# Licensure of Biotechnological Products in KFDA

**Moo-Young Yoo**

*Pharmaceutical Safety Bureau, KFDA*

We are living in a truly remarkable era in science and in medicine. New therapies and biotechnological products are not only achieving breakthroughs in the laboratory, but also accomplishing a great success in industrial field. Biopharmaceutical industry is making growing contributions to our economy, and our public health that helps us better lives than ever before. Therefore, the issue of the evaluation of biotechnological products has been gaining great emphasis. The increasing interest of the society at large has induced governments to exert efforts toward ensuring the safety and efficacy of biotechnological products

The rapid advances in commercial development of new biotechnological products and therapeutic approaches have, however, left us in difficult tasks to control their quality, safety and efficacy as they are put into medical practices. Such a technological advance in biotechnological products has also provided new opportunities for both developers and regulatory authority to challenge new ways and means to control the safety and quality of new therapeutic products in processes of development, manufacturing as well as patients cares in medical treatment.

However, we have to face the reality that there are differences and gaps in technological capacities and regulatory guidelines between those countries who have already made considerable advancement and those who are late starters in quality, safety and efficacy evaluation of new biotechnological products.

Being a late starter in new drug development and a large consumer of bio-generic drugs such as EPO and somatropin, we should put more efforts to establish better infrastructure and system for safety evaluation and quality control of new biotechnological products to produce and supply high quality products for the public. In this regard, the role of KFDA is becoming increasingly important to lead local pharmaceutical companies to build relevant knowledge and to practice international guidelines in development and manufacturing of next generation biotechnological products. KFDA will put enormous efforts to strengthen the regulatory system for biotechnological products so that our service capacity will be remarkably promoted enough to support commercialization and registry processes of newly developed biotechnological products.