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Regulatory sciences in Asia: current and future aspect of regulatory sciences in Thailand

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Regulatory science has been used to develop tools, standards, and process to assure the efficacy, safety and performance of all products regulated. Thai Food and Drug Administration is the major agency to regulate the health products to protect and promote the safety and quality of all products for the good health of Thai population. The main products are food and drug consumed by Thais and for export to other countries. The regulation of all food products is operated under the Food Act B.E. 2522 (A.C. 1779) and amendment followed. Many types of regulation science are applied, the risk analysis process conformed to international procedure, is the major process used. The risk assessment is the scientific basis for creating management options. The risk management is the policy to evaluate and the decision is made to select an appropriate option for the regulation, such as standard setting, registration process and code or guideline of practice, which is (are) suitable for country. For drug regulation, the process is quite complicated under the Drug Act B.E. 2510 (A.C. 1967) and amendment followed. The data and information on the efficacy test is needed to prove the therapeutic benefit of the product. The safety assessment is also based on the best possible science to assure the safety of the drug which needs comprehensive toxicity testing. Before the drug is marketed, the prove of efficacy and safety in human through the clinical trials according to the best guideline must be performed. Based on this process, the regulation on registration and authorization are established.

Both food and drug regulations, the pre-marketing and post-marketing processes are applied. The pre-marketing process is to assure that the product is good quality and safe for the consumer. While the post-marketing process is the system of monitoring and surveillance on unexpected effect and expected efficacy and quality of the product are followed. The adverse drug reaction (ADR) monitoring program and the food safety monitoring program are established. The data from the monitoring program is then used to improve the regulation for the optimum management. Various guidelines to ensure the efficacy, quality and safety of the products are implemented mandatorily, such as good hygienic practice (GHP), good manufacturing practice (GMP), PICS (in the process of drug regulation) and hazard analysis of critical control point (HACCP).

The application of new available regulatory science is used to modernize, improve and ensure the readiness of the agencies to evaluate the innovative emerging technologies. The strengthening of consumers and professionals is important and help the Thai FDA and related agencies to make proper and appropriate decision on the regulation. The other products under the regulation of Thai FDA and other agencies in Thailand are also based on best possible regulatory science available. The future regulation will be harmonized with the regional as ASEAN and global regulatory process.

AS5-6

Regulatory science of nonclinical drug development in Japan

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Japanese society of regulatory science, named “Society for Regulatory Science of Medical Products”, has been founded in 2010. Since then discussion has been made on this matter. Regulatory Science is necessary for nonclinical drug development as well as clinical and post marketing phases. We can see drug development as a series of decision making for Go/No go. Nonclinical studies provide data necessary for the decision making throughout all drug development phases. There are regulations like ICH guidelines for these nonclinical studies conducted before New Drug Application. Regulatory Science is necessary for preparation, harmonization and implementation of these guidelines. However, we usually need to conduct additional studies other than required ones in order to solve safety-related issues. Investigative nonclinical studies are essential when unexpected safety findings are found in regulatory required nonclinical studies and/or clinical trials to know mechanism(s) of these toxicities. Data derived from these investigative nonclinical studies are critical for the decision making. Thus Regulatory Science is essential to design and perform these studies. In this presentation, significance of Regulatory Science in nonclinical drug development will be discussed with some examples of our investigative studies.