



# PHARMACEUTICAL ENGINEERING.

**2020 Author Guidelines**

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# Part I: About *Pharmaceutical Engineering*

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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* (PE) 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Only original, complete, unpublished articles will be considered for publication. We do not review or evaluate incomplete articles, outlines, concepts, etc. This is because all subject-matter content is subject to peer review.

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. If you are submitting an article to multiple publications at the same time, PE cannot consider the content for publication.

All graphic material—including tables, charts, and photographs—must be original and unpublished, or **you must have written permission from the source to reprint the image**. It is the responsibility of the submitting author to obtain this permission. For more information see the [Using copied graphics](#) sections.

## Simultaneous submission

Simultaneous submission (submitting the same article to several journals or other publications) is not permitted. You may not submit your article to another journal or publication unless you withdraw it from consideration or it is rejected by the *Pharmaceutical Engineering* Editorial Review Board.

## Technical evaluation

If you are 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; ISPE/*Pharmaceutical Engineering* 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.

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.

### Open Access

Effective with the November-December 2019 issue, two to three articles per current issue will be “unlocked” for non-member access. This affords authors the opportunity to reach a broader audience beyond ISPE members. If you would like to have your article considered for Open Access if it is accepted for publication, please indicate this when you submit your manuscript. Selections for Open Access are made by the editorial staff in conjunction with the *Pharmaceutical Engineering* Committee (PEC).

### 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.** If your organization requires legal or corporate review, determine the timeframe in order to avoid publication delays.

# Part II: Writing your article

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## Article types

### Editorials and Perspectives

#### *Guest editorials*

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

Approximate length: 1,000 words

#### *Perspectives*

Cover recent industry developments, strategic issues, technical developments, trends, or innovative solutions. Perspectives articles 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 graphics

### 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*

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 graphics

#### *Case studies*

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 graphics

#### *Research articles*

Topics 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 graphics

## White Papers and Sponsored Content

*Pharmaceutical Engineering* Online accepts White Papers and Sponsored Content. These paid content formats are managed by the Advertising Sales Group. Contact them for current rates and additional information. White Papers and Sponsored Content do not undergo peer review, and are published only online (not in the print magazine). Content requires sign off by the Senior Director, Editorial.

## Revision, review, and approval

### Peer review

PE uses a double-blind peer review process: authors and reviewers are not identified to each other. After submitting your manuscript, you will receive a decision letter that details editor and reviewer feedback. If revisions are required, you will be given a deadline for submitting a revised draft through ScholarOne.

In addition to our slate of industry reviewers, you may [specify additional qualified reviewers](#) when you submit the article using the online manuscript portal ScholarOne. These additional reviewers do not have to be ISPE members. There is no guarantee that the suggested reviewers will be invited to comment.

### Editorial review

All content submitted for publication in *Pharmaceutical Engineering* undergoes an editorial review for style, tone, flow, cohesion, and organization. ISPE reserves the right to edit, revise, and delete copy as appropriate.

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

Following editorial review, the edited manuscript will be returned to the authors for review and approval.

## Using text and graphics from other sources

### Copyright

Copyright laws protect original works by requiring permission from the author (or publisher, who acquires rights from the author) to reuse or adapt it.

### 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. Citing the work of others 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.

**For more information, see the Resources at the end of the Author Guidelines (Page 19).**

#### ***Self-plagiarism***

Authors who have published books or articles usually do not own the copyright to those materials. 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 original publisher.

#### ***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.

It is acceptable 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. It is always wise to check web sites or publishers to make sure that a source is in the public domain—not all content on the Internet is public domain content! You still have to provide the citation and use quotation marks when you are using public domain 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; if not, they may be subject to Crown Copyright.
- Most European Union documents, including EurLex data, 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 by copyright and permission is required to use it. Consider these misconceptions about copying graphics:

***I’ve cited the source:*** 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”. 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

To avoid copyright issues, we encourage authors to create original graphics (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.

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 a graphic.*
- **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 written 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, you must sign a copyright release and consent to publish form.

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 Senior Director, Editorial 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 Senior Director, Editorial.

## Article content

### Text

Article text must be in \*.doc or \*.docx format. PDFs, screenshots, or hard copy documents will not be accepted. The file should be double spaced and include page and line numbers.

