



## **Guidelines for Authors – 2012**

**This guide includes information about submitting papers for peer review and columns to *Journal of GXP Compliance* and *Journal of Validation Technology*.**

## ABOUT US

### Coverage

*Journal of Validation Technology* (JVT) provides useful information on processes and systems associated with pharmaceutical and medical device validation. General information on validation topics applicable to both pharma and biotech products and medical devices is also provided. Subjects addressed include manufacturing and packaging processes; cleaning processes; analytical methods; equipment, facilities, utilities, control systems; computer system qualification; and associated topics. The Journal embraces a comprehensive approach to validation. This includes design and development information conducted preliminary to validation and qualification, conformance testing that confirms development, and subsequent maintenance of the validated state. Information may include basic concepts, strategic approaches, laboratory studies, practical applications, experimental or process data, case studies, and expert commentary. Technical papers are peer reviewed.

The *Journal of GXP Compliance* (JGXP) provides useful information on regulated activities including good laboratory practice (GLP), good clinical practice (GCP), and good manufacturing practice (GMP). The Journal embraces a comprehensive approach to compliance. This includes information on activities in advance of and in support of respective compliance performance, demonstration of compliance, and activities to maintain a compliant state. Information may include basic concepts, strategic approaches, expert commentary, experimental and laboratory studies, applications, actual compliance performance, and case studies. Technical papers are peer-reviewed.

JVT and JGXP welcome the submission of manuscripts for publication as peer-reviewed papers, articles for features, and personal commentaries. Papers may be submitted as individual papers or multiple documents in a series addressing a specific topic.

Proposals for new regular feature topics (publication in each issue for an extended period) are also requested.

*Manuscripts may be submitted by either of two approaches:*

- **Proposals for future manuscripts to be written may also be submitted for consideration.**

Authors are then advised if proposals are acceptable. Completed manuscripts are expected to be submitted within a reasonable time period. Submitting proposals for future manuscripts will enable the journal to advise authors regarding an approximate publication date or whether other approved papers on the same topic are in queue for publication.

- **Completed manuscripts submitted as peer-reviewed papers, features, or commentaries.**

All papers must be submitted as a complete and final draft, including figures and tables, before being considered for publication. Technical papers are subject to peer review before being accepted for publication. Accepted papers will be edited for grammar and style by the journal editorial staff.

Before submitting the final manuscript, authors are urged to review their documents for clarity of expression, details of grammar, and typographical accuracy. Acronyms and abbreviations used in manuscripts should be defined. Submitted papers should be original and not previously published elsewhere. The author is responsible for all statements in his or her work. All accepted manuscripts are subject to copyediting. The journal is not responsible for the safety of artwork or photographs. The journal's art department may recreate submitted graphics and tables.

**More information at [gxpandjvt.com/editorial](http://gxpandjvt.com/editorial)**

### **Deadlines**

We have no specific deadlines for peer-reviewed submissions. Depending on the manuscript (and the time constraints of the author), articles usually take approximately 1–2 months for review, revision, and acceptance by the editors. Once accepted, an article is published within 4 to 8 months.

Deadlines for column contributions are as follows:

JVT Winter Issue	January 3
JVT Spring Issue	April 1
JVT Summer Issue	July 1
JVT Autumn Issue	October 1
GXP Winter Issue	December 1
GXP Spring Issue	March 1
GXP Summer Issue	June 1
GXP Autumn Issue	September 1

### **Frequency**

Our journals are published quarterly.

## **SUBMISSION INFORMATION FOR PEER-REVIEWED PAPERS**

All papers undergo a double-blind peer-review process by members of the Editorial Advisory Board to determine whether they are appropriate for publication (see below for more details).

### ***About the peer-review process***

Submitted papers undergo internal review to make sure that the papers fit within our editorial scope, report something sufficiently novel and original, and that the conclusions are supported by

the data. Papers satisfying these general criteria are then sent out for expert peer review by Editorial Advisory Board members or by members of the Board of Reviewers. The process is double-blind, meaning that the reviewer's identity and affiliation are unknown to the author(s) and vice versa. Reviewers may recommend that papers be rejected, accepted, or more likely, reviewers may request additional modifications or experiments to be performed before a paper is suitable for publication.

Reviewers' comments are returned to the author(s) who will make the necessary revisions and will then return the paper to *JVT/JGXP*. We will then send the revised work to the original reviewers to make sure that the revisions adequately address the reviewer's concerns. If they do, the paper is accepted for publication and assigned to the next available issue (we try to publish it within 4 to 8 months of acceptance.)

