RAPS REGULATORY FOCUS Feature articles
GUIDELINES FOR AUTHORS and STYLE GUIDE

Last updated March 2023

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 that 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 p. 14)

Article presentation

Length

Articles should run to at least 2,800 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 document lines (not 'Multiple')
- Paragraphs set flush left (no para indent)
- No extra spacing after paragraphs – just a single line space
- Avoid excessive formatting. **Please do not use Headers, Footers, Endnotes, or Footnotes**
- Lists should be bulleted, not numbered
- Do not include notes in the Reference section
- Website links (URLs) in the Reference section must be confirmed as correct and functional
- Try to avoid links that require registration fees
- 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 – 70-75 words
- Keywords or phrases – 3-5, in alphabetical order, all lowercase, except for proper nouns
- 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
- Brief bio for each author – no more than 100 words (see below, under Biography)
- Acknowledgment or Disclaimer, if needed
- Reference List – in increasing numerical order, corresponding to text citations (see below, under References)

Author biography

A biographic summary for each author, of no more than three to five sentences, should be submitted with the article. It should include the author's name and degrees; current job title; years of experience in regulatory affairs; area(s) of regulatory specialty/expertise; degree(s)/qualifications and the conferring institution(s) and whether the author holds the RAC and/or is a RAPS member or fellow (FRAPS); 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 sent for review.**

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 or phrases Each article should include 3-5 keywords or phrases presented in alphabetical order, separated by commas, and all lowercase except for proper nouns.

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 content-specialist reviewers for timeliness and contribution to the regulatory literature, 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 acronyms

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 word of its name is capitalized 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. These 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 uppercase for "Phase" – Phase 2.

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 all postgrad degrees: master’s (MS, MA, MBA, MPH), doctorates (PhD), medical degrees (MD, MBBS, MB BCh), and doctor of pharmacy and law (PharmD, JD). Certifications should also be included: Regulatory Affairs Certification (RAC) and RAPS Fellows (FRAPS).

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 numbers from one to nine should be spelt out. Cardinal numbers for 10, 11, and onward should be written as Arabic numbers.

Ordinal numbers (first, second, third, etc.) should be written out for first to ninth, but numbers should be used for 10th, 11th, and onward.

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

Articles with no references or with references that do not adhere to the guideline requirements will not be sent for review. They will be returned to the author(s) for references to be added and/or completed in accordance with the style.

References are important because they:

- Provide verification/evidence for claims made in an article,
- Acknowledge authors whose content/ideas have informed an author's work, and
- Allow readers to go to full and original sources should they wish.

Please note the following before beginning the References –

- Do not use the Ibid/Op cit system of referencing,
- Do not use endnotes or footnotes – the information should be written into the text and referenced as per the guidelines.
- Do not include endnotes or footnotes in the Reference list,
- Do not use reference management software,
- Do not use italics or quote marks for journal or article titles, and
- Do not hyperlink titles in references to the original source – always provide the full URL.

General guidance

- Use the **primary source** for a document, e.g., if an FDA guidance has been posted on multiple sites, use the version posted on the FDA site and not one posted on a consulting firm's website.
- The superscripted text citation numbers (e.g., 1-5 in above example) should be presented sequentially, in increasing numeric order.
- The sources listed in the reference section should be presented sequentially, in increasing numerical order, reflecting the order in which they are first cited in the text.
- The superscripted number should go after the punctuation, e.g., … risk strategy.[45]
- If a reference is cited a second time, or multiple times, in the article, use the number applied at the first mention of the reference for each subsequent mention of the reference in the text.

The passage below shows how the text citations (highlighted in yellow) and the references (under the heading "References" are styled in the article:

> This figure reflects a two-fold increase from that of 2018, and a 12-fold increase from the $1.23 billion spent in 2013.[1] According to Indegene, who conducted a survey in 2019 of 100 pharma and bioscience companies, the anticipated spend will equate to 50% of the industry's allotted 2022 marketing budget.[2] The exponential growth of digital advertising spend is not surprising considering the increasingly high level of consumer use of social media platforms, such as Facebook and YouTube, to obtain health related information and the potential for leveraging consumer and prescriber influence.[3-5]