### 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

Please submit high-resolution files suitable for printing for all images. We prefer vector files (PDF, EPS, SVG, AI). Other graphic files such as JPGs or TIFFs that are at least 300 dpi or 1 MB in size are also acceptable. PE is unable to publish formatted for web publication or artwork inserted into PowerPoint, Word, or Excel files, or PDFs created by saving these types of files.

- 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, authors may insert figures and tables within the document as long as they are legible and clear at 100% zoom. Note that authors will be required to upload figures and tables as separate files if the submission is 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.

## 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

All information sources used to write the article must be listed in a References list at the end of the manuscript file.

References should be cited in the main text by number and in square brackets. For example: [11]

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 in the article. 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

Tables created in Word may be included in your submission. You can also create your table in Word and paste it into your Word submission. If your submission is accepted, Excel files for tables are easiest for our designers to work with and the editors may ask you to provide these. For ScholarOne, Excel files can cause problems in the compiled PDF, particularly if it's overly long or wide. Asking for a Word-created table makes for easier peer review, but they can also create it in Excel and then paste it into Word. Include a title for each table. Place significance values, other statistical data, and footnotes below the table.

Include an attribution when the material has been copied from another source (see [Using copied graphics](#)).

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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.

## Author biography

Each author must supply a short biography ( $\leq 150$  words) with the article submission. The Author Information and Copyright Form provides a field for this information. The editors will send you this form to complete during the revision process. 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.

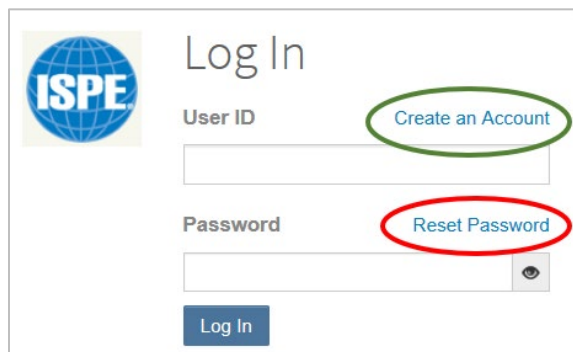
# Part III: Submitting your article

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## ScholarOne online portal

Submit articles and their accompanying graphs, tables, and illustrations through *Pharmaceutical Engineering's* online portal, [ScholarOne Manuscript Central](#).

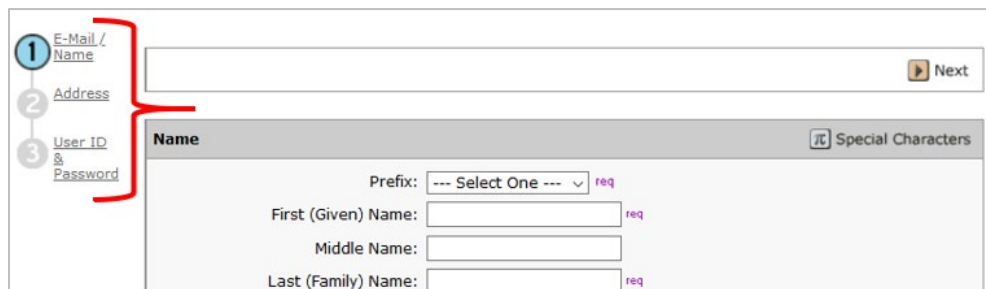
If you have a user account, enter your User ID and Password to log in. If you are unsure about whether or not you have an account, or have forgotten your password, click Reset Password.



## Create an account

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

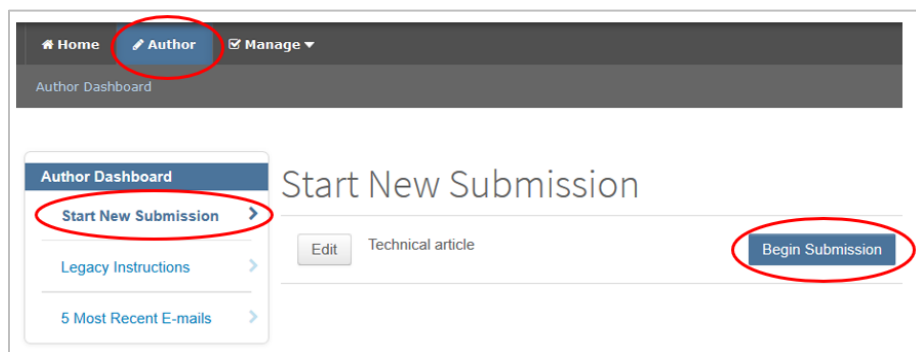
Enter the required information in Steps 1-3 (the **E-Mail/Name**, **Address**, and **User ID & Password**), then log in using your User ID and Password.



