

## Article/Paper Submission Guidelines

Use these instructions to prepare peer-review papers, technical articles, and other contributions for publication in *BioPharm International* and on [www.BioPharmInternational.com](http://www.BioPharmInternational.com).

### Submission Process

Publishing is a deadline-focused business; the editors rely on the cooperation of contributors to meet deadlines and following the editorial review process.

The editorial process is summarized as follows:

- The editors begin work on topics on the editorial calendar approximately four months prior to the month of publication; early contact with the editors via email inquiry is recommended.
- Authors are asked to submit an abstract (250 words) describing the topic and content of the proposed submission, potential figures, expected length and submission date, and a list of authors. The editors review the abstract, offer suggestions, and provide a word count and deadline. Abstracts are due approximately three months prior to the month of publication.
- Final articles, figures, and signed license agreements are due approximately two months prior to publication. Please obtain all necessary legal and company clearances prior to submission.
- The typical word count for a technical article is 1800 to 2000 words, with up to three figures. The word count will be confirmed after review of the abstract.
- Articles are assigned to a lead editor, who will work with the corresponding author through the editing process. Authors will be sent an edited Word document, as well as a layout page proof. Authors must return the edited document and proofs within a few days.

The editors cannot guarantee publication of a submission in a specific issue. All submissions are reviewed and edited for style, content, and length. All peer-review papers are subject to advisory board review. Proofs of edited articles are sent to authors prior to publication.

## **Originality and Licensing**

### **Originality and Rights**

Manuscripts are reviewed with the understanding that they have not been published previously in any format—print or electronic—are not ghostwritten, and are not under consideration for publication elsewhere, including on the Internet.

All articles undergo a thorough check for plagiarism; if plagiarism is found, the article will automatically be rejected, and the author(s) will be banned from publishing in *BioPharm International* and its sister publications.

### **Image, Figure, and Table Rights**

The author must own the rights to all submitted images, tables, and figures. Graphics from other sources or third-party sources will not be accepted for publication.

### **License Agreement**

The author and any coauthors are required to sign a license agreement before a manuscript is accepted for publication to provide UBM (a part of Informa plc) permission to publish the original article and its associated figures/tables in print and online.

## **Editorial Contacts**

Submit your article to your corresponding editor or:

Chris Spivey, editorial director, [cspivey@mjhlifesciences.com](mailto:cspivey@mjhlifesciences.com)

Susan Haigney, managing editor, [shaigney@mjhlifesciences.com](mailto:shaigney@mjhlifesciences.com)

Feliza Mirasol, science editor, [fmirasol@mjhlifesciences.com](mailto:fmirasol@mjhlifesciences.com)

# Prepare Article for Submission

## Length

The word count for peer-review papers and technical articles varies between 1000 and 3000 words and may include up to 5 figures and tables. The editors will specify an article length and number of figures for each submission. Manuscripts and figures/tables that exceed the editor's instructions may not be accepted for consideration or will be edited to fit the available space.

## Accuracy and style

Before submission, authors are urged to review manuscripts for clarity of expression, grammar, and typographical accuracy. Acronyms and abbreviations used in manuscripts should be defined on first reference and within tables and figures. The author is responsible for all statements in his or her work.

Articles should be written in third person. Do not use "I" or "we" or other first-person pronouns.

## Document format

The article's text should be formatted in Microsoft Word and submitted in American English. Do not use any special text formatting codes or control characters.

Beginning with the first page of the text, number each page of the article consecutively.

References should be called out in text, using (1), (2), (3), etc., and cited at the end of the article. Do not use superscripts when citing references in the article. Do not use Microsoft Word's footnote or reference features. See below for reference style and formatting.

Refer to figures and tables in the article text (Figure 1, Table I, etc.). Include the table and figure captions, as well as the actual figure/table, at the end of the article. High-resolution versions of figures, illustrations, or photos must be sent separately. See the **Images and Figures** section below for details.

**Author contact information**

Include a cover sheet with author names, titles, company or organization affiliation, address where the work was completed, phone number, and email address.

For articles with multiple authors, designate one corresponding author who will handle correspondence at all stages of refereeing, editing, publication, and post-publication; provide contact information (email, telephone, and mailing address).

One email address to a lead author will be published. This email address should be for confirming technical information provided in the article only. Email addresses and website links used for marketing or lead-generation purposes will not be published.

