75 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand | 15:45-17:00        | D1-9               |  |
| <b>Day 2</b>  |   |         |      |   |                    | <b>22-Aug-17</b>   |  |
|   | The role of Pharmacology<br>- Pharmacological Evaluations (Selectivity screening, Pharmacological profiling, Testing in animal models of disease, Safety pharmacology)<br>- Examples      | Lecture | 0.75 | Professor Dr. Yoshimasa Tanaka, Nagasaki University, Japan        | 09:00-09:45        | D2-1               |  |
| <b>Session 2 : Preclinical Development</b>  |   |         |      |   |                    |                    |  |
| Describe the process of pharmacological development   | Overview: Pre-clinical study requiments for human clinical studies  | Lecture | 0.50 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand | 09:45-10:15        | D2-2               |  |
|   | Assessing of Drug Safety.<br>the role of toxicology<br>- Objective and Type of Toxicology<br>- Exploratory Toxicology<br>- Regulatory Toxicology<br>- Toxicity Measures and Toxicity Test | Lecture | 0.75 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand | 10:15-11:00        | D2-3               |  |
| <b>Break</b>  |   |         |      |   |                    | <b>11:00-11:15</b> |  |

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|---|---|------------|------|--|--------------------|------|
|   | Biopharmaceuticals<br>- Development of Biopharmaceuticals<br>- Type of Biopharmaceuticals<br>- Issues Related to the use of Biopharmaceuticals (Antigenicity, Stability, Drug delivery)       | Lecture    | 0.50 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand                    | 11:15-11:45        | D2-4 |
| <b>Lunch</b>  |   |            |      |  | <b>11:45-12:45</b> |      |
|   | Pharmaceutical Development and CMC  | Lecture    | 1.00 | Professor Dr. Hiroshi Sasaki, Nagasaki University, Japan                             | 12:45-13:45        | D2-5 |
|   | Patents in Drug Discovery:<br>- Publication VS Patents<br>- Patent system<br>- Type of Patent   | Lecture    | 1.00 | Professor Dr. Hiroshi Kato, Nihon University, Japan                                  | 13:45-14:45        | D2-6 |
| <b>Session 3: Clinical Development</b>                  |   |            |      |  |                    |      |
|   | Overview of clinical development  | Lecture    | 0.50 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan                            | 14:45-15:15        | D2-7 |
| <b>Break</b>  |   |            |      |  | <b>15:15-15:30</b> |      |
|   | Regulatory Framework  | Lecture    | 1.00 | Dr. Hiroshi Yamamoto Nagasaki University, Japan                                      | 15:30-16:30        | D2-8 |
| <b>Day3</b>   |   |            |      |  | <b>23-Aug-17</b>   |      |
|   | Investigational Phases of Clinical Research (I-IV) and Study Design   | Lecture    | 0.50 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan                            | 09:00-09:30        | D3-1 |
|   | Clinical Development Plan   | Lecture    | 1.00 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan                            | 09:30-10:30        | D3-2 |
| <b>Break</b>  |   |            |      |  | <b>10:30-10:45</b> |      |
|   | Pharmacogenomics<br>- Anticipated Benefits<br>- Polymorphisms in Drug Targets<br>- Polymorphisms in ADME<br>- Pharmacogenomics Testing<br>- Pharmacogenomics in Clinical Trials<br>- Examples | Lecture    | 1.50 | Dr. Shyh-Yuh Liou, Ono Pharmaceutical Company Limited Head Office, Japan             | 10:45-12:15        | D3-3 |
| <b>Lunch</b>  |   |            |      |  | <b>12:15-13:00</b> |      |
|   | Pharmacokinetics (Non-clinical & Clinical)  | Lecture    | 1.25 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand                    | 13:00-14:15        | D3-4 |
|   | Case studies  | Group Work | 2.50 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan                            | 14:30-16:30        | D3-5 |
| <b>Day4</b>   |   |            |      |  | <b>24-Aug-17</b>   |      |
| <b>Session 4: Traditional Medicine</b>                  |   |            |      |  |                    |      |
| Underline the importance of traditional medicine in PRD | Introduction of Traditional Medicine and guidance on herbal medicines   | Lecture    | 1.00 | Professor Dr. Kiichiro Tsutani, Tokyo Ariake university of medical and health, Japan | 09:00-10:00        | D4-1 |