Accepted papers are copyedited, formatted, and published in print.

### ***Make sure your paper is suitable for peer-review***

Peer reviewed research articles present novel scientific findings and data that significantly advance a technology, a process, a synthesis, a formulation. They set out a hypothesis, describe experiments (including proper control experiments), present data derived from those experiments, offer a discussion of the data, and then draw a conclusion from them.

Peer-review papers follow a general format as follows:

1. **Abstract:** of under 200 words briefly lays out the hypothesis and conclusion
2. **Introduction:** sets the hypothesis within a context of the state of the art and explaining how the presented data change or advance the current theory or practice
3. **Materials and Methods:** sets out the experimental procedure, including all equipment used, settings, buffer compositions and concentrations, ingredients, and other materials and procedures. The information given here should be detailed enough to allow any other researcher to duplicate the experiments described. Experimental and control experiments must be described.
4. **Results:** Presents raw data (photos of Southern, Northern, or Western blots; histological slides; electron micrographs; NMR spectra, etc. Also presented are tables, graphs, charts summarizing data values and showing standard deviations). Results must include those for the experimental and control conditions.
5. **Discussion:** This is truly the meat of the article where the author reviews the data and demonstrates how they support the conclusions. The authors may want to raise alternate hypotheses and demonstrate how the data fit one of these in particular. They may also suggest future experiments that will eliminate other hypotheses or advance the current one.
6. **Conclusion:** A short section restating the hypothesis that has been (in theory at least) proved in the article. Authors may also choose to comment on current and potential future applications of the work.
7. **References:** Throughout the article, the authors should cite papers, books, abstracts, posters, conferences, in which data were presented either by them or others who

developed methods used, advanced supporting or competing hypotheses, or drew conclusions related to the work being presented. See section on “References” for appropriate format and style.

***Prepare your paper for submission:***

**Accuracy and Style.** Before submitting a paper, authors are urged to review manuscripts for clarity of expression, grammar, and typographical accuracy. Acronyms and abbreviations used in manuscripts should be defined on first reference and within tables and figures. The author is responsible for all statements in his or her work. All accepted manuscripts are subject to editing.

**Originality and Rights.** Manuscripts are reviewed with the understanding that they have not been published previously in any format—print or electronic—are not ghostwritten, and are not under consideration for publication elsewhere, including on the Internet. The author and any coauthors will be required to sign a license agreement before a manuscript is accepted for publication.

\*PLEASE NOTE that we will only accept and publish original content that has not been published elsewhere, including online, or that is not being considered by another publication or website. All articles undergo a thorough check for plagiarism and if plagiarism is found, the article will automatically be rejected and the author(s) will be banned from publishing within the IVT journals and their sister publications.\*

**Electronic File:** The paper’s text should be formatted in Microsoft Word and include a cover sheet with the Title, Author and Coauthor names and affiliations, and contact information for the corresponding author. Paper titles should be short and specific and should accurately reflect the content of the article. Do not use any special text formatting codes or control characters. Strip out any special-character codes as well as any font-change codes. Please include tables and figure captions in the electronic file at the end of the article (see below for submission of actual figures and images). Beginning with the first page of the text, each page of the hard copy should be numbered consecutively.

**Length.** Manuscripts should be between 2400 and 3600 words. No more than 8 figures and tables combined should be submitted. Manuscripts and figures/tables that go beyond these requirements will not be accepted for review.

**Illustrations and Figures.** Original photographs, line drawings, graphs, charts, and other illustrations may be submitted in color or black and white and must be referred to in the text in consecutive order: Figure 1, Figure 2, and so forth. Be sure to include descriptive captions and credit information for all figures and images. All symbols, acronyms, and abbreviations used in figures and tables should be explained. All illustrations that do not increase the reader’s understanding of the text should be omitted. In addition to the

substantive figures and images provided, a four-color photograph may be used on the opening page of the article. Color photos that an author wishes to submit for consideration should be submitted with the article. All images and figures should be submitted as image files (tiff, jpeg, or eps files of at least 300 DPI.)

**Tables.** Original tables or charts must be identified by number (e.g., Table I, Table II) and have been created by the author (s). These can be submitted as part of the Word text file.

**Illustration, Image, Figure, and Table Rights.** Please note that the author must own the rights to all submitted images, tables, and figures.

**Authors' Information:** Present the authors' affiliation addresses (where the actual work was done) Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author.

- **Corresponding author.** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address. Contact details must be kept up to date by the corresponding author.

- **Present/permanent address.** If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name.

