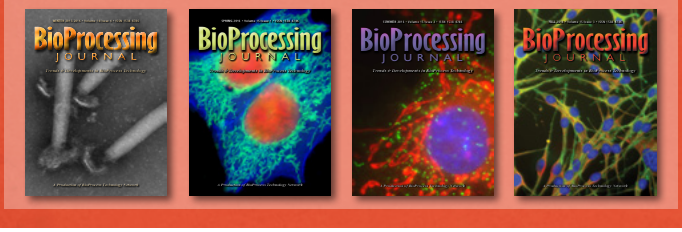
BioProcessing JOURNAL | AUTHOR GUIDELINES

Trends & Developments in BioProcess Technology



The BioProcessing Journal (BPJ) is a peer-reviewed, quarterly publication that features the latest technological advancements and best practices for the development and production of safe and effective biologics. Since 2002, BPJ has been a leading source of industry trends and techniques for process efficiency with its content specifically designed for professionals in process and analytical methods development, manufacturing, quality systems, regulatory affairs, facility design, and contract services.

Article Focus

Here are some recommendations for the particular focus and direction the author(s) might want to consider when planning a manuscript. We encourage the inclusion of photos, images, tables (up to 12), and figures (up to 12) to enhance and/or substantiate the article's content.

ANALYSIS & QC – Based on cGMP and regulatory standards. (1,800 – 3,000 words)

CASE STUDY – Collaborations between product suppliers or contract service groups and their customers reflecting their combined efforts in furthering method development and product optimization. (1,800 – 4,200 words)

CONFERENCE EXCLUSIVE – Based entirely (or in part) on a presentation given at an ISBioTech meeting. The author may elaborate on the presentation with additional data, results, and overall scope. (2,500 – 4,800 words)

ESSAY / OPINION EDITORIAL– Written from your point of view. (6000 – 1,200 words)

LEAD-IN ARTICLE – Offers insights, reviews, and analysis of the bioprocessing industry. (1,800 – 3,500 words)

LETTER TO THE EDITOR – Subject to editing by the publisher. Questions, criticisms, or responses to points in a previously published article will be sent to the article's author for a reply without divulging the name of the letter writer. (100 – 250 words)

METHODS AND DATA – Descriptions of new and improved methods, or new applications of established technologies. (1,200 – 3,750 words)

PRODUCT DEVELOPMENT – Detailed study with data. (2,500 – 4,000 words)

PERSPECTIVES – Providing an overview and commentary on a technology or application. (1,000 – 3,800 words)

REGULATORY – From those who work in a regulatory role. (1,000 – 3,800 words)

SUPPLIER TECHNOLOGY – Where product or service providers present their core technologies. Scientific information is presented in a commercially balanced form, avoiding the excessive use of trade names and marketing claims. Unsubstantiated benefits or direct comparisons to a competitor's products or services should be avoided and will be subject to screening by the editor. (1,800 – 4,200 words)

OR PERHAPS ONE OF THESE – *Cell Banking – Cell Engineering – Facility – Lab Notes – Protein Expression – Process Development – Raw Materials – Single-Use Components – Production Management – Application Notes.* The important thing is that it best represents your organization's particular focus. Include hands-on observations and details/data on the processes and protocols that were followed. (1,000 – 4,200 words)

Consult our latest Editorial Calendar for additional target topics.
And don't let our word counts limit you. They are guidelines, not absolutes.
A solidly crafted and comprehensive manuscript is what we're looking for.

Submission Overview

We welcome original articles from all areas of bioprocessing that are not under consideration for publication by another periodical, and are not already available on the internet. Occasionally manuscripts containing non-copyrighted information that has been presented in other non-competing publications will be considered — but this is done on a case-by-case basis.

Authors are responsible for obtaining the appropriate permissions if their manuscript includes previously published graphs, tables, or images. Authors must state affiliations with organizations that have a direct or indirect financial interest in the editorial content or products that are discussed in the manuscript. Authors are responsible for all statements made in their work.

Manuscripts are accepted in Microsoft Word format (or comparable). Please arrange all references and figures (with captions) at the end of the manuscript, and provide separate (high-resolution) files for figures and images. Abbreviations, symbols, and acronyms should be spelled out the first time they appear in the text unless they are so well-known and standardized as to not allow ambiguity (*e.g.*, DNA).

