

PHARMACEUTICAL ENGINEERING.

2022 Author Guidelines

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Part I: About Pharmaceutical Engineering®

Pharmaceutical Engineering® (PE) is the flagship membership magazine of the International Society for Pharmaceutical Engineering (ISPE). It is a magazine that inspires engineers, scientists, regulators, and others in the pharmaceutical industry across all ranks, around the world, with useful articles that come from trustworthy and reliable sources.

A bimonthly print publication and a website that includes all content from the print editions as well as original Online Exclusives, 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: professionals 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Only original, complete, unpublished articles will be considered for publication.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, abstracts, outlines, concepts, etc. This is because all subject-matter content is subject to peer review. We also do not publish press releases, industry announcements, executive changes, or other information being sent to multiple media.

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All graphic material—including tables, figures, and photographs—must be original and unpublished or in the public domain, or you must have written permission from the copyright holder to reprint the image. It is the responsibility of the submitting author to obtain this permission. For more information see the Copyright and plagiarism section.

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 by PE 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 <u>Community of Practice</u> (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. The editorial staff cannot provide an opinion about concepts, abstracts, or outlines.

Accuracy and correctness

Authors are responsible for the accuracy and correctness of all statements contained in the article; ISPE and *Pharmaceutical Engineering* assume 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 <u>Editorial Calendar</u> for themes and conference distributions.

However, final placement into an issue of the magazine depends on multiple factors, only one of which is the editorial focus of each issue. Other factors include—but are not limited to—date of submission, duration of the review and revision process, 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.

Print PE and PE Online

PE publishes a print magazine six times a year, every other month. The content of each issue is published online in two ways: (1) the complete PDF of the print issue and (2) individual articles (the latter are all tagged for easy searchability by topic). In addition, PE Online has Online Exclusives, content that only publishes on the website. Articles may be selected for publication in print/online or for Online Exclusives. The editorial staff makes the final determination about where and when an article publishes.

Open Access

Two to three articles per current issue may be "unlocked" for non-member access (non-members are required to complete a short, standard form with basic information before they may view the member content). This affords authors the opportunity to reach a broader audience in addition to 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. Please note that the editorial staff cannot guarantee all requests for Open Access can be provided.

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 time frame required and inform the editorial staff to avoid publication delays.

Copyright

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 from ISPE.

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

If you want to share an article you've published, you may order hard-copy reprints of most *Pharmaceutical Engineering* articles by contacting Sheridan Content Solutions at sheridancontentsolutions@sheridan.com

PE allows authors to reuse any figures, graphics, or tables that they created for their published article and to 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 editorial team.

Part II: Writing your article

Article types

NOTE: *All* articles must be grounded in current evidence (with references to peer-reviewed literature, regulatory guidance, and credible industry resources as appropriate) and must comply with the prohibition on commercialism (see Part I).

All subject-matter content is subject to peer review by industry experts.

Submissions are welcome from ISPE member or nonmember authors. These Author Guidelines apply to all submissions from all authors.

Features

Articles about trends and developments in the pharmaceutical engineering industry, including product development, manufacturing process, facilities management, sustainability, biopharmaceuticals, regulatory and quality initiatives, continuous manufacturing, and more.

Approximate length: from 1,500 to 4,000 words, up to 5 graphics

Technical articles

Detailed articles of a highly technical nature addressing engineering and design, development, manufacturing process, critical utilities, cell and gene therapy, ATMPs, product life-cycle management, and more.

Approximate length: 5,000 words, up to 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 versus other, more established methods.

Approximate length: 4,000 words, 4 graphics

Research articles

Articles describing innovative methods and techniques related to 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 Carol Nettles, Advertising Sales Manager, cnettles@ispe.org or JT Hroncich, Advertising Sales Manager, ihroncich@ispe.org 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 editorial team.

The editorial process

Submission and preliminary editorial evaluation

Authors should submit their manuscripts through *Pharmaceutical Engineering*'s online portal, ScholarOne Manuscript Central (see Part III for detailed instructions).

