



# **Preclinical Safety Evaluation of Biopharmaceuticals: A Science-Based Approach to Facilitating Clinical Trials**

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# Preclinical Safety Evaluation of Biopharmaceuticals: A Science-Based Approach to Facilitating Clinical Trials

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"The goal is to provide a comprehensive reference book for the preclinical discovery and development scientist whose responsibilities span target identification, lead candidate selection, pharmacokinetics, pharmacology, and toxicology, and for regulatory scientists whose responsibilities include the evaluation of novel therapies."

—From the Afterword by Anthony D. Dayan

Proper preclinical safety evaluation can improve the predictive value, lessen the time and cost of launching new biopharmaceuticals, and speed potentially lifesaving drugs to market. This guide covers topics ranging from lead candidate selection to establishing proof of concept and toxicity testing to the selection of the first human doses. With chapters contributed by experts in their specific areas, *Preclinical Safety Evaluation of Biopharmaceuticals: A Science-Based Approach to Facilitating Clinical Trials*:

- Includes an overview of biopharmaceuticals with information on regulation and methods of production
- Discusses the principles of ICH S6 and their implementation in the U.S., Europe, and Japan
- Covers current practices in preclinical development and includes a comparison of safety assessments for small molecules with those for biopharmaceuticals
- Addresses all aspects of the preclinical evaluation process, including: the selection of relevant species; safety/toxicity endpoints; specific considerations based upon class; and practical considerations in the design, implementation, and analysis of biopharmaceuticals
- Covers transitioning from preclinical development to clinical trials

This is a hands-on, straightforward reference for professionals involved in preclinical drug development, including scientists, toxicologists, project managers, consultants, and regulatory personnel.

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