PHARMACEUTICAL ENGINEERING

2018 Author Guidelines

GUEST EDITORIALS, PERSPECTIVES, TECHNICAL ARTICLES, CASE STUDIES, AND RESEARCH ARTICLES

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Part I: Introduction

Pharmaceutical Engineering is the flagship membership magazine of the International Society for Pharmaceutical Engineers (ISPE). It is a magazine that inspires engineers across all ranks, around the world, with provocative and useful articles that come from trustworthy and reliable sources.

A bimonthly publication, *Pharmaceutical Engineering* covers topics from across the spectrum of the pharmaceutical and biotechnology industries. From technical articles that provide how-to advice that is current and immediately applicable on the job to thought-provoking features on current issues, *Pharmaceutical Engineering* offers a snapshot of the profession and the industry.

Pharmaceutical Engineering's reach is global. Our readers are a diverse group: professional engineers working across all facets of the pharmaceutical, biotechnology and manufacturing industries, as well as regulators, business leaders, academics, and students.

In addition to technical and editorial articles, *Pharmaceutical Engineering* publishes Special Reports, which provide global perspectives on broad industry topics such as drug shortages, biotechnology, data integrity, quality metrics, and sustainability.

Only original, complete, unpublished drafts
will be considered for publication

Original material
Only original, complete, unpublished drafts will be considered for publication. We do not review or evaluate incomplete articles.

If your organization has already published the article on its website, that is considered previously published content. In most cases, PE will be unable to republish this content.

All graphic material—including tables, charts, and photographs—must be original and unpublished, or you must have permission from the source to reprint the image. For more information see the Using copied graphics sections.

Simultaneous submission
Simultaneous submission is not permitted. You may not submit your article to another journal unless you withdraw it from consideration or it is rejected by the editorial review board.

Technical evaluation
If you're an ISPE member and want to evaluate the potential of a topic or article before you write, contact the community of practice (CoP) that covers your technical area. These online

communities provide opportunities for discussion with technical experts who can offer valuable counsel. Authors who are not ISPE members should consult resources available through their employers or universities.

Accuracy and correctness

Authors are responsible for the accuracy and correctness of all statements contained in the article; the publisher assumes no liability.

Commercialism

Commercialism is strictly prohibited.

- Commercialism is the inclusion of visual, written, or verbal references to any specific company and/or product for promotion or commercial advantage.
- The article must not promote a specific product or company to the exclusion of other similar products that could be used to resolve the problem.
- The article must focus on novel and innovative technical approaches to resolve a problem without excluding alternative options.

Issue placement

You may request publication in an upcoming issue when you submit your article. Please consult the online editorial calendar for themes, special report topics, and conference distributions.

Commercialism is strictly prohibited

Final placement depends on multiple factors, however, only one of which is editorial focus. These include—but are not limited to—date of submission, length of review and revision process(es), and available space. We encourage you to take the time to develop a solid and well-written article, not to focus on publication in a specific issue.

Legal and corporate review

If you or any of your coauthors require legal and/or corporate review of the article before publication, you must indicate this in the cover letter when you submit the article.

Promise of publication

There is no guarantee that a submitted article will be published. Publication depends on the assessment of our reviewers and the decision of the editorial director.

Part II: Writing your article

Article types

Editorials and perspectives

Guest editorials

These are short, thought-provoking articles that provide a personal perspective on contemporary issues, hot topics, or controversies.

Maximum length: 1,000 words

Perspectives

These can cover recent industry developments, strategic issues, technical developments, trends, or innovative solutions. They should stimulate debate, present new models or hypotheses, speculate on the meaning and interpretation of new data, or outline suggestions for future experiments.

Maximum length: 1,500 words, 2 figures

Technical articles, case studies, and research articles

The following article types undergo industry review by the *Pharmaceutical Engineering* Committee and the *Pharmaceutical Engineering* review board, which includes designated members of CoPs.

Final placement depends on multiple factors

Technical articles

These are practical-application articles that define and demonstrate global best practices in engineering and design, product development, technology transfer, manufacturing process development and scale-up, commercial manufacturing, quality and compliance, and product life cycle management.

