1. Record Nr. UNINA9910808405203321

Titolo	Nonclinical safety assessment : a guide to international pharmaceutical regulations / / edited by William J. Brock, Kenneth L. Hastings, Kathy M. McGown
Pubbl/distr/stampa	Chichester, West Sussex, : John Wiley & Sons, 2013
ISBN	1-118-51700-8 1-299-24266-9 1-118-51701-6
Edizione	[1st ed.]
Descrizione fisica	1 online resource (487 p.)
Altri autori (Persone)	BrockWilliam J HastingsKenneth L McGownKathy M
Disciplina	615.1/901
Soggetti	Drug development - International cooperation Drugs - Toxicology - International cooperation
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Introduction to the development of drugs / Kathy McGown -- ICH / Ken Hastings -- USFDA / Bill Brock -- Latin America : MERCOSUR countries / Cristiana Leslie Corra -- Canada / Mark T. Goldberg -- EMEA / Adam Woolley -- Africa / Fariza Feraoun -- China / Lijie Fu -- Japan / Kazuichi Nakamura -- India / K.S. Rao -- Australia / Doug Francis -- Chronic repeat dose testing / Shana Azri-Meehan -- Carcinogenicity / James Popp -- Genotoxicity / Mark Powley -- Developmental and reproductive toxicology / Robert Parker -- Juvenile testing and pediatric claim / Melissa Tassinari -- Immunotoxicology / Leigh Ann Burns Naas -- Biologics / Chris Ellis -- Vaccines / Robert House -- Phototoxicity and photocarcinogenicity / Chris Sambuco -- Degradants, impurities excipients, and metabolites / Bob Osterberg.
Sommario/riassunto	Bringing a new drug to market is a costly time-consuming process. Increased regional and international regulation over the last twenty years, while necessary, has only served to amplify these costs. In response to this escalation, developmental strategies have shifted towards a more global approach. In order to create the most cost-

effective and safe processes, it is critical for those bringing drugs to market to understand both the globally accepted regulations and the local variations. Nonclinical Safety Assessment: A Guide to International Pharmaceutical Regulations provides a practi