Foreword

Pharmaceutical BIOPROCESSING

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Pharmaceutical Bioprocessing: a new voice for the biopharmaceuticals community

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»»"*Pharmaceutical Bioprocessing* is an interdisciplinary resource for all stakeholders in the development and manufacture of novel biopharmaceutical products."««

Welcome to the inaugural issue of *Pharmaceutical Bioprocessing* – a new peer-reviewed journal dedicated to addressing all aspects of bioprocessing for the development and manufacture of biopharmaceutical healthcare products.

Pharmaceutical Bioprocessing captures the latest key innovations and debate emerging in this burgeoning field. The journal provides an authoritative forum for the publication of original research articles, reviews and perspectives covering all areas of advanced bioprocess science and technology – from manufacturing to purification, through to the assessment and preparation of the final product for patient delivery. Each issue also features news updates along with regular guest editorials and opinions on hot topics and pressing areas of debate, and interviews with international experts.

The journal fills an important gap in the literature with its exquisite focus on the most significant research developments, providing readers with concise, high-value information, enriched with expert commentary and analysis. We believe that the journal will be an invaluable resource for researchers, both in academia and industry, and other professionals who want to remain abreast of developments within this fast evolving field.

The way forward…

With the launch of this new journal, it would seem opportune to take a closer look at the current status of the field of pharmaceutical bioprocessing. The phenomenal success of biological products in recent years has driven substantial advances in the science and technology surrounding bioprocessing. Biopharmaceuticals, including recombinant proteins, monoclonal antibodies and nucleic acid-based products, represent the fastest growing sector within the pharmaceutical industry. Approximately one in every four drugs introduced to the market is a biopharmaceutical, and sales of biopharmaceutical products are forecast to exceed US$200 billion in 2013.

The growing demand to fulfill market need has created imperatives for increased capacity and efficiency, and for reduced production costs and batch-production timeframes. There is also the pressure to obtain adequate yields and meet the necessary standards of purification and stabilization. Furthermore, emergent areas of research, such as tissue engineering, are often accompanied by their own complex and unique challenges.

The development of biopharmaceutical products is, to a large extent, challenging, inefficient and costly, with current cell and process-engineering approaches. Some $1.5 billion in development costs and 12 years of development time are required to bring a product to market. This presents the industry with the challenge to develop better products faster and at a lower cost, and requires the regulatory filing path and approval procedures to be significantly improved among the regulatory agencies. To overcome the challenges from developers and regulatory agencies, two initiatives were proposed to hasten the process of technology transfer into manufacturing:

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process analytical technology (PAT) and the development of platform technologies. Regulatory agencies and industry believe that PAT will provide improved process knowledge to resolve common challenges, and reduce the risks associated with biopharmaceutical development and manufacturing. Platform technologies were adapted as a common operational paradigm that would remove process reinvention for each new product and reduce manufacturing investments. With platform technologies, new manufacturing technologies can be introduced systematically. Both platform technology and the implementation of PAT should facilitate industrial challenges for achieving common goals and introducing new technologies with the eventual goal of improvements in drug safety and efficacy.

Against this rapidly changing and complex backdrop, we can expect to see developments in technologies and their implementation, requirements for regulatory clarity, new challenges and much controversy and debate. In this context, *Pharmaceutical Bioprocessing* is an interdisciplinary resource for all stakeholders in the development and manufacture of novel biopharmaceutical products – from biopharmaceutical developers, to system suppliers, to the academic institutions that provide the fundamentals for applied research, priming the future success of biopharmaceuticals.

Editorial Board

Pharmaceutical Bioprocessing is supported by a multidisciplinary and international editorial board, comprising leading researchers and opinion leaders from academia and industry. Their collective experience and input has been invaluable in laying the foundations for the journal and will be a great strength in maintaining high editorial standards and responsive coverage in future.

In-house journal team

Our in-house editorial team would be delighted to answer any queries you may have regarding potential submissions. We hope that readers will enjoy the format of the journal either in print or via our website [1]. We welcome your feedback on the journal and suggestions for content and other features. We can offer authors responsive editorial support, high visibility and impact for their articles. There are no page charges to authors, and publication is rapid (typically 8–10 weeks from submission to acceptance) and peer review is speedy, yet rigorous.

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Want to get involved?

The readership and contributors play a key role in ensuring that *Pharmaceutical Bioprocessing* truly reflects the needs, interests and trends within the research community. You can engage directly in this dialogue – the *Pharmaceutical Bioprocessing* LinkedIn group is open for new members to keep abreast of the latest journal news and updates [2], and you can sign up for electronic table of contents alerts on our website [3]. Please contact our editorial team with feedback, suggestions and ideas; we would be delighted to hear from you.

We hope you enjoy this and the coming issues of *Pharmaceutical Bioprocessing*!

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties. No writing assistance was utilized in the production of this manuscript.

Websites

1 Future Science Group. www.future-science.com

2 *Pharmaceutical Bioprocessing* LinkedIn group. www.linkedin.com/groups/pharmaceutical-bioprocessing-4627526

3 *Pharmaceutical Bioprocessing* eTOC alerts link signup page. www.future-science.com/action/showAlertSettings