



Guidelines for Authors

(rev. 01/2013)

**This guide includes information about submitting papers for peer review,
as well as other ways to contribute to
Pharmaceutical Technology and *Pharmaceutical Technology Europe*.**

Editorial Coverage

Pharmaceutical Technology and *Pharmaceutical Technology Europe* cover formulation development, process development, and manufacturing of active pharmaceutical ingredients (both small molecule and large molecules) and finished drug-products (solid dosage, semisolid, liquids, parenterals drugs, topical drugs), drug-delivery technologies, analytical methods development, analytical testing, quality assurance/quality control, validation, and advances in pharmaceutical equipment, machinery, instrumentation, facility design and plant operations. Our readers are PhD-level scientists, senior-level scientists, or senior production professionals specifically involved in those areas.

Manuscripts accepted for peer review will be published simultaneously in both *Pharmaceutical Technology* and *Pharmaceutical Technology Europe* and will reach 56,600 industry scientists and professionals who receive the publications in print and another 40,000 who receive these publications digitally. Articles are also posted on our website, www.PharmTech.com. Peer review is double blind, where the identity of reviewers is unknown to authors and vice versa.

Our journals are published monthly. We also publish supplements throughout the year (see separate guidelines).

Article Content

Articles submitted for peer review may fall into four main categories: standard data-driven, novel research paper; topical literature or patent review; technical case studies/technical application notes; and science-based opinion papers. These four categories are described below:

Peer-Review Definitions

Standard data-driven, novel research paper

Peer-review articles that present novel scientific findings and original data that advance a technology, a process, a synthesis, a formulation/drug delivery method, or manufacturing scalability or operability. The article sets out a hypothesis, describe experiments (including proper control experiments), present data derived from those experiments, offer a discussion of the data, and then draw a conclusion from them. Reviewer evaluates technical interest and content of the article, including the data and conclusions derived from data. [target 2000 to 3600 words, with no more than 6 figures and tables combined]

Topical literature or patent review

Peer-review articles offering a topical literature or patents review to inform the reader of the latest scientific/technical advances in a given area with proper citation to literature and/or patents. The article summarizes and objectively explains the importance of the work in this field and/or comparison of this work to other approaches in the field. Reviewer reviews the interest of the topic overall and the saliency/importance of the material cited by the author in advancing knowledge of the subject. [target 2000 to 3600 words, with no more than 6 figures and tables combined]

Technical case studies/technical application notes

Peer-review articles offering a technical case study that provides the reader with practical guidance and understanding to resolve a problem or challenge in formulation development, process development, manufacturing, drug delivery, analytical methods development and analysis. Condition of novelty in terms of research and/or method does not have to be met, but instead the article is evaluated based on whether it provides sound scientific/technical understanding of a problem/issue and related guidance for scientific/technical personnel specifically involved in this field. [target 1500 to 1800 words, with no more than 3 figures and tables combined]

Science-Based Opinion Papers

Peer-review articles that offer an opinion on current industry thinking and practices or other developments supported by scientific/technical information. Reviewer does not evaluate the opinion per se, but evaluates whether sufficient an accurate science/technical support is offered in any such opinion. [target 1000 to 1500 words]

Audience. For all peer-reviewed papers, authors should regard the reader as an informed scientist or technical professional specifically involved in the area of discussion who is interested in objective, well-researched, and scientifically/technically relevant content for his/her work. *Pharmaceutical Technology* and *Pharmaceutical Technology Europe* follow peer-review procedures standard for scholarly and technical journals, including inclusion of relevant data, literature citations, and graphics (tables, charts, figures, images, etc).

Deadlines. We accept manuscripts for peer review on an ongoing basis. Publication priority is given to accepted articles first received, so early submission is encouraged for editorial consideration.

