



# **PHARMACEUTICAL ENGINEERING**

## **2019 Author Guidelines**

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

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# Part I: Introduction

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*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 useful articles that come from trustworthy and reliable sources.

A bimonthly print publication and a digital website, *Pharmaceutical Engineering* covers topics 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.

## 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Only original, complete, unpublished drafts will be considered for publication.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All graphic material—including tables, charts, and photographs—must be original and unpublished, or you must have permission from the source to reprint the image.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.

## 2019 Author Guidelines

- 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.

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

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## 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.

Approximate 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.

Approximate 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.

#### *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.

Approximate 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.

Approximate 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.

Approximate 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. 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.

## How to Avoid Plagiarism and Properly Cite the Work of Others

Plagiarism is using another person’s work—copyrighted or not—and representing it as the product of your own effort. This does not mean that you can’t cite to the work of others in your article—you just need to make sure that you do it the right way.

You can avoid plagiarism and properly cite to another source’s work by revising and restating the idea and providing a numbered endnote reference that cites to the material you have restated.

The other option is to use a direct quote from the source, then add a reference and cite the source from which you copied the text.

Here are some examples to help you see the difference:

### **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. If an article reuses too much information from another source (even when properly cited), it would not be original. It is also the right way to give others credit for their ideas. Finally, when the uncited material is copyrighted, reusing it without citation and permission could violate the copyright laws in the US and in other countries.

### **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.

### Using text copied from other sources

Even when you properly cite content that you want to include in your article, there can still be problems with copyright infringement. This usually has to do with how much content you can safely include without violating the original publisher's copyright. In the United States, this is called "fair use" and it allows "limited" use of copyright-protected works for discussion or analysis. In a scholarly or technical work, you can use "short passages" for illustration, comment, or clarification.

### 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.

It is also all right to cite to content that is in the public domain: This means works where the copyright has expired or works that have been published without copyright protection. You still have to provide the citation and use quotation marks when you are using content verbatim.

Here are some examples of public domain content:

- 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.

### 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.

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.

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## ISPE retains copyright to all the articles it publishes

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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.

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

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### 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.

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All image files must 300 dpi or at least 1 MB

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### 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.

**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 and photo

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. If possible, please submit a photo (300 dpi/1 MB minimum) of each author.

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\* 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.

## 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.

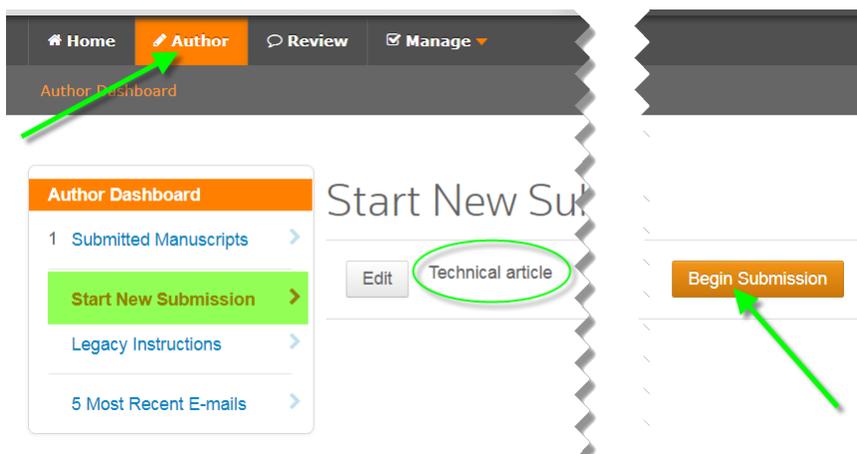
Enter the information requested in the **E-Mail/Name, Address,** and **User ID & Password** screens, then log in using your User ID and Password.

**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. Don't change it, 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

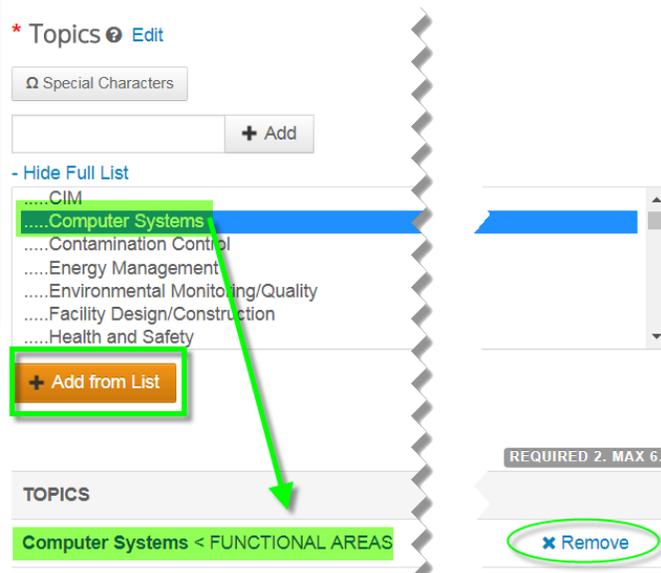
You must select at least two, but no more than six topics for your article.