Maximum length: 5,000 words, 5 figures

Case studies

These are critical analyses of new approaches to industry problems. Each article should describe the method, process, and technology, discuss any difficulties encountered, and provide a balanced and supported view of the pros and cons of this approach vs. other, more established methods.

Maximum length: 4,000 words, 4 figures

Research articles

These describe innovative methods and techniques covering any aspect of the pharmaceutical industry. They must emphasize sound research methods and results, with conclusions supported by adequate evidence. Scientific rigor and reproducible results are required.

Maximum length: 4,000 words, 4 figures

Revision, review, and approval

Industry review

In addition to our slate of industry reviewers, you may specify additional reviewers when you submit the article on ScholarOne; they do not have to be ISPE members.

- About 6–8 weeks after submission, you'll receive a revision letter that details reviewer's feedback and recommendations or requirements for revision.
- If your article is granted conditional acceptance at this time, you'll be given a deadline for submitting a revised draft to ScholarOne.

Every article undergoes an editorial review

Editorial review

Every article submitted for publication in *Pharmaceutical Engineering* undergoes an editorial review for style, tone, flow, cohesion, and organization. ISPE has full editorial control of magazine content*,* and reserves the right to edit, revise, and delete copy as appropriate.

- Editorials and perspectives are edited after conditional acceptance.
- Technical articles, case studies, and research articles are edited after authors have revised content based on industry review.

Following editorial review, the revised draft will be returned to you for review and approval.

Final review

You will receive a PDF of the article in preliminary layout for final sign off.

Using text and graphics from other sources

Copyright

Copyright is a form of intellectual property law. It protects original works by requiring permission from the author (or publisher, who acquires rights from the author) to reuse or adapt it. Copyright exists as soon as an original work is "fixed in a tangible medium of expression" (including thumb drives and cocktail napkins); even unpublished works are protected by copyright. [1]

As part of the scientific community, ISPE is committed to a fair editorial process that protects copyright for all authors and publishers. This upholds the foundation of trust at the heart of scientific scholarship and research, [2] and reduces the potential for copyright infringement, which may result in significant legal penalties.

Plagiarism

Plagiarism is using another person's work—copyrighted or not—and representing it as the product of your own effort. You may think it's sufficient to make a few tweaks, change a few words, add a footnote, and cite the source from which you copied the text. But that's still plagiarism.

You must *completely revise and restate* the idea(s) in your own words. Note that you must still document the source in which you found the information, and you must do this *for every item in the article that you took from another source.*

ISPE is committed to a fair and open editorial process

If you can't or don't want to do this, you must mark the copied material as a quotation—then add a reference and cite the source from which you copied the text.

Original
The emergence of "big data" has allowed pharmaceutical organizations to harness the vast amount of information they generate. [1]

Insufficient tweak
"Big data" has allowed pharmaceutical organizations to harness the information they generate. [1]

Revise and restate
As metrics and statistics have evolved into "big data," the pharmaceutical industry has learned how to tap the enormous reservoirs of information it produces. [1]

Quotation
As Ingram et al. noted, "The emergence of 'big data' has allowed pharmaceutical organizations to harness the vast amount of information they generate. "[1]

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1. Ingram, Marzena, et al. "Manufacturing Excellence Utilizing a Life Cycle Approach." *Pharmaceutical Engineering* 37, no. 5 (September-October 2017): 69–69.

Why is plagiarism wrong—even if the material is drawn from a public domain source? Because *Pharmaceutical Engineering* publishes original thought, research, and content. Failing to disclose copied material and presenting it as original work perpetrates a fraud on our readers and undermines our integrity as a publisher of scientific and technical knowledge.

Self-plagiarism

Authors who have published books or articles usually do not own the copyright to those materials. Most publishers, however, grant authors the right to reuse their published work (see the Taylor and Francis and Elsevier author policies as examples). If your article includes text or graphics from a work you published elsewhere, be sure that the quoted material does not exceed the bounds of your agreement with the initial publisher. You must also supply a credit

line/attribution to document the material's source and copyright holder; this text is usually supplied by the publisher.