PE editorial staff will perform a preliminary assessment of its potential suitability for publication. Manuscripts that meet the basic criteria for a PE article move forward in the editorial process. Authors will be notified if their manuscripts will not move forward or need additional work before moving forward.

Peer review and revision

PE uses a double-blind peer review process: authors and reviewers are not identified to each other. Peer review generally takes several weeks. Editorial staff are unable to guarantee completion of peer review within a set time period.

Authors receive a decision email that details reviewer feedback. If revisions are required, a deadline for submitting a revised draft will be provided. Revision timelines will depend on the level of revision requested; two to six weeks is typical.

When revising a peer-reviewed article, please used Tracked Changes in the manuscript. Also, please include a point-by-point response to the reviewer feedback so that it is clear that you have addressed the reviewer feedback in full.

If a revision meets the reviewers' expectations and editorial requirements, the manuscript will be provisionally accepted and moved forward to editing. Some manuscripts may require more than one round of review/revision before they are provisionally accepted.

Editing and approval

All content provisionally accepted for publication in *Pharmaceutical Engineering* will be edited for style, tone, flow, cohesion, and organization. This includes formatting references. **ISPE reserves the right to edit, revise, and delete text or graphics as appropriate.**

The edited manuscript will be returned to the authors for their review and approval. At this point, authors must also submit final graphics, their completed copyright transfer/author information forms, and any supporting documentation required to publish their article.

Using text and graphics from other sources

Copyright and plagiarism

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

Plagiarism is using another person's work—copyrighted or not—and representing it as the product of your own effort.

All PE authors must respect copyright requirements and avoid plagiarism (including self-plagiarism and plagiarism from public domain resources). For more information, see the Resources at the end of the Author Guidelines.

How to avoid plagiarism and properly cite the work of others

When you refer to the work of others in your article, you need to make sure that you do it the right way. You can avoid plagiarism by restating *in your own words* ideas or information derived from other sources. (Note: Changing a few words or reorganizing phrases and sentences is insufficient.) Also, each time that you restate ideas or information, be sure to provide numbered endnote references for every source of the material.

Another option is to use a direct quote from the source, then add a reference and cite the source from which you copied the text. The length of a quotation should usually be limited to a maximum of a few sentences or a paragraph.

Here are some illustrative examples:

Original wording from source

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

Insufficient tweak

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

Appropriate restatement

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].

Avoiding self-plagiarism

Self-plagiarism occurs when an author reuses material (text or graphics) that they have published previously without acknowledging the source of the material. To avoid self-plagiarism, restate or quote your previously published work and include references. See also "Using text or graphics copied from other sources" (below).

Fair use

Even when you properly cite content, there can still be problems with copyright infringement. In the United States, a legal standard called "fair use" allows "limited" use of copyright-protected works for discussion or analysis. In a scholarly or technical work (such as a PE article), you can use "short

^{1.} Ingram, M., A. B. Pazhayatti, N. Sayeed-Desta, and G. Ayyoubi. "Manufacturing Excellence Utilizing a Life Cycle Approach." *Pharmaceutical Engineering* 37, no. 5 (September-October 2017): 67–69.

passages" of text for illustration, comment, or clarification. Generally, tables, figures, illustrations, and photos cannot be reused without permission of the copyright holder.

Using materials from your own past publications

Authors of published books or articles usually do not own the copyright to those materials. If your PE article includes text from a work you published elsewhere, be sure that the quoted material does not exceed the bounds of your agreement with the initial publisher, and that you clearly indicate in your PE article what material is quoted.

If your article contains graphics that you previously published, you will need permission from the copyright holder to reuse them in PE. 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.

Public domain and government/regulatory content

Content that is in the public domain can be used without applying for permission from a copyright holder. (Works in the public domain are works where the copyright has expired or works that have been published without copyright protection.)

Although you do not need permission to use content or graphics from public domain works, you still must provide citations/references. Additionally, use quotation marks when you copy public domain content verbatim.

