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Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

For decades gas chromatography has been and will remain an irreplaceable analytical technique in many research areas for both quantitative analysis and qualitative characterization/identification, which is still supplementary with HPLC. This book highlights a few areas where significant advances have been reported recently and/or a revisit of basic concepts is deserved. It provides an overview of instrumental developments, frontline and modern research as well as practical industrial applications. The topics include GC-based metabolomics in biomedical, plant and microbial research, natural products as well as characterization of aging of synthetic materials and industrial monitoring, which are contributions of several experts from different disciplines. It also contains best hand-on practices of sample preparation (derivatization) and data processing in daily research. This book is recommended to both basic and experienced researchers in gas chromatography.