**Article titles**

Articles titles should be short and specific and accurately reflect the content of the article.

**Other content**

Please provide a list of keywords relevant to the article, as well as non-promotional websites or additional online references and materials that supplement the article text. *BioPharm International* will consider publishing video demonstrations, audio tutorials, and downloadable tools related to the article on its website, [www.BioPharmInternational.com](http://www.BioPharmInternational.com). Mention such items, if applicable and available, with your article.

## Images and Figures

The illustrations, images, and figures must be original to the author(s). Credit is provided as “All figures are courtesy of the author(s).”

Figures, charts, photos, or illustrations that do not increase the reader’s understanding of the text should be omitted. Promotional images, such as those with a company logo, will not be published.

Follow these specifications when submitting illustrations, images, and figures:

- Limit the number of figures/tables in the article to five, or as specified by the editor.
- Original photographs, line drawings, graphs, charts, and other illustrations may be submitted in color or black/white (color is preferred) and must be referred to in the text in consecutive order: Figure 1, Figure 2, etc.
- Do not include company logos, stylized fonts, or trademark symbols. Do not use colors that simulate the company’s branding.
- Include descriptive captions and credit information for all figures and images in a Word document.
- Format all text/labels/words within a figure to be in the following font: Myriad Pro Regular. Font size should a minimum 12 points. Adobe OpenType fonts are preferred. Adobe Type 1 fonts are acceptable.
- All symbols, acronyms, and abbreviations used in figures should be spelled out. Label all values, including axes in graphs, with appropriate units. Abbreviate units of time and measurements:
  - h for hours
  - min for minutes
  - s for seconds
  - mL for milliliters
  - L for liters

### **File types for images**

Submit high-resolution figures and images as separate eps, jpg, or tiff files. To ensure adequate print reproduction quality, images and figures must be 300-dpi resolution and measure at least 3 inches wide or deep in the shortest dimension.

Do not embed figures or images within Word documents, PowerPoint slides, or email messages. Send via email as separate file attachments, or request FTP access information from the editor.

[Please note: changing an image's resolution in Photoshop from 72 DPI to 300 DPI will not increase the actual resolution—the image must have been drawn or photographed at the original high resolution for the best print quality].

### **Tables**

Please follow these specifications when submitting text tables:

- Original tables or charts must be identified by number (e.g., Table I, Table II) and have been created by the author (s). These can be submitted as part of the Word text file in Word or Excel. Do not submit text tables as an image.
- Uppercase only the first letter of the first word for row heads, column heads, or information in a given cell.
- All symbols, acronyms, and abbreviations used in tables should be spelled out.
- Abbreviate units of time and measurements:  
h for hours  
min for minutes  
s for seconds  
mL for milliliters  
L for liters



# Style Guidelines for References

*Pharmaceutical Technology, Pharmaceutical Technology Europe, BioPharm International*

## Guidelines for Authors

References are used to connect the reader to supporting information from published literature, conference proceedings, regulatory and compendial guidances, and other authoritative sources. References also credit the original work of authors.

For digital links, the reference should connect the reader to substantive content related to the cited text. Links to company sites—as a pseudo-reference or an unassociated link included with the article for free publicity—are prohibited.

Always use the original source for a citation.

- If a news story cites a journal, research study, article, website, or government resource, do not cite the news story; find the original source for the citation.
- Do not cite ResearchGate or other content aggregation sites as a source for journal papers. Attribute the original journal paper as the source of the information.

## Unacceptable sources

- Social media and publicly compiled information such as *Wikipedia* are not valid sources.
- References and links to marketing or advertising content are not acceptable.
- Lead-generation or gated sources are prohibited. Exception: journals or news sources that require a subscription to view are acceptable (examples: *New York Times*, *Nature*).

### **Formatting references**

- Literature citations in the text should be numbered consecutively by Arabic numerals in parentheses after appropriate sentences and/or paragraphs as part of the sentence and not as superscripts. Please do not use endnotes or footnotes.
- References should be grouped at the end of the manuscript and arranged in order of their appearance in the text. Format references according to the guidelines provided below.
- Each reference begins with the name of the author(s) or the organization that provided the information, if no individual is named.
- For more than three authors, list the primary author and “et al.,” to denote that additional authors contributed.
- Each reference ends with a period.

