Handbook of Downstream Processing

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Preface

The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products–typically through the manipulation and growth of different types of microorganisms, followed by the recovery and purification of the associated products.

The engineers and biotechnologists who are involved in the full-scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements.

This book describes current commercial practice and will be useful to those engineers working in this field in the design, construction and operation of pharmaceutical and biotechnology plants. It will be of help to the chemical or pharmaceutical engineer who is developing a plant design and who faces issues such as:

Should the process be batch or continuous or a combination of batch and continuous?
How should the optimum process design be developed?
Should one employ a new revolutionary separation which could be potentially difficult to validate or use accepted technology which involves less risk?
Should the process be run with ingredients formulated from water for injection, deionized water, or even filtered tap water?
Should any of the separations be run in cold rooms or in glycol jacketed lines to minimize microbial growth where sterilization is not possible?
Should the process equipment and lines be designed to be sterilized-in-place, cleaned-in-place, or should every piece be broken down, cleaned and autoclaved after every turn?

Handbook of Downstream Processing focuses on the operations which promise to produce genetically engineered materials for use in producing end products such as enzymes, antibiotics, hormones, peptides, polypeptides, proteins, amino acids, veterinary drugs, steroids, herbicides, growth promoters, liposomes, diagnostic kits for infectious diseases, and many other materials that focus on pharmaceutical needs.

Contributors to this volume come largely from industry—from both engineering and pharmaceutical/biotech firms and from equipment manufacturers. The remainder come from academia.

The choice of chapters for this volume was dictated by the editor's

experience and modified by recommendations and suggestions by knowledgeable associates.

The chapters have been grouped into three categories: Unit operations; Specialized techniques; Engineering and design.

Many chapters belong in two categories, some in all three, and some do not fit comfortably in the categories in which they have been included. All the chapters are excellent reviews of the areas of technology currently used in the field of interest.

Unit operations

Descriptions of unit operations currently in use for the separation and purification or downstream processing of products developed by biochemical processing, including lysing, filtration, drying, extraction, affinity adsorption, membrane technology, electrodialysis, chromatography, precipitation, mixing and distillation.

Specialized techniques

Some of the specialized techniques used for processing materials being purified are included in the unit operations above and in the engineering and design sections below, and include chapters on CIP/SIP systems, clean room design, clean room testing and certification, sterilization and pure water facilities.

Engineering and design

Biotech facility project execution, controls and automation, bulk pharmaceutical plant design, optimization of downstream processing of protein, pharmaceutical finishing operations, wastewater treatment, offsite construction, regulatory considerations and validation.

Most of the chapters include references to current papers, which are not intended to be exhaustive.

Many contributed in the development of this book. Firstly, thanks to the chapter authors who are listed on p. xix. Then there are the unsung reviewers who made their critiques and offered suggestions for each chapter. We owe a depth of gratitude to the following reviewers: Richard Lang, Sheldon Finkler, Joel Kirman, and Robert Torregrossa, all of Lockwood Greene; Robert Clement and Peter Notwick of Jacobs Engineering; Jack Kearns and Anthony Dearning of Liposome Inc.; Francessa McBride of Triad Technologies; Mark Milano of Merck and Co.; John Bergen of E&V Services; Tom Davis, Consultant; Jim Banafato of Plastic Engineered Products; Dave Alterman of E.I. Associates Inc.; Richard Lesnik of John Brown E&C and Louis Bernero.

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Lastly, thanks to my wife, Shirley, for putting up with the many hours I spent during weekends working on this handbook instead of enjoying the company of our family.

E.G.

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