Once the article is received, it is first evaluated internally for consideration for peer review, and after this initial review, the article is submitted to a member of our editorial advisory board, who will review the article for technical interest and content in a double-blind review process (where the identity of reviewers is unknown to authors and vice versa). Our internal editor staff acts as the conduit between the reviewer and author in the event of any questions, queries, or requests for additional information/data for the article. Depending on the manuscript (and the time constraints of the author), articles usually take about 1–2 months for review, revision, and acceptance. Article acceptance is conditioned on the reviewer's acceptance. Once accepted for publication, an article is published within 1 to 6 months. Accepted papers are copyedited and formatted. A galley proof is provided to the author for review prior to publication. Articles are published in print and posted on line at www.PharmTech.com

Length. Word counts are given in the peer-review definition area above. Manuscripts and figures/tables that go beyond these requirements will not be accepted for review.

SUBMISSION INFORMATION FOR PEER-REVIEWED PAPERS

Pharmaceutical Technology and *Pharmaceutical Technology Europe* welcome manuscripts about subjects relevant to formulation development, process development, and manufacturing of active pharmaceutical ingredients (both small molecule and large molecules) and finished drug-products (solid dosage, semisolid, liquids, parenterals drugs, topical drugs). The following subjects are covered:

- Formulation development (solid dosage, semisolids, liquids, parenterals, topical drugs), inclusive of excipient selection and functionality and solubilization strategies
- Drug-delivery technologies, including nanotechnology and other emerging technologies
- Finished drug product manufacturing for solid dosage, semisolids, liquids, parenterals, and topical drugs, inclusive of specific unit operations in solid dosage manufacturing (milling, blending, granulation, tableting, coating) as well as sterile manufacturing, aseptic processing, lyophilization, and fill–finish
- Drug substance manufacturing, scale-up, and process development for chemically synthesized active ingredients and biologic-based active ingredients, including both upstream and downstream bioprocessing
- Analytical methods development and testing for drug substances, finished drug products, and impurities, including process analytical technology (PAT)
- Regulatory and pharmacopeial requirements and compliance, quality assurance, quality control, and validation
- Pharmaceutical facility design, plant operation, engineering, process control and automation
- Quality by design, continuous processing, and emerging manufacturing approaches

Make Sure Your Article is Ready for Peer Review

Original research

Peer-reviewed research articles present novel scientific findings and data that significantly advance a technology, a process, a synthesis, a formulation, or manufacturing scalability or operability. They set out a hypothesis, describe experiments (including proper control experiments), present data derived from those experiments, offer a discussion of the data, and then draw a conclusion from them. *Pharmaceutical Technology* and *Pharmaceutical Technology Europe* follow peer-review procedures standard for scholarly and technical journals.

Peer-review papers offering original research follow a general format as follows:

1. **Abstract:** of under 200 words briefly lays out the hypothesis and conclusion

2. **Introduction:** sets the hypothesis within a context of the state of the art and explaining how the presented data change or advance the current theory or practice
3. **Materials and Methods:** sets out the experimental procedure, including all equipment used, settings, buffer compositions and concentrations, ingredients, and other materials and procedures. The information given here should be detailed enough to allow any other researcher to duplicate the experiments described. Experimental and control experiments must be described.
4. **Results:** Presents data in tabular format, spectra, and other graphics summarizing data values and showing standard deviations. Results must include those for the experimental and control conditions
5. **Discussion:** The discussion is truly the meat of the article where the author reviews the data and demonstrates how he/she supports the conclusions. The authors may want to raise alternate hypotheses and demonstrate how the data fit one of these in particular. They may also suggest future experiments that will eliminate other hypotheses or advance the current one.
6. **Conclusion:** A short section restating the hypothesis that has been (in theory at least) proved in the article. Authors may also choose to comment on current and potential future applications of the work.
7. **References:** Throughout the article, the authors should cite papers, books, abstracts, posters, conferences, in which data were presented either by them or others who developed methods used, advanced supporting or competing hypotheses, or drew conclusions related to the work being presented. See section on “References” for appropriate format and style.

Topical literature or patent review articles

Peer-review articles offering a topical literature or patents review should inform the reader of the latest scientific/technical advances in the field, with proper citation to literature and/or patents. The article summarizes and objectively explains the importance of the work in this field and/or comparison of this work to other approaches in the field.

