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Translational Medicine Joy A. Cavagnaro

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translational medicine optimizing preclinical safety evaluation of biopharmaceuticals provides scientists responsible for the translation of novel biopharmaceuticals into clinical trials with a better understanding of how to navigate the obstacles that keep innovative medical research discoveries from becoming new therapies or even making it to clinical trials the book includes sections on protein based therapeutics modified proteins oligonucleotide based therapies monoclonal antibodies antibody drug conjugates gene and cell based therapies gene modified cell based therapies combination products and therapeutic vaccines best practices are defined for efficient discovery research to facilitate a science based efficient and predictive preclinical development program to ensure clinical efficacy and safety key features defines best practices for leveraging of discovery research to facilitate a development program includes general principles animal models biomarkers preclinical toxicology testing paradigms and practical applications discusses rare diseases discusses what why when how highlighting different considerations based upon product attributes includes special considerations for rare diseases about the editors joy a cavagnaro is an internationally recognized expert in preclinical development and regulatory strategy with an emphasis on genetic medicines her 40 year career spans academia government fda and the cro and biotech industries she was awarded the 2019 arnold j lehman award from the society of toxicology for introducing the concept of science based case by case approach to preclinical safety evaluation which became the foundation of ich s6 she currently serves on scientific advisory boards for advocacy groups and companies and consults and lectures in the area of preclinical development of novel therapies mary ellen cosenza is a regulatory toxicology consultant with over 30 years of senior leadership experience in the biopharmaceutical industry in the u s europe and emerging markets she has held leadership position in both the american college of toxicology act and the international union of toxicology iutox and is also an adjunct assistant professor at the university of southern california where she teaches graduate level courses in toxicology and regulation of biologics

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