1. Record Nr. UNINA9910437852303321

Titolo	Global approach in safety testing : ICH guidelines explained
Pubbl/distr/stampa	New York, : Springer, 2012
ISBN	1-299-33560-8 1-4614-5950-8
Edizione	[1st ed. 2013.]
Descrizione fisica	1 online resource (320 p.)
Collana	AAPS Advances in the Pharmaceutical Sciences Series ; ; v.5
Altri autori (Persone)	van der LaanJan Willem DeGeorgeJoseph J
Disciplina	615.190218
Soggetti	Pharmaceutical industry - Quality control Drugs - Law and legislation Drugs - Testing - Standards Pharmaceutical technology - Standards
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di contenuto	The International Conference on Harmonisation. History of Safety Guidelines -- EU Perspective on ICH -- The Value and Benefits of the International Conference on Harmonisation (ICH) to Drug Regulatory Authorities Advancing Harmonization for Better Public Health -- A Japanese Perspective on Implementation of the Three Rs: Incorporating Best Scientific Practices into Regulatory Process -- Towards more Scientific Relevance in Carcinogenicity Testing -- The Evolution, Scientific Reasoning and Use of ICH S2 Guidelines for Genotoxicity Testing of Pharmaceuticals -- Toxicokinetics: A Guidance for Assessing Systemic Exposure in Toxicology Studies , Where are we now; an S3A/S3B update (1995-2011) -- Duration of Acute and Chronic Toxicity Testing in Animals (ICH S4A and S4B) -- Why and how did Reproduction Toxicity Testing make its early entry into and Rapid Success in ICH? -- ICH S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals -- Safety Pharmacology: Guidelines S7A and S7B -- ICH S8: History and Perspectives -- ICH S9: Nonclinical Evaluation of Anticancer Pharmaceuticals a Perspective from Regulators on the Development of the Guideline -- Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals

ICH M3 and M3(R2).

Sommario/riassunto

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the US and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. In Japan, the members are the Ministry of Health, Labour and Welfare (MHLW), and the Japan Pharmaceutical Manufacturers Association (JPMA). In Europe, the members are the EU (Representatives of the European Commission and the European Medicines Agency [EMA]), and the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the United States, the members are the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) is the secretariat of the ICH. Additional members include Observers from WHO, European Free Trade Association (EFTA), and Canada. The Observers represent non-ICH countries and regions. This volume considers one of ICH's major categories, Safety, covering topics relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.). Since the start of the ICH process, many guidelines have been written, but in most cases there is a lack of awareness of the many issues that were addressed during the development of the consensus guidances. Further, just as it is important to understand what the guidances state, it is also important to understand the thoughts, debates, and intent of the experts involved, which are not included in the guidance documents. Why has the guideline been written as it is written, why are some topics ignored, and why have some initial guidance proposals have been deleted. These and other related questions and answers are the contents of this book, written by experts who were directly involved in writing the ICH guidances that drive drug development today.