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Education and training in regulatory science for medical device development

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Abstract— **Regulatory science can be defined as the science aimed at the optimal introduction into society of new products of science, such as discovered substances and new scientific tools and technologies as well as knowledge and information. In addition to engineering researches that create novel medical devices, scientific methods for evaluating efficacy, safety and quality of medical devices are necessary to enable rational and scientific evaluation of the device in device approval process. Engineers and medical doctors involving research and development of novel medical devices are required to have basic knowledge on medical device safety standard, medical device regulation, and relevant methodologies. In Japan, several graduate schools in Japan have started educational programs on regulatory sciences in collaboration of Pharmaceuticals and Medical Devices Agency (PMDA), Japan. In 2012, program for researches for development of evaluation guidelines for novel medical device products started where personnel exchanges between academic researches institutes and PMDA. Example of these programs will be introduced in the presentation and its impact on improvement of medical device research and development process will be discussed.**

I. Introduction

"Medical Innovation" are common keywords among developed and developing countries for creation of new industries to strengthen economic activities. Many developed and developing countries have been recently emphasizing importance of promotion of medical devices industries for their economic growth. At the same time, most of countries will face aging of the society that will cause increase in health care cost regardless of developed and developing countries. Thus, it is expected that biomedical engineering should contribute to meet requirements for developing medical devices to support preventive medicine (e.g. self-diagnostic tools for home health care), devices for minimally invasive intervention, and medical information system to improve efficiency and effectiveness of the health care service.

In addition to traditional scientific researches, studies for developing scientific methods for evaluating efficacy, safety and quality of medical devices are necessary to enable rational and scientific evaluation of the device in device approval process. This field of research is known as "Regulatory Science (RS)". There are several definitions[1]. Tominaga et al. proposed the following broader definition: the science aimed at the optimal introduction into society of new products of science, such as discovered substances and new scientific tools and technologies as well as knowledge and information[2]. In this mini symposium, importance of RS related education is discussed. Then recent Japanese activities for education in RS will be presented.

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II. Role of regulatory science education in biomedical engineering

A. academic fundamentals of the biomedical engineering

In the department of bioengineering, School of Engineering, The University of Tokyo, a new educational program of specialists in medical device/material/system industries and research institutes was developed. This program includes three sets of fundamental academic areas: engineering studies for 1) Interaction between artificial materials/systems and biological systems, 2) Biomedical information acquisition and processing, and 3) Control of biological responses as shown in figure 1. Area 1 includes basic studies on biocompatible materials and biomedical studies on physiological responses caused by artificial stimuli. Area 2 includes biomedical instrumentation and medical image analysis. Area 3 includes therapeutic engineering and regenerative medicine. Biomedical engineers in charge of advanced medical devices/materials/systems research and development should have basic knowledge on these three areas. It is also recommended to give students research experience in at least one of three research areas. Most of the research topics lie on intersection among three research areas. In addition, internship in hospitals and biomedical industries will be implemented. [4]

B. Need for regulatory science education and discussion on its effective training method

In developing biomedical devices and materials, basic studies on mechanism of new biomedical engineering and development of device/material design method are important. However, additional studies are required for translation of basic research to clinically applicable products. In developing medical devices, materials, and systems, performance, safety and reliability of the product should be scientifically validated. In particular for novel medical devices /materials, evaluation methods are not always established. In developing evaluation methods, scientific approach based on advanced science and engineering knowledge is important.