Copyright infringement

According to the Copyright Clearance Center, "copyright infringement occurs when a copyrighted work is reproduced, distributed, performed, publicly displayed, or made into a derivative work without the permission of the copyright owner." [3–4] Copyright infringement can have serious legal, financial, and professional consequences.

Pharmaceutical Engineering publishes
original thought, research, and content

Using text copied from other sources

Plagiarism and copyright infringement are common problems in scientific and technical writing. [5–6] While scientific research builds on others' work, you may not understand the difference between paraphrasing information and importing someone else's content (see the Plagiarism section). Requesting permission also takes time that you may not have. If you're an author for whom English is a second language, you may find it faster and easier to use existing copy than to write in a foreign syntax—but that's still plagiarism. [7]

There are only two ways in which you may use copyrighted material without permission from its author or publisher: fair use and public domain.

Fair use

In the United States, whose copyright laws govern *Pharmaceutical Engineering*, the "fair use" legal doctrine permits *limited* use of copyright-protected works for purposes of discussion, analysis, or parody. In a scholarly or technical work, fair use allows excerpts of *short passages* of text for illustration, comment, or clarification. [8] In both cases, copied material must be marked as a quotation, and the source must be cited.

Public domain

Works in the public domain fall into two categories: 1) works for which the copyright has expired (Newton's *Principia*, for example), and 2) works deliberately published without copyright protection. Works in the public domain may be used without permission, although as with fair use, copied material must be marked as a quotation and the source must be credited.

- In the United States, most (but not all) work published by the federal government is in the public domain.
- Works produced by United Kingdom departments and agencies may be available under an open government license; [9] if not, they may be subject to Crown Copyright.
- Most European Union documents, [10] including EurLex data, [11] may be used without permission provided the source is acknowledged.

Note: *You must check each source to determine whether it is in the public domain.*

Unless it's clear that a graphic is in the public domain,
assume that it's protected by copyright

Using copied graphics

Unless it's clear that a graphic is in the public domain, you must assume that it's protected and permission is required to use it.

Unfortunately, misconceptions about copyright and graphics also exist: [12]

I've cited the source: Many people make this mistake with text as well. It is not permissible to use a figure (or portion of it) without permission even if you acknowledge the source. Unless the figure is in the public domain, using it without permission may well be copyright infringement.

I'm not using much: It doesn't matter how large the original work is, or how much of it you're using. If you want to borrow a figure, you must have the copyright holder's permission.

I'm going to modify it: Incorporating new material into a copyrighted graphic or figure may produce what's known as a "derivative work" (see the Copyright infringement section). This can only be done with authorization from the original holder, and must usually be credited as "adapted with permission."

It's from a nonprofit organization: Nonprofit doesn't mean public domain. Some organizations, like ICH, allow material to be used without permission as long as they are identified as the copyright holder and any modifications to the original are noted. Others, like ISO and ISPE, require written permission to republish material. Be sure to check the organization's website for reuse parameters and contact information.

Securing permission to use a copyrighted work

We encourage authors to create original illustrations (including tables, charts, and graphs) for their articles whenever possible.

Published material

You must identify materials copied from (or based on) outside sources in your cover letter when you submit the article.

If the copied material has been published in a book or journal, the *Pharmaceutical Engineering* editorial staff will attempt to acquire the reprint permissions necessary.

We encourage authors to create original illustrations

To help us do so, you must supply the following information:

- **Title of the original work:** The book or journal in which the figure *first* appeared—and that may not be the work in which you found it. *Please be aware that you may have to do some research to find the original owner of an illustration.*
- **Author of the original work:** The person who wrote the book or article in which the figure first appeared. If your source is a book that contains chapters by multiple authors, please provide the name of the book author/editor and the chapter author.
- **Publisher:** The company (Elsevier, Springer, ACS) that published the book or journal in which the figure first appeared.
- **Publication information:**
  - Book: Chapter title, page, and/or figure number, edition and date of publication
  - Journal: Volume, issue, date of publication, page numbers

Note: *It will be difficult (if not impossible) to request reuse permission without this information. Material copied from works that are out of print or unidentifiable may be unusable.*

Company-supplied material

If you or one of your co-authors have included copied material supplied by a company, you must supply written consent from the company, along with any required attribution. ("Graphic of XYZ process © 2017 by PharmaCorp. Reprinted with permission.")

