



Guidelines for Authors



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Information for Authors.

The *Journal of Validation Technology* provides information on science-based and risk-based processes in the pharmaceutical, medical device, and associated industries. The Journal is looking for papers in the following areas:

- Validation, including design and development information conducted prior to validation and qualification, confirmatory conformance testing, and subsequent maintenance of the validated state.
- Manufacturing and packaging processes
- Cleaning processes
- Equipment, facilities and utilities
- Control systems
- Computer systems
- Analytical methods and topics associated with quality systems.

The *Journal of GXP Compliance* provides information to professionals involved in regulated activities including Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP). The Journal publishes information in advance of and in support of respective compliance performance, as well as information to maintain a compliant state.

Before submitting the completed work, authors are urged to review manuscripts for clarity of expression, details of grammar, and typographical accuracy. Acronyms and abbreviations used in manuscripts should be defined. The author is responsible for all statements in his or her work. All accepted manuscripts are subject to copy editing. Advanstar is not responsible for the safety of artwork or photographs.

Manuscripts are reviewed with the understanding that they have not been published previously 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.

Manuscripts may be submitted in the following ways: E-mail Susan Haigney, coordinating editor at shaigney@advanstar.com.

Preparing the electronic file. The text file should be formatted in Microsoft Word. Disks should be labeled with the file name in addition to any graphics and spreadsheet programs used. Do not use any special text formatting codes or control characters. Please include tables and figure captions in the electronic file at the end of the article. Equations, graphs, and any other material that requires special characters or formatting can be in-

cluded electronically, but a printout also must be included.

Authors should furnish two hard copies of the manuscript. Each component of the manuscript should begin on a separate page. These components include the title page (with author's name, title, company affiliation, address, phone, fax, and e-mail), a synopsis or abstract, the first page of the text, references, tables, and legends for illustrations. Titles should be short and specific and should accurately reflect the content of the article. Beginning with the first page of the text, each page of the hard copy should be numbered consecutively.

Illustrations. Photographs, line drawings, and other illustrations may be in color or black and white and must be referred to in the text in consecutive order: Figure 1, Figure 2, and so forth. All illustrations that do not increase the reader's understanding of the text should be omitted. However, 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 enclosed with the article and should be in the form of a tTIFF (Mac), TIF (PC), JPEG, or EPS/EPSF (Mac or PC) file. Images must have a minimum resolution of 300 dpi.

Figures and tables. Line drawings, graphs, photos, and charts must be identified with the figure number and principal author's name. Figure legends should be collected on a separate page, each identified by its proper number. All symbols, acronyms, and abbreviations used in figures and tables should be explained.

In the text, tables should be referred to by Roman numerals in consecutive order: Table I, Table II, and so forth.

Credits. All images, figures, graphs, and tables must be accompanied by the source (creator) name so that the editors can provide appropriate credit. If the author(s) or the author's company created and/or own the rights to the images, figures, tables or graphics, please note that this is the case. If a third party created and/or owns the rights to such illustrations, the author is responsible for acquiring rights permissions and providing the related documentation. Please note that the journals will only publish original tables, graphics, and figures.

References. Literature citations in the text should be numbered consecutively and indicated by Arabic numerals in parentheses. References should be grouped at the end of

the manuscript and arranged in order of their appearance in the text — not alphabetically. The following information should be included in references:

- names of all authors (and editors of books);
- complete title of the article (or book);
- name of publication, publisher, and publisher's location (for books);
- identifying information such as "paper presented at," where applicable;
- volume and issue numbers (for journals);
- year of publication; and the
- first and last page numbers of the article, chapter, or section cited.

The following are reference examples:

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, 3d ed., 1986), pp. 171–194.

Article in a journal:

2. G.M. Golden, J.E. McKie, and R.O. Potts, "Role of Stratum Corneum Lipid Fluidity in Transdermal Drug Flux," *Pharm. Tech.* 22 (1), 25–28 (2003).

Published conference proceedings:

3. J.B. Dressman, "Predicting Release Kinetics from Enteric-Coated Dosage Forms," in *Proceedings of Pharm Tech Conference '88* (Aster Publishing Corporation, Eugene, OR, 1985), pp. 239–250.