Note that not all information on the Internet is public domain content! Even some government publications are not in the public domain. Here are some examples:

- In the United States, most (but not all) work published by the federal government is in the public domain. Agency logos are usually trademarked, which means permission may be required to use graphics that include logos.
- 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 EudraLex data, may be used without applying for written permission, provided the source is acknowledged.

It is always wise to check websites, review the copyright information in print publications, or contact publishers to determine whether a source is copyrighted or in the public domain.

Figures, tables, photos, and other 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, photo, or table (or portion of it) without permission even if you acknowledge the source. Unless the item is in the public domain, using it without permission may 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, photo, or table, 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 is known as a "derivative work." This can only be done with authorization from the original copyright 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.

It's from an open source publication: Open source publications are copyrighted, although the policies for reusing graphics may be different than those for traditional publications. You must review the open source publication's copyright language/license and follow the publisher's instructions with regard to reusing material. Even if the publisher's license allows for reusing material without seeking permission in advance, you must provide correct attribution to the original publication and copyright holder.

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. As noted earlier, if authors choose to use copyrighted graphics, they are responsible for obtaining written permission or a copy of the license from the copyright holder and providing the documentation to *Pharmaceutical Engineering*. Authors are also responsible for paying any permissions fees.

Published material

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

When requesting permission from a publisher or other organization to use copyrighted materials, check their website for instructions and the appropriate contact person. Generally, you must supply the following information in your request:

- **Title of the original work:** The book, journal article, online publication, website, or other source 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 copyright owner.*
- Author of the original work: The person who wrote the book, article, or paper in which the figure or table first appeared. If your source is a book that contains chapters by multiple authors, you will need to provide the name of the book author/editor and the chapter author.
- **Publisher:** The company (e.g., Elsevier, Springer, ACS) that published the book or journal in which the figure first appeared.
- Publication information:
 - Book: Chapter title, page, and/or figure/table 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 include material (text, photos, graphics, or tables) copied from a company's website or publication, you must request and be granted written reuse permission before it can be republished in *Pharmaceutical Engineering*. This is required even if the material is from your employer. The permission must indicate any credit or attribution required by the copyright holder (e.g., "Graphic of XYZ process © 2017 by PharmaCorp. Reprinted with permission.").

Article content

Text

Article text must be in *.doc or *.docx format. PE cannot accept PDFs, screenshots, or hard-copy documents.

Article title

You may include a suggested title for your manuscript; note that there is a 60 character limit on titles and the editors may edit the title.

Editorial style

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

Figures, tables, and other graphics

Please note that PE places limits on the number of total graphics (figures, photos, and tables), and these limits vary by article type (see <u>Articles types</u>). If your article exceeds those limits, it may not be accepted for review or publication until cuts are made.

When you submit a manuscript, you may insert graphics within the Word document as long as they are legible and clear at 100% zoom.

Include a brief caption or title for each table and figure. This will assist the reviewers and editor in assessing the manuscript and in the editing and layout process.

If your article is accepted for publication, you will be required to upload figures and photos as separate files that meet the printer's requirements (refer to the Requirements chart).

General requirements

- Submit high-resolution photos or vector files for all figures.
 - High-resolution photos are at least 300 dpi and saved as JPG or TIFF files.
 - The typical high-resolution JPG or TIFF is ≥1 MB in size.
 - When taking a photo with a smart phone, saving the photo in the largest file size possible should create a high-resolution file.
 - Vector files are used for drawings, charts, plans, and graphs. They can be resized without
 affecting the crispness/clarity of the image. Examples include AI, EPS, and some PDF files.
 - Images copied from websites or social media, screenshots, and images created using a "snipping" tool are **not** acceptable because the resolution will be too low.

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- Provide a brief title or caption for every figure and table.
- Include a key, legend, or footnotes, if appropriate, to define acronyms, abbreviations, variables, units of measure, and significance values if they are not defined in the article text.
- Graphics must be legible. Choose easy-to-read fonts and minimize clutter in designs.
- Include a credit line if the graphic was published previously and/or copyrighted.
- If a graphic is from another publication/website, include the source on the reference list.