References

1. Statista Research Department. Healthcare & pharma social media ad spend US 2020. Statista. Published online 7 December 2021. Accessed 10 October 2022. https://www-statista-com.proxy.libraries.rutgers.edu/statistics/1251970/healthcare-pharma-industry-social-media-ad-spend-us/
2. Kapoor G. The digital shift in pharma marketing: Indegene's surveys in 2016 and 2019 show a spike in digital spend. PMLiVE Digital Handbook. Published online 23 January 2020. Accessed 10 October 2022. https://www.pmlive.com/blogs/digital_intelligence/archive/2020/the_digital_shift_in_pharma_marketing
3. Zhao Y, Zhang J. Consumer health information seeking in social media: A literature review. Health Information & Libraries J. 2017;34:268-283. Accessed 10 October 2022. https://onlinelibrary.wiley.com/doi/epdf/10.1111/hir.12192
4. Kim H. Trouble spots in online direct-to-consumer prescription drug promotion: A content analysis of FDA warning letters. Int J Health Policy Manag. Published online 25 August 2015. Accessed 10 October 2022. https://www.ijhpm.com/article_3083_c5885a53cd19640e9d9aa3171a12269f.pdf
5. Jameison S, et al. Leveraging digital/social media platforms to meet business goals: A US case study. Regulatory Focus. Published online 16 December 2020. Accessed 10 October 2022. https://www.raps.org/news-and-articles/news-articles/2020/12/leveraging-digitalsocial-media-platforms-to-meet-b

Table 1. Basic elements of an article reference *(See specific examples, pp. 10-13)*

Element	Example
Name of content originator, e.g., author or agency	*Authors* (One) Agwuegbo CA. Article title … (Two) Agwuegbo CA, Olsen DJ. Article title … (Three) Agwuegbo CA, et al. Article title … *Agencies* Food and Drug Administration. Article title … European Medicines Agency. Article title …
Title of document, sentence case, unless it is a law – do not use no italics or quotation marks	*Article* The primary cilium as a therapeutic target in ocular diseases. *Law* Federal Food, Drug, and Cosmetic Act.
Abbreviated journal name – single period at the end of the title, not italic. Use PubMed abbreviations for journal titles.	Am J Physiol Heart Circ Physiol.
[Print] Year;Volume(Issue):page range	2009;296(1):43-50.
[Print] Page range numbers are separated with a hyphen	2016;48(6):109-128
Print example 6. 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. Verified 10 October 2022.	
[Online] If a URL is used, include the date the item was published/posted/last updated or revised.	Published 16 November 2019. Last updated 16 November 2019.
[Online] Include the most recent date on which the article was accessed through the URL.	Accessed 15 January 2020.
[Online] URL should be hyperlinked to source,	https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(22)00282-8/fulltext
Online example 7. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. Front Pharmacol. Published online 26 June 2020. Accessed 10 October 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/	

Examples of style for specific references – text format *(See Table 2, pp. 12-13)*

Report to US Congress
34. Food and Drug Administration. Performance report to Congress for the Office of Combination Products as required by the Medical Device User Fee and Modernization Act of 2002. FY 2017. Accessed 10 October 2022. https://www.fda.gov/media/128892/download

Act
4. US Congress. Safe Medical Devices Act of 1990. Last action 28 November 1990. Accessed 10 October 2022. https://www.congress.gov/bill/101st-congress/house-bill/3095/actions

Guidance, draft
22. Food and Drug Administration. Content of premarket submissions for device software functions [draft guidance]. Issued 4 November 2021. Accessed 10 October 2022. https://www.fda.gov/media/153781/download

Guidance, final
12. Food and Drug Administration. How to write a request for designation (RFD) [guidance]. Current as of 26 March 2018. Accessed 10 October 2022. http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm

Code of Federal Regulations, Part
32. 21 CFR Part 820, Quality System Regulation. Current as of 20 July 2022. Accessed 10 October 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

Code of Federal Regulations, Section
4. 21 CFR §3.2(o). Definitions: Product jurisdiction officer. Current as of 20 July 2022. Accessed 10 October 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=3.2

Federal Register, Final Rule
18. Food and Drug Administration. Assignment of agency component for review of premarket applications, Final Rule, 68 Fed. Reg. 37075. Federal Register website. Effective 23 June 2003. Accessed 10 October 2022. https://www.federalregister.gov/documents/2003/06/23/03-15698/assignment-of-agency-component-for-review-of-premarket-applications

US Pharmacopeia
26. US Pharmacopeia. <1225> Validation of compendial procedures. Pharmacopeia Online. Not dated. Accessed 10 October 2022. http://www.uspbpep.com/usp29/v29240/usp29nf24s0_c1225.html

EU regulations
16. Official Journal of the EU. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Published 5 May 2017. Accessed 10 October 2022. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

Legal and laws
3. US District Court for D.C. Genus Medical Technologies LLC v. US Food and Drug Administration, No. 19-544 (JEB), Memorandum Opinion, Dec. 6, 2019. Accessed 10 October 2022. https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv0544-19

Journal article, print only
42. 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. Verified 10 October 2022.

Journal article, online
16. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. Front Pharmacol. Published online 26 June 2020. Accessed 10 October 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/

Article on an agency website
2. National Medical Products Administration. NMPA issued the 2019 annual report for medical device registration. Last updated 17 March 2020. Accessed 10 October 2022. http://english.nmpa.gov.cn/2020-03/17/c_471589.htm

Article or document in a language other than English
7. [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]. Last updated 19 August 2020. Accessed 10 October 2022. https://www.education.gouv.fr/rentree-2020-modalites-pratiques-305467

Presentation at a conference
1. 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. Accessed 10 October 2022. https://www.abstractsonline.com/pp8/#!/9045/presentation/10523

Book, whole
8. Venables WN, Ripley BD. Modern applied statistics with S. 4th ed. Springer; 2003. Verified 10 October 2022.

