

# Preface

Animal cells are the preferred ‘cell factories’ for the production of complex molecules and antibodies for use as prophylactics, therapeutics or diagnostics. Animal cells are required for the correct post-translational processing (including glycosylation) of biopharmaceutical protein products. They are used for the production of viral vectors for gene therapy. Major targets for this therapy include cancer, HIV, arthritis, cardiovascular and CNS diseases and cystic fibrosis. Animal cells are used as in vitro substrates in pharmacological and toxicological studies. *Animal Cell Culture* is designed to serve as a comprehensive review of bioprocessing of animal cells for the production of biopharmaceuticals, covering the current status of both research and applications. For the student or R&D scientist or new researcher, the protocols are central to the performance of cell culture work, yet a broad understanding is essential for the translation of laboratory findings into the industrial production.

This book brings together the knowledge and experience of those who are using animal cells for the production of proteins. The chapters review the state of the art with in-depth assessments that emphasize the practical aspects of efficient operation of cell culture techniques. The book indicates those aspects of cell line development, optimization and large-scale production encountered in cell culture processes and shows how the recent development in cellular and molecular biology and omics technology can help the full realization of the potential of biotechnological exploitation of animal cells.

To optimize quality and quantity in the production of biopharmaceuticals from animal cells, researchers have developed many new methods. Considering that the global market is around 200 billion dollars and is growing at a compound annual rate of 13.5 % and that high clinical dose requirements over long periods of time have pushed demand, the optimization and scale-up of recombinant protein production technologies have become quite important.

Mass transfer, mixing and hydrodynamic forces in bioreactors are critical parameters that need to be controlled to provide cells with a satisfactory level of oxygen without damaging or stressing cells in culture. Two chapters are included to discuss the current knowledge with respect to these issues.

Selection of cell lines, suitable type of bioreactor system, optimal physical and chemical environment and appropriate production mode are of particular importance as an aid to achieving high and stable productivity. Many of the authors lay emphasis on such studies. The importance of DNA technologies, cell line stability and product quality, safety and efficacy are now widely recognized, and information is presented here on the methods to monitor, investigate and improve the selection, stability and productivity of cell lines. Transient gene expression is dealt with, as are hybridoma technology and baculovirus insect cell culture, which have been used to produce recombinant products. Perfusion processes and cell immobilization allow for far greater cell densities to be achieved, thus providing economic advantages as time is saved in turnaround and inoculum build-up. This book contains chapters to review the practical aspects of these processes for the production of biopharmaceuticals and vaccines.

Cell engineering is a new research approach which began in the early 1990s, coinciding with an increasing interest in apoptosis. There have been numerous innovative strategies based on cell engineering and molecular analysis, together with metabolite data aimed to optimize culture productivity. These strategies are described, including the proteomic and metabolic profiling of cell culture.

Although the adoption of process analytical technology (PAT) in the biopharmaceutical industry is in its infancy, it was felt that it is essential for a book on animal cell culture to include a discussion of PAT instruments, techniques and strategies of relevance. In the final chapter, experts provide the reader with an overview of the biopharmaceutical products that have been approved by the regulatory agencies from 1989 till the first quarter of 2014, including biosimilars.

I am grateful to the staff at Springer for their efficiency in preparing this volume and to Meran Owen and Tanja Koppejan in particular for their help and patience. I would also like to thank each contributor for their diligence and perseverance in preparing the chapters, which I am sure will be enjoyed and valued by everyone who reads this book.

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