### *Using Web links in references*

Full URLs are spelled out in print on a limited basis, in accordance with these guidelines. Links are provided in online content at the discretion of the editors.

For contributed articles, authors should format the reference to online content as described in the sections below and provide the link at the end of the reference. The editors will determine if the link should be included in print or online.

- Links to company literature or press release for a commercial enterprise are not published.
- Add an access date (e.g., “accessed May 9, 2009”) only if the document changes frequently, such as a list of statistics that is updated regularly.

## Reference formats

The following examples should be used as a guide for formatting references in print and online.

### BOOKS

#### Book

Author's First Initial. Author's Last Name, *Title of Book in italics and Title Caps* (Publisher, Publisher Location, Edition, Date).

Example:

T. Pyzdek and P.A. Keller, *The Six Sigma Handbook: A Complete Guide for Green Belts, Black Belts, and Managers at All Levels* (McGraw-Hill, New York, 3rd ed., 2009).

#### Chapter in a book

Author's First Initial. Author's Last Name, "Title of Chapter," in *Title of Book in italics and Title Caps*, Editors of Book, pages (Publisher, Publisher's location, edition if applicable, year published).

Example:

E.F. Fiese and T.A. Hagen, "Preformulation," in *Theory and Practice of Industrial Pharmacy*, L. Lachman, H.A. Lieberman, and J.L. Kanig, Eds., pp. 171–194 (Lea & Febiger, Philadelphia, PA, 3rd ed., 1986).

### JOURNALS OR MAGAZINES

#### Article in a journal/magazine:

The primary source should be the print version of the article, unless the article is online only.

Author's First Initial. Author's Last Name, *Publication name in italics and abbreviated Volume Number (issue number) pages (date)*.

Example:

G.M. Golden, J.E. McKie, and R.O. Potts, *J. Pharm. Sci.* 76 (1) 25-28 (1987).

#### DOI articles

Author's First Initial of First Name and Full Last Name [et al., for more than 3 authors], *Journal Name abbreviated and in italics* online, DOI number (Date).

Example:

D. Trauner et al., *Nature Chem. io.* online, DOI:10.1038/nchembio.107 (Aug. 1, 2008).

#### Online-only journal articles if no DOI number

Author's First Initial. Author's Last Name, *Journal Name abbreviated and in italics* online, Volume Number (issue number) (date).

Example:

T. Qu, *J Drug Target* online, 10 (2) (Feb. 1, 2020).

## REPORTS

Use for market research and industry studies.

Author's First Initial. Author's Last Name/Organization, *Title of Report in italics and Title Caps* (Edition, Date).

Example:

Evaluate Pharma, *World View 2019, Outlook to 2020* (12th edition, June 2019).

## REFERENCES FOR CONTENT ORIGINATING ONLINE

### Articles/news stories

Author's First Initial. Author's Last Name/Organization, "Title of Document," *sitename.com in italics*, publication date.

Example:

J. Wechsler, "FDA Encourages Development of Regenerative Medicines," *PharmTech.com*, Feb. 20, 2019.

### Online content/webpages

Organization/Author's First Initial. Author's Last Name, "Title of document/heading," URL, publication date, access date if non-static.

Example:

FDA, "Q&A on Drug Topics," *www.fda.gov/qadrugtopics*, accessed May 1, 2012.

Provide a link to the referenced content. The editors will determine if a link will be provided.

## CONFERENCES

### Published conference proceedings

Author's First Initial. Author's Last Name, *Title of Proceedings Publication*, pages (location, year).

Example:

J.B. Dressman, *Proceedings of PDA Biologics Conference*, xx–xx (Washington, DC, 2009).

### Oral presentations

Author's First Initial. Author's Last Name, "Title of Talk," presentation at the Xxxxxx Conference (location, Date).

Example:

M. Jornitz, "PDA Update: The PUPSIT (SFQR) Initiative," presentation at the 2019 PDA/FDA Joint Regulatory Conference (Washington, DC, Sept. 16–18, 2019).

## **GOVERNMENT AND STANDARD-SETTING BODY DOCUMENTS**

Use official government sources for proposed legislation, regulations, official commentary, etc. Cite the *Federal Register* as the source and provide a link from the official online *Federal Register* (<https://www.federalregister.gov/>) to the direct citation.

### **Code of Federal Regulations**

*CFR* Title 21, Part XYZ (Government Printing Office, Washington, DC) pages.

