



# Handbook of Analytical Validation

*Michael E. Swartz, Ira S. Krull*

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Written for practitioners in both the drug and biotechnology industries, the **Handbook of Analytical Validation** carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook:

- Contains practical, up-to-date guidelines for analytical method validation
- Summarizes the latest regulatory requirements for all aspects of method validation, even those coming from the USP, but undergoing modifications
- Covers development, optimization, validation, and transfer of many different types of methods used in the regulatory environment

Simplifying the overall process of method development, optimization and validation, the guidelines in the Handbook apply to both small molecules in the conventional pharmaceutical industry, as well as well as the biotech industry.

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