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Abstract

Characterization of Recombinant Therapeutic Monoclonal Antibodies and role of Compendial standards

Ranjan Chakrabarti
United States Pharmacopeia, India

Abstract:

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.

Various analytical procedures defined by ICH Q6B are required to be performed to test the physiochemical, biological and immunochemical properties of monoclonal antibody products. Assessment of product quality attributes is essential to ensure product safety, efficacy and consistency throughout its life cycle. 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, non-profits, government, and academia.

Case Model: The catherter lock or flush solutions containing either an anticoagulant or an antimicrobial agent are intended to maintain catherter potency. The Request for Designation (RFD) requested FDA for clarification of primary jurisdiction over these products. The device component is in compliance with the definition of device that affects either the structure or function of body in humans. However, the solution component (anticoagulant) acts by physically occupying space in the device and peventing the backflow of blood and clotting in to the catherter. Also if the solution component is an antimicrobial agent, it typically combines chemically with micro-organisms thus giving drug component a secondary role.

The physical and chemical compatibility of the medicinal product with its device/device component should be investigated throughout its use and shelf life. Microbiological attribute should demonstrate the drug-device integrity. Along with above mentioned characteristics the DDC should safely and effectively deliver medicinal product.

Biography:

Dr. Ranjan Chakrabarti has over 26 years of experience in Pharmaceutical and Biopharma industries. Before joining to Industry, he worked in Academics at USA and successfully coordinated research projects in Cancer Cell Biology and Diabetes. He has guided several Ph. D. students.

Dr. Ranjan is the Co-Inventor of 32 US Patents; published 59 papers in peer reviewed International Journals and presented 75 lectures in International and National Conferences.

Publication of speakers:

1. Chakraborty, Ranjan & Storey, Erin & Helm, Dick. (2007). Molecular mechanism of ferricsiderophore passage through the outer membrane receptor proteins of Escherichia coli. Biometals : an international journal on the role of metal ions in biology, biochemistry, and medicine. 20. 263-74. 10.1007/s10534-006-9060-9.

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