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Book review

Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation.
Kenneth E. Avis and Vincent L. Wu (Editors), Drug Manufacturing Technology Series Volume 2, Interpharm Press, Buffalo Grove, IL, 1996; xiv+386 pp., $179.00; ISBN 1-57491-016-7.

This volume contains six chapters of uneven size and interest for the reader of this Journal, Introduction (6 pp.), Large-Scale Freezing and Thawing of Biopharmaceutical Products (54 pp.), Process Design Considerations for Large-Scale Chromatography of Biomolecules (138 pp.), Lyophilization of Protein Pharmaceuticals (66 pp.), Advances in Blow/Fill/Seal Technology: A Case Study in the Qualification of a Biopharmaceutical Product (28 pp.), Multiproduct Facility Design: An Integrated Approach (40 pp.), and Economic and Cost Factors of Bioprocess Engineering (22 pp.). For obvious reasons, this reviewer will concentrate on the third chapter which is of direct interest to chromatographers. It is instructive, however, to browse through the other ones to understand how the products that we are purifying are generated and what happens to the output of an industrial chromatography unit. This explains some of the constraints encountered in developing new applications of preparative chromatography. I have found the last chapter extremely enlightening and I wish all my colleagues in academy would read and digest it. This material will be incorporated in all my graduate courses.

Liquid chromatography plays in the biotechnologies a role comparable to that of distillation in the petrochemical industry. The method is much more complex because it is more flexible, however, it is recent, still incompletely understood in all its details, and rarely well taught in chemical engineering departments. The optimization of its parameters is difficult because it is a multiparameter, nonlinear optimization. Its use is resisted by many biochemists who have not yet entirely overcome the fears summarized long ago by Cs. Horvath as adiaphanophobia, barophobia, lithophobia and siderophobia. The third chapter, on Process Design Considerations for Large-Scale Chromatography of Biomolecules by R. Wisniewski, E. Boschetti and A. Jungbauer, contains a mine of useful, practical information on how to successfully develop and run chromatographic separations of biochemicals. It will be most useful to the community and should help to cure many of the phobia cases.

Successful development of a new separation requires knowledge in several poorly related areas, molecular interactions, packing media properties and preparation, physicochemical properties of proteins, process design and its physics, chromatography theory, cGMP and other regulatory issues. This chapter addresses most of these issues in details and provide a useful overview of the problems of industrial chromatography. The sections on System Design, Chromatographic Media, and Validation are particularly good, with an excellent balance between important details and basic principles. The section on Process Development and Scale-up also contains many excellent parts. We are, unfortunately, spared most of the enlightenment which careful use of theoretical consideration could provide.

This book is strongly recommended to those involved in the design, construction, and operation of large-scale chromatography units for industrial separations.

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