Oral presentations:

4. B.L. Hawkins, A. Baxter, and G.E. Masters, "NMR Preview: A Look to the 1990s," paper presented at the *25th Experimental NMR Conference*, Wilmington, DE, February 19–20, 1984.

Government publications:

5. *Code of Federal Regulations, Title 21, Food and Drugs* (General Services Administration, Washington, DC, 1 April 1973), Part 121, pp. 270–290.
6. FDA, "Human and Veterinary Drugs, Good Manufacturing Practices and Proposed Exemptions for Certain OTC Products," *Fed. Regist.* 43 (190), 45013–45089 (September 29, 1978).

Keywords. Please provide a listing of keywords relevant to the article.

Weblinks. Please provide a list of relevant websites and/or additional online references and materials that might be of interest to readers.

About the Editors.

Paul L. Pluta, Ph.D.

Editor-in-Chief
Paul.Pluta@comcast.net

Paul Pluta, Ph.D., has more than 30 years of pharmaceutical industry experience and is a long-standing adjunct faculty member at the University of Illinois College of Pharmacy in Chicago. Pluta has coordinated the JVT "Benchmarking" column and was a valued member of the JVT Editorial Advisory Board for several years.

Additionally, Pluta was Validation Manager at Abbott Global Pharmaceutical Operations in North Chicago, Illinois, where he was responsible for validation projects and associated activities including manufacturing process validation, cleaning validation, packaging validation, and support systems qualification. Pluta has been involved in nearly all phases of pharmaceutical development and manufacturing, including R&D formulation and process development, dissolution, regulatory, stability, quality assurance, compliance, specifications, technical support, and validation/qualification. Dr. Pluta's experience as an adjunct faculty member at the University of Illinois College of Pharmacy in Chicago has included graduate student teaching, undergraduate teaching, and the student externship program. He has presented numerous academic lectures and scientific presentations at pharmaceutical industry meetings. He coordinates both the "Benchmarking" and "Validation Learning Center" column in the *Journal of Validation Technology*. He is a member of AAPS, ISPE, and PDA.

Michelle Hoffman

Editorial Director
732.346.3014, mhoffman@advanstar.com

Michelle joined Pharmaceutical Technology in 2007. She previously served as editor-in-chief of Drug Discovery & Development, G&P, and BioPerform. She has served as the senior science editor for Harvard Medical School followed by almost a decade as the associate editor (life sciences) for American Scientist magazine. In addition, she was formerly a member of the news staff at Science magazine and an editor at Cell. During her business career, she has been a member of the launch teams of two biotech startups, Quantum Genomics (functional genomics) and Karyogen (drug discovery). Michelle also analyzed new ventures at BD Technologies (part of Becton Dickinson) as a member of the business development group. She was trained in molecular biology at Brown and Harvard and holds an MBA from the University of North Carolina at Chapel Hill, where she specialized in corporate finance and entrepreneurship.

Melissa McEvoy

Art Director
732.346.3023, mmcevoy@advanstar.com

Melissa has worked as an art director and designer in the publishing field for more than seven years on a variety of medical and pharmaceutical journals. Currently, she is Art Director for Pharmaceutical Technology as well as two journals for the Institute of Validation Technology. She holds a BFA in art and technology/computer art from Ramapo College of New Jersey, and completed courses at Parsons School of Design. Melissa is a member of the Art Directors Club of New Jersey.

Susan Haigney

Coordinating Editor
732.346.3045, shaigney@advanstar.com

Susan joined the IVT team in 2008 as Coordinating Editor for both the Journal of GXP Compliance and the Journal of Validation Technology. Before coming to Advanstar, Susan served as Managing Editor of Physician's Money Digest. Susan's diverse background includes eight years as an editor of travel publications at Northstar Travel Media, three years as a technical editor, and two years as an Aide to New Jersey Governor Christine Whitman. Susan has a Bachelor of Arts in Communications, with an additional major in English, from Trinity College of Vermont.