The required skills for medical devices/materials/systems developments based on basic scientific and engineering studies are summarized as follows:

1) *Skills for Development*
   Analysis of clinical needs
   Analysis of required technologies for clinical trials

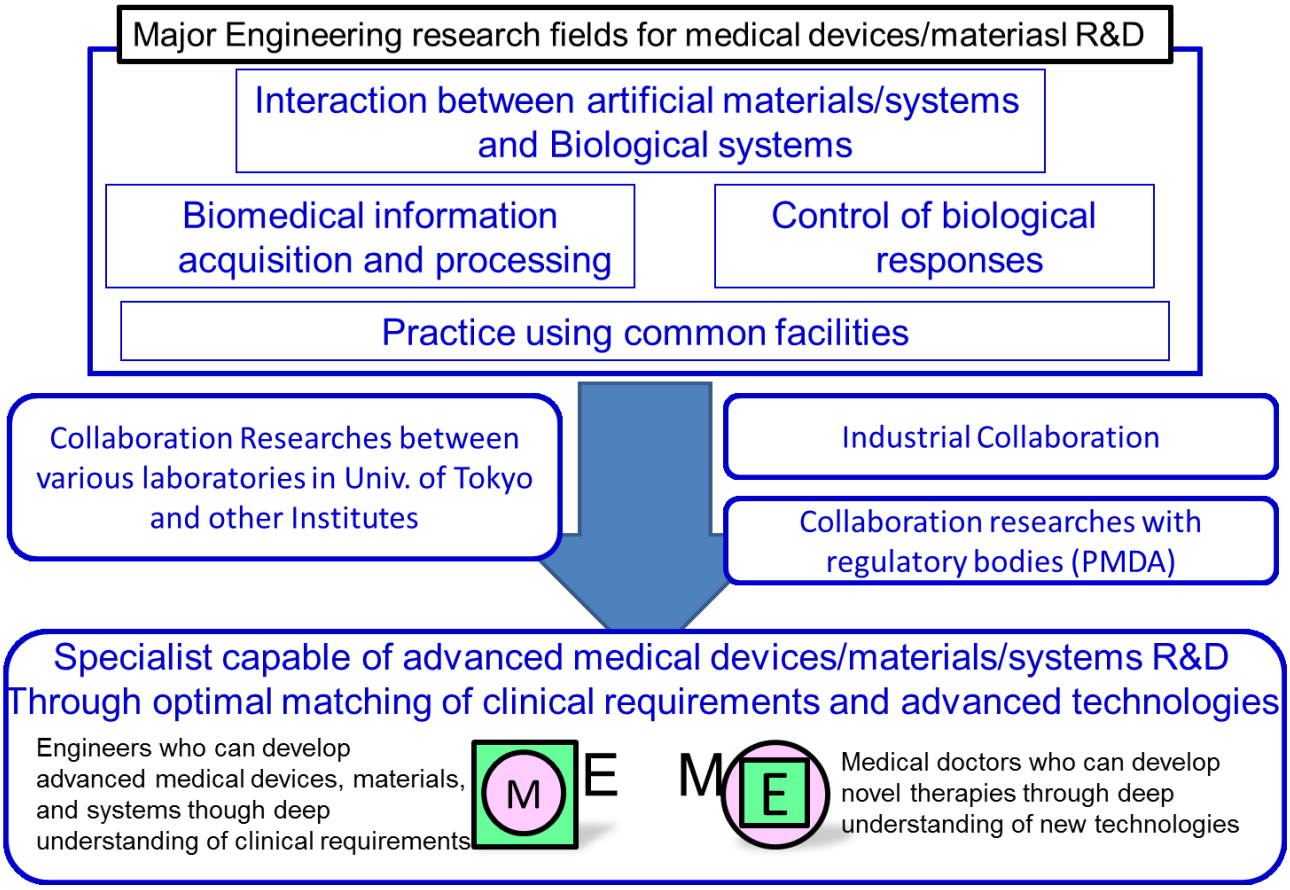

Figure 1 A new educational program for specialists in medical devices/materials/systems industries and research institutes in Department of Bioengineering, School of Engineering, The University of Tokyo

Development of appropriate R&D plan

2) *Skills for Evaluation*
Physical Mechanical Performance Evaluation
Evaluation of Usability and User Performance
Identification of required evaluation items and pre-clinical evaluation tests design
3) *Skills for Risk analysis and management*
Risk analysis of clinical application
Training method of users
Design of post-market surveillance and appropriate risk management

In education programs, it is required to provide lectures and seminars dealing with regulatory process and medical device standards. As an education program, teaching the fundamental framework of medical devices regulation and medical device standard is important rather than teaching detailed guidelines for specific medical devices. To augment lecture and seminar based education, education through case study where students analyze examples of specific medical device approval process will be effective. These training should be implemented together with research activities conducted by students. It is important that graduate students conducting advanced biomedical engineering research also participate in RS education program to educate leaders in medical devices industries.

