



# Analytical Chemistry in a GMP Environment: A Practical Guide

By Jim Miller

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## Analytical Chemistry in a GMP Environment: A Practical Guide By Jim Miller

How to hone your analytical skills and obtain high-quality data in the era of GMP requirements

With increased regulatory pressures on the pharmaceutical industry, there is a growing need for capable analysts who can ensure appropriate scientific practices in laboratories and manufacturing sites worldwide. Based on Johnson & Johnson's acclaimed in-house training program, this practical guide provides guidance for laboratory analysts who must juggle the Food and Drug Administration's good manufacturing practices (GMP) rules with rapidly changing analytical technologies. Highly qualified industry experts walk readers step-by-step through the concepts, techniques, and tools necessary to perform analyses in an FDA-regulated environment, including clear instructions on all major analytical chemical methods—from spectroscopy to chromatography to dissolution. An ideal manual for formal training as well as an excellent self-study guide, *Analytical Chemistry in a GMP Environment* features:

- \* The drug development process in the pharmaceutical industry
- \* Uniform and consistent interpretation of GMP compliance issues
- \* A review of the role of statistics and basic topics in analytical chemistry
- \* An emphasis on high-performance liquid chromatographic (HPLC) methods
- \* Chapters on detectors and quantitative analysis as well as data systems
- \* Methods for ensuring that instruments meet standard operating procedures (SOP) requirements
- \* Extensive appendixes for unifying terms, symbols, and procedural information

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"...chemists...explain how to comply with US Food and Drug Administration's Good Manufacturing Practice rules as analytical technologies are changing rapidly." (*SciTech Book News*, Vol. 24, No. 4, December 2000)

"Anyone...involved in training exercises and in...gathering...pertinent material from different sources will find this book very helpful." (*Journal of Medicinal Chemistry*, Vol. 44, No. 21, 2001)

"I recommend this book for anyone who recognizes a need for more and better training of pharmaceutical laboratory analysts...a remarkably rich resource." (*Clinical Chemistry*, Vol. 48, No. 3, 2002)

"...provides a much needed perspective on the role of analytical chemistry in the pharmaceutical industry and is a welcome addition...a useful resource." (*Journal of Chemical Education*, December 2002)

#### From the Back Cover

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