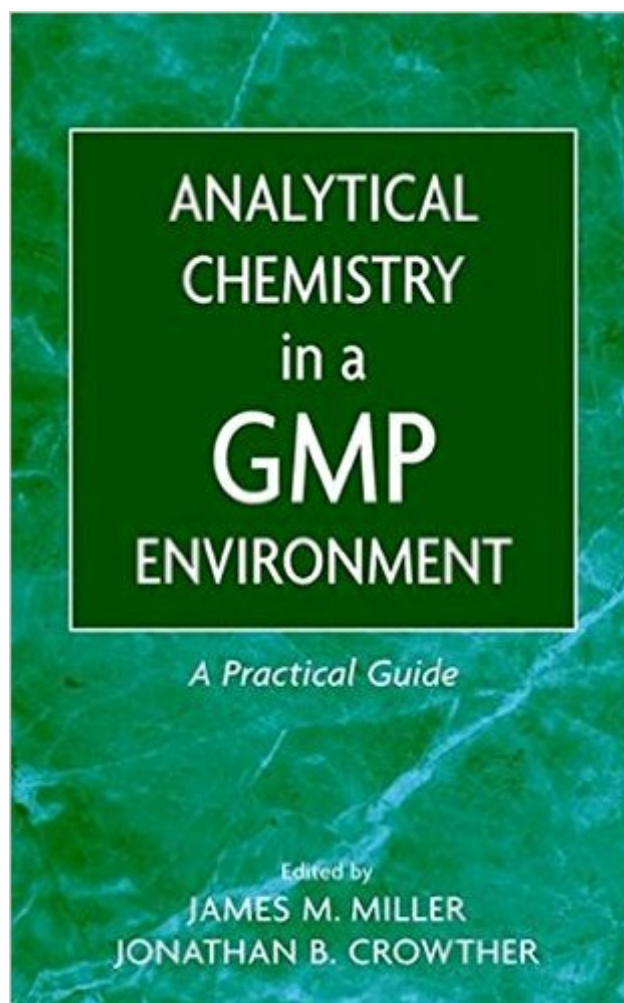


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Analytical Chemistry In A GMP Environment: A Practical Guide



Synopsis

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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Customer Reviews

This is the book if you work in a pharmaceutical analysis laboratory. The book combines the

technical and practical aspects of pharmaceutical analysis in an easy to understand language. All chapters have been written by area experts making it very useful and comprehensive.

This is an excellent reference for any scientist at any level. There are days that you are burnt out and your analytical reasoning has failed. This book helps a lot.

Very informative. An old classic with a great breadth of information with adequate detail.

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