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INTRODUCTION

This document details the style guidelines for authors who are writing and preparing a book chapter or long-form article for publication with Regulatory Affairs Professionals Society (RAPS). It is to ensure that the initial submission is presented with accuracy, clarity, and consistency in line with the best practices for writing evidence-based content. The guidelines are also intended to assist editors throughout the submission, review and revision, editing, and production stages of the workflow. Authors and editors should consider this style document as their main reference for guidance in preparing content for RAPS publications.

The guidelines have been substantially revised, updated, expanded, and restructured. The current structure reflects elements from the style manuals of the American Medical Association and American Psychological Association and the Chicago Manual of Style. The revisions and updates are supported with practical, regulatory-specific examples of the application of some style requirements.

The guidelines are available as a searchable [online](#) PDF. Users can also download the PDF. The guidelines will be updated regularly based on emerging developments and feedback from users.

The regulatory context: Sectors and reader areas of interest

RAPS content spans three primary areas that broadly align with regulatory sectors:

- **Pharmaceuticals and biologics** – including advanced therapies/cellular and gene therapies; active pharmaceutical ingredients; biologics, biosimilars, vaccines and biotechnology; generics; and combination products
- **Medical devices** – including in vitro diagnostics; SaMD; AI/ML-enabled devices; wearable devices; reusable devices; 3-D printing for medical devices; and combination products/diagnostics
- **Science and technology** – including non-medical device-related AI (e.g., in writing, submissions, data systems, and management) and cybersecurity; non-medical device-related digital health, such as mobile health, health information technology, telehealth/medicine, and personalized medicine; and other regulated industries such nutrition (including medical food, food/dietary/health supplements, and nutraceuticals) and cosmetics.

In addition, there are secondary areas of focus, most of which are sector agnostic, meaning they are broadly applicable across the sectors. These may include:

Advertising, promotion, and labeling	Project management
Audit/inspection	Postmarket surveillance
Chemistry, manufacturing, and controls	Quality assurance and control
Clinical and preclinical trials	Regulatory intelligence
Compliance	Regulatory policy (government, regulatory bodies, law, and legislation)
Ethics	Regulatory writing/documentation
Health authority meeting/communication	Research, design, and development
Pharmacovigilance	Regulatory science
Preclinical trials	Strategy and risk management
Product development	Supply chain management
Product lifecycle	Sustainability
Professional development/training	

About RF QUARTERLY and peer-reviewed articles

RF QUARTERLY and monthly peer-reviewed articles are published online by RAPS and fall under the society's News and Content division. These evidence-based, peer-reviewed articles are original to RAPS and are a member-exclusive benefit. They are written by global regulatory subject matter experts (SMEs), although newcomers to the profession are also encouraged to contribute.

The content is available on the [RAPS website](#) and is disseminated through newsletters, special email messages, and on social media, reaching 30,000 regulatory professionals globally. Full lists of [RF QUARTERLY](#) and [monthly](#) articles are also available, as is the [current RF QUARTERLY issue](#), which includes a full archive of previous issues of the publication.

The articles are peer-reviewed by a body of reviewers, including the RAPS Editorial Advisory Committee, that consists of experts in regulatory subject matter. There is a 12-month [editorial calendar](#) focusing on key topical areas and emerging issues. Authors may select to write on a particular topic on the editorial calendar or they can submit an ad hoc article on a topic of their choice, provided that it aligns with the following stated mission and scope for content.

Mission

- To publish in-depth, research-based, original content, exclusive to [RAPS members](#);
- Address current global regulatory issues and trends;
- Provide information for use as guidance or a resource in daily regulatory work;
- Give authors the opportunity to share their knowledge, expertise, and experience with their peers; and
- Advance existing regulatory literature.

Scope

- Global drug and medical device regulation and related science and technology;
- Product lifespan from development through postmarket surveillance; and
- Career- and workplace-related topics, e.g., professional development, career advancement, mentoring, leadership, and diversity, skills development.