Requirements for specific graphic types

Type of Graphic	Acceptable (Preferred) Formats	Possibly Acceptable Formats (submit for evaluation)	Unacceptable Formats
Photos (including headshots) • High-resolution JPG or TIFF	PDF saved from a high- resolution photo	 Low-resolution files of any type (PNG, JPG, TIFF, GIF) 	
			 PDFs or slides created from low-resolution files
Flowcharts, algorithms, graphs, floorplans, drawings, and	 Vector files (EPS, AI, some PDFs) High-resolution JPG or TIFF files 	 Charts/algorithms created using Word or PowerPoint design tools (without photo or illustration inserts) 	Same as for photos
other illustrations	(if vector files are unavailable) • Graphs plotted in Excel (submit the Excel file)		
Tables	Tables created using Word's Table Design tools	Tables saved as vector files (EPS, AI, some PDFs)	Tables that use spaces or tabs to align rows and columns
	Tables created in Excel (submit the Excel file)		 Low-resolution images

Units of measure

You may use either metric or imperial/avoirdupois measurements.

Equations

Use Microsoft Word's **Insert Equation** function for long or complex equations.

Abbreviations and acronyms

Please only use abbreviations and acronyms that are standard in the industry (do not create your own).

Use the spelled-out term followed by the abbreviation/acronym in parentheses at the first mention; then use the abbreviation/acronym for all subsequent mentions. For example: *This article focuses on artificial intelligence (AI). It includes the perspectives from several AI experts.*

PE does not include a key to abbreviations/acronyms in articles.

Acknowledgments

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

Footnotes

It is usually preferable to integrate explanations into the text itself instead of using footnotes to explain terms or concepts. Footnotes are permitted for tables and figures.

References

Complete references are required for *all* information sources you used to write the article. Please also provide references for information in tables and figures that are copied or adapted from another source, or that use data from other sources.

Please cite references in the main text by number, in the order in which they appear in the article, with the complete references listed at the end of the article in the same order. Place the reference numbers in the main text in square brackets. For example: [11] for one reference; [5, 7] for two references; [17-19] for three consecutive references.

In the reference list, include only those sources that you cite in the text. For each reference, please list as much publication information as possible (e.g., authors, titles, publication date, publisher/organization, URLs, volume and page numbers). Use the bibliography examples in the *Chicago Manual of Style's* Chicago-Style Citation Quick Guide as models for formatting references.

Note: Never copy references from other reference lists or bibliographies—the bibliographic details are often incorrect. Instead, check the original sources for accurate information.

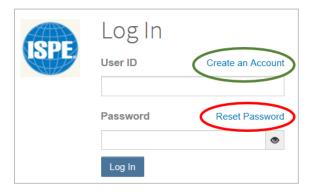
Author biography

During the revision process, the editors will send you the Author Information and Copyright Form. On this form, each author must supply a short biography (≤150 words) to be published with the article. Please include the following information: educational background, current title and company affiliation, responsibilities, and major areas of accomplishment. If possible, please submit a high-resolution photo (300 dpi/1 MB minimum) of each author. Also provide a mailing address so we can send you the print magazine if your article is published in print; we recommend using your home address for this purpose.

Part III: Submitting your article

Submit articles and their accompanying figures and tables through *Pharmaceutical Engineering*'s online portal, <u>ScholarOne Manuscript Central</u>.

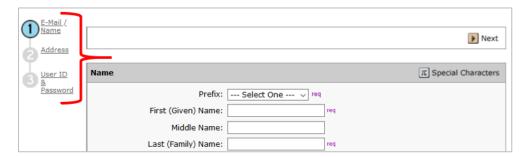
If you have a user account, enter your User ID and Password to log in. If you are unsure whether you have an account, or have forgotten your password, click Reset Password.



Create an account

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

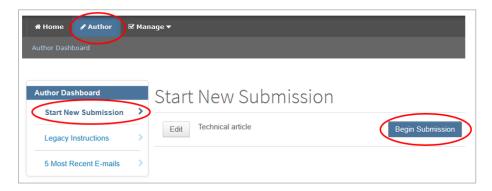
Enter the required information in Steps 1-3 (the **E-Mail/Name, Address**, and **User ID & Password**), then log in using your User ID and Password.