Please indicate the corresponding author(s) for the manuscript, and include complete contact information such as name, organizational title, post-graduate degree (PhD, MD, *etc.*), address, phone number, and email address. Include job titles, affiliations, and doctoral designations for co-authors.

Submit manuscript, images, and a completed Copyright Transfer form (on pg. 3) to publisher@bioprocessingjournal.com. If you have a particular publication date in mind, please refer to our Editorial Calendar for details and deadlines.

The Review Process

Manuscripts are subject to peer review and will be edited for clarity, grammar, and conformity to the styles established for BPJ. If substantial revisions are recommended (as determined by the editors and peer reviewers), the author(s) will be given the opportunity to make appropriate updates.

Manuscript Acceptance

Once your article has been accepted, the BPJ managing editor will schedule it for production and notify you. We reserve the right to assign any article to the issue in which it will best fit BPJ's content and production schedule, and to republish any article in whole or in part in any subsequent issues.

Reference Formatting

List references sequentially, with numbers in brackets, as they appear in the text. At the end of the article, provide the references in numerical order. Please refer to the examples shown on this page. Be sure to include the full title of the article, book, presentation, *etc*. Provide the DOI and PubMed ID information when available. Unless a reference has been accepted for publication, it must be designated as "Unpublished."

Image Specifications

Submit illustrations, photos, and figures as separate, high-res digital files: EPS, PSD, TIFF, PDF, PNG, PPT, or JPG formats (~300 dpi). Authors will be contacted if improved resolution is required. For tables, we prefer working with text rather than images for greater layout flexibility and enhanced readability. Figures and tables should be numbered in the order that they appear in the manuscript.

Front Cover Page

BPJ is well-known for striking cover photographs and illustrations, and we encourage your submissions. Credits and descriptive text will be shown. Fluorescent micrographs of cells used in the bioprocess industry are ideal, and those pertaining to articles featured within an issue are a plus.

Article Processing and Journal Wrap-Up

After layout, the corresponding author will be emailed an article proof (in PDF format) to review for accuracy. Production staff will incorporate the author's designated corrections/revisions, obtain final approval, and turn materials over to the printer. Our BPJ webmaster will post the issue on the Journal website in flip-page format for readers worldwide to view and enjoy.

Additional Information

Please send your manuscripts, questions, comments, cover images, and article abstracts to:

publisher@bioprocessingjournal.com

Magazine or Journal Articles:

[1] Hahn TJ *et al.* Rapid manufacture and release of a GMP batch of avian influenza A(H7N9) virus-like particle vaccine made using recombinant baculovirus-Sf9 insect cell culture technology. *BioProcess J*, 2013; 12 (2): 4-17. http://dx.doi.org/10.12665/J122.Hahn

[2] Schlaeger EJ. The protein hydrolysate, primatone RL, is a cost-effective multiple growth promoter of mammalian cell culture in serum-containing and serum-free media and displays anti-apoptosis properties. *J Immunol Methods,* 1996; 194 (3): 191-199. PMID 8765172

[3] Nims R, Plavsic M. A proposed modeling approach for comparing the heat inactivation susceptibility of viruses. *BioProcess J*, 2013; 12 (2): 25-35. http://dx.doi.org/10.12665/J122.Nims

[4] Sarwar UN *et al.* Safety and immunogenicity of DNA vaccines encoding Ebolavirus and Marburgvirus wild-type glycoproteins in a phase I clinical trial. *J Infect Dis*, 2014. Epub ahead of print. PMid 25225676, http://dx.doi.org/10.1093/infdis/jiu511

[5] Lövgren Bengtsson K, Song H *et al.* Matrix-M adjuvant antibody, cellular, and protective immune responses of a Zaire ebolavirus glycoprotein nanoparticle vaccine in mice. (Unpublished, manuscript in preparation.)

