Perspectives on Regulation of Biopharmaceuticals (Cell and tissue engineered products, and *in vitro* diagnostics using recombinant technology)

홍충만*
식품의약품안전청
(lizahong@kfda.go.kr*)

Biotechnology products for therapeutic use include a various range of products, including vaccines, gene transfer products, and cell and tissue engineered products. Most of these products are regulated as biologicals in Korea. KFDA was recently reorganized relating scientific review(quality and safety) on biologicals. Therefore I will briefly introduce the important roles of biologicals evaluation departments in approval process. Also, I will generally introduce current approval status of various biopharmaceuticals in Korea. It may provide related researchers and developers with insights on the approval process of biopharmacuticals.

In addtion, I will explain some guidelines and key considerations for scientific reviews, especially on quality control of cell and tissue engineered products, and in vitro diagnostics developed by recombinant technology, which are mainly reviewed by Blood Products Division, at current organization structure.

Finally, I will also present some challenges posed in the process of scientific reviews of the products. These challenges should be overcome by strong collaboration among industry, academy and regulatory authority together.