

Launch of a New Diploma, MSc & PhD Programme in Research & Development of Products to Meet Public Health Needs

Kenji Hirayama, M.D., Ph.D.

Institute of Tropical Medicine, Nagasaki University

Based on the idea that more human resources are needed in the drug/vaccine/diagnostics research and development in the developing countries where new products are required to improve their unique health situation different from developed countries, a new educational programme has been launched in Japan. Here, I would like to show briefly its philosophy, strategy and contents. This programme has not been completed, however, we have started a core diploma course that is consisted of seven modules that cover all the steps to develop a new product from a very basic discovery. This course has been made possible by a synergistic cooperation between several persons from various institutions. Their names and institutions are as follows, Win Guttridge, Janis Lazdins, Juntra Karbwang (World Health Organisation, Switzerland), JinHong Hu (Second Military Medical University, China), Kesara Na-Bangchang (Thammasat University, Thailand), Chitr Sitthi-amorn (Chulalongkorn University, Thailand), Kiichiro Tsutani (University of Tokyo, Japan), Ivan Valez (University of Antioquia, Colombia), and Kenji Hirayama (Nagasaki University, Japan).

I would like to acknowledge Eiji Uchida, Showa University, Kazuhiko Mori, Center for Product Evaluation, Pharmaceutical and Medical Devices, PMDA, Japan, Kihito Takahashi, Japanese Association of Pharmaceutical Medicine (JAPHMED), Masaru Iwasaki, GlaxoSmithKline, Tokyo, Japan, Masakatsu Shibasaki, (The University of Tokyo, and The Pharmaceutical Society of Japan,PSJ), Hiroshi Saitoh (President, Nagasaki University) for their great contribution to the diploma course.

Website: http://www.tm.nagasaki-u.ac.jp/hiraken/information/deploma/diploma_top_frame.html

Background

The development of new drugs, vaccines and diagnostics is complex, requiring many different skills. Each individual involved in a part of product R&D must be aware of the process overall and be able to relate their activities to it and to the needs of the other participating scientists and clinicians. Research scientists seek the discovery and confirmation of new knowledge by initiating or creating a hypothesis and then transforming it first into a theory and later into a new discovery. Product developers turn such discoveries into full-grown products which address public health needs through a

long and quite different processes. Generally, research and development are two different disciplines. People working in these two areas do not think alike; they have different cultures. Often they work in isolation from each other, so they do not understand each other well. However, both disciplines are essential for the development of new drugs, vaccines and diagnostics. Furthermore, discovery of new knowledge is meaningless if it is not translated into new products that meet the needs of the public health.

Currently, there are only few courses in the north that give a good overview of the entire drug discovery and development process such as post-graduate courses at University of Cardiff, ECPM at University of Basel, University of Lyon and may be a few others. In majority of countries around the world, most of the topics related to product R&D are scattered throughout the various university curricula, including basic science, organic chemistry, immunology, pharmacy, pharmacology, vaccinology and clinical pharmacology. However, everyone involved in research or development must know their responsibilities and able to relate their tasks to all the others which make up the process of product R&D. The objective of the proposed course is to pull together the various components needed for product R&D into a dedicated MSc-PhD course. Discussions between different universities who are interested in this project have taken place on several occasions. Recently, six universities in four countries (Japan, Thailand, China and Colombia) have started working together to draft the content of the curriculum.

The curriculum is designed to provide basic knowledge of the product R&D process. It aims to demonstrate that new product discovery and the various development activities such as chemistry, toxicology, clinical investigations and regulatory practices are related as a continuous process, and that one discipline cannot carry out the whole process on its own.

Format of the course

This is a joint project involving a number of universities in different countries. During the first five weeks, all students will take a core course on product R&D aimed at giving them an overview of the process. It will be held on a rotational basis in one of the participating universities. During the next ten weeks, students will select for in-depth exploration an area of their special interest, for example drug discovery, toxicology or clinical, and for this period will work in an institution that offers that specific area.

For the last 8 months, students will be attached to a specific institution, pharmaceutical company or biotech to work on a particular project.

The first four months of the course will be mainly lectures and case studies. The remaining 8 months will be mainly practical, including laboratory studies or clinical practice. The course is modular to allow those who already work in the area of product R&D to attend the appropriate parts of the course. This would provide such personnel with the opportunity of reviewing and discussing the special problems they encountered in their routine, real world work.

At the end of five weeks, students will be awarded a diploma in product research and development from Nagasaki University.

