RAPS AUTHOR AND STYLE GUIDE: FEATURE ARTICLES

About Regulatory Focus
Regulatory Focus (RF), the flagship publication of the Regulatory Affairs Professionals Society (RAPS), provides in-depth feature articles for those involved with the regulation of healthcare and related products, including pharmaceuticals, medical devices, biologics, biotechnology, in vitro diagnostic devices, nutritional products, cosmetics, veterinary products and related fields.

Delivered digitally on the RAPS website, RF provides ongoing access to timely information addressing real issues in the regulatory environment. RF is the only source of timely, quality regulatory news, information and analysis fully dedicated to covering regulatory issues associated with healthcare products and the regulatory profession.

Areas of Interest to our Readers
Advertising, Promotion and Labeling
Biologics and Biosimilars
Business and Economics (Regulatory Business Acumen)
Ethics
Medical Devices
Pharmaceuticals
Policy (Government, Regulatory Bodies, Law and Legislation)
Quality and Compliance
Regulatory Profession (Education and Professional Development)
Science and Research (Regulatory Science and Leading-Edge Technology)

Articles are written by industry professionals and reviewed by body of volunteer technical reviewers, consisting of regulatory subject matter experts from around the world. Approximately 10 feature articles are published each month and there is a 12-month editorial calendar focusing on key topical areas and emerging issues. RAPS members can benefit from in-depth examination and analysis of regulatory and related topics with monthly themes in addition to continuous access to feature articles, guest editorials, perspectives, opinion pieces, case studies and research studies.

RF accepts unsolicited articles but does not guarantee publication of all submissions. It is preferred a potential author first submit a two- to three-sentence synopsis of the fact-based, in-depth article topic specifying its relevance to the regulatory profession.

AUTHOR GUIDELINES

Article Format
Avoid excessive formatting.

All articles should be written in the third person. For example, instead of “in my experience,” use “in the author’s experience.” Similarly, instead of “you should follow,” use “the regulatory professional should follow.”

Please do not use automatic numbering or the automatic endnote/footnote tools in Word.
If any website links (URLs) are included, please confirm that they are correct. Try to avoid links that require registration fees. If multiple sources for a document exist, use the source most likely to remain
unchanged, e.g., for an FDA guidance, FDA’s website instead of a link to a copy of the document on a consulting firm’s website.

All articles should be written in a formal, non-conversational tone. Use only one space after a period, question mark or exclamation at the end of a sentence.

Biography
An author biographical summary of no more than three or four sentences must be submitted with the article. The summary must include current job title, years of experience in regulatory affairs, area of responsibility, graduate degrees, professional affiliations and contact email.

Commercialism
Commercialism is strictly prohibited. Commercialism is deemed to be the inclusion of visual, written or verbal references to any specific company and/or product for its promotion or commercial advantage. Articles promoting a specific product or company will not be accepted.

Correctness and Accuracy
Authors are responsible for the correctness and accuracy of all statements contained in the article (the publisher assumes no liability). Accepted articles become the property of the publisher and may not be published elsewhere without the written permission of both the author and publisher.

Figures and Tables
Only figures and tables meeting the following criteria will be accepted:

- 300 dpi (high-resolution suitable for printing at actual size or larger). **Line art, usually tagged as .gif and low-resolution photographs, tagged as .jpg (.jpeg) downloaded from websites are not acceptable.**
- **PC Format:** images must be in .bmp, .psd, .tif, .pdf, .eps, .ai (Illustrator only) [Adobe InDesign does not read Illustrator .eps files], submitted via email. Please compress artwork using .zip software. Files in .txt cannot be used.
- **MAC Format:** images must be in .tif, .pdf, .psd, .eps, high-resolution .jpeg, .ai (Illustrator only).
- We cannot accept digital figures created in CAD, Visio or other drafting programs.
- We cannot accept figures only as embedded graphics in a Word or multi-page PowerPoint document. They must be submitted in the formats noted above. PowerPoint figures submitted with one page per file are acceptable.
- Figures are referenced in the text by Arabic numbers, in consecutive order, e.g., Figure 1, Figure 2. Please label your figures as such.
- Please refer to your tables in consecutive, alphabetical order: Table A, Table B, etc.
- Tables must not be submitted as images.
- For each table, a table heading may be included. The table column/row header should explain clearly and concisely the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Figure and table captions must be included with the figures and tables. All necessary symbols, notations and axes must be of sufficient size to be legible when reduced for publication.
- Author must provide appropriate credit for figures and tables if from another source and must obtain the necessary permissions of figures that already have been published. Source should be included as a reference and the reference number placed at the end of the caption.
Only simple or text-heavy tables should be created in Word. If submitting the actual data to plot the figures or charts, the information must be provided in Excel.

