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Publisher *Taylor & Francis*

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Journal of Liquid Chromatography & Related Technologies

Publication details, including instructions for authors and subscription information:

<http://www.informaworld.com/smpp/title~content=t713597273>

Filtration in the Biopharmaceutical Industry

To cite this Article (1998) 'Filtration in the Biopharmaceutical Industry', Journal of Liquid Chromatography & Related Technologies, 21: 19, 3065 – 3067

To link to this Article: DOI: 10.1080/10826079808006886

URL: <http://dx.doi.org/10.1080/10826079808006886>

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THE BOOK CORNER

FILTRATION IN THE BIOPHARMACEUTICAL INDUSTRY, T. H. Meltzer, M. W. Jornitz, eds., Marcel Dekker, Inc., New York, 1997, 933 pp., \$225.00

When I received this book, I wondered why such a massive, 933 page book, is needed for such a simple topic. Reading the book, I realized that filtration is complex. It is also an important topic and not a trivial one which requires a good deal of attention. I thank the editors for their effort in educating me as well as others on the pitfalls of filtration. The editors state, "Most certainly within these last years filtration technology and all accompanying issues including regulatory topics have developed rapidly and changed. Filter systems and components have become more sophisticated and have achieved even higher quality, security, and economics, and production processes have improved dramatically.

New filtration flow methods have been developed and optimized, and filter validation has become a firm part of every process and is now well understood within the industry. Integrity testing of filters has also experienced a high degree of positive changes, especially in respect to test sensitivity, automation, and ease of use. Nowadays most integrity tests are performed with automatic test machines, which again raises issues of computer validation requirements. Additionally, processes and theoretical hypotheses not fully understood in earlier years are now clearly defined and questions of the past have been answered.

This book elaborates on all the above-described points of filtration and their implications and discusses regulatory issues in detail. Not only are all different types of filters, their construction, and their retentive capabilities reviewed, but also specific issues such as extractables, endotoxins, unspecific adsorption, and filter validation are fully covered. Furthermore, the most common applications are discussed and specific experiences are pointed out."

The book is divided into five parts and 29 chapters (see contents for details) dealing with filter characterization, regulatory considerations, and an extensive applications section.

This is a book worth having as a reference to all analytical chemists. The material is well presented and discussed. The flow of topics is excellent. The editors should be commended on a book well done.

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Editor
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