**Note:** Your email becomes your ScholarOne User ID. If you change companies or email addresses, be sure to update your ScholarOne account. Changes to this information within the ISPE membership system do not update your ScholarOne account.

## Submit the article

Once you have logged in, click **Author** at the top of the page and then select the **Start New Submission** link. Select the **Begin Submission** button and walk through the 7 steps below.



**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.

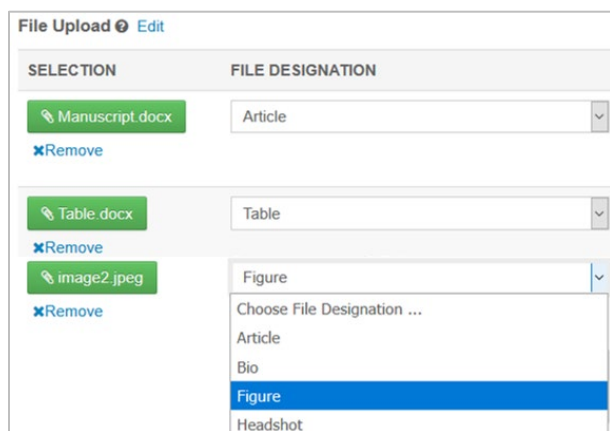
### Step 1: Type, title, & abstract

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

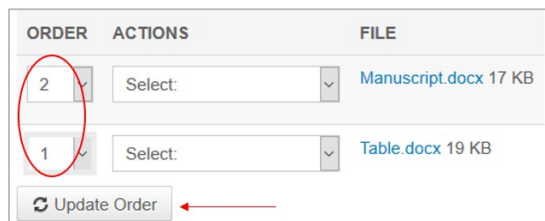
### Step 2: File upload

Submit your article and graphics. Figures and tables may be embedded in the Word document to provide guidance for reviewers and editors, attached as separate files, or both. You will need to provide original graphics if the article is accepted for publication.

Select the correct **File Designation** from the drop-down menu for each file.

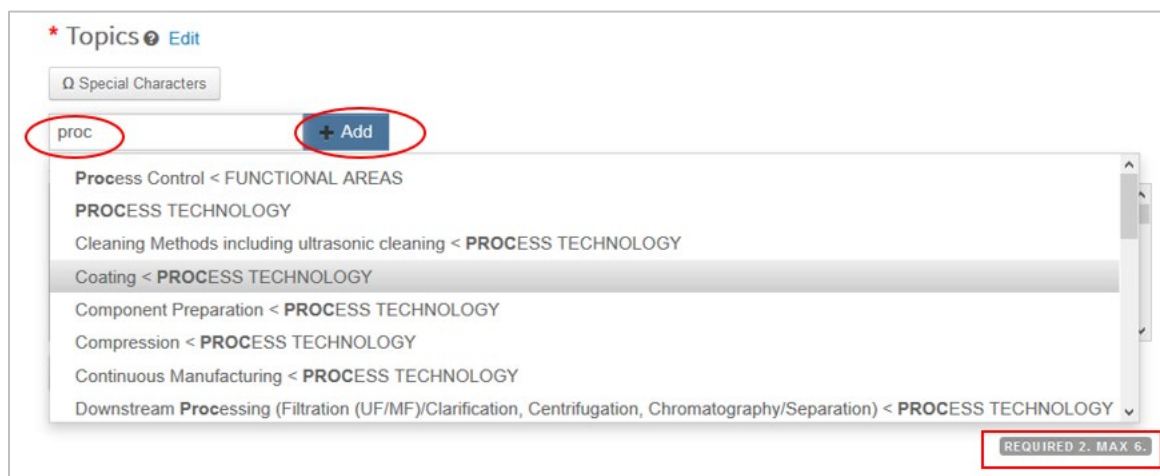


Once uploaded, you can change the order of the files in the left-most column, then click **Update Order**.