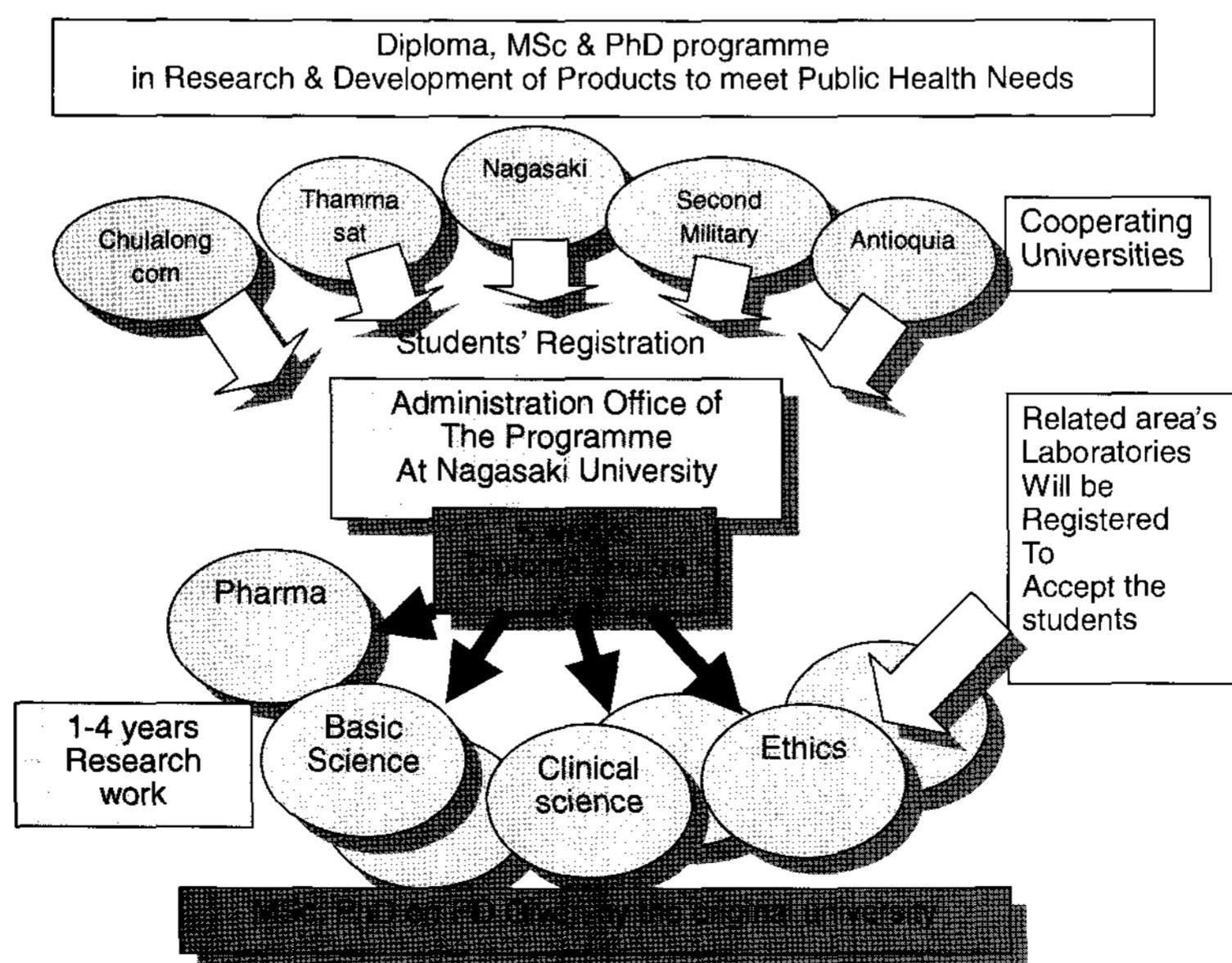
At the end of the first year, the successful students may receive a MSc (subject to university requirement). Progression to PhD will depend on the evaluation of their first year performance. Those chosen as PhD candidates will do their thesis in the area of interest in one of the companies with on-going activities. Each student will receive their degree from the university that they registered for the course.

Contents of the core diploma course

This part of the course will begin with a general overview of product R&D (drugs, vaccines and diagnostics), continue with a series of lectures on discovery research, transitioning between research and development, CMC (chemical, manufacturing and control) requirements, toxicology requirements from development to product license, pharmaceutical and analytical development, pharmacokinetics and metabolic studies, clinical studies - phase I-IV trial design and protocols - project planning and management, handling of safety data in development, regulatory requirements, post regulatory clinical studies, patents issues and other aspects of product development i.e. international standards of good practice, ethics in clinical research, DSMB (Data and safety Monitoring Boards), commercial and marketing activities, and public health implementation.

Contents of the course during the next ten weeks

The students will focus on the area of their interest. They will attend seminars and lectures in specific area such as discovery, CMC, toxicology, vaccinology, pharmacology, clinical development and regulatory requirements. For this, the student can choose to attend at their registered university (if such course is running during the period) or at another affiliated institution.



◆ Kenji Hirayama, M.D., Ph.D. ◆

Present Title: Deputy Dean and Professor, ITM, Nagasaki University
March, 1981 Bachelor of Medicine from Tokyo Medical and Dental University, Tokyo.
May, 1981 Medical Doctor's National License, Japan (No.262445)
March, 1985 Ph.D from Tokyo Medical and Dental University
Thesis: Genetic control of immune response in humans.
April, 1986 Research Fellow at Kyushu University
September, 1986 Assistant Professor at Kyushu University
April, 1988 Lecturer at St.Marianna Medical University
August, 1988 Research Fellow at Harvard School of Public Health.
April, 1991 Lecturer at St.Marianna Medical University
February, 1993 Associate Professor at Saitama Medical School
May, 1995 Professor at Saitama Medical School
April, 2001 Professor at Nagasaki University
April, 2004 Vice President, Nagasaki University until March, 2006
September, 2006 Deputy Dean, Institute of Tropical Medicine

Associations

The Japanese Society of Parasitology
Japanese Society of Tropical Medicine
Japanese Society for Immunology
The Japanese Society for Histocompatibility and Immunogenetics
Royal Society of Tropical Medicine and Hygiene
American Society of Tropical Medicine and Hygiene

Social Activity

Editor in Chief, Tropical Medicine and Health
Steering Committee member of Forum for Ethical Review Committees in Asia and Pacific regions
Clinical monitor (WHO/TDR)
Visiting Professor of Thammasat University