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 **x 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.

\* Topics  Edit

 Special Characters

+ Add

+ Show Full List

---

**TOPICS**

Ozone Generation

### 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**.

### Authors

\* Selected Authors  Edit

ORDER	ACTIONS	AUTHOR	INSTITUTION
 Drag	1  	Loerch, Amy <a href="mailto:aloerch@ispe.org">aloerch@ispe.org</a>	1. ISPE Tampa, FL, USA

### Add Author

Find using Author's email address

 Search

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

### Add Author

 No co-author found. Please search again using another e-mail address or [create a new co-author](#).

Find using Author's email address

 Search

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.

**Create New Author** [Edit](#)

Special Characters

\* Prefix: None Selected

\* First (Given) Name:

Middle Name:

\* Last (Family) Name:

\* E-Mail:

Institution 1

Quick Fill [Edit](#)

Begin typing in the **Institution** field to see any possible matches already on file. To choose one, select and click on the entry.

**Create New Author** [Edit](#)

Institution 1

Quick Fill [Edit](#)

Institution Number: 1

Institution: Pfi

Department: Pfizer AB  
Sollentuna, 191 90, SE  
Bund Freikirchlicher Pfingstgemeinden KdoR  
Erzhausen, Hessen, 64390, DE  
Zoetis Research and Development  
(Pfizer Veterinary Medicine Research and Development) Kalamazoo, MI, 49001-0199, US

\* Country: United States

State/Province: Connecticut

\* City: Groton

Phone Number:

**Create New Author** [Edit](#)

Quick Fill [Edit](#)

Institution Number: 1

Institution: Pfizer Global Research and Development

Department:

\* Country: United States

State/Province: Connecticut

\* City: Groton

Phone Number:

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

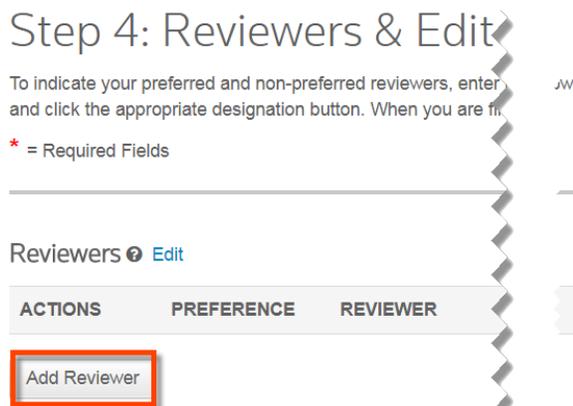
**Note: Please provide a complete mailing address for each author.** Our mail houses need this information to send copies of the magazine when the article has been published.

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

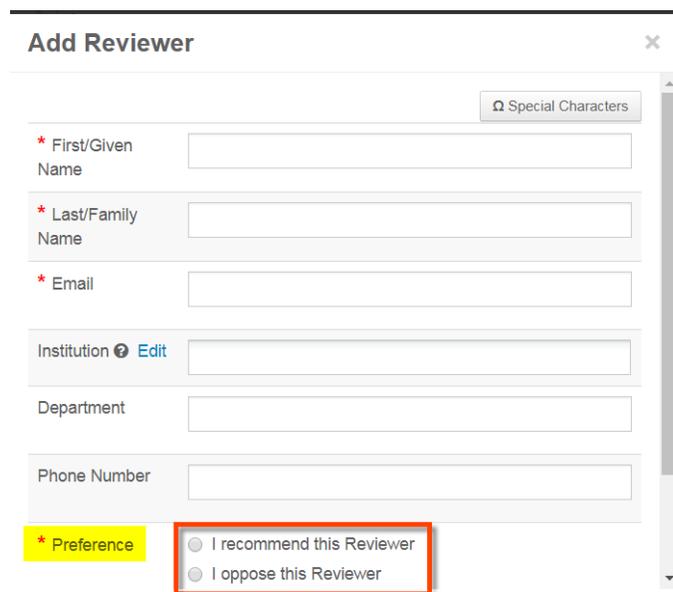
### Reviewers & editors

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 V: For more information

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### Contact

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

- [Susan Sandler](#), editorial director: 301-364-9212 ext. 415 or [ssandler@ispe.org](mailto:ssandler@ispe.org)

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](http://www.copylaw.com/new_articles/copy_myths.html)