As off-label use of medicines in children is no longer acceptable today, paediatric drug development is currently in transition from an almost exclusive academic specialty towards an integrated part of the global process that drives the development of new pharmaceuticals. US and EU governments have made it mandatory for the pharmaceutical industry to investigate medicines in children, thus exposing a multitude of different institutions to paediatric research. Written by exponents of the academia as well as the pharmaceutical industry, regulators and patient advocacy groups, this book explains the background of the US and EU paediatric legislations, gives an analysis of their probable short-, mid- and long-term impact, addresses key operational challenges in paediatric research, and develops a tentative vision where paediatric drug development needs to go.

Helping to understand the role of the different stakeholders, the spectrum of readers to profit from this book ranges from paediatricians, general medical personnel and pharmacologists to those involved in regulatory affairs and clinical trials, pharmaceutical company management, patient advocacy groups, ethical committees, politicians and interested lay persons.

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An indispensable companion for those involved in clinical trials

Gerhard Fortwengel

Guide for Clinical Trial Staff Implementing Good Clinical Practice

The standard to which clinical trials must conform is called ‘Good Clinical Practice’ (GCP). GCP is defined as a standard that ensures adequate protection of subjects participating in clinical trials; Furthermore, it ensures that all trial activities and data are meticulously documented and reported. The latest GCP guideline was developed by the International Conference on Harmonization (ICH) and was first published in May 1996. This guideline is based on ethical principles that have their origin in the Declaration of Helsinki (1964, last modified in October 2000). Besides GCP, clinical trials must also comply with the local law of the country where the study is being conducted. This book will be an indispensable companion for those conducting clinical trials and should have a fixed place in the library of every investigator and his staff.

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