If you include material copied from a company's website or publication without their knowledge, you must request and be granted reuse permission before it can be republished in *Pharmaceutical Engineering*.

Author copyright release

ISPE retains copyright to all the articles it publishes.

Once we have granted your article provisional acceptance (usually after the industry review), you must sign a copyright release and consent to publish form; if you are a primary author, you must also complete an article categorization form to ensure that the article will be categorized by topic in ISPE's online article index.

ISPE retains copyright to all the articles it publishes

Accepted articles become the property of ISPE and may not be published elsewhere without written permission (see [Author rights to reuse material](#)).

Once published in *Pharmaceutical Engineering*, articles may not be posted on any website, blog site, page, or reproduced in any form without written permission from ISPE.

If you want to share an article you've published, you have two options:

1. Once your article has been published, we can post it as an article on the iSpeak blog. (*Note:* Longer articles may be published in two or more segments.) You'll receive a link (or links) that you can post on your website, along with a summary of the article. This provides access for both ISPE members and nonmembers. Here's an example of an article that was published as a multipart blog post.

2. You may order hard-copy reprints of most *Pharmaceutical Engineering* articles. Please contact the managing editor for more information about this option.

Author rights to reuse material

You may reuse any figures or graphics that appear in a published article and quote up to 10% of the article text in subsequent publications or presentations without requesting permission. All such use must include the following attribution:

> Originally published in *Pharmaceutical Engineering* Vol XX, no. X (Month–Month YYYY). © ISPE YYYY. All rights reserved. Reprinted with permission.

Requests to republish larger sections of *Pharmaceutical Engineering* content should be submitted to the managing editor.

Article content

Text

Article text must be in *.doc or *.docx format. PDFs, screenshots, or hard copy documents will not be accepted.

Article text must be in *.doc or *.docx format

Editorial style

Pharmaceutical Engineering follows the *Chicago Manual of Style*, 17th edition, and *Scientific Style and Format*, 8th edition, both published by the University of Chicago Press.

Figures and graphics

All image file formats **except Microsoft Visio** are acceptable. If your figures were created in Visio, you must export them as a high-resolution graphics file (JPG, BMP, TIFF, PNG, or PDF).

All image files must be suitable for print: 300 dpi or at least 1 MB.

- Graphs, charts, and tables created in Microsoft Excel or PowerPoint should be submitted in their original file format.
- Graphs, charts, and tables created in other mathematics graphing programs must be submitted as high-resolution PDFs or in another image file format.
- Screenshots will not be accepted.
- Each figure must include a brief caption.

- To make the article easier to review, insert figures and tables within the document; you may also upload them with your submission as separate files.

Note: Unless text, figures, and graphics comply with these guidelines, the article will not be accepted.

Units of measure
You may use either metric or imperial/avoirdupois measurements.

Equations
Simple equations may be displayed as regular text. Longer, more complex mathematics may be created using Microsoft Word's **Insert Equation** function.

Acknowledgments
If you include an acknowledgments section, you may place it at the end of the article.

All image files must 300 dpi or at least 1 MB

Footnotes
Footnotes explain a term or concept, are flagged with a symbol instead of a number, and placed at the bottom of a page.

> **Example**
> Both individuals and research groups were involved in identifying the CRISPR system in nature, then adapting it as a genome-editing technology.∗

References
References list the information sources you used to write your article. They may be published, unpublished, or personal communications.

When you place a reference in the article text, number it and enclose the numeral in square brackets. These citations may be placed in the middle of a sentence, or *following* punctuation. (See the Using Text and Graphics from Other Sources section for examples.)

List all references at the end of the article, numbered in the order in which they appear. Include only those sources that you cite in the text. Please list as much information about each source as possible. You may use the references at the end of this document as a template for your own citations.