Keywords
Each article must include four to six keywords.

Ownership
Authors must sign a copyright release form transferring copyright ownership to RAPS before an article is published. (This does not apply to government employees.)

Payment
RAPS does not pay any financial remuneration to authors.

Permissions
Authors wishing to include figures, tables or text passages that already have been published elsewhere are required to obtain permission from the copyright owner(s) and to include evidence that such permission has been granted when submitting their articles. Any material received without such evidence will be assumed to originate from the authors.

Recertification
RACs earn five recertification points for each article published.

Reprints
After the article is published, it may be posted on the company website. Contact the editor for more information.

Technical and Editorial Review
All articles published in Regulatory Focus are reviewed by a body of volunteer technical reviewers for timeliness, quality of presentation, relevance to audience, technical accuracy and areas for improvement. Reviewers evaluate article submissions and provide feedback on the article, suggest improvements and make a recommendation to the senior editor about whether to accept, reject or request changes to the article. The ultimate decision rests with the senior editor but reviewers play a significant role in determining the outcome. Authors have the opportunity to review the final version of the article before it is published. Articles also will be edited for style, content, grammar and punctuation in accordance to the RAPS Style Guide.

STYLE GUIDE

Abbreviations

Degrees and Credentials
Periods are not used in abbreviations for educational degrees or certifications, e.g., PhD, MBA, RAC.
Note: avoid prefixes including Dr.

The United States
When referring to the United States, use US without periods—both as a noun and as an adjective.

The United Kingdom
Use UK, without periods, rather than spelling out United Kingdom.
**The European Union**
Use EU, without periods, rather than spelling out European Union.

**Acronyms and Abbreviations**

**Acronyms**
Acronyms should follow the full spelling in parentheses upon first reference. Example: The Federal Bureau of Investigation (FBI) is looking into the matter. For each subsequent reference, use only the acronym. If the name is to be referenced only once, do not use the acronym at all—spell out the name completely.

**Benefit-Risk**
Use the format, benefit-risk, with a hyphen. Do not use a colon or any version of “risk-benefit.”

**Capitalization**

**Commonly Used Words**
Abbreviated New Drug Application
Biologics License Application
Cabinet
Congress
current Good Manufacturing Practice
Federal Register
Good Clinical Practice
Good Distribution Practice
Good Documentation Practice
Good Laboratory Practice
Investigational New Drug (application)
Marketing Authorization
Marketing Authorization Holder
New Drug Application
Parliament
Phase
Premarket Approval Application

**Do Not Capitalize:**
agency
congressional
mark, marked, marking in reference to the CE Mark
ministry
quality assurance
regulatory affairs
sponsor
treaty, act, regulation, federal (unless in title)

**Clinical Trial Phases**
Phases of clinical trials are identified using Arabic numerals and capitalize “Phase,” i.e., Phase 1, Phase 2, etc.
Contractions
Limit the use of contractions, such as “don’t” and “isn’t,” except in direct quotations. Spell out “do not,” “is not,” etc., since RAPS’ audience is global and includes non-native English speakers who may be less familiar with contractions. Note: It is best to avoid regional idioms for the same reason.

Dates
Use the international style for dates for all RAPS documents, e.g., 16 February 1971. Spell out the months—do not use abbreviations unless space considerations make it absolutely necessary. Do not use numerical dates, e.g., 2/16/1971.