It is preferred that a prospective author first submits a proposal for their article before they begin writing it, specifying its relevance to the regulatory profession and including the following elements:

- A working headline of no more than 70 characters, including spaces
- The authors' names, degrees, and affiliations
- An abstract of no more than 75-80 words
- 3-5 keywords in alphabetical order

This information can be emailed to Renée Matthews, Senior Editor, at rmatthews@raps.org

It should be noted that authors with the Regulatory Affairs Certification (RAC) who publish an article can earn credits toward their recertification requirements (see [Recertification Guide](#)).

As already mentioned, content should be original and exclusive to RAPS. Articles should be submitted as a Word document with accompanying figures as editable PowerPoint slides.

The submitted article must be in accordance with the style guidelines, with particular attention paid to the requirements set out in the Presubmission Checklist (p. 44). Failure to adhere to the guidelines, especially those for formatting the article and references and their corresponding text citations, will result in the article being returned to the author(s) for correction before it is sent for peer review. Authors should also note certain basic expectations for a submitted article, namely, that it:

- Adds value to and expand the broader body of regulatory writing;
- Is not AI generated – such content is not considered for publication and will be returned to the person who sent it;
- Supports statements of fact with references to original sources in existing regulatory and scientific literature, laws, and regulations/guidance;
- Is structured to include a title, author(s) byline, an abstract, 3-5 keywords or phrases, an introduction/background that includes the stated purpose of the article, the main body of the article, a conclusion, author bios and disclosures, and references;
- Includes tables and figures, where appropriate;
- Is written from a neutral, nonadvocating perspective;
- Is more formal in tone rather than conversational or journalistic (no clichés, verb contractions, or addressing the reader as “you”); and
- Does not promote a product and or service offered by any author’s or authors’ company.

Article structure

The structure and flow of an article are as important as its content. *Structure* refers to the chronological organization of content under specific headings; *flow* refers to the ease of reading and logical development of the content based on structural organization. These elements, along with accuracy, clarity, and consistency, are crucial for effectively informing and retaining the reader. Typographic styling for each of the following sections is shown in this [article sample](#).

All articles must be structured under the following headings when they are submitted for consideration for publication. Articles not structured in this way will be returned to the author(s) for structuring before being sent for peer review.

Article title

The article title is the reader's first engagement with the content and is important in their decision to read the article or not. It should therefore be:

- Succinct and clear, written in statement form using the active voice;
- No more than 70 characters, including spaces
- Written in sentence case, that is, the first word is title-cased; the rest are lowercase, except for proper nouns and abbreviations.

The title does not have a period at the end, and it should not be presented as a question.

Author name(s)

Articles must include the author names at the top of the article, just after the article title. Each name should be on a separate line, with degrees/certifications after the name.

Abstract

The abstract is a summary of 70-75 words about the article. It should start with an introductory sentence or two that provide background or context for the reader and should also include a sentence beginning with, "This article discusses/examines/presents ..."

Keywords

Authors must provide three to five keywords or phrases that reflect key elements or points in the article. The words or phrases should not be too general in meaning and should not repeat words and abbreviations already used in the article title. Use abbreviations as keywords only if they are established in the regulatory setting (e.g., NDA, CE Mark, or EMA). In general, keywords or phrases should be:

- In alphabetical order;
- All lowercased, except for proper nouns and abbreviations; and
- Separated by commas, with no period after the last item in the list.

Introduction

The introduction should provide background information about the topic, supported by references, and context for the rest of the article. It should mention the specific points that will be addressed in the article include a statement about the purpose of the article.

The definitions of technical words or terms used in the article should be provided in the last paragraph of the Introduction and can be introduced with a phrase such as "In this article, the term xxx will refer to ..."

Body of text

This is the section of the article in which the author presents the core information about the topic under specific subheads and with supporting references and accompanying tables and figures. The subheads and associated content should be developed logically and chronologically to ensure the information is accessible and easy to retain for readers with varying levels of regulatory knowledge and experience.

