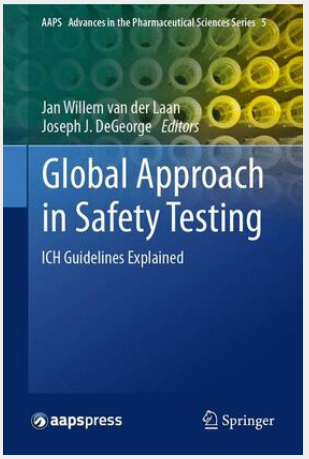
DeGeorge / van der Laan

Global Approach in Safety Testing

ICH Guidelines Explained



This volume will consider one of ICH's major categories, Safety i.e. 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 even after ICH6 no explanations have been given during a formal Congress about the background of the ICH Guidance documents. Even more important than what has been written, might have been those thoughts of the experts that are not included in the Guidance documents. Why has the guideline been written as it is written, and why have some aspects been deleted. These and other related questions are the contents of this book, written by experts who were involved in the ICH process. Furthermore, the chapters will contain discussions on the "lessons learnt" and "future developments".

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 answersare the contents of this book, written by experts who were directly involved in writing the ICH guidances that drive drug development today.

160,49 €
149,99 € (zzgl. MwSt.)

Lieferfrist: bis zu 10 Tage

Artikelnummer: 9781461459491
Medium: Buch
ISBN: 978-1-4614-5949-1
Verlag: Springer
Erscheinungstermin: 08.02.2013
Sprache(n): Englisch
Auflage: 2013
Serie: AAPS Advances in the Pharmaceutical Sciences Series
Produktform: Gebunden
Gewicht: 6151 g
Seiten: 315
Format (B x H): 160 x 241 mm

Kundenservice Fachmedien Otto Schmidt
Neumannstraße 10, 40235 Düsseldorf | kundenservice@fachmedien.de | 0800 000-1637 (Inland)