∗ Briefly, repeated sequences of 30 bases separated by spacers of approximately 36 bases were identified in an archaeal microbe by Francisco Mojica in 1993. Over a decade later, Mojica realized that CRISPR loci are part of an adaptive defense system that protects microbes against specific infections.

Note: Don't copy references from other authors—they are often incorrect. Find and cite the original sources.

Tables

Create tables using the table function in Word.

- Include a caption for each table.
- Place significance values, other statistical data, and notes below the table.
- Include an attribution when the material has been copied from another source (see [Using copied graphics](#)).

Author biography

Each author must supply a short biography (≤ 150 words) with the article submission. Please include the following information: educational background, current title and company affiliation, responsibilities, and major areas of accomplishment.

Don't copy references from other authors.
They are often incorrect.

Part III: Submitting your article

ScholarOne online portal

You must submit articles and their accompanying graphs, tables, and illustrations through our online portal, Manuscript Central/ScholarOne.

If you have a user account, enter your User ID and Password to log in.
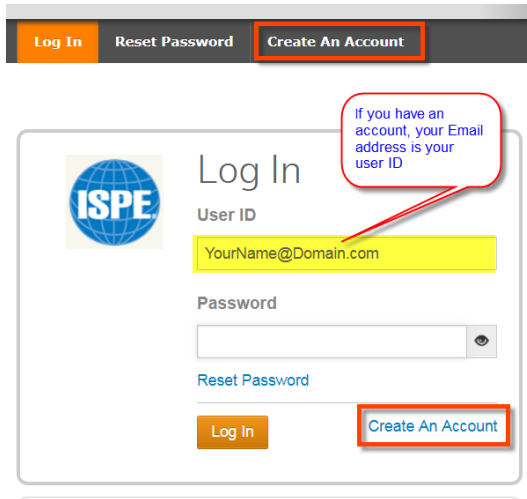
Create an account

If you do not have a user account, select **Create An Account** on the **Log In** page.

Enter the information requested in the **E-Mail/Name, Address**, and **User ID & Password** screens, then log in using your User ID and Password.

Note: Be sure to indicate a prefix at the top of the page.

Note: *Your email becomes your ScholarOne User ID. If you change companies or email addresses, be sure to update your ScholarOne account.*

Submit the article

Once you have logged in, select the **Author Center** link, then select the **Start New Submission** link.
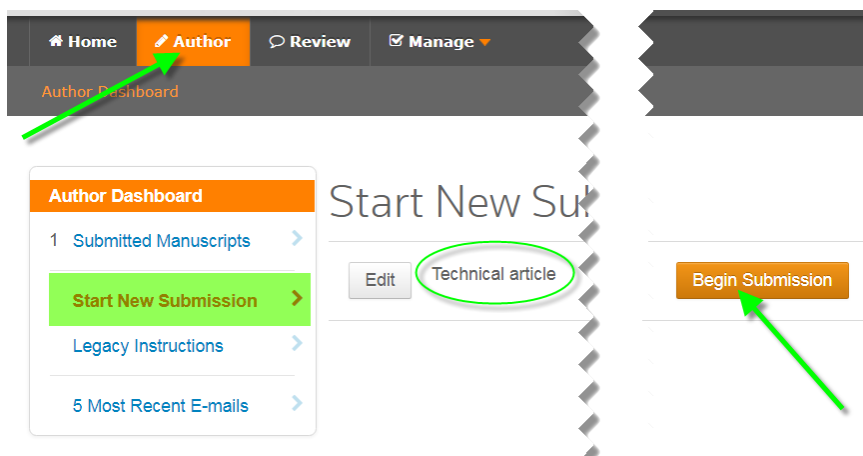
Select the **Begin Submission** button.

Note: *This screen displays **Technical Article** by default. <u>Don't change it</u>, even if you're submitting a different kind of article. You will indicate the article type in the* [Details & comments](#) *section.*

Type, title, & abstract

Select your article type (original, revised, or final), enter the title, then write or paste an abstract and synopsis.