Example:

*CFR* Title 21, 211 (Government Printing Office, Washington, DC) 158-179.

Provide URL from <https://www.govinfo.gov/app/collection/cfr> or <https://www.federalregister.gov/>

### **Bills**

If a bill is approved and not amended, the introduction date should be used. Once a bill is approved by both houses, it loses the S. or H.R. classification and will have a *CFR* name.

Examples:

S. 3633, US Senate, 110th Congress, 2nd Session (Washington, DC), Sept. 26, 2008. [date refers to bill introduction date]

S. 3633, US Senate, 110th Congress, 2nd Session (Washington, DC), amended Sept. 30, 2000. [date refers to date bill amended]

### ***Federal Register* references**

Organization, "Title of Content," Type [proposed rule, notice, etc.], *Federal Register*, document citation, pages.

Example:

FDA, "Biosimilar User Fee Rates for Fiscal Year 2020," Notice, *Federal Register*, 84 FR 37888, 37888-3789.

## Guidance and Standards Documents

Agency Acronym, *Title of Guideline or Guidance in Italics*, Version if appropriate (FDA department abbreviated, date).

### FDA

Examples:

FDA, *Guidance for Industry, INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information* (CDER, May 2003).

FDA, *Draft Guidance for Industry, Using the Inactive Ingredient Database Guidance for Industry* (CDER, July 2019).

### ICH

Agency Acronym, Document number not in italics, *Title of Guideline or Guidance in Italics*, Version (date).

Example:

ICH, Q1B *Photostability Testing of New Drug Substances and Products*, Step 2 version (1996).

### Other regulatory/standards authorities

Agency Acronym, document number not italicized, *Title of Guideline or Guidance in Italics*, Version (date).

Examples:

EMA, EMA/CHMP/QWP/245074/2015, *Manufacture of the Finished Dosage Form* (Feb. 14, 2017).

- Provide a link to the official EMA site.

EC Directive 2010/13/EU, *Audiovisual Media Services Directive* (March 2010).

- Directive number not italicized.
- Provide a link to the official EC site.

ISO, ISO 21748:2010, *Guidance for the Use of Repeatability, Reproducibility and Trueness Estimates in Measurement Uncertainty Estimation* (2010).

## US Pharmacopeia

USP, *USP General Chapter* <chapter number>, "Chapter Title," *USP Vol No.-NF Vol No*, pages if appropriate (Rockville, MD, date).

Example:

USP, *USP General Chapter* <1151>, "Pharmaceutical Dosage Forms," *USP 41-NF 36* (Rockville, MD, 2018).

- USP is converting from print to online documents, with changes to update frequency. Authors should provide the volume, number, and page (if appropriate) to indicate which version they are referencing, which may include a date and ID number.

USP Proposed Test, etc., in *Pharmacopeial Forum*:

Example:

L. Furr, M. Eakins, and D. Hunt, "USP Packaging Standards—Strategy and Overview, Stimuli Article, *Pharmacopeial Forum* 45 (5) (Sept. 3, 2019).

## European Pharmacopoeia

Example:

EDQM, *EurPh*, General Text 5.2.8 pages (EDQM, Strasbourg, France, YEAR).

## LEGAL DOCUMENTS

### Patents

Author or Company name, "Transmitter Switch for Wireless ID," US patent 125356, December 2003.

### Court/Legal decisions

*Name v. Name*, Volume Source Page (Court, Date)

Example:

*Regents of the University of California v. The Broad Institute*, 903 F.3d. 1286 (Fed. Cir., 2018).

## **MARKETING CONTENT**

### **Press Releases**

Name of Company Issuing Release, "Title of Press Release," Press Release, Date.

Example:

Anergis, "Anergis Presents Sustained Efficacy Data from its AllerT Phase IIb Trial at the AAAAI Annual Meeting," Press Release, Feb. 23, 2015.

- Provide links to press statements. The editors will determine if the links will be included.

### **Whitepapers/Application Notes**

Whitepapers, application notes, videos, position statements, product literature, and other marketing-related content should be used sparingly. Links to commercial content for are prohibited.

Author's First Initial. Author's Last Name/Organization, "Title of Document," Type (whitepaper, app note, video, brochure, etc.) Date.

Example:

Nelson Laboratories, "When Drug Meets Device," Whitepaper, Jan. 20, 2020.