RAPS REGULATORY FOCUS Feature articles
GUIDELINES FOR AUTHORS and STYLE GUIDE

Last updated 21 July 2021
(includes information about corresponding authors)

About REGULATORY FOCUS

REGULATORY FOCUS (RF) is the flagship online publication of the Regulatory Affairs Professionals Society (RAPS). It 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.

RF provides ongoing access to timely information addressing real-world issues in the regulatory environment. It 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.

The publication is delivered digitally on the RAPS website (www.raps.org).

Reader areas of interest

- Advertising, promotion, and labeling
- Biologics and biosimilars
- Business and economics (regulatory business acumen)
- Manufacturing
- Medical devices
- Pharmaceuticals
- Policy (government, regulatory bodies, law and legislation)
- Quality and compliance
- Regulatory profession (education and professional development)
- Risk strategy and management
- Science and research (regulatory science and leading-edge technology)

Feature articles are written by industry professionals and reviewed by a body of volunteer technical reviewers, including the RAPS Editorial Advisory Committee, which consists of experts in regulatory subject matter from around the world. About 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, case studies, and research studies.

RF accepts unsolicited articles but does not guarantee publication of all submissions. It is preferred a prospective author first submit a two- to three-sentence synopsis of the fact-based, in-depth article topic specifying its relevance to the regulatory profession. This information can be emailed to Renée Matthews, Senior Editor, REGULATORY FOCUS, at rmatthews@raps.org.

Author Guidelines/page 2

GUIDELINES FOR AUTHORS (also see **Presubmission Author Checklist** on page 10)

Article presentation

Length

Articles should run to at least 2,200 words, including references but excluding tables. Most articles submitted range between 3,200 and 4,200 words (6-8 pages as per specs outlined under the Format heading below).

Format

- 11 pt Calibri
- Single-line spacing between sentences
- Paragraphs set flush left (no para indent)
- No extra spacing after paragraphs
- Line between paragraphs
- Avoid excessive formatting. **Please do not use Headers, Footers, Endnotes, or Footnotes.**
- Please do not use automatic numbering or the automatic endnote/footnote tools in Word.
- Do not include notes in the Reference section.
- If any website links (URLs) are included, please confirm that they are correct.
- Try to avoid links that require registration fees.
- All articles should be written in a more formal, non-conversational tone.
- Use only one space after a period, question mark, or exclamation at the end of a sentence.

Elements

- Headline – no more than 70 characters
- Byline – e.g., First Author, PhD, Second Author, MSc, and Third Author, MD
- Brief summary/abstract of article – no more than 85 words
- Introduction to article – provides background information and states goals of article
- Subheads
    - Level 1 subheads – bold typeface
    - Level 2 subheads – bold, italic typeface
- Bulleted points – not numbered (see below, under Punctuation, Bulleted lists)
- Tables and Figures – in increasing numeric order (see below, under Tables and figures)
- Text citations – superscripted numbers (e.g.,[1]) in increasing numerical order (see below, under References)
- Conclusion summary
- Abbreviations list – in alphabetical order, after text and before Reference section
- Reference List – in increasing numerical order, corresponding to text citations (see below, under References)
- Brief bio for each author (see below, under Biography)

Biography

A biographic summary for each author, of no more than three or four sentences, should be submitted with the article. It should include: current job title; years of experience in regulatory affairs; area(s) of specialty/expertise; degree(s)/qualifications and conferring institution(s), whether the author holds the RAC and or is a RAPS member; and a 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 multipage PowerPoint document. They must be submitted in the formats noted above. PowerPoint figures submitted with one page per file are acceptable.
- Tables and figures are referenced in the text by Arabic numbers, in increasing consecutive order, e.g., Table 1, Table 2; and Figure 1, Figure 2.
- Tables must not be submitted as images.
- Each table must have a heading. 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.
- If abbreviations are used in the table or figure, list the abbreviation and with term written out in full at the end of the table/figure, in alphabetical order.

- 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 should include four to six keywords, in alphabetical order.

Ownership
Authors must sign a copyright release form transferring copyright ownership to RAPS before an article is published. The article is not published until the release form has been received from the authors. 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 has been published, it may be posted on the author's company website. Contact the editor for more information.

Technical and editorial review
All articles published in REGULATORY FOCUS undergo double-blind peer review. Each article is reviewed by at least three reviewers from a pool of technical reviewers for timeliness, quality of presentation and original source references, relevance to audience, technical accuracy, and areas for improvement.

Reviewers evaluate submissions and provide feedback on the article, suggest improvements, and make a recommendation to the editor about whether to accept, reject, or request changes to the article. The ultimate decision rests with the editor, but reviewers play a significant role in determining the outcome.