Attributes

You must select at least two, but no more than six topics for your article.
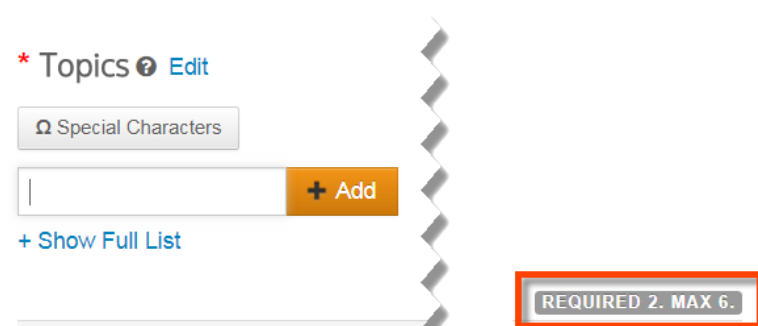
Start typing in the empty **Topics** field to retrieve possible matches from the existing topics list. To add that topic, select it and click the **+ Add** button.
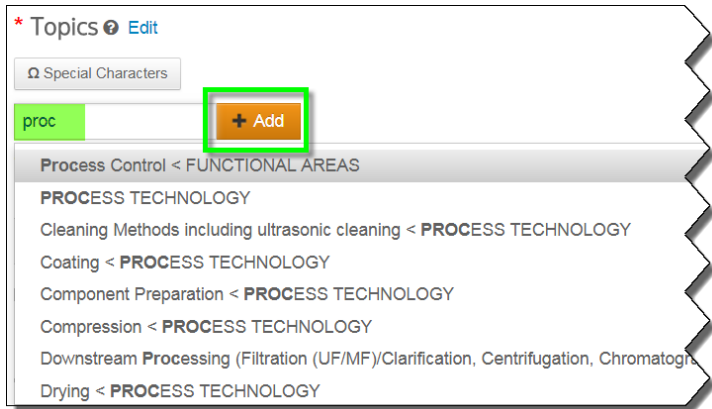
You may also select the **+ Show Full List** link to display the entire list. Select a topic line, then select the **+ Add from List** button. Be sure to scroll through the entire list to see all available topics.
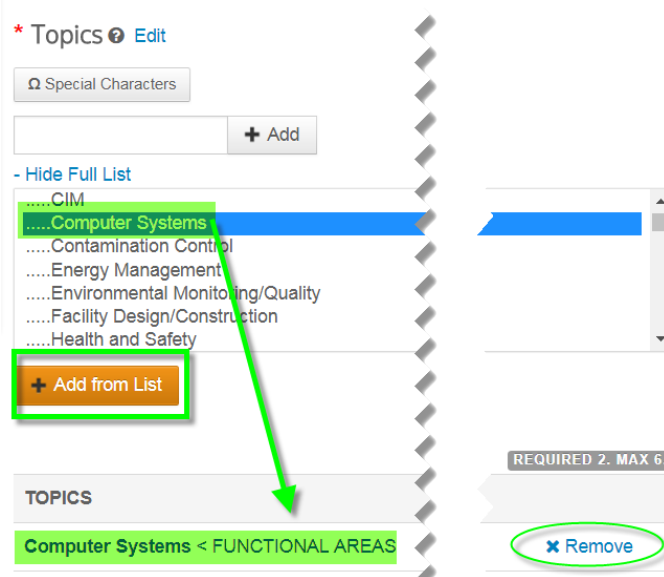
Note: You can remove topics from the list by selecting the × **Remove** link

If no matches exist, you may type a new topic into the empty **Topics** field, then select the **+Add** button.
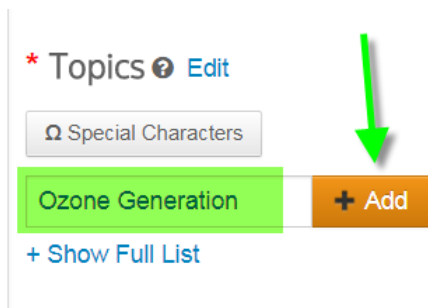
Your topic will appear in the **TOPICS** list at the bottom of the page.