|   | Regulation for traditional medicine development   | Lecture    | 1.00 | Professor Dr. Ichiro Arai, Nihon Pharmaceutical University, Japan                    | 10:00-11:00        | D4-2 |
|   | Rev and Exam 2 (Module 2)   |            | 1.00 | Profesoor Dr. Hirayama or Professor Dr. Kesara                                       | 11:00-12:00        | D4-3 |

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| <b>Lunch</b>   |   |         |      |   | <b>12:00-13:00</b>   |                            |  |
| <b>Module5: Good Clinical Practice</b>   |   |         |      |   |  |                            |  |
| Describe the concepts of GCP, Recognise the principles of Ethics in research and the functions of Ethics Committee | Concept of Good Clinical Practice   | Lecture | 0.50 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan         | 13:00-13:30  | D4-4                       |  |
|  | Principles of Research Ethics and Ethics codes and Guidance                           | Lecture | 1.00 | Professor Dr. Juntra Karbwang, Nagasaki University, Japan         | 13:30-14:30  | D4-5                       |  |
|  | <b>Break</b>  |         |      |   |  | <b>14:30-14:45</b>         |  |
|  | Responsibilities: Sponsor, Monitors, audit, DSMB                                      | Lecture | 1.00 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand | 14:45-15:45  | D4-6                       |  |
|  | Clinical Data Management  | Lecture | 0.75 | Professor Dr. Kesara Na-Bangchang, Thammasat University, Thailand | 15:45-16:00  | D4-7                       |  |
| Exam 3 Module 5  |   |         | 0.50 | Profesoor Dr. Hirayama or Professor Dr. Kesara                    | 16:00-16:30  | D4-8                       |  |
| <b>Day5</b>  |   |         |      |   | <b>25-Aug-17</b>   |                            |  |
| <b>Field Trip to Hisamitsu Pharmaceutical Co.,Inc</b>  |   |         |      | <b>site visit</b>   | <b>Mr.Hideyuki Nakano,Hisamitsu Pharmaceutical Co.,Inc</b> | <b>10:00-17:00</b><br>D5   |  |
| <b>Day6</b>  |   |         |      |   | <b>28-Aug-17</b>   |                            |  |
| <b>Module3: Vaccine Discovery and Development</b>  |   |         |      |   |  |                            |  |
| <b>Session 1: Discovery</b>  |   |         |      |   |  |                            |  |
| Describe the principles of basic immunology. Describe the process of vaccine discovery                             | Historical overview of vaccine Discovery  | Lecture | 0.50 | Professor Dr. Kenji Hirayama, Nagasaki University, Japan          | 09:00-09:30  | D6-1                       |  |
|  | Vaccines for infection control  | Lecture | 1.00 |   | 09:30-10:30  | D6-2                       |  |
| <b>Session 2: Pre-Clinical Development</b>   |   |         |      |   |  |                            |  |
| Describe the principles of basic immunology. Describe the process of vaccine discovery                             | Vaccine Platform Technology and Adjuvant Development (Dr.Arakawa)                     | Lecture | 1.00 | Dr. Takeshi Arakawa, University of the Ryukyus, Japan             | 10:30-11:30  | D6-3                       |  |
|  | CMC   | Lecture | 0.50 | Dr. Takeshi Arakawa, University of the Ryukyus, Japan             | 11:30-12:00  | D6-4                       |  |
| <b>Lunch</b>   |   |         |      |   | <b>12:00-13:00</b>   |                            |  |
| Describe the process of pre-clinical development of vaccine  | Immunogenicity and protect activity assessment  | Lecture | 1.00 |   | 13:00-14:00  | D6-5                       |  |
|  | <b>Break</b>  |         |      |   |  | <b>14:00-14:30</b>         |  |
|  | Safety assessment:Toxicity test in animals: regional complications, systemic toxicity | Lecture | 1.50 | 14:30-16:00   | D6-6   |                            |  |
| <b>Day7</b>  |   |         |      |   | <b>29-Aug-17</b>   |                            |  |
| <b>Session3:Clinical Development</b>   |   |         |      |   |  |                            |  |
| Describe the process of vaccine clinical development   | Assessment of pre-clinical information  | Lecture | 1.00 | Dr.Daisuke Tsuzuki  | 09:00-10:00  | D7-1                       |  |
