

1. Record Nr.	UNINA9910253895003321
Titolo	Validation of Alternative Methods for Toxicity Testing // edited by Chantra Eskes, Maurice Whelan
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2016
ISBN	3-319-33826-9
Edizione	[1st ed. 2016.]
Descrizione fisica	1 online resource (XX, 407 p. 44 illus., 40 illus. in color.)
Collana	Advances in Experimental Medicine and Biology, , 0065-2598 ; ; 856
Disciplina	615.704028
Soggetti	Pharmaceutical technology Molecular biology Pharmaceutical Sciences/Technology Molecular Medicine
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Introduction -- Validation in support of internationally harmonised OECD Test Guidelines for assessing the safety of chemicals -- Regulatory acceptance of alternative methods in the development and approval of pharmaceuticals -- Validation of alternative in vitro methods to animal testing: concepts, challenges, processes and tools -- Practical aspects of designing and conducting validation studies involving multi-study trials -- Validation of computational methods -- Implementation of New Test Methods into Practical Testing -- Pathway Based Toxicology and Fit-for-Purpose Assays -- Evidence-based toxicology -- Validation of transcriptomics-based in vitro methods -- Ensuring the quality of stem cell-derived in vitro models for toxicity testing -- Validation of bioreactor and human-on-a-chip devices for chemical safety assessment -- Integrated approaches to testing and assessment -- International harmonization and cooperation in the validation of alternative methods -- Evolving the principles and practice of validation for new alternative approaches to toxicity testing. .
Sommario/riassunto	This book provides information on best practices and new thinking regarding the validation of alternative methods for toxicity testing. It covers the validation of experimental and computational methods and

integrated approaches to testing and assessment. Validation strategies are discussed for methods employing the latest technologies such as tissue-on-a-chip systems, stem cells and transcriptomics, and for methods derived from pathway-based concepts in toxicology. Validation of Alternative Methods for Toxicity Testing is divided into two sections, in the first, practical insights are given on the state-of-the-art and on approaches that have resulted in successfully validated and accepted alternative methods. The second section focuses on the evolution of validation principles and practice that are necessary to ensure fit-for-purpose validation that has the greatest impact on international regulatory acceptance of alternative methods. In this context validation needs to keep pace with the considerable scientific advancements being made in toxicology, the availability of sophisticated tools and techniques that can be applied in a variety of ways, and the increasing societal and regulatory demands for better safety assessment. This book will be a useful resource for scientists in the field of toxicology, both from industry and academia, developing new test methods, strategies or techniques, as well as Governmental and regulatory authorities interested in understanding the principles and practicalities of validation of alternative methods for toxicity testing. .

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2. Record Nr.	UNINA9910735299003321
Titolo	Expert opinion on orphan drugs
Pubbl/distr/stampa	[London] : , : Informa Healthcare, , 2013- [Abingdon, UK] : , : Taylor & Francis
Descrizione fisica	1 online resource
Disciplina	615
Soggetti	Rare diseases Orphan drugs Chemotherapy Orphan Drug Production Rare Diseases Periodical Periodicals.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Periodico
Note generali	Refereed/Peer-reviewed