Authors & institutions

Since you added your name and contact information when you created your account, you must now add your coauthors (if any).

Begin by searching to see if they are already in the ScholarOne system.

Enter an email address in the **Find using Author's email address** box, then select **Search**.

If no match for the email is found, select the **create a new co-author** link in the **Add Author** box.

You will be redirected to the **Create New Author** screen.

Enter the requested Prefix, First, and Last name, then scroll down to enter the coauthor's company name and address.
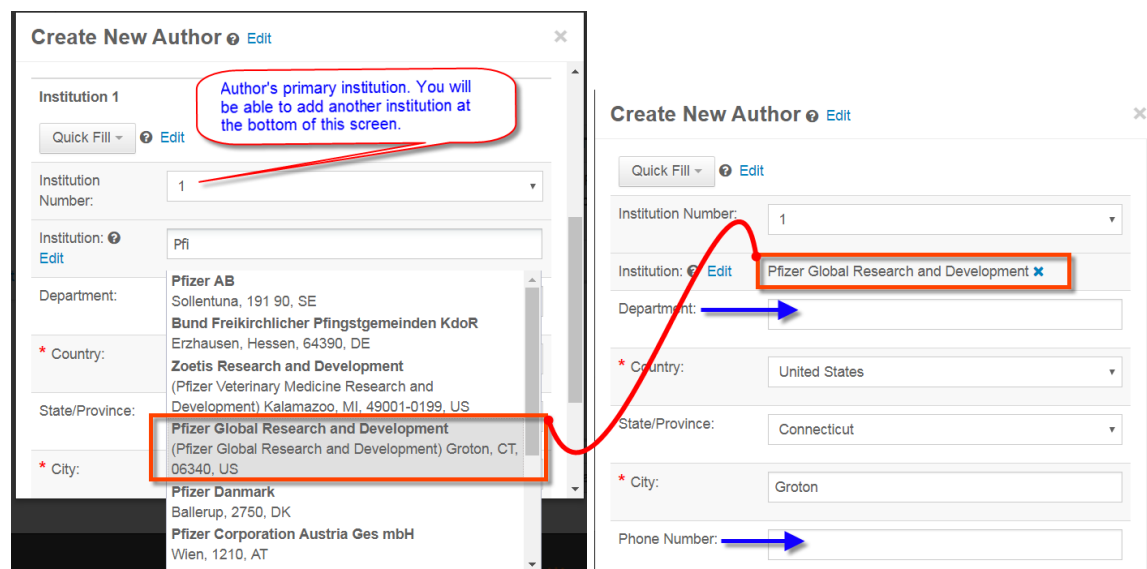
Begin typing in the **Institution** field to see any possible matches already on file. To choose one, select and click on the entry.

Existing information on that institution will be added to the screen. Add any other individual information available.

Note: Please provide a complete mailing address for each author. Our mail houses need this information to send copies of the magazine when the article has been published.

If no match exists, enter the information required for each field.

Reviewers & editors

In addition to the [panel of reviewers](#) in our [industry review](#) process, you may also indicate additional people that you want to review your article, and/or reject those that you oppose. They do not have to be ISPE members.

Select the **Add Reviewer** button.
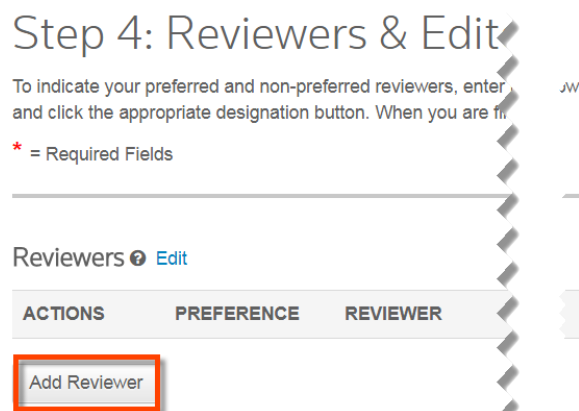
Enter the requested information on the **Add Reviewer** screen as you did on the **Create New Author** screen. Indicate your choice in the **Preference** section by choosing the appropriate radio button.