Conclusion

The Conclusion should include a brief summation of key points presented and addressed in the article. It should highlight their importance or relevance to current practice and their future role or impact in the regulatory setting. New references should not be introduced in the Conclusion, neither should tables or figures.

Articles submitted without a Conclusion will be returned to the author(s) to add one before the article is sent for peer review.

Abbreviations list (see [article sample](#))

About the author(s)

The biography should be no longer than 100 words and should include the following elements:

- Author name and degrees
- Current position(s)
- Area(s) of specialty/expertise
- Degree(s)/qualification(s) and the conferring institution(s)
- Whether the author is a RAPS member
- Whether the author holds the RAC
- The author's email

The language should be clear and to the point, written in an active voice. Phrases such as *passionate about*, *proven track record*, and *enthusiasm for* should not be used.

Disclaimers

Not all articles require a disclaimer. Authors are responsible for adding this information if their employers require them to do so.

Acknowledgment

This element is not required and should be included only if authors choose to acknowledge editorial support and feedback. The language should be clear and to the point, written in an active voice. Phrases such as *eternally grateful* and *above and beyond* should not be used.

References

It is essential that authors follow the directions for formatting and presenting references and the corresponding text citations. The **References and Text Citations** section (p. 7) addresses the importance of references in peer-reviewed content and presents a comprehensive list of examples formatting different kinds of source materials.

Articles with references that do not follow guidelines will not be sent for review and instead, returned to authors for correct formatting.

About RAPS Books

RAPS publishes an extensive line of books for professionals dealing with regulated healthcare products, offering resources for every level of expertise across all product lines and lifecycles. RAPS books are written by regulatory professionals, for regulatory professionals.

Readers expect the most up-to-date, accurate, and insightful information available, and RAPS makes every effort to ensure its books are of the highest quality. Each book has one or more lead editors who are experts in the field. The lead editors are assisted by a pool of selected reviewers to ensure all content is accurate and relevant. Book manuscripts are managed by RAPS editorial staff within an established editorial process, from submission to publication. The staff work collaboratively with authors throughout the process. Information about manuscript submission and editorial process is provided to editors and authors on a book-by-book basis.

Fundamentals series

The Fundamentals series is a collection of robust, comprehensive references on foundational regulatory knowledge, written for industry professionals at all career stages. The Fundamentals books are designed to provide the basics across the full product lifecycle and are updated every two years to ensure consistent integration of regulatory changes and industry innovation.

Topical books

In addition to the Fundamentals series, RAPS books cover dynamic topics in regulatory affairs. The catalog includes books on regulatory writing, regulatory intelligence, software as a medical device (SaMD), regulatory strategy, product labeling, and more.

The [full catalog](#) of RAPS books is available online.

The editorial process: A general outline for books and articles

RAPS follows a journal workflow for books and peer-reviewed content, although there is some variation between the two.

Corresponding author

If an article or book chapter has more than one author, then the author group should assign a single author as the corresponding author to serve as the interface between the editorial office and the group. Having a single corresponding author is integral to streamlining the editorial process and ensuring overall quality of the final product.

The corresponding author will co-ordinate the authors' proofreading of the article/chapter and collate their respective responses and decisions as a final, single instruction in the Word document that is returned to the editorial office. Instructions should be in Comment boxes, with all editing and changes to the document in Track Changes. Articles in which changes are not in Track Changes will be returned to the corresponding author to add them.

Stages of the peer-review workflow

- Article and accompanying figures submitted as Word documents and editable PPT files, respectively
- Editorial technical review and follow-up with authors
- Formatting and de-identifying article for peer review
- Peer review
- Revision as outlined by the reviewers
- Substantive editing (Word document)
- Copy editing (Word document)
- Proofreading and approval by corresponding author (Word document) – all major editing and substantive queries must be addressed and resolved by this stage
- Production – includes design, second proofreading (PDF; only minor changes are accommodated)
- Publication
 - Monthly articles – online as HTML, with an accompanying PDF
 - RF QUARTERLY – online PDF of full issue, articles are also online as HTML with accompanying PDF
 - Books – online as e-books and in print form, with selected titles available as e-books only
 - Articles as also disseminated through newsletters, LinkedIn, and social media

A submitted article would be sent to reviewers (usually two or three) for double-blind peer review, after which the corresponding author would be informed of their decision. Usually, the article will require revision based on feedback and reviewer requests. Once the revisions have been received, the article will be edited, copy-edited, and returned to the corresponding author for a final round of proofing before publication.