Degrees and Certifications
Generally, include an individual’s credentials for doctorates (PhD), medical degrees (MD), doctor of pharmacy degrees (PharmD) and Regulatory Affairs Certification (RAC). If referring to or quoting a lawyer, it is acceptable but not mandatory to indicate the JD. Do not include any degree lower than a master’s level. Offset a person’s degree with a comma. Do not use periods in abbreviations of degrees and credentials, e.g., PhD, JD, MD. Do not use prefixes, including Dr.

Emphasis
Do not use uppercase, boldface or italics as a device to emphasize a point.

Foreign Words or Phrases
Non-English words or phrases should be set off in italics.
Example: The court appointed a guardian for the children, to serve in loco parentis.

Gender-Specific Pronouns
Often sentences can be constructed so no gender-specific pronoun is necessary, e.g., Regulatory professionals make important contributions to their employers’ organizational strategies, instead of a regulatory professional makes an important contribution to his or her employer’s organizational strategy. Use “his or her” or “he or she” only when absolutely necessary. Avoid using a construction such as “he/she.” When referring to an individual, never use “their.”

Medical Device Classifications
Medical device classes are identified using Roman numerals, and “Class” is capitalized, i.e., Class I, Class II, etc.

Medical Devices: 510(k) Clearance
When referring to the US Food and Drug Administration’s clearance of medical devices through what is known as the 510(k) process, always used the term “clearance” or “cleared,” never “approval” or “approved.”

Numbers
Cardinal (one, two, three, etc.) and ordinal numbers (first, second, third, etc.) from one to nine should be spelled out. Numbers 10 and higher should be written as numerals (10, 11, 12, etc.).

Punctuation
Bulleted Lists
When creating a vertical bulleted list, RAPS adheres strictly to The Chicago Manual of Style. This reference states that no punctuation is to follow a bulleted list if the list contains words, phrases or sentence fragments. Bulleted lists that are not complete sentences are not capitalized.

If the bulleted or numbered list contains complete sentences (subject and verb), capitalize the first letter and place a period after each item in the list.

**Hyphen**
To decide whether a word is one word, two separate words or two words, hyphenated, reference a dictionary.

There are a few terms that are always written as one word in RAPS style even though they may be listed elsewhere as two words. These terms include healthcare, drugmaker and lifecycle.

**To Hyphenate or Not: Commonly Used Words**
Asia-Pacific
benefit-risk
co-sponsor
e-book
e-mail
decision making
direct-to-consumer
drugmaker
FDA-approved (drug, biologic and PMA submissions)
FDA-cleared (510(k) submissions)
First-in-Man
healthcare
lifecycle
multi-center
multi-site
nonbinding
nonclinical
noncommercial
noncommunicable
noninferiority
non-medical
on-site (when used as an adjective)
on site (all other instances)
over-the-counter
pre-authorization
preapproval
preclinical
premarket
presubmission
postauthorization
postapproval
postmarket
postsubmission
roundtable
shelf life
subsection
third-party (when used as an adjective)
third party (when used as a noun)
timeframe
timeline

Quotation Marks
Periods (.) and commas (,) always go inside the quotation marks. Semicolons (;) and colons (:) always go outside the quotation marks. Question marks (?) and exclamation points (!) go inside the quotation marks if they are part of the quotation, outside if they are not.

References
RAPS follows the American Medical Association Manual of Style for references citing sources for article content. Titles of articles and book chapters should be spelled out and enclosed within quotation marks. References should be sequentially numbered in the body of the article and appear after a period in superscript.1 In the ‘Reference’ section after the conclusion, any repeat references should utilize Ibid (“in the same place”) for a repeat immediately following the original reference or Op cit for repeated use of an earlier reference.

7. Ibid.

When including a URL, please add the date the website or web page was accessed.

For more information, contact:
Gloria Hall
Senior Editor
Regulatory Focus, Feature Articles
Regulatory Affairs Professionals Society
5635 Fishers Lane, Suite 400
Rockville, MD 20852
813-748-1415
e-mail: ghall@raps.org