polymers have been addressed through the use of a nondegrading solvent consisting of dimethylacetamide and lithium chloride (J.D. Timpa), and subsequent characterization by size-exclusion chromatography with viscometry and refractive index detectors. The utility of size-exclusion chromatography with multi-angle light scattering, viscosity, and refractive index detectors as a means to characterize pullulans and dextrans was studied (W.S. Bahary, M.P. Hogan, M. Jilani, and M.P. Aronson). The second section ends with a presentation dealing with the characterization of star-branched model copolymers using refractive index and viscometric detection with an on-line light-scattering detector (J. Lesec, M. Millequant, M. Patin, and P. Teyssie).

The third and final section contains topics concerned with the analysis of compositional heterogeneity in copolymers and blends. A method was presented for obtaining the molecular weight and composition of copolymers using thermal field-flow fractionation and viscometry (M.E. Schimpf). The use of coupled techniques with chromatographic columns and multidetectors is discussed, primarily as related to the practice of size-exclusion chromatography (J.V. Dawkins). The advantages of using various nonexclusion chromatography methods in conjunction with size-exclusion chromatography to provide accurate compositional information on copolymers was presented (S. Mori). Methodology for the totally automated characterization of complex copolymers and blends by two-dimensional liquid chromatography-size-exclusion chromatography has been developed (P. Kilz, R.-P. Kruger, H. Much, and G. Schulz), and applied to the analysis of a 16-component mixture of a star block copolymer. The problems caused in size-exclusion chromatography by the superimposition of chemical composition distributions onto molecular weight distributions were addressed through the use of ultraviolet absorption and differential refractive index detectors (E. Meehan and S. O'Donohue). An interface between gel permeation chromatography and infrared spectroscopy has been developed, and applied to the analysis of copolymers (J.N. Willis and L. Wheeler). The final contribution to this section discusses the use of a solvent-evaporative interface to isolate the fractions obtained after the performance of size-exclusion chromatography onto a surface suitable for infrared spectral analysis (P.C. Cheung, S.T. Balke, and T.C. Schunk).

This volume presents the results of a number of investigations, where advances in the field continue to extend the arsenal of analysis methods available for the characterization of polymers. Viewed within this context, the book fulfils its mission to encourage and catalyze additional activity and method development in hyphenated chromatographic separation techniques for polymer characterization. However, research papers are not review articles, and those seeking such presentations on the main characterization methods, or on the hyphenated hybrids, will need to search elsewhere.

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Validation Compliance Biannual, 1996-1997, The International Validation Forum, Marcel Dekker, 1996, 848 pp., $195.00, ISBN 0-8247-9746-9.

Validation has become one of the most important issues within the pharmaceutical industry, and the range of associated activities increases practically with each new issue of the Federal Register. This present book seeks to encapsulate the essential elements of this ever-growing field into a single volume which provides a concise summary of current expectations. The primary focus is that of the United States Food and Drug Administration, although some information is provided regarding other venues. The editors have recognized that validation is a developing and changing creation, and thus have chosen to update their series on a periodic basis. As indicated by the title, the latest validation compliance volume seeks to remain current for the 1996–1997 time period.

Each section of the volume follows the same general pattern, which facilitates updating of the work from previous editions. The editors begin with a very short overview of a defined subject matter, and follow with a voluminous reproduc-

tion of published regulations. As an example, consider, Section II, which covers governmental regulations. After a brief overview of the need for validation and the present state of the regulatory climate, the editors quote the entire code of FDA and EPA regulations contained in the Federal Register. While it is convenient to have the regulations presented in this manner, it might have been better to have the information summarized and interpreted.

Owing to the breadth of coverage within this validation compliance volume, its acquisition is certainly recommended by all those who require a reference work on the subject. It is not likely that anyone will ever read this volume from cover to cover, but when specific details are needed on a given topic this will be the book to consult. The reviewed volume is perhaps the best place to find validation regulations as issued by the authorities, but those interested in more detailed commentaries on these would be better served by consulting other works on the subject.

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