Details & comments

Enter, paste, or upload your cover letter here.

Note: Be sure to indicate whether your document *[contains graphics or text that will need reprint permission](#), and/or if the article will require [legal or corporate review](#) before publication.*

You must also indicate:

- Number of figures
- Number of tables
- Article word count
- Companies that provide equipment or services related to this product or process
- Article topics
- The issue (if any) in which you would like to publish
- Your ISPE chapter or affiliate
- Article type: Guest editorial, perspective, technical article, case study, or research article

File upload

Submit your article, biography, and figures. Figures and tables may be embedded in the Word document, attached as separate files, or both.

Review & submit

You can review and edit the information you've entered, then approve the file upload.

Part IV: Article of the Year Award

Each technical article, case study, and research article published in *Pharmaceutical Engineering* automatically becomes a candidate for the Article of the Year Award.

History

ISPE's Roger F. Sherwood Article of the Year Award was established in 1993 to increase article submissions and improve the quality of those received. In the early years, judges rated each issue's technical articles against a set of six criteria, then selected an annual winner.

In 2016 the award was refreshed to showcase the best content in *Pharmaceutical Engineering* magazine, increase industry recognition, highlight ISPE's reputation as a global knowledge leader, and bolster magazine content quality.

Criteria

A panel of judges—comprising two Board members, the Knowledge Network Council Chair, *Pharmaceutical Engineering* Committee Chair, Guidance Documents Committee Chair, one PEC member, two Young Professionals, and two senior ISPE staff members—reviews and ranks the technical articles, case studies, and research articles published in each issue of *Pharmaceutical Engineering* during a calendar year.

To be considered as a finalist, each article must:

- Be cited in other articles or presentations at ISPE (and other) forums
- Describe or provides industry-leading concept/position/development
- Be well written and referenced
- Demonstrate a progressive and productive approach for the industry

Selecting the winner

After reviewing all qualifying articles, the judges choose a list of five finalists. ISPE members then vote to determine the overall winner.

Part V: For more information

Contact

If you have any questions regarding the article-submission process please contact:

- Susan Sandler, editorial director: 438-406-3340
- Amy Loerch, managing editor: 813: 960-2105 x 225

We look forward to working with you!

References

1. United States Copyright Office. "Copyright in General." https://www.copyright.gov/help/faq/faq-general.html

2. Das, Natasha, and Monica Panjabi. "Plagiarism: Why Is It Such a Big Issue for Medical Writers?" *Perspectives in Clinical Research* 2, no. 2 (April–June 2011): 67–71. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3121267

3. Copyright Clearance Center. Copyright FAQ. "What Is 'Copyright Infringement'?" http://support.copyright.com/index.php?action=article&id=240

4. United States Copyright Office. "Copyright in Derivative Works and Compilations." Circular 14. https://www.copyright.gov/circs/circ14.pdf

5. Masic, Izet. "Plagiarism in Scientific Publishing." *Acta Informatica Medica* 20, no. 4 (December 2014): 208–213. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3558294

6. Butler, Declan. "Journals Step Up Plagiarism Policing." *Nature* 466 (5 July 2010): 167. http://www.nature.com/news/2010/100705/full/466167a.html

7. Editorial. "The Insider's Guide to Plagiarism." *Nature Medicine* 15 (2009): 707. http://www.nature.com/nm/journal/v15/n7/full/nm0709-707.html

8. United States Copyright Office. "More Information on Fair Use." https://www.copyright.gov/fair-use/more-info.html

9. United Kingdom National Archives. "Licensing for Re-Use." http://www.nationalarchives.gov.uk/information-management/re-using-public-sector-information/licensing-for-re-use

10. Official Journal of the European Union. "Commission Decision of 12 December 2011 on the Reuse of Commission Documents." 14 December 2011. http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32011D0833

11. European Union. Copyright Notice. http://eur-lex.europa.eu/content/legal-notice/legal-notice.html#droits

12. Jassin, Lloyd J. "Ten Common Copyright Permission Myths." Copylaw.com. http://www.copylaw.com/new_articles/copy_myths.html