There is another factor to be considered in conducting RS research and education. In conducting scientific researches, researchers focus on creation of new engineering method, discovery of new phenomena, and development of novel theories. On the other hand, evaluating risks related to safety of the devices requires different way of thinking than that required for conventional research activities.

One trial is found in the Department of Bioengineering, School of Engineering, the University of Tokyo is the global center of excellence program "Center for Medical System Innovation (CMSI) " funded by the Ministry of Education, Culture, Sports, Science & Technology. The program aimed at nurturing and training leaders who promote innovation in the medical field from a global perspective. In this program, case study method is used where PhD students from different expertise form a team to develop business plan to translate one of their research outputs into a specific medical products/service. In this process, the students investigate and analyze unmet clinical needs and various inexplicit requirements found in needed for commercialization. This method conducted in CMSI global COE program is one of the effective ways to train the students to think in a different way. It is also important to study actual pharmaceuticals/medical

devices approval processes to transfer practical and effective knowledge on regulatory issues. Students can evaluate their own technologies not only from scientific and engineering aspects mainly focusing its function but also related various factors such as risk analysis, risk management, economic performance and business planning. They can consider what the most efficient and financially affordable strategy to implement their own technologies in the society is. These ways of training is suitable in regulatory science defined as "the science aimed at the optimal introduction into society of new products of science, such as discovered substances and new scientific tools and technologies as well as knowledge and information".

Finally, education on medical ethics is important so students can acquire ability to evaluate risk and benefit balance considering patient safety.

Ⅲ. Examples of Educational Programs of RS in Japan

A. Joint Graduate School Program between Pharmaceuticals and Medical Device Agency (PMDA) and schools of medicine of universities and colleges

Pharmaceuticals and Medical Devices Agency (PMDA) has been conducting joint graduation program where graduate students having MD conduct research at PMDA concerning regulation of medical devices and drugs in addition to studies at school of medicine. Though this program, specialists with MD PhD having fundamental knowledge both on medical science and pharmaceuticals and medical devices regulation will be educated. In this program, student can access to part of confidential data in pharmaceuticals and medical devices regulation under strict legal regulation with penal code. PhD students conducting basic and applied medical scientific research can have opportunities to study real cases in pharmaceuticals and medical devices regulation. It is expected that researchers and officials in both academia and the regulatory organization can improve quality of translational research and pharmaceuticals and medical devices regulation

B. Research programs on medical devices evaluation guidelines development at universities and research institutes

In 2012, the Ministry of Health, Labour and Welfare started research program for development of evaluation guidelines for novel medical device products. In this program, personnel exchanges between academic researches institutes and PMDA are implemented. Under appropriate avoidance of conflicts of interests, researchers can be involved in medical device regulation activities at PMDA while designated staffs of PMDA conduct collaboration research keeping in touch of technologies under investigation at universities and research institute. Academic researchers can obtain knowledge on medical device regulation and PMDA staffs can obtain scientific frontiers in this field. In this program, guidelines for medical device evaluation useful for medical device regulation process will be developed.