|  | Clinical development plan   | Lecture | 0.50 |   | 10:00-10:30  | D7-2                       |  |
|  | Dose selection and regimen  | Lecture | 1.00 |   | 10:30-11:30  | D7-3                       |  |
|  | Rev and Exam 4 (Module 3)   |         | 1.00 | Professor Dr. Kenji Hirayama, Nagasaki University, Japan          | 11:30-12:30  | D7-4                       |  |
| <b>Lunch</b>   |   |         |      |   | <b>12:30-13:30</b>   |                            |  |
| <b>Visit Laboratory</b>  |   |         |      | <b>Dr, Cherif Mahamod Sama, Nagasaki University Japan</b>         |  | <b>13:30-14:30</b><br>D7-5 |  |
|  |   |         |      | <b>Dr, shusaku Mizukami, Nagasaki University Japan</b>            |  |                            |  |

| <b>Day8</b>   |   |                     |      |  | <b>30-Aug-17</b> |       |
|---|---|---------------------|------|--|------------------|-------|
| <b>Module4: Diagnostic Development</b>                                |   |                     |      |  |                  |       |
| Describe the process of discovery and development of diagnostic tools | Discovery and development of diagnostic tools   | Lecture             | 0.50 | Dr. Masato Sasaki, QIAGEN, Japan   | 09:00-09:30      | D8-1  |
|   | Prototype production and assessment   | Lecture             | 0.50 |  | 09:30-10:00      | D8-2  |
|   | Scale-up, manufacture and control   | Lecture             | 0.50 |  | 10:00-10:30      | D8-3  |
|   | <b>Break</b>  |                     |      |  | 10:30-10:45      |       |
|   | Development of kits   | Lecture             | 0.50 |  | 10:45-11:15      | D8-4  |
|   | Quality assurance/quality control: evaluation of efficacy after application                             | Lecture             | 0.50 |  | 11:15-11:45      | D8-5  |
|   | <b>Lunch</b>  |                     |      |  | 11:45-13:00      |       |
|   | Clinical development: validate prototype, manufacture pilot lot, initiate clinical trial                | Lecture             | 0.50 |  | 13:00-13:30      | D8-6  |
|   | Clinical development: Supply chain logistics and production, Statistical                                | Lecture             | 0.50 |  | 13:30-14:00      | D8-7  |
|   | Rev and Exam 5 (Module 4)   |                     | 1.00 | Professor Dr. Kenji Hirayama and Professor Dr.Kesara Na-Bangchang          | 14:00-15:00      | D8-8  |
| <b>Day 9</b>  |   |                     |      |  | <b>31-Aug-17</b> |       |
| <b>Module 6: Post-registration Activities</b>                         |   |                     |      |  |                  |       |
| Describe post-registration activities for medicinal products          | Overview  | Lecture             | 0.75 | Professor Chitr Sitthi-amorn, Chulalongkorn University, Bangkok, Thailand  | 09:00-09:45      | D9-1  |
|   | How to solve Access to Medicines (ATM) problems in developing countries                                 | Lecture/ Discussion | 0.50 |  | 09:45-10:15      | D9-2  |
|   | Improving the quality of new products in health systems: International network of rational use of drugs | Lecture             | 1.00 |  | 10:15-11:15      | D9-3  |
| Describe post-registration activities for medicinal products          | Post-marketing product vigilance  | Lecture             | 1.00 |  | 11:15-12:15      | D9-4  |
|   | <b>Lunch</b>  |                     |      |  | 12:15-13:00      |       |
|   | Stakeholders to be involved in making product development work for the intended beneficiaries           | Lecture/ Discussion | 1.00 |  | 13:00-14:00      | D9-5  |
|   | Rev and Exam 6 (Module 6)   |                     | 0.50 | Professor Dr. Kenji Hirayama, Nagasaki University, Japan                   | 14:00-14:30      | D9-6  |
| <b>Day 10</b>   |   |                     |      |  | <b>1-Sep-17</b>  |       |
| <b>FINAL EVALUATION. COURSE ASSESSMENT</b>                            |   |                     |      | Professor Dr. Kenji Hirayama, Nagasaki University, Japan                   | 09:00-11:00      | D10-1 |
|   |   |                     |      | Professor Dr. Juntra Karbwang, Nagasaki University, Japan, Course Director |                  |       |
| <b>CLOSING CEREMONY</b>   |   |                     |      |  | 11:00-12:00      | D10-2 |