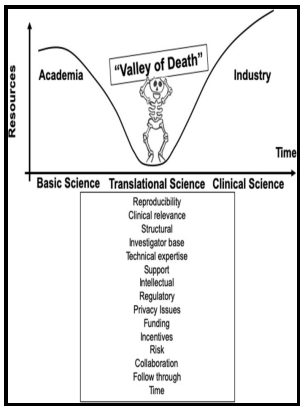
# Handbook of biogeneric therapeutic proteins - regulatory, manufacturing, testing, and patent issues

## Taylor & Francis - Federal :: Immunogenicity Testing of Therapeutic Protein Products




Description: -
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Technology, Pharmaceutical.
Drug Industry.
Recombinant Proteins -- therapeutic use.
Pharmaceutical biotechnology industry.
Recombinant proteins.
Generic drugs.
Protein drugs.Handbook of biogeneric therapeutic proteins - regulatory, manufacturing, testing, and patent issues
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Notes: Includes bibliographical references and index.
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Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent i. The Eprex® preparation showed an increase in the levels of aggregates during storage, although the level was never reported to have exceeded specifications.

**Regulatory and Development Issues in the Demonstration of Therapeutic Equivalence for Multisource Biotech**

GMP Audit Template, EU Guidelines. According to critics of the practice, branded firms game the system by seeking secondary patents of dubious validity and then paying generic entrants not to challenge the patents.

**Handbook of Biogeneric Therapeutic Proteins**

BIO Biotechnology Industry Organization Presentation by Dr. Kitch, The Nature and Function of the Patent System, 20 J.

**Handbook of Pharmaceutical Manufacturing Formulations**

This interaction undermines the policy choice, made explicit in the BPCIA, that biologics, like small-molecule drugs, should have a limited period of exclusivity and then be opened up to competition. Eisenberg, The Role of the FDA in Innovation Policy, 13 Mich.

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For a useful review of scholarly views in this area, see Lisa Larrimore Ouellette, Do Patents Disclose Useful Information? Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances. This example illustrates just one of the issues to be considered when dealing with these large and complex proteins.

**Research List of Guidance Documents**

A more transparent label that included relevant clinical data for the biosimilar, i. Although the analytical methods available are substantial, they cannot ensure that two proteins are identical. Packed with tables and figures that provide speedy access to precise, timely data, including full formulation details on all FDA approved biological product, this book contains a broad range of resource materials about suppliers, manufacturers, and testing facilities.

**FDA Reform: Promote the Approval of Life**

Demonstrating therapeutic equivalence to an innovator compound, however, does not result in an AB rating since there is no mechanism under the Hatch-Waxman Amendments or current FDA policy that would allow assignment. Many factors have the potential to influence the immunogenicity of proteins.

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Details about NDA Classification Codes are available in , including a list of all the codes and their meanings.

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