Point to Consider in Recombinant Products Evaluation

Jeewon Joung

Recombinant products team, KFDA

Recombinant product was first marketed in the 1980s and came to describe a class of therapeutic protein produced by modern biotechnological techniques, specially via genetic engineering and cell culture techniques. By 2002, about 120 recombinant products had gained marketing approval in the USA and/or EU. Collectively, these represent a global biopharmaceutical market in the region of $15 billion. At least 500 potential recombinant products are currently being evaluated in clinical trials. Vaccines and monoclonal antibodies represent the two biggest product categories. Hormones and cytokines also represent significant groupings. Interestingly, the generic biopharmaceuticals are already entering the market. Patent protection for many first-generation recombinant products (including somatropin, insulin, erythropoietin, interferon and granulocyte colony stimulating factor) is now coming to an end. Most of these drugs command an overall annual market value in excess of $1 billion, rendering them attractive potential products for many biotechnology pharmaceutical companies.

There is a growing trend in the global pharmaceutical industry toward internationalization. Many pharmaceutical companies are developing drugs which they aim to register in several world regions. EU, USA and Japan –based industry and regulatory authorities developed the harmonized requirement called ICH (International conference on harmonization). In this symposium, the overview of recombinant products evaluation for marketing approval is aimed principally based on ICH guidelines.