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Safety evaluation of biological products in Korea

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Biological products are composed of vaccines, antitoxin, blood products, DNA recombinant protein drugs, monoclonal antibody, cell therapy and gene therapy. Biological products are divided into traditional (i.e. recombinant proteins and monoclonal antibodies) and novel biological products (gene and cell therapy) and will require a similar re-evaluation of the approaches taken during each development program. The scientific principle of traditional biological products is a ritualistic standards-based approach, but the scientific principle of novel biological products is a rational science-based approach. While the key variables of selection of a testing model, doses, regimens, and endpoints have not changed, but the tools to better design and evaluate these variables have changed. The design, evaluation, and regulation of novel biological products have demanded state-of-the art knowledge of the latest science and technology to anticipate risks and devise methods to address them. Science-based regulation requires safety reviewers (regulators) with expertise both in the use of laboratory animal models to develop information about products and in the science of drug development and applicable laws, regulation and policy. Effective regulation requires that safety reviewers (regulators) recognize the careful balance of potential but unproven benefits against real or theoretical risks. Responsible regulation requires a commitment by safety reviewers (regulators) to surveillance and compliance activities, sensitivity to public concerns including safety and ethics, and the support for and facilitation of active and ongoing scientific exchange among academia, industry and regulatory groups. Regulations continually evolve as regulatory experience grows from the generation of increasingly more and better data.

Regulations related to safety of biological products includes; Regulation for Review of safety and efficacy of biological products (KFDA Notification No. 2003-26, May 23, 2003), Guideline for toxicological studies of drugs, etc (KFDA Notification No. 1999-61, Dec. 22, 1999), Guidelines to Clinical Study Authorization for Drugs (KFDA Notification No. 2002-65) and Preclinical safety evaluation of biotechnology-derived pharmaceuticals

ICH guideline S6 (Step 4, 1999. 6). philosophy of science-based regulation, limitation of in vivo nonclinical toxicity studies, general difference between conventional drugs and biological products, the goal of nonclinical toxicity studies, point to consider; toxicity studies of biological products, safety evaluation of biologics will be presented.

Success of new biological products has been enabled by the availability, validation and implementation of new technologies not only for production process, but also for preclinical safety testing and evaluation. Authorities and institutions responsible for regulatory oversight have recognized the need for and updating of the necessary programs to support the continued progress in the novel biological products leading to safe and effective therapies. Understanding of clear regulatory pathways and requirements for GLP facility and new biological products developers are critical to future successes.