Book, chapter
9. 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. Verified 10 October 2022.

Package insert/prescribing information
12. Qinlock [prescribing information]. Deciphera Pharmaceuticals; 2020. Accessed 10 October 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213973s000lbl.pdf

Table 2. Examples of style for specific references *(See text format, pp. 10-11)*

Reference type	Formatted example
Report to US Congress	34. Food and Drug Administration. Performance report to Congress for the Office of Combination Products as required by the Medical Device User Fee and Modernization Act of 2002. FY 2017. Accessed 10 October 2022. https://www.fda.gov/media/128892/download
Act	22. US Congress. Safe Medical Devices Act of 1990. Last action 28 November 1990. Accessed 10 October 2022. https://www.congress.gov/bill/101st-congress/house-bill/3095/actions
Guidance, draft	6. Food and Drug Administration. Content of premarket submissions for device software functions [draft guidance]. Issued 4 November 2021. Accessed 10 October 2022. https://www.fda.gov/media/153781/download
Guidance, final	14. Food and Drug Administration. How to write a request for designation (RFD) [guidance]. Current as of 26 March 2018. Accessed 10 October 2022. http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm
Code of Federal Regulations, Part	1. 21 CFR Part 820, Quality System Regulation. Current as of 20 July 2022. Accessed 10 October 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1
Code of Federal Regulations, Section	1. 21 CFR §3.2(o). Definitions: Product jurisdiction officer. Current as of 20 July 2022. Accessed 10 October 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=3.2
Federal Register, Final Rule	2. Food and Drug Administration. Assignment of agency component for review of premarket applications, Final Rule, 68 Fed. Reg. 37075. Federal Register website. Effective 23 June 2003. Accessed 10 October 2022. https://www.federalregister.gov/documents/2003/06/23/03-15698/assignment-of-agency-component-for-review-of-premarket-applications
US Pharmacopeia	26. US Pharmacopeia. <1225> Validation of compendial procedures. Pharmacopeia Online. Not dated. Accessed 10 October 2022. http://www.uspbpep.com/usp29/v29240/usp29nf24s0_c1225.html
EU regulations	4. Official Journal of the EU. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Published 5 May 2017. Accessed 10 October 2022. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
Legal and laws	12. US District Court for D.C. Genus Medical Technologies LLC v. US Food and Drug Administration, No. 19-544 (JEB), Memorandum Opinion, Dec. 6, 2019. Accessed 10 October 2022. https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv0544-19
Journal article, print	6. 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. Verified 10 October 2022.
Journal article, online	4. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. Front Pharmacol. Published online 26 June 2020. Accessed 10 October 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/ ***Continued on p. 13***

Table 2 (continued). Examples of style for specific references

Reference type	Formatted example
Article or document in a language other than English	7. [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]. Last updated 19 August 2020. Accessed 10 October 2022. https://www.education.gouv.fr/rentree-2020-modalites-pratiques-305467
For website URLs	8. National Medical Products Administration. NMPA issued the 2019 annual report for medical device registration. Last updated 17 March 2020. Accessed 10 October 2022. http://english.nmpa.gov.cn/2020-03/17/c_471589.htm
Presentation at a conference	9. 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. Accessed 10 October 2022. https://www.abstractsonline.com/pp8/#!/9045/presentation/10523
Book, whole	10. Venables WN, Ripley BD. Modern applied statistics with S. 4th ed. Springer; 2003. Verified 10 October 2022.
Book, chapter	11. 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. Verified 10 October 2022.
Package insert/ prescribing info.	12. Qinlock [prescribing information]. Deciphera Pharmaceuticals; 2020. Accessed 10 October 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213973s000lbl.pdf

Presubmission Checklist on page 14

FOR MORE INFORMATION
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Regulatory Affairs Professionals Society, 5635 Fishers Lane, Suite 400, Rockville, MD 20852

PRESUBMISSION 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 company/organization logos**

□ Article is at least 2,800 words (including references, but excluding tables)

□ Headline – no longer than 70 characters

□ Byline – FirstName LastName, postgrad degrees

□ Brief summary, abstract of article – 70-75 words

□ Keywords or phrases – 3-5, in alphabetic orders, all lowercase, except for proper nouns

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

□ Text citations – superscripted numbers in increasing numerical order, placed *after* punctuation marks

□ 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 author bios

□ Brief bio for each author (no more than 100 words), including author name and degrees; 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.

□ 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.

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

□ URLs – do they go to the correct source?

Thank you