For books, the submitted chapter manuscript will be reviewed by the book lead editors and revised by the chapter authors as needed. On acceptance of the revisions, the chapter will be edited by RAPS editors for accuracy, structure, and consistency. Integral to this process is to ensure that the references, table and figure presentation, and grammar and language use are in accordance with the style guidelines.

The edited chapter will be returned in the Word template to the designated corresponding author for proofreading and approval. Any substantive edits and/or changes should be addressed at this stage and must be done in Track Changes in the Word template. If the changes are not tracked, the chapter will be returned to the corresponding author for the changes to be executed as stipulated, and the document returned to the editorial office. Having to include this additional step will delay progression to the layout and production stages of the workflow.

After the chapter has been proofread and the tracked edits have been checked and accepted, it will be sent for layout and design. The corresponding author will receive a chapter PDF for final proofreading and approval. At this stage, only minor changes can be accommodated.

**Note about the use of highlighted and bold text in some examples of usage: These two features are used occasionally in the working examples of the application of some style requirements. Guidelines users should be aware that the features are for highlighting the style point being made and are not suggested style for authors.*

REFERENCES AND TEXT CITATIONS

References are integral to the value, quality, and integrity of evidence-based content because they:

- Provide verification and evidence for claims made in the text;
- Root the chapter or article in the existing regulatory literature, providing context for the reader;
- Acknowledge authors whose content/ideas have informed an author's work;
- Allow readers to go to full and original sources should they wish; and
- Are a way for reviewers to assess the relevance and quality of a chapter or article.

Chapters or articles submitted without references or that do not follow the formatting style outlined here will be returned to the author(s) for revision in accordance with the guidelines before the submission can be sent for review.

Please note the following before beginning the references:

- Do not use the Ibid/Op cit system of referencing;
- Do not use endnotes or footnotes as supplemental information to the text – 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 quotation marks for journal, book, chapter, or article titles;
- Do not link titles in references to the original source – always provide the full URL;
- Do not include PMIDs and PMCIDs; and
- The DOI number should always be preceded by the *https://doi.org/* construction, as in the following example: <https://doi.org/10.1007/s43441-024-00661-2>

See pp. 9-11 for specific examples of references.

General guidance

- Use the primary source for a document. For example, if an FDA guidance has been posted on the agency's site and multiple others, use the version posted on the FDA site instead of linking to a copy of the document on, say, a consulting firm's website.
- The superscripted in-text citation numbers (e.g., 1-4 in the example below) should be presented in increasing numeric order.
- The superscripted in-text citation number should go after the punctuation:
... a comprehensive overview of risk strategy.⁴⁵
- The sources in the Reference list should be presented sequentially, in increasing numeric order, and correspond to the order in which they are first cited in the text.

The example below and continuing on p. 8 shows how the text citations (in yellow) and the references (under the heading *References*) are styled in the text.

Example

In a 2019 survey of 100 pharma and bioscience companies, the anticipated spend will equate to 50% of the industry's allotted 2022 marketing budget.¹ The growth of digital advertising spend is not surprising considering the 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.²⁻⁴

References

All references were last checked and verified on 6 March 2024.

