



Global Approach in Safety Testing: ICH Guidelines Explained: 5 (AAPS Advances in the Pharmaceutical Sciences Series)

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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".

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