[6] Bu N *et al*. Exosome-loaded dendritic cells elicit tumor-specific $CD8^+$ cytotoxic T cells in patients with glioma. *J Neurooncol*, 2011;104(3):659-67. Epub 2011 Feb 19. PMid:21336773, http://dx.doi.org/10.1007/s11060-011-0537-1

Press Releases:

[7] J. Craig Venter Institute. (2013). Prepared statement from J. Craig Venter, PhD, and the J. Craig Venter Institute and Synthetic Genomics Vaccines, Inc. on the H7N9 avian flu strain in China [Press release]. Retrieved from http://www.jcvi.org/cms/press/press-releases/full-text/article/prepared-statement-from-j-craig-venter-phd-and-the-j-craig-venter-institute-and-synthetic-geno/.

Regulatory Agency or Standardization Organization Publications:

[8] FDA (CDER/CBER/CVM) Guidance for Industry. *Process validation: general principles and practices*. Jan. 2011, CGMP, Rev. 1. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf (Accessed 24 March 2015)

[9] Centers for Disease Control (CDC). US Public Health Service guideline on infectious disease issues in xenotransplantation. *Morbidity and Mortality Weekly Report* (MMWR) Atlanta (GA): CDC; 2001 Aug 24. Vol 50, No. RR15.

[10] Center for Biologics Evaluation and Research (CBER). Draft guidance for industry: *Source animal, product, preclinical, and clinical issues concerning the use of xenotransplantation products in humans.* Rockville (MD): CBER; 2001 Feb.

[11] International Conference on Harmonization. ICH Topics Q5A – Notes for guidance on quality of biotechnological products: *Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin. Step 4 consensus guideline.* 4 March 1997 (CPMP/ICH/295/95).

[12] *Cell cultures for veterinary vaccines.* European Pharmacopoeia, 4th ed. General chapter 5.2.4; 2002.

[13] Interim definition and elimination of lot-by-lot release for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. *Federal Register* 1995; 60: 63048.

[14] Pharmaceutical Manufacturers and Research of America (PhRMA). *Biotechnology products in development.* Washington, DC: PhRMA; 2002.

[15] The Biotechnology Industry Organization (BIO). *Approved biotechnology drugs.* Washington, DC: BIO; 2003 Feb. http://www.bio.org

Information Published By Companies:

[16] Milroy D, Auchincloss C. Monoclonal antibodies – on the crest of a wave. In: *Horizons.* London, United Kingdom: Wood Mackenzie; 2003.

[17] Mallik A, Pinkus G, Sheffer S. Biopharma's capacity crunch. In: *The McKinsey Quarterly 2002 Special Edition: Risk and Resilience.* McKinsey & Co., 2002. p 9-11.

Books, Sections, or Chapters in Books:

[18] Sambrook J. *Molecular cloning: a laboratory manual, 2nd ed.* New York: Cold Spring Harbor Laboratory; 1989.

[19] Ausubel FM, Brent R, Kingston, RE, Moore DD, Seidman JG, Smith JA, Struhl K. Analysis of proteins. In: *Short Protocols in Molecular Biology, 4th ed.* New York: John Wiley & Sons Inc.; 1999. p 10-44.

[20] Morgan C, Rose HM. The application of thin sectioning. In: Maramorosch K, Koprowski H, editors. *Methods in virology, Vol. 3.* New York: Academic Press; 1967. p 576-616.

[21] Kozak CA, Ruscetti S. Retroviruses in rodents. In: Levy JA, editor. *The Retroviridae, Vol. 1.* New York: Plenum Press; 1992. p 405-430.

Patents:

[18] Blom WR, Kunst A, van Schie BJ, Luli GW, inventors; Quest International Flavors & Food Ingredients Company, assignee. *Method for in vitro growth of eukaryotic cells using low molecular weight peptides.* US patent 5,741,705. 1995 Feb 23.

Papers Presented at Meetings:

[22] Petry H *et al. Hurdles faced from the quality perspective during the Glybera® approval process.* Paper presented at the ISBioTech 3rd Annual Meeting; 2013 March 11-15; Rosslyn, Virginia USA.

[23] Vasilyeva E *et al. Development of a chip-based electrophoresis method for the determination of half-antibody molecules in IgG4.* Poster presented at the 2002 WCBP Conference; 2002 January 21-27; San Francisco, California USA.