

ANALYTICAL PROCEDURES FOR RECOMBINANT THERAPEUTIC MONOCLONAL ANTIBODIES

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Antibody-based therapy for cancer and immunological disorders has become established over the past 20 years and is now one of the most successful and important strategies for treating patients. The development of therapeutic antibodies requires a deep understanding of protein-engineering techniques, mechanisms of action, cancer serology, and resistance, and the interplay between the immune system and cancer cells. Monoclonal antibodies for human use are preparations of an immunoglobulin or a fragment of an immunoglobulin with specificity for a target ligand and produced from a single clone of cells.

A healthier world needs a strong foundation – one that establishes quality, sets the bar for scientific rigor and technological progress, and epitomizes collaboration between industry, nonprofits, government, and academia. Public standards provide tools to industry, regulators, and other stakeholders that can be utilized throughout a product lifecycle—development, approval, compliance, market surveillance—to help ensure patient access to quality biological medicinal products. They are intended to support and complement regulatory assessment. *United States Pharmacopeia (USP)* is the oldest Pharmacopeia in the world involved in Standard setting process for Biological Medicines. Standard setting process for Biologics is based on the Quality Attributes of the specific drugs.

USP is developing Quality Standards for the Therapeutic mABs. Chapter <129> *Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies* has been developed for monoclonal antibodies that defines and recommends accepted methods for quality control of antibodies. The chapter focuses on IgG monoclonals. This chapter provides analytical procedures for murine, chimeric, and humanized IgG isotype monoclonal antibodies and subtypes (e.g., IgG1 and IgG2) along with the IgG system suitability RS. <212> on Oligosaccharide analysis is another important chapter for glycan analysis for Monoclonal antibody characterization.