

Foreword

We are delighted to write the foreword for this special issue of the Journal of Chromatography B entitled *Polyclonal and Monoclonal Antibody Production, Purification, Process and Product Analytics*. This special issue was conceived through the consideration of the growing significance of biopharmaceuticals and the emerging technological advances that permit large scale, cost-effective production to meet (current and future) anticipated market demands.

Modern biopharmaceutical development offers both enormous challenges and opportunities. This special issue is dedicated to the pursuit of technological and analytical innovations and provides an insight and understanding of both contemporary and emerging techniques for the production of therapeutic antibodies. Indeed, the importance of technical and analytical innovation to the enhancement of antibody production and manufacture has already been recognized and supported within the European Union through their Framework VI program. The European Commission has launched a new 11.5 million euro Integrated Project (IP) with the acronym AIMS (advanced interactive materials by design). The IP (<http://www.aims-eu.de/>) gathers 24 partners from industry, academia and other stakeholder groups from 12 European countries collaborating on a 4-year project with the broad aim of improving production technologies and cost-effectiveness of monoclonal antibody manufacturing.

In this Special Thematic Issue, we have attempted to focus on downstream processing operations (in particular purification) and analytical development. The articles presented here illustrate both the existing purification rationales and also champion emerging technologies that are challenging discrete purification steps; for instance, the replacement of chromatography operations with membrane-based processes.

Advances in upstream processing and fermentation development are, of course, of considerable importance and have a significant role in the future of biopharmaceutical development. However, this decision reflects our own background and expertise within the industry and the potential future manufacturing bottlenecks that may be encountered with the ever increasing recombinant antibody titers reportedly obtained from mammalian expression systems.

The articles presented in this issue have been written by many of the most active and prominent scientists in the field within both academia and industry and we have selected the subject areas in an attempt to provide a broad overview of antibody production (articles with A.R. Newcombe as a co-author have been independently and objectively handled by an alternative Journal Editor). The authors present their respective views of the current state of their chosen field of expertise and we hope that the review and research articles published within the issue provide both a general overview of the current status of the biopharmaceutical production, but also provide a glimpse into the future of biotherapeutics.

We hope that the readers of J. Chromatography B will gain not only an understanding of the advantages and limitations of existing techniques and technologies, but may also gain an insight into biotherapeutic antibody production as the industry drives forward into the 21st century.

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