



Validating Chromatographic Methods: A Practical Guide

By David M. Bliesner

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Validating Chromatographic Methods: A Practical Guide By David M. Bliesner

All the information and tools needed to set up a successful method validation system

Validating Chromatographic Methods brings order and Current Good Manufacturing Practices to the often chaotic process of chromatographic method validation. It provides readers with both the practical information and the tools necessary to successfully set up a new validation system or upgrade a current system to fully comply with government safety and quality regulations. The net results are validated and transferable analytical methods that will serve for extended periods of time with minimal or no complications.

This guide focuses on high-performance liquid chromatographic methods validation; however, the concepts are generally applicable to the validation of other analytical techniques as well. Following an overview of analytical method validation and a discussion of its various components, the author dedicates a complete chapter to each step of validation:

- Method evaluation and further method development
- Final method development and trial method validation
- Formal method validation and report generation
- Formal data review and report issuance

Templates and examples for Methods Validation Standard Operating Procedures, Standard Test Methods, Methods Validation Protocols, and Methods Validation Reports are all provided. Moreover, the guide features detailed flowcharts and checklists that lead readers through every stage of method validation to ensure success. All of the templates are also included on a CD-ROM, enabling readers to easily work with and customize them.

For scientists and technicians new to method validation, this guide provides all the information and tools needed to develop a top-quality system. For those experienced with method validation, the guide helps to upgrade and improve existing systems.

Note: CD-ROM/DVD and other supplementary materials are not included as part of eBook file.

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Editorial Review

Review

"...very useful to people responsible for validating chromatographic methods..." (*CHOICE*, May 2007)

From the Back Cover

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About the Author

DAVID M. BLIESNER, PhD, is the founder and President of Delphi Analytical Services, Inc., an organization dedicated to improving clients' level of compliance with Current Good Manufacturing Practices, Quality System Regulations, and Current Good Clinical Practice Regulations by providing training technology, training, and compliance products and services. Dr. Bliesner also offers lectures, short courses, and hands-on training on compliance issues for analytical laboratories. He is the author of *Establishing a CGMP Laboratory Audit System*, also available from Wiley.

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