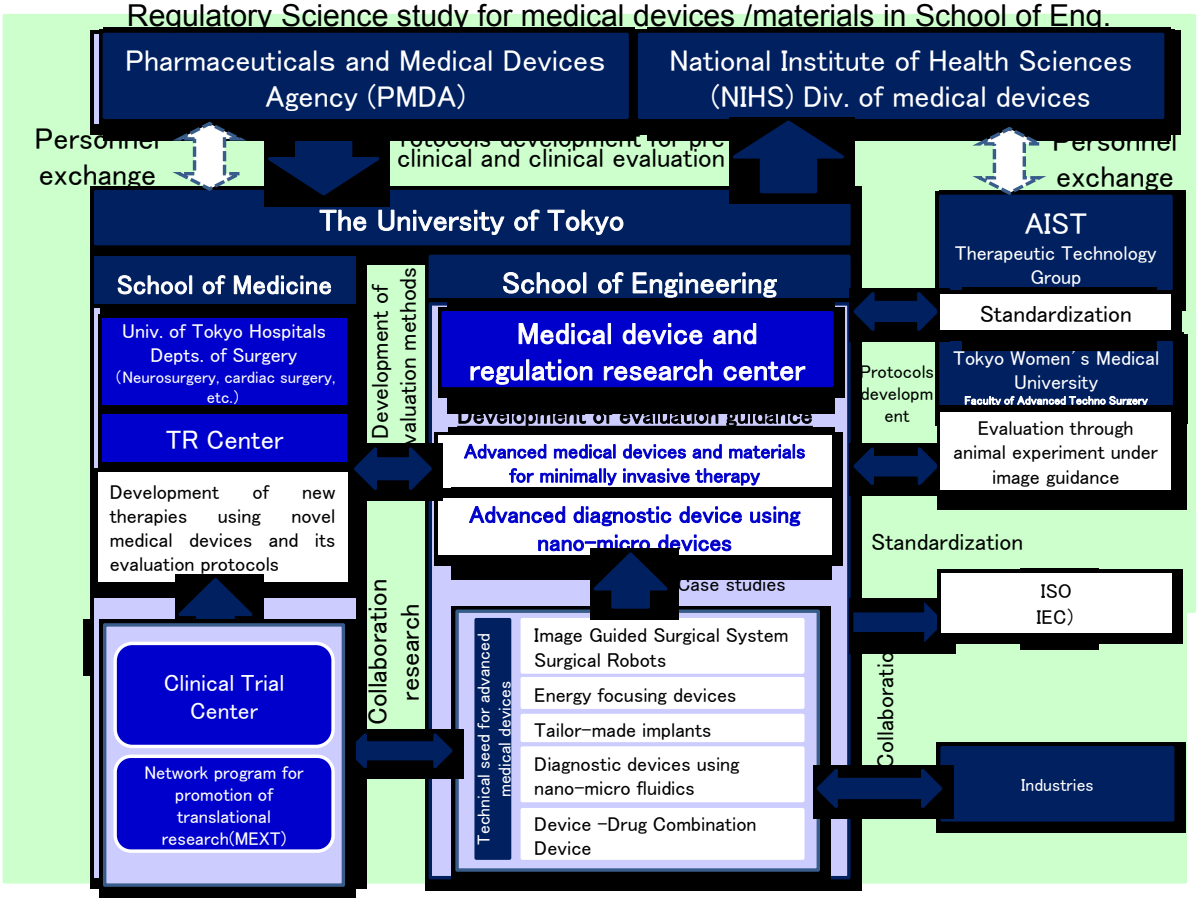

Figure 2 Regulatory Science study for medical devices /materials in School of Eng. The University of Tokyo

In the School of Engineering, the University of Tokyo, a program was initiated to develop guidelines for medical devices for minimally invasive intervention, advanced materials and novel microchip based diagnostic tools. As shown in figure 2. The collaboration researche with PMDA, National Institute of Health Sciences (NIHS) Div. of medical devices, The National Institute of Advanced Industrial Science and Technology (AIST), and Tokyo Women's Medical University will be conducted. It is expected that quality of academic research in terms of implementation of new sciences and technologies on societies and quality of medical device approval process will be improved.

III. CONCLUSION

For efficient translation of novel scientific knowledge and technologies studies in academia to actual clinical device, education concerning medical device regulations including international standards is essential in addition to conventional training programs in biomedical engineering. In education programs, it is required to provide education through case study where students analyze examples of specific medical device approval process together with lectures and seminars. It is important that graduate students conducting advanced biomedical engineering research also participate in RS education program to educate leaders in medical devices industries.

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