People • Science • Regulation

PDA Letter

www.pda.org/pdaletter

Submission Guidelines

PDA Letter is PDA's membership magazine covering the scientific, technological, regulatory and Association news relevant to the PDA community. Articles and other multimedia content are published weekly on the *PDA Letter* website (www.pda.org/pdaletter).

All submissions, inquiries, requests for article ideas must be submitted to:

submissions@pda.org

Note: All PDA Letter articles should be well-written in clear U.S. English.

Feature Articles

PDA Letter publishes feature articles on the following topics:

- Aseptic Processing & Sterilization
- Biopharmaceuticals & Biotechnology
- Manufacturing Science
- Quality & Regulatory
- Supply Chain

Feature articles are 1500 – 2000 words, are well-written in clear U.S. English. Acronyms should be spelled out first time, except for well-known acronyms such as:

- GMP
- U.S. FDA
- USP
- ICH

Authors should avoid making/using acronyms for common terms like “drug product” and “drug substance” as the publisher prefers not to use the acronyms DP or DS for these terms.

Other Article Types

"People" articles cover common PDA Volunteer Activities, such as PDA Chapter events, networking events, career development/advancement, training/education, and other topics relevant to the people who make up PDA.

"Science" and "Regulatory" Snapshot articles are welcome that cover the scientific and technical aspects of drug and device manufacturing, with a focus on aseptic processing, microbiology, sterilization science, biopharmaceuticals, ATMPs (cell and gene production), including case studies, overviews of new technologies, short research reports, etc. These articles range from 350-1500 words and should have limited references.

Highly-referenced and detailed scientific studies, new methods, and the like ***should be submitted to the PDA Journal of Pharmaceutical Science and Technology*** ***https://journal.pda.org/content/author-resourcessubmit-paper***

"Regulation" articles cover the impact of global regulatory actions in the pharma and medical device spaces. These can include comparisons of international regulations and analysis of recent regulatory developments. Articles range from 350-1500 words.

NOTE: Articles should not promote use of a specific product, service or company. If interested in advertising in the Letter, please email Vice President of Sales Dave Hall at hall@pda.org.

All Submissions Checklist

- All PDA Letter articles should be well-written in clear U.S. English.
- Articles should be submitted as a Word document.
- Any accompanying graphics should be submitted separate from the Word document using raw or original source files. These could be PowerPoint slides or gif, tiff or jpeg file types. **Note:** We do NOT accept Visio files.
- All articles should include an "About the Author" (brief 1-3 sentence bio) for each author and a headshot for each author (high resolution jpeg/gif, 300 dpi or better, with a minimum dimension of 4" wide, or 288 pixels).
- Appropriate references should be included when applicable. Use the ACS Style Guide (Third Edition) to format references.
- Photos and graphics, if any, should be labeled (Figure for images and other graphics; Table for tables) in order (Figure 1, Table 2, etc.) *and referenced in the text (i.e., see Table 1)*. A title for the Figure or Table should be included as well (e.g., Figure 1: Data from Assays).
- Sidebar or other supplementary information counts towards word count. Graphics may also reduce word count as well.
- The *PDA Letter* Editors reserve the right to rewrite headlines, select pull quotes, insert subheads, etc., and to edit unclear language, make changes per the *PDA Letter* style, and correct spelling and grammatical errors.
- All submissions should be sent via email at submissions@pda.org.

General Advice

1) Avoid: "This article is about" – The opening, or lede, should be compelling and draw the reader into the article. It could be a question or statement that creates a sense of urgency for the reader.

Here are some examples of ledes to articles published in the *PDA Letter:*

> "Has the time finally arrived when parametric release and real-time release testing can be implemented for sterile drug products without a sterilization phase, even those manufactured in aseptic processes?"

> "How much variation is acceptable in our products and processes? For such a simply stated question, the answer can be quite complex, especially when applied to drug product Stage 2 testing (Process Performance Qualification, or PPQ)."

> "As single-use technology using plastic bag containers expands across the pharmaceutical industry, there is growing concern about oxidation of methionine (Met) as a major degradation pathway, particularly for interleukin-2, human growth hormones and monoclonal antibodies (Mab)."

2) Clear conclusion to the article – A conclusion can be a thought-provoking quote, compelling questions or a statement that captures the overall message of the article without summarizing.

Here are examples of conclusions to articles published in the *PDA Letter*:

> "It is well worth your time to find out if there are shared audits available for materials and suppliers used for your drug substance and drug product manufacturing and to review any databases that may be available on supplier compliance status and certification. These options will save you time and effort that you can spend on your other materials suppliers that are not evaluated by an independent organization."

> "Whatever solutions are found, Woodcock and Wosinska's article shows that regulators are demonstrating a greater awareness of the economic pressures facing manufacturers of sterile injectables. The question is, what can be done to ensure their products are of the highest quality?"

> "She concluded by urging further dialogue between industry and regulators. 'We have to continue the collaboration established to

define how QbD and other approaches will be applied to the development and manufacturing of vaccines,' she stressed."

3) Take-home message/news you can use – Articles published in the *PDA Letter* should offer overviews of important topics within the industry, suggest solutions for common problems, or just generally provide useful, relevant information to readers.

Thank you for taking time to read this guide, and we look forward to your submission!