People • Science • Regulation

PDA Letter

www.pda.org/pdaletter

Submission Guidelines

The *PDA Letter* is another forum for members of the Parenteral Drug Association to communicate their thoughts and expertise. Original articles (unpublished in other publications) that are relevant to the PDA community will be considered for publication.

The *PDA Letter* is published 10 times a year and is sent as a membership benefit to all PDA members around the world, approximately 10,000 individuals. The Editorial staff is always interested in science and regulatory articles on aseptic processing, sterile products, supply chain and distribution, pharmaceutical microbiology, biologics and manufacturing quality control. In addition, the Letter includes member-oriented content about upcoming PDA events, profiles of volunteers and other industry leaders, and articles on career advancement.

Feature Articles

Feature articles (1500 – 2100 words) must be relevant to the *PDA Letter* editorial themes (below), unless otherwise discussed with the *PDA Letter* editors or members of the *PDA Letter* Editorial Committee.

To view a list of themes for upcoming issues, visit www.pda.org/pdaletter.

Other Articles

Besides features, the *PDA Letter* includes sections focused on general people (career advice and volunteer news), science and regulatory content. Articles in these sections generally range from 350-750 words. If interested in writing for these sections, please send an email with an abstract of your topic to stauffer@pda.org.

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.

Technical Requirements – All Submissions

The editors recommend that authors interested in writing for the letter submit an abstract first. The abstract will then be sent to the *PDA Letter* Editorial Committee for review and approval.

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 1-2 sentence bio) for each author and a headshot for each author (high resolution, 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 charts, Table for tables) in order (Figure 1, Table 2, etc.).

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 to the *PDA Letter* Assistant Editor Rebecca Stauffer, stauffer@pda.org. Write "PDA Letter Submission" in the subject line.

General Advice

1) Don't start article with "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.