

# Preface

Single-use (disposable) systems that are discarded after one-time usage have become well-established in modern biopharmaceutical production processes. In addition to disposable bags for storage and transport, as well as disposable filters and mixers, disposable bioreactors in particular are replacing their reusable counterparts. However, the application of disposable bioreactors has led to technological innovations, resulting in an increase in cell densities, product titers and process safety, and has contributed to further reductions in time and costs for development and manufacturing of new products. Examples include, amongst others, large-scale cell banking in bags, one-step inoculation, the omission of intermediate cultivation steps and an increase in the scale-up factor.

These trends have also been influenced by further developments in hollow fiber technology. The availability of improved hollow fiber systems such as the ATF module from Refine Technologies has increased the focus on perfusion and concentrated fed batch processes among users. This is no surprise since it has been demonstrated that these strategies are accompanied by more efficient and more controllable operations for reduced bioreactor volumes.

In addition, published data using insect, stem and plant cells as well as microorganisms has shown that the beneficial usage of disposable bioreactors can exceed mammalian cell-based cultivations. Besides wave-mixed and stirred disposable bioreactors, orbitally shaken systems, which have recently become available for up to pilot-scale, are now dominant.

This volume, entitled “Disposable Bioreactors II”, contains ten chapters, written by renowned experts, and presents novel developments in and applications for disposable bioreactors. Starting with a summary of engineering parameters for the most often used disposable bioreactors, for the first time, methods for their characterization are recommended. Furthermore, the availability of suitable disposable bioreactors for production of cell therapeutics based on human mesenchymal stem cells is discussed, and the suitability of wave-mixed bioreactors for rapid virus-like particle vaccine production processes with insect cells and the baculovirus expression vector system is highlighted.

Three chapters alone deal with the cultivation of microorganisms (bacteria, yeasts, microalgae) and allow us to conclude that there is future potential for the development of disposable bioreactors. Using the example of the Process4Success approach from Sartorius Stedim Biotech, the advantages of flexible production

facilities based on process platforms using disposables, which are becoming increasingly accepted for antibody production processes using mammalian cells, are presented. Finally, aspects of quality management, including risk analyses prepared by users and manufacturers, make a major contribution to the success of disposable bioreactors.

We are grateful to all the authors, the series editor, Prof. Dr. Thomas Scheper, and the publisher for their support, and hope that this volume will be helpful for your studies, research and production processes.

Wädenswil, Summer 2013

Dieter Eibl  
Regine Eibl

Disposable Bioreactors II

Eibl, D.; Eibl, R. (Eds.)

2014, VIII, 292 p., Hardcover

ISBN: 978-3-642-45157-7