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This book is the first edition entirely dedicated to immunotoxicology testing during pharmaceutical drug development. Immunotoxicology is a highly specialized discipline that addresses potential adverse effects on the immune system, including immunosuppression, immunogenicity, hypersensitivity and other immune system functional disorders. A broad spectrum of xenobiotics, including agents present in our environment as well as pharmaceutical molecules may adversely affect the immune system. In pharmaceutical drug development, testing of drug candidates involves not only potential immunotoxic hazard identification but also risk assessment in the context of therapeutic use of a given drug. Thus, testing for potential immunotoxicity of drug candidates should be an integral part of overall safety evaluation in both preclinical and clinical phases of drug development. This approach is different from immunotoxicity testing of environmental agents where any immunotoxicity is hazardous and unacceptable in light of potential uncontrolled exposure of healthy population.

In the development of novel therapeutic entities (chemicals, proteins and vaccines), strong immunotoxicity signals can be detected by hematology and/or lymphoid tissue histopathology evaluation as part of standard toxicity studies. However, potential immunotoxicity related to immune dysregulation by drugs, may only manifest at the functional level during an immune response to a challenge with an antigen (e.g., foreign protein, pathogen, toxin). Thus, evaluation of the functional immune system requires studies involving ‘activated’ immune cells, organs or entire hosts in response to an outside challenge. To detect and characterize such hazards, immunotoxicology assessment involves not only conventional toxicology endpoints (i.e., hematology, clinical chemistry and histology) but also a broad spectrum of specialized testing to evaluate potential immune dysregulation, including specific immune response tests (cellular or humoral), immunophenotyping, cytokine expression, immunoassays to address immunogenicity, and *in vivo* models of immune disorders to characterize potential impairment of host defense to infections, tumors and autoimmune diseases.
This book is focused on discussions of strategies for application of immunotoxicology testing during drug development, in other words it addresses ‘what’ and ‘how’ can be performed in such evaluation.

We hope this new book will be found valuable to both the experienced and novice immunotoxicologists who work, teach and study immune-related aspects of safety assessment of drug candidates in pharmaceutical development.

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