
**Analytical Chemistry in a GMP Environment:
A Practical Guide**

edited by James M. Miller and Jonathan B. Crowther

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Industrial analytical chemists have noted that students with undergraduate and graduate degrees in chemistry are often insufficiently prepared to work in an analytical laboratory that is subject to federal regulations such as the U.S. Food and Drug Administration's Good Manufacturing Practice rules. Although undergraduate and graduate programs continue to provide a solid foundation in the fundamental principles of analytical chemistry, they cannot always provide the necessary knowledge, skills, and abilities required in today's regulatory environment. Industries, therefore, are left to provide this additional training through in-house programs. This text emerged from Johnson & Johnson's Laboratory Analyst Training and Certification Program, first offered in 1996, and emphasizes issues faced by analytical chemists working in the pharmaceutical industry.

For the purpose of this review it is convenient to divide the text into three parts: a review of the drug development process and the regulatory environment (Chapters 1–3); a review of basic analytical chemistry, much of which is included in the undergraduate or graduate analytical curriculum (Chapters 4–10 and 13); and a review of analytical topics unique to the industrial laboratory (Chapters 11, 12, 14, and 15). Although the level of presentation is intended for students who have a bachelor's degree in chemistry and some experience in the pharmaceutical industry, undergraduate chemistry majors and faculty will find the material to be accessible.

The strength of this book, at least for academic analytical chemists, is its presentation of the relationship between the regulatory environment and the operation of analytical laboratories. The importance of method development and method validation, and the need for the transferability of methods between laboratories are made clear. These are critical areas of analytical chemistry that are ignored by most textbooks intended for undergraduate and graduate courses. For example, academic courses in analytical chemistry routinely discuss the use of Dixon's Q -test for evaluating outliers. How many academic analytical chemists, however, are aware that a court decision allows outlier tests in microbio-

logical assays but forbids their use with chemical analyses? Or, how many students completing an undergraduate or graduate course in analytical chemistry understand the importance of validating analytical methods?

The text's review of basic analytical chemistry, which includes chapters on statistics, solution chemistry, spectroscopy, and chromatography, is less satisfying and usually falls short of that included in most undergraduate analytical chemistry textbooks. The chapter on statistics, for example, includes only a cursory discussion of significance testing or linear regression analysis. Spectroscopy, including UV-vis, IR, MS, ICP, AAS, NMR, and Raman, is covered in only 36 pages. One important exception to this brief coverage is the chapter on HPLC Column Parameters (Chapter 10), which provides an excellent and thorough discussion of solute retention, column efficiency, and column equivalency.

With each chapter written by a different author or team of authors, there is always a concern that the resulting book will be fragmented. For the most part, the editors have done an excellent job of producing a book in which the chapters complement each other without introducing too much redundancy or omitting crucial material. An exception, however, is Chapter 5 (Basic Analytical Operations and Solution Chemistry), which assumes a knowledge of gas chromatography and liquid chromatography before these instrumental techniques have been discussed in the text. This chapter is also poorly organized, including, for example, discussions of acid-base titrimetry and the need for buffering HPLC mobile phases in a section on reduction-oxidation equilibria.

The text is generally free of errors and oddities, although there are a few worth noting. The discussion of outliers, for example, includes an older table of Q -values that has since been revised (see Rorabacher, D. B. *Anal. Chem.* **1991**, *63*, 139–146). The use of ergs instead of joules in Chapter 6 is an odd choice. An incorrect equation for chromatographic resolution is included in Chapter 12. Finally, a calculation in Chapter 13 illustrating the proper choice of an instrument's time constant is worked incorrectly.

Because this text is intended for an industrial training program, it is not a suitable primary or secondary text for undergraduate or graduate courses in analytical chemistry. Nevertheless, it does provide a much needed perspective on the role of analytical chemistry in the pharmaceutical industry and is a welcome addition to academic libraries. Faculty interested in providing students with an industrial perspective will find this text to be a useful resource.

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