### Step 3: Attributes

You must select at least two (no more than six) topics relevant to your article. This will help the editorial team identify suitable reviewers for the submission. 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.

\* Topics [Edit](#)

Ω Special Characters

+ Add

+ Show Full List

- Hide Full List

- .....Standardized Testing and Sampling Techniques/Controls
- .....Training
- .....Validation
- PROCESS TECHNOLOGY
- .....Cleaning Methods including ultrasonic cleaning
- .....Coating
- .....Component Preparation

+ Add from List

REQUIRED 2, MAX 6

Minimum entries for attribute Topics not entered. Enter one attribute at a time prior to clicking the (+) plus sign.

TOPICS

Coating < PROCESS TECHNOLOGY [✕ Remove](#)

**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.

\* Topics [Edit](#)

Ω Special Characters

Ozone Generation + Add

Once added, your selected topics will appear in the **TOPICS** list at the bottom of the page.

#### Step 4: 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**.

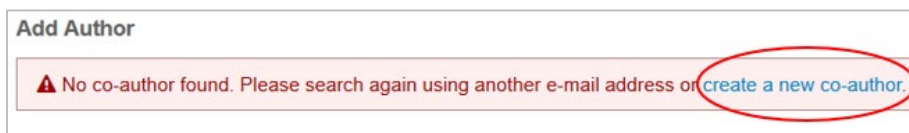
Add Author

Find using Author's email address

AuthorsEmail@example.com



If the email is not found, select the **create a new co-author** link in the **Add Author** box.



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

Complete the required fields (Prefix, First Name, and Last Name, E-mail Address) 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:

\* Country:

State/Province:

\* City:

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  
Pfizer Global Research and Development  
(Pfizer Global Research and Development) Groton, CT, 06340, US  
Pfizer Danmark  
Ballerup, 2750, DK  
Pfizer Corporation Austria Ges mbH  
Wien, 1210, AT

Author's primary institution. You will be able to add another institution at the bottom of this screen.

**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. Pharmaceutical Engineering** needs this information to send copies of the magazine to each author after the article has been published.

If the institution does not appear in the list automatically, enter the information required for each field.

### Step 5: Reviewers & Editors

The Editorial Review Board will be involved in the [peer review](#) process, but you may also indicate other experts that you would recommend as reviewers for your article. If there are conflicted experts that you oppose as reviewers, those can be listed here as well. The names listed here do not have to be ISPE members.

Select the **Add Reviewer** button.

Enter the required information and indicate your preference, then click **Add New Reviewer**.

### Step 6: Details & Comments

Enter, paste, or upload your cover letter here.

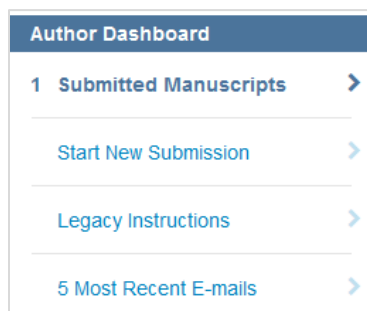
**Note: Be sure to indicate whether your document [contains graphics or text that will need reprint permission](#), and/or if the article will require [legal or corporate review](#) before publication.**

On this step, please provide the requested information including article topics that are relevant to your submission and article type (guest editorial, perspective, technical article, case study, or research article). you must also indicate:

### *Step 7: Review & Submit*

Review the information you've entered and edit or add as needed. Once all steps have been completed, you will be required to download the PDF proof. Review this carefully to ensure your files are being compiled and presented to your satisfaction. If so, click **Submit**.

You will receive a confirmation e-mail indicating that the submission was received. The paper will now appear under "Submitted Manuscripts."



## Part IV: For more information

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### Contact

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

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

We look forward to working with you!

### Resources

1. Copyright Clearance Center. Copyright FAQ. "What Is 'Copyright Infringement'?" <http://support.copyright.com/index.php?action=article&id=240>
2. United States Copyright Office. "Copyright in Derivative Works and Compilations." Circular 14. <https://www.copyright.gov/circs/circ14.pdf>
3. 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>

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