



# Method Validation in Pharmaceutical Analysis: A Guide to Best Practice

*Joachim Ermer*

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## **Method Validation in Pharmaceutical Analysis: A Guide to Best Practice** Joachim Ermer

This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) and lifecycle concepts in pharmaceutical manufacturing.

As in the first edition, the fundamental requirements for analytical method validation are covered, but the second edition describes how these are applied systematically throughout the entire analytical lifecycle. QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives. For analytical methods these predefined objectives are established as an Analytical Target Profile (ATP). The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle: Method Design, Method Performance Qualification, and Continued Method Performance Verification. Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout.

The undisputed gold standard in the field.

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