Approach of pharmaceutical companies on 3Rs for the animal experiment

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To study and confirm the efficacy and safety of pharmaceutical candidates, animal experiments are considered an essential process; however, this process is achieved at the sacrifice of precious lives. Internationally, the role and methods of non-clinical safety studies, which are essential before clinical trials in the pharmaceutical development, have been redefined by the ICH.   Throughout the ICH processes, the necessity of each safety study was discussed and each experiment was standardized according to ICH safety guidelines based on science and the 3Rs.   In the ICH, continuous efforts toward standardization are ongoing based on progress in science and technology. In Japan, the Japan Pharmaceutical Manufacturers Association (JPMA), a voluntary organization of research-based pharmaceutical manufacturers in Japan, established "the guidance for animal experiments" in January 2005, which can be used as a guide for member companies to establish a company standard for the management of animal experiments.   Based on this guidance, each member formulated or revised their company regulations, and promoted appropriate self-management of animal experiments based on the 3Rs, addressing the reduction of animals use, development of alternative methods as well as the refinement of animal experiments such as modification of anesthesia.   In June 2006, the revised "Law for the Humane Treatment and Management of Animals" came into effect and "Basic Policies for the Conduct of Animal Experimentation" was notified by the Japanese MHLW.   Based on these law and policies, pharmaceutical companies have revised their own internal rules and self-management systems for animal experiments.   Today, to increase the transparency of self-management systems, Japanese pharmaceutical companies have started to study external evaluation.

In this workshop, I will introduce the activities of Japanese pharmaceutical companies, and introduce the current external evaluation system for the self-management of animal experiments.