Safety Evaluation of Pharmaceuticals and Medical Devices: International Regulatory Guidelines

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The inspiration for this text was the 1988 volume by Alder and Zbinden, written before the ICH harmonization process for drug safety evaluation (or its ISO analog for device biocompatibility evaluation) had been initiated or come to force. Since then, much has changed in both the world and practice of medicine and the regulation of drugs. The intent of this volume is to provide similar guidance as to what nonclinical safety assessment tests need to be performed to move a drug into man, through development and to market approved (this intent was subsequently extended to cover the closely related medical device biotechnology, and combination product fields) in a concise, abbreviated manner for all the major world market countries.

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