United States Pharmacopeia

The USP (http://www.usp.org) promotes public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients, and consumers. USP works closely with the FDA, the pharmaceutical industry, and the health professions to establish authoritative drug standards. These standards are enforceable by the FDA and the governments of more than 35 other countries and are recognized worldwide as a hallmark of quality. More than 3700 standard monographs are published in the USP and the National Formulary, the official drug standards compendia. USP also provides more chemical reference standards to carry out the tests specified in USP-National Formulary [13].

International Conference on Harmonisation

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is composed of the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration (http://www.ifpma.org/ich1.html).

The purpose of the International Conference on Harmonisation is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonization is a more economical use of human, animal, and material resources and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health [14].

BIOTECHNOLOGY-DERIVED DRUG PRODUCTS (BIOSIMILARS)

Biotechnology-derived drugs (biologics and biopharmaceuticals), in contrast to drugs that are chemically synthesized, are derived from living sources such as humans, animals, or microorganisms. Many biologics are complex mixtures that are not easily identified or characterized and are manufactured using biotechnology or are purified from natural sources. Other biological drugs, such as insulin and growth hormone, are proteins derived by biotechnology and have been well characterized. In recent years, there have been various discussions whether a generic biotechnology-derived drug product can be developed and be considered both bioequivalent and interchangeable to the brand alternative. Issues have included the ability to fully characterize the active ingredient(s), that immunogenicity-related impurities may be present in the product, and that the manufacture of a biological drug product is process dependent.