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Quality attributes of biologic products and standard setting process – USP perspective

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Quality attributes of a biologic product have the potential to impact pharmacological properties of a molecule including toxicity, safety and efficacy. Product quality attributes can be categorized into 2 classifications – Critical Quality Attributes (CQA) and non-critical Quality Attributes. Commonly acknowledged CQAs for drug substance and product play an important role in standard setting process. United States Pharmacopeia (USP) is the oldest Pharmacopeia in the world involved in Standard setting process for both Chemical and Biological Medicines. Biological Standards work in done through 2 Compendium - Medicines Compendium (MC) based in India in addition to its traditional US Compendium National Formulary (NF). Both the compendium activities are supported by global expert committees, which, in turn is supported by expert panels. The members of these committees and panels are from Manufacturers, International standard setting organization and government laboratories. USP is developing both vertical (monograph) and horizontal (general chapters) documentary standards in the area of Biologics supported by pharmacopeial reference standards. Standard setting process for Biologics is based on the Quality Attributes of the specific drugs. USP is developing standards in the area of Therapeutic Proteins and Vaccines. Several monographs and supporting General Chapters are being developed in these areas. Global reference standards to support these monographs are being developed in collaboration with NIBSC, UK.

Biography

Ranjan Chakrabarti is currently Vice President – Biologics and Biotechnology at United States Pharmacopeia Convention at their India office. He has over 18 years of experience in Pharmaceutical and Biopharma industries. Before joining to Indian Industry, he worked in USA. Before joining USP, he was leading the Biology Group at Dr. Reddy's Drug discovery and also served at key management position in GVK Biosciences. He has worked with several National and International companies for discovery and development of both chemical and biological molecules. He is the Co-Inventor of 32 US Patents; published 52 papers in peer reviewed international journals and presented 57 lectures in international and national conferences.

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