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. <u>Don't change it</u>, even if you're submitting a different kind of article. You will indicate the article type in the <u>Details & comments</u> section.

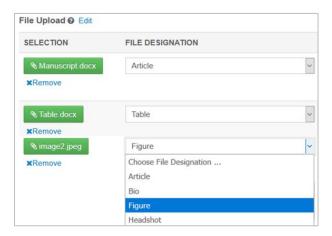
Step 1: Type, title, & abstract

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

Step 2: File upload

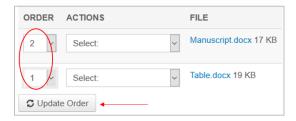
Submit your article and graphics. Figures and tables may be embedded in the Word document to provide guidance for reviewers and editors, attached as separate files, or both. Note that Excel tables can cause problems in the compiled PDF proof sent to reviewers, particularly if the tables are overly long or wide.

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



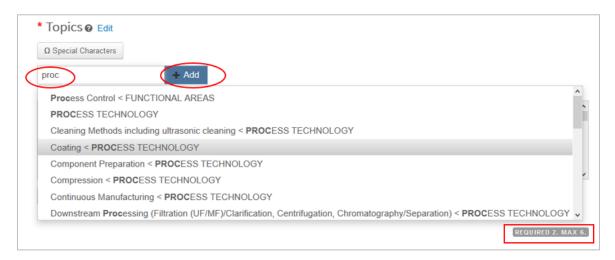
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Once uploaded, you can change the order of the files in the left-most column, then click **Update Order**.

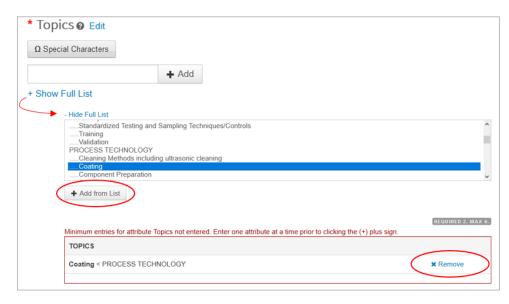


Step 3: Attributes

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.



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.



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**.

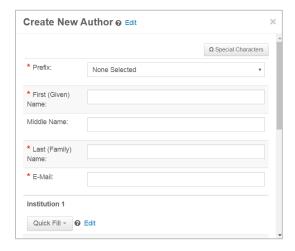


If the email is not found, select the create a new co-author link in the Add Author box.



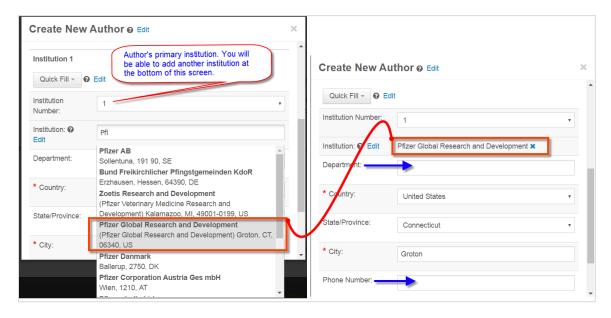
You will be redirected to the Create New Author screen.

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.



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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.

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

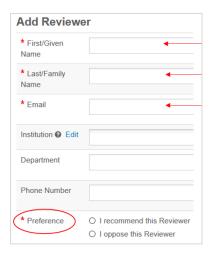
Step 5: Reviewers & Editors

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

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 <u>contains graphics or text that will need reprint</u> <u>permission</u>, and/or if the article will require <u>legal or corporate review</u> 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).

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

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

We look forward to working with you!

Resources

- 1. Copyright Clearance Center. "About Copyright." Accessed 10 January 2021. http://www.copyright.com/learn/about-copyright
- 2. US Copyright Office. "Copyright in Derivative Works and Compilations." Circular 14. July 2020. https://www.copyright.gov/circs/circ14.pdf
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