Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics

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Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics is a complete reference devoted to the nonclinical safety assessment of novel biopharmaceuticals, biosimilars, vaccines, cell and gene therapies and blood products. This book compares and contrasts these types of biologics with one another and with small molecule drugs, while incorporating the most current and essential international regulatory documents. Each section discusses a different type of biologic, as well as early characterization strategies, principles of study design, preclinical pharmacokinetics and pharmacodynamics and preclinical assays. An edited book that is authored by leading experts in the field, this comprehensive reference provides critical insights to all researchers involved in early through late stage biologics.

- Provides in-depth coverage of the process of nonclinical safety assessment and comprehensive reviews of each type of biopharmaceutical
- Contains the most pertinent international regulatory guidance documents for nonclinical evaluation
- Covers early de-risking strategies and designs of safety assessment programs for novel biopharmaceuticals and vaccines, as well as follow-on biologics or "biosimilars"
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