DESCRIPTION

"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.

ABOUT THE AUTHOR

Joy A. Cavagnaro, PhD, is the President of Access BIO, a consultancy specializing in science-based regulatory strategies and product development services. She has over twenty-five years of experience in biotech spanning academia, the CRO and biotech industries, and government. During her tenure at the FDA, Dr. Cavagnaro served as rapporteur for ICH S6. She is founder and past chair of the BIO Preclinical Safety Expert Group (BioSafe) and was the U.S. BIO Representative to the 2006 ABPI/BIA Early Stage Clinical Trials Taskforce. Dr. Cavagnaro is currently North American Chair of the Drug Information Association–Biotech SIAC and Chair of the Clinical and Regulatory Affairs Committee of the American Society of Gene Therapy. She serves on a number of scientific advisory boards and lectures internationally in the area of preclinical development of novel therapies.

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