After revisions and acceptance of the article, it will be edited for style, content, presentation of references, grammar, and punctuation in accordance with the Author Style Guide. The article is sent to the designated corresponding author for proofing and sign-off before it is published. Articles are not published until the signed copyright agreement has been returned to the editor.

STYLE GUIDE

Abbreviations and acroynms

Abbreviations and acronyms should follow the full spelling of the term in parentheses after first reference.

Example 1, The US Food and Drug Administration (FDA) is looking into the matter. (Note capitalization.)
Example 2, … sponsors must submit a clinical trial application (CTA) for authorization. (Note lowercase.)

Note, if the abbreviation is for an established group or agency, then the first letter of each world words of its name are title capitalize when written out in full. For each subsequent reference, use only the abbreviation. If the name is referenced only once, there is no need to include the abbreviation after that single reference.

Acronyms are abbreviations that can be pronounced as words, for example, AIDS, COVID, and NASA. RAPS style is to use uppercase for acronyms.

Some common abbreviations that need not be spelled out at first mention would include COVID-19, HIV-AIDS, US, EU, UK.

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, United Kingdom, and the European Union

Abbreviate as US, UK, and EU, respectively, and use without periods. The abbreviations can be used both as nouns and as adjectives.

Capitalization

Commonly used words

Cabinet, Congress, Federal Register

Do not capitalize:

- agency
- congressional
- mark, marked, marking (referring to "CE Mark")
- ministry
- good clinical practice
- quality assurance
- regulatory affairs
- sponsor
- treaty, act, regulation, federal (unless in title)
- EU member state

Clinical trial phases

Phases of clinical trials are identified using Arabic numerals and lowercase for "phase" – phase 1, phase 2, phase 3.

Contractions
Limit use of contractions, such as “don’t” and “isn’t,” except in direct quotations. Spell out “do not,” “is not,” etc.

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, e.g., in tables and figures. 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.

Gender-specific pronouns
Often sentences can be constructed so that 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.”

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

510(k) clearance
When referring to the US Food and Drug Administration’s clearance of medical devices through the 510(k) process, always use the term “clearance” or “cleared.” Do not use “approval” or “approved.”

Numbers
Cardinal (one, two, three, etc.) and ordinal numbers (first, second, third, etc.) from one to nine should be spelled out if they are not used with a unit, such as 3 miles, 6.2 kg.

Numbers 10 and higher should be written as numerals (10, 11, 12, etc.).

Punctuation

Bulleted lists

When creating a vertical bulleted list there should be no punctuation 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.

Comma **Use the serial comma.**

Hyphen

Reference a dictionary or guidance on whether a word is used as one word; two separate words; or two words, hyphenated.

There are a few terms that are always written as one word in RAPS style even though they are used elsewhere as two words, e.g., healthcare, drugmaker, and lifecycle.

Note use of the hyphen in the following:

Asia-Pacific
benefit-risk
cosponsor
e-book, email
decision making
direct-to-consumer (adjectivally)
FDA-approved (drug, biologic)
FDA-cleared (510(k) submissions)
first-in-human (not first-in-man)
multicenter, multisite
nonbinding, nonclinical, noninferiority
on-site (adjectivally), on site (all other instances)
over-the-counter (adjectivally)
pre-authorization
preapproval, preclinical, presubmission
postauthorization, postapproval, postmarket, postsubmission
roundtable
shelf life
subsection
third-party (adjectivally), third party (as a noun)

Quotation marks and punctuation

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

Spelling Use standard American spelling, unless in a quotation; the name of an organization, law, or regulation; or book, article, or newspaper titles or headlines.

References and text citations

In Reference lists, please do not use:

- Endnotes or footnotes, auto-numbering, or italics or quote marks for titles; or
- The Ibid/Op cit system of referencing.

If there are multiple sources for a document, use the source most likely to remain unchanged, e.g., for an FDA guidance, use the agency website instead of linking to a copy of the document on a consulting firm's website.