**References.** Literature citations in the text should be numbered consecutively indicated by Arabic numerals in parentheses after appropriate sentences and/or paragraphs. Please do not use endnotes or footnotes. References should be grouped at the end of the manuscript and arranged in order of their appearance in the text not alphabetically. Please also be sure to style and format your references according to the guidelines provided herein. If the style and format do not adhere to our guidelines, we will return the paper to you to do so before it is accepted for publication.

***Submit your paper and materials electronically to:***

Paul Pluta, editor-in-chief, paul.pluta@comcast.net  
Cale Rubenstein, managing editor, crubenstein@advanstar.com

## REFERENCE GUIDELINE

**Papers must use the following reference style and format below**

### *Chapter in a book:*

1. E.F. Fiese and T.A. Hagen, "Preformulation," in *Theory and Practice of Industrial Pharmacy*, L. Lachman, H.A. Lieberman, and J.L. Kanig, Eds. (Lea & Febiger, Philadelphia, PA, 3rd ed., 1986), pp. 171–194.

### *Book:*

1. E.F. Fiese and T.A. Hagen, *Theory and Practice of Industrial Pharmacy*, Lea & Febiger, Philadelphia, PA, 3rd ed., 1986.

### *Article in a journal:*

2. G.M. Golden, J.E. McKie, and R.O. Potts, "Article Title," *J. Pharm. Sci.* **76** (1), 25–28, 1987.

### *Published conference proceedings:*

3. J.B. Dressman, Proceedings of PDA Biologics Conference (Washington, DC, 2009), PP. X-XX.

### *Oral presentations:*

4. B.L. Hawkins, A. Baxter, and G.E. Masters, PDA Biologics Conference (Washington, DC, 2009).
5. J. Woodcock, MD, Statement, House Committee on Energy and Commerce Hearing, Apr. 29, 2008.

### *Government publications:*

7. *Code of Federal Regulations*, Title 21, Food and Drugs (Government Printing Office, Washington, DC), Part 121, pp. 270–290.
8. J. Dingell, "Letter to Democratic Caucus" (Washington, DC), Nov. 6. 2008.
9. S. 3633, US Senate, 110<sup>th</sup> Congress, 2<sup>nd</sup> Session (Washington, DC), Sept. 26, 2008.
10. US House Committee on Energy and Commerce, "Food and Drug Administration Globalization Act," Revised Discussion Draft, July 24, 2008 (Washington DC).
11. FDA, "Human and Veterinary Drugs, Good Manufacturing Practices and Proposed Exemptions for Certain OTC Products," *Fed. Regist.* **43** (190), 45013–45089 (Sept. 29, 1978).

12. ICH, Q1B *Photostability Testing of New Drug Substances and Products*, Step 2 version (1996).
13. FDA, *Guidance Title* (Rockville, MD, Nov. 2004).

*Pharmacopeia:*

14. *USP 27–NF 22* (US Pharmacopeial Convention, Rockville, MD, 2003), pp. X–X. (Note: N dash between USP and NF, numbers are not italicized but USP and NF are.)

Note if the above is the reference for an entire General Chapter or other **titled** section, then it follows the style as for the chapter in a book, referenced as follows:

15. *USP 30–NF 25* General Chapter <1231>, “Water for Pharmaceutical Purposes,” page–page.
16. USP Proposed General Test <429>, “Light Diffraction Measurement of Particle Size,” *Pharmacopeial Forum* **28** (4), 1293–1298.
17. *EurPh*, General Text 5.2.8 (EDQM, Strasbourg, France, YEAR), pp–pp.

*Patents*

18. Author or Company name, “Transmitter Switch for Wireless ID,” US patent 125356, Dec. 2003.

*Online-only DOI articles*

19. D. Trauner et al., “Biomimetic Synthesis of the IDO Inhibitors Exiguamine A and B,” *Nature Chem. Bio.* online, DOI:10.1038/nchembio.107, Aug. 1, 2008.

*Other*

- Federal Register
- ICH Q8 *Pharmaceutical Development*
- USP General Chapter <1078>
- Italicize USP when referring to the book, not the organization (National Formulary or “NF” is always italicized)
- Italicize titles of Guidelines and Guidances
- Critical Path Initiative (no italics)
- FDA’s Quality–by–Design and cGMPs for the 21<sup>st</sup> Century Initiative (no italics)

- Only include urls if critical to finding document online. If a url is included, do not include [http://](#) unless necessary and be sure to add an access date (e.g., “accessed May 9, 2009”) to the end of reference.