

Biologics 2000 - Comparability of Biotechnology Products

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The globalization of research and development considering collaborative arrangements among companies for producing biotechnology-derived products often raises product comparability issues that are expected to be increased in frequency and complexity.

This volume reviews current scientific developments and regulatory issues related to establishing comparability of biological products when manufactured within a single company or jointly among two or more companies (e.g. manufacturing changes, site changes, etc.). Recommendations for a framework constituting a harmonized document on comparability are also provided.

A cadre of international regulatory and industry experts concluded and recommended that:

- a) the unprecedented record of product safety enjoyed by the biotech industry is founded on the vigilance dedicated to process controls and product quality throughout the drug development continuum;
- b) intra-manufacturer process changes are in line with modern global practices, scientific and economic considerations;
- c) the innovators' proprietary development history, production experience, training, validated assays and standards constitute a solid basis for performing legitimate and scientifically rigorous comparisons of products when introducing manufacturing changes. Importantly, depending on the nature of the product, comparisons may, at times, dictate expanded investigations in clinical trials;
- d) comparability, while robust in concept and application within one manufacturer's product, is not a surrogate for establishing inter-manufacturer therapeutic equivalence, which is the foundation for "generic" products;
- e) an international guidance document on a harmonized approach is timely.

Summarizing current thinking and practical experience, these proceedings should be read by academic, industry and regulatory scientists who work with biological products prepared for use as vaccines, plasma derivatives or therapeutic products.

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