S21-3 Expectation of Regulatory Science Education; Administrator Perspective

◯Toshiro NAKAGAKI[1]
[1]MHLW

MHLW's policies and activities on pharmaceuticals, quasi-drugs, cosmetics, foods, food additives, and chemicals are based on regulatory sciences. Decisions are made by comparing risks and benefits through evaluation of collected non-clinical and clinical data. There are limitations on the quality and quantity of collectable data. In addition, evaluations and decisions are made under time constraint. Data can be categorized as physiochemical and biological data including manufacturing methods, specification and testing methods, and stability, non-clinical data including pharmacology, ADME (absorption, distribution, metabolism and excretion) and toxicology, clinical data including PK, PD and comparative study, and postmarketing data including adverse drug reaction reports. Information on medical environment such as availability of other therapies, approval status in US/EU, usages in overseas is also necessary. Although MHLW utilize internal and external experts for evaluations of individual data, the most important duty for MHLW is to make responsible decisions within given time.