Technical case studies, technical notes

Peer-review articles offering a technical case study, including troubleshooting/problem resolution in manufacturing, should follow the guidelines for submission of content for original research, providing the reader with data, methods, and discussion.

Prepare your article for submission:

Length. Manuscripts should be between 2000 and 3600 words. No more than 6 figures and tables combined should be submitted. Technical case studies and technical notes may be shorter in length, 1200 to 1800 words, with 2 to 4 figures. Manuscripts and figures/tables that go beyond these requirements will not be accepted for review.

Accuracy and Style. Before submitting a paper, 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. All accepted manuscripts are subject to editing.

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

Illustration, Image, Figure, and Table Rights. Please note that 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.

PLEASE NOTE that we will only accept and publish original content that has not been published elsewhere, including online, or that is not being considered by another publication or website. All articles undergo a thorough check for plagiarism and if plagiarism is found, the article will automatically be rejected and the author(s) will be banned from publishing within Pharmaceutical Technology and its sister publications.

Article Format

- The article's text should be formatted in Microsoft Word and include a cover sheet with the Title, Author/ Coauthor names, titles (if PhD, please specify in title), and company/university/affiliation. For the authors' affiliation addresses, provide address where the actual work was done. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author. If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name.

Designate one corresponding author and contact information (email, telephone, and mailing address) for the corresponding author. Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address. Contact details must be kept up to date by the corresponding author.

- Articles titles should be short and specific and should accurately reflect the content of the article.
- Do not use any special text formatting codes or control characters. Strip out any special-character codes as well as any font-change codes. Please include tables and figure captions in the electronic file at the end of the article (which includes a high-resolution (300 dpi version of any images, see below for specification for figures and images). Beginning with the first page of the text, each page of the hard copy should be numbered 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 (see below for references).

Keywords, Weblinks, and Online Tools. Please provide a list of keywords relevant to the article, as well as websites or additional online references and materials that might be of interest to readers. *Pharmaceutical Technology* is specifically interested in publishing video demonstrations, audio tutorials, and downloadable tools that are related to the article. Such interactive items would be published on its website, www.PharmTech.com, with the full article at the same time it appears in the print magazine. Please include mention of such items, if applicable and available, when you submit your paper.

Illustrations, Images, and Figures. Please follow these specifications when submitting illustrations, images, and figures

- All illustrations that do not increase the reader's understanding of the text should be omitted. Limit the number of figures/tables in the article to six.
- Original photographs, line drawings, graphs, charts, and other illustrations may be submitted in color or black/white (although color is preferred) and must be referred to in the text in consecutive order: Figure 1, Figure 2, and so forth.
- Be sure to include descriptive captions and credit information for all figures and images. The illustrations, images, and figures must be original to the author(s). Credit for the graphics is provided as "All figures are courtesy of the author(s). Captions should be submitted separate from image files in a Word document.
- All symbols, acronyms, and abbreviations used in figures and tables should be spelled out. Use "h" for hours, "min" for minutes, "s" for seconds, "mL" for milliliters and "L" for liters. Please be sure to label all values with appropriate units, including axes in graphs.
- Please format all text/labels/words within a figure to be in the following font: Myraid Pro Regular. Font size should be a minimum 12 points. Adobe OpenType fonts are preferred/Adobe Type 1 fonts are acceptable.
- We cannot use figures or images that are embedded within Word documents. We need the original image file(s) in an eps, jpg, or tiff format. Images and figures must be 300 dpi resolution. [Please note: changing an image's resolution in Photoshop from 72 DPI to 300 DPI, for example, will not increase the actual resolution—the image must have been drawn or photographed at the original high resolution for the best print quality]. Captions and credits should be submitted separate from image files in a Word document.
- If possible, please include a four-color photograph for use on the opening page of the article in high-resolution (300 dpi format)

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.
- Please uppercase only the first letter of the first word for row heads, column heads, or information in a given cell. If your table includes any symbols or acronyms, please define them in a footnote at the end of the table. Use “h” for hours, “min” for minutes, “s” for seconds, “mL” for milliliters and “L” for liters.

