

A valuable reference for professionals involved in the development of biotechnology products

Characterization of Biotechnology Pharmaceutical Products

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This publication addresses the parameters necessary for characterizing the safety identity, purity, consistency and potency of biotechnology-derived products. The abilities and limitations of current analytical methodologies for defining such products and for assessing their comparability during development are examined. The data reviewed in this volume serve as a foundation for defining the properties of well-characterized products, including proteins and other molecular entities. Discussions span the evaluation of antigenic potential, potency, impurities, DNA/plasmid products, multiantigen peptides, polysaccharides, derivatized proteins, monoclonal antibodies and proteins from natural sources. Finally, recommendations for a consistent approach to the regulation of well-characterized biotechnology products are provided.

Authoritative and up-to-date, this book will be a valuable reference for professionals involved in the development of biotechnology products, including manufacturing process engineers and individuals concerned with quality assurance, quality control, validation, regulatory affairs and preclinical/clinical development.

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