- All statements of fact within the text sourced from an original document must be noted next to the corresponding text using a superscripted number and listed in the reference section, using the same number as the text citation.
- Superscripted text citation numbers (e.g.,[11-16,32]) should be presented sequentially, in increasing numerical order.
- The superscripted number should go after the punctuation, e.g., … risk strategy.[45,56,59]
- The sources listed in the reference section should be presented sequentially, in increasing numerical order, reflecting the order in which the references are cited in the text.
- If a reference is cited a second time, or multiple times, in the article, use the first number applied to the reference for each subsequent mention of the reference in the text. **Do not use the Ibid/Op cit system**.
- References with URLs should include the date of publication or of last update (e.g., Last updated 7 April 2019. or Published 3 March 2020.), as well as the date on which the author last accessed the article through the URL (e.g., Accessed 14 July 2020.)
- Where possible, use PubMed abbreviations for journal titles. The titles are not italicized and take a single period at the end of the full title, not after each abbreviated word in the title.
- A reference entry for a source should generally include the following elements, in this order:
    - Name of content originator, e.g., author or organization.
    - Title of document, sentence case – no italics or quotation marks.
    - Abbreviated journal name – period at the end of the title, not italic (see PubMed for guidance).
    - Year;Volume(Issue):page range
    - Page range numbers are separated with a hyphen; don't repeat duplicate numbers, e.g., pages 103 to page 109, would be 103-9; pages 1175-1190, would be 1175-90.
    - URL, if applicable – hyperlinked to source.
    - If a URL is used, include the date the item was published/posted/last updated or revised, e.g., Published 16 November 2019. or Last updated 23 December 2020.
    - Also include the most recent date on which the article was accessed through the URL, e.g., Accessed 15 January 2020.

Author names

Last name first, then initials – no comma after last name, no periods between initials, period at end:

- For one author – Agwuegbo CA. Article title …
- For two authors – Agwuegbo CA, Olsen DJ. Article title …
- For three authors or more – Agwuegbo CA, et al. Article title …

Style for specific references

Journal article, prints

5. Sun J, et al. Improvement in cardiac function after bone marrow cell therapy is associated with an increase in myocardial inflammation. Am J Physiol Heart Circ Physiol. 2009;296(1):43-50.

Journal article, online

7. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. Front Pharmacol. htt ps://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/. Published online 26 June 2020. Accessed 17 January 2021.

For website URLs

26. National Medical Products Administration. NMPA issued the 2019 annual report for medical device registration. http://english.nmpa.gov.cn/2020-03/17/c_471589.htm. Last updated 17 March 2020. Accessed 1 May 2021.

For website URLs when the document is in a language other than English

37. [In French] Le Ministère de l'Education Nationale et de la Jeunesse et des Sports. Rentrée 2020: Modalités pratiques [*Back to school 2020: Practical guidelines*]. https://www.education.gouv.fr/rentree-2020-modalites-pratiques-305467. Last updated 19 August 2020. Accessed 7 April 2021.

Presentation at a conference

37. Du X, et al. Orally available small molecule CD73 inhibitor reverses immunosuppression through blocking of adenosine production. Paper presented at: American Association for Cancer Research Virtual annual meeting; 27 April 2020. https://www.abstractsonline.com/pp8/#!/9045/presentation/10523. Accessed 30 July 2020.

Book (whole)

25. Venables WN. Modern applied statistics with S. 4th ed. Springer Publishing; 2003.

Book chapter

17. Solensky R. Drug allergy: Desensitization and treatment of reactions to antibiotics and aspirin. In Lockey P, ed. Allergens and Allergen Immunotherapy. 3rd ed. Marcel Dekker; 2004:585-606.

FOR MORE INFORMATION
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PRESUBMISSION AUTHOR CHECKLIST

Before submitting your article, please ensure the following requirements have been met:

□ Formatting
- 11 pt Calibri
- Single-line spacing between sentences
- Paragraphs set flush left (no para indent)
- Single line between paragraphs
- No extra spacing after paragraphs
- No Headers, Footers, Endnotes, or Footnotes
- No pages with company/organization logos

□ Article is at least 2,200 words (including references, but excluding tables)

□ Headline – no longer than 70 characters

□ Byline – FirstName LastName, postgrad degrees

□ Brief summary, abstract of article – no longer than 85 words

□ Introduction to article includes topic background/context and purpose of article

□ Text citations – superscripted numbers in increasing numerical order

□ Tables – heading, notes, abbreviation list, source (if applicable)

□ Figures – heading, legend, abbreviation list, source (if applicable)

□ Level 1 subheads – **bold typeface**

□ Level 2 subheads – ***bold, italic typeface***

□ Bulleted points (not numbered)

□ Abbreviations list in alphabetical order – after text, before Reference section

□ References are complete, as per Author Guidelines. Articles not following the guidelines will not be sent out for review and will be returned to author(s) for reformatting.

□ References – URLs must be accompanied by publish/update/revise and access dates

□ URLs – do they go to the correct source?

□ Brief bio for each author, including: current job title; years of regulatory experience; area(s) of specialty/ expertise; degree(s)/qualifications and conferring institution(s), RAC and/or RAPS member; contact email.

□ Corresponding Author – state clearly which author is the Corresponding Author and provide an email contact for that person. Ghostwriters or communications staff should not be listed as corresponding authors.

Thank you