REFERENCES

Literature citations in the text should be numbered consecutively indicated 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 not alphabetically. Please also be sure to style and format your references according to the guidelines provided below. If the style and format do not adhere to our guidelines, we will return the paper to you to do so before it is accepted for publication. Be sure that volume, issue, and page numbers (beginning and end page numbers) are included and that information is in the correct order. Do not worry about bolding or italicizing the references. Make sure that every reference is called out in the article text.

Chapter in a book:

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. (Lea & Febiger, Philadelphia, PA, 3rd ed., 1986), pp. 171–194.

Article in a journal:

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

**Note: The number 76 in the above example refers to the Volume; (1) refers to the issue number.

Continued on next page

Published conference proceedings:

J.B. Dressman, Proceedings of PDA Biologics Conference (Washington, DC, 2009), pp. X-XX.

Oral presentations:

B.L. Hawkins, A. Baxter, and G.E. Masters, PDA Biologics Conference (Washington, DC, 2009).

J. Woodcock, MD, Statement, House Committee on Energy and Commerce Hearing, Apr. 29, 2008.

Government publications:

Code of Federal Regulations, Title 21, Food and Drugs (Government Printing Office, Washington, DC), Part 121, pp. 270–290.

J. Dingell, “Letter to Democratic Caucus” (Washington, DC), Nov. 6, 2008.

S. 3633, US Senate, 110th Congress, 2nd Session (Washington, DC), Sept. 26, 2008.

US House Committee on Energy and Commerce, “Food and Drug Administration Globalization Act,” Revised Discussion Draft, July 24, 2008 (Washington DC).

FDA, “Human and Veterinary Drugs, Good Manufacturing Practices and Proposed Exemptions for Certain OTC Products,” *Fed. Regist.* **43** (190), 45013–45089 (Sept. 29, 1978).

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

FDA, *Guidance Title* (Rockville, MD, Nov. 2004).

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

Pharmacopeia:

USP 27–NF 22 (US Pharmacopeial Convention, Rockville, MD, 2003), pp. X–X. (Note: N dash between USP and NF, numbers are not italicized but USP and NF are.)

Note if the above is the reference for an entire General Chapter or other titled section, then it follows the style as for the chapter in a book, referenced as follows:

USP 30–NF 25 General Chapter <1231>, “Water for Pharmaceutical Purposes,” page–page.

USP Proposed General Test <429>, “Light Diffraction Measurement of Particle Size,” *Pharmacopeial Forum* **28** (4), 1293–1298.

16. *EurPh*, General Text 5.2.8 (EDQM, Strasbourg, France, YEAR), pp–pp.

Continued on next page

Patents

Author/Company name, “Transmitter Switch for Wireless ID,” US patent 125356, Dec. 2003.

Press Release

Name of Company Issuing Release, “Title of Press Release,” Press Release (Location, Date of issuance).

For example:

PwC, “Patient Over Product,” Press Release (London, Feb. 21, 2011).

Supplement article in one of our journals:

G.M. Golden, J.E. McKie, and R.O. Potts, "Name of Supplement Title Here" supplement to *Pharm. Technol.* 34, NO ISSUE NUMBER UNLESS SUPP IS INSERTED IN MAIN ISSUE, s25–28 (2009).

Online-only DOI articles:

D. Trauner et al., "Biomimetic Synthesis of the IDO Inhibitors Exiguamine A and B," *Nature Chem. Bio.* online, DOI:10.1038/nchembio.107, Aug. 1, 2008.

Only include urls if critical to finding document online. If a url is included, do not include <http://> unless necessary and be sure to add access date (e.g., "accessed May 9, 2009") to end of reference.

Contacts for Article Submissions

Submit your article and materials electronically to:

Rita Peters, Editorial Director

rpeters@advanstar.com, tel. 732.346.3038

or

Patricia Van Arnum, Executive Editor

pvanarnum@advanstar.com, tel. 732.346.3072