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Sommario/riassunto	This book focuses on the principles, methods, and interpretation involved in establishing the safety, risk, and hazard assessment of small molecules. It presents the regulatory requirements for risk and hazard identification as per the guidelines of the Organization for Economic Cooperation and Development (OECD), Paris, and the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use ICH and Schedule ‘Y’,

India. It serves as reference material for undergraduate and postgraduate pharmacy degree students as well as senior researchers to learn about the principles, methods, and interpretations of systemic dosage (acute and repeated dose) and genotoxicity (in vitro and in vivo), special toxicological investigations such as reproductive and developmental toxicology, carcinogenicity, and toxicokinetics using animal models or in vitro methods, as applicable. This book is the first of its kind in providing information on the principles and methods of implementation of Good Laboratory Practice based on the guidelines of OECD. It includes detailed chapters about the regulatory requirements and guidelines in pharmaceutical products and agrochemicals. It also describes the infrastructure needed for preclinical studies, including in vivo and in vitro facilities.