

The United States Pharmacopeia is Developing New Types of Reference Standards for Biologics and Biotechnology

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Summary

The United States Pharmacopeia (USP) develops public standards for medical products that are enforceable by FDA. USP is a not-for-profit non-government organization founded in 1820.

This article outlines several new initiatives of USP in the area of biologics and biotechnology. USP is seeking to provide new types of standards for this rapidly expanding area of pharmaceutical development that specifically address the complex and process-driven nature of biologics and biotechnology-derived articles. Rapid advances in biotechnology research and manufacturing continue to challenge the regulatory environment and necessitate the availability of expert guidance in step with state-of-the-art technology. This pertains to both documentary standards and physical reference materials or etalons. In the area of documentary standards, USP General Chapters and General Information Chapters have been providing industrial and academic researchers alike with crucial guidance, particularly in areas where there is a regulatory void. In the area of physical reference standards, USP etalons are traditionally tied to product monographs, with a few exceptions where General Test Chapters require the use of a reference standard. For the area of Biologics and Biotechnology, USP will expand the role of etalons that are tied to procedures in General Chapters and General Information Chapters in various ways, as it is understood that the complex manufacturing processes in the biotechnology arena require equally sophisticated measurements to assure product quality and ultimately public health.