1. 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
2. Zhao Y, Zhang J. Consumer health information seeking in social media: A literature review. Health Information & Libraries J. Published December 2017. Accessed 10 October 2022. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/hir.12192>

3. 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
4. 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-digital-social-media-platforms-to-meet-b>

BASIC ELEMENTS OF A REFERENCE	
<i>Element</i>	<i>Example</i>
Name of content originator (e.g., author or agency)	<p><i>Authors</i></p> <p>(One) Agwuegbo CA. Article title ... (Two) Agwuegbo CA, Olsen DJ. Article title ... (Three) Agwuegbo CA, et al. Article title ...</p> <p><i>Agencies</i></p> <p>Food and Drug Administration. Article title ... European Medicines Agency. Article title ...</p>
Title of document, sentence case, unless it is a law – do not use italics or quotation marks	<p><i>Article</i> The primary cilium as a therapeutic target in ocular diseases. <i>Law</i> Federal Food, Drug, and Cosmetic Act.</p>
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.
<i>Print</i>	
Year;Volume(Issue):page range	2009;296(1):43-50.
Page-range numbers are separated with a hyphen	2016;48(6):109-128
<i>Print example</i>	
6. Sun J, et al. Improvement in cardiac function after bone marrow cell therapy is associated with an increase in myocardial inflammation. <i>Am J Physiol Heart Circ Physiol</i> . 2009;296(1):43-50. Verified 10 October 2022.	
<i>Online</i>	
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.
Include the original date on which the author(s) accessed the article through the URL.	Accessed 15 January 2020.
URL hyperlinked to source	https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(22)00282-8/fulltext
<i>Online example</i>	
7. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. <i>Front Pharmacol</i> . Published online 26 June 2020. Accessed 10 October 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/	

Accessed, Verified, and Last Checked and Verified dates

Authors must include either an Accessed or Verified date with each Reference entry in the submitted article. These dates will likely not be identical for all references since research will likely have been done over a period of days or even weeks, and not in a single day.

- The **Accessed date** informs the reader when the author(s) *accessed* an *electronic* source during preparation of the content; the date must be followed by the active URL to that source; and
- The **Verified date** informs the reader when the author(s) *read* a *print-only* source during preparation of the content; see reference examples for Books (whole and chapter) and Journal article (print only).

Once the article has been edited, which includes checking and verifying each reference, the editor will add a Last Checked and Verified tagline above Reference 1 to confirm that all the reference sources are current, accurate, and accessible (if electronic). This is an internal editorial function – this information is not needed in the initial submission of the article. The tagline is in italics:

References

All references were last checked and verified on 6 June 2023.

1. International Council for Harmonisation. Stability testing of new drug substances and products – Q1A (R2). Dated 6 February 2003. Accessed 16 April 2023.
<https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf>
2. Venables WN, Ripley BD. Modern Applied Statistics With S. 4th ed. Springer; 2003. Verified 25 April 2023.

Examples of style for specific references

Act

16. 21st Century Cures Act, HR 6. 114th cong. Accessed 16 April 2023.
<https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

Article or document in a language other than English

7. [In French] Le Ministère de l'Éducation 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>

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.

Book, whole

8. Venables WN, Ripley BD. Modern Applied Statistics With S. 4th ed. Springer; 2003. Verified 10 October 2022.

US Code, Section

14. 21 USC 355: New drugs. Current as of 13 December 2023. Accessed 13 December 2023.
<https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section355&num=0&edition=prelim>

US 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>

US 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>

EU regulations

16. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Published 5 May 2017. Accessed 10 October 2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>

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>

Guidance, US draft (no US after Food and Drug Administration)

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, US final (no US after Food and Drug Administration)

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>

Guideline, ICH

34. International Council for Harmonisation. Stability testing of new drug substances and products – Q1A (R2). Dated 6 February 2003. Accessed 16 April 2023.

<https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf>

Guideline, USP

14. US Pharmacopeia. <1225> Validation of compendial procedures. Pharmacopeia Online. Not dated. Accessed 16 April 2023. http://www.uspbpep.com/usp29/v29240/usp29nf24s0_c1225.html

Guideline, adding country name after agency title if the country's name is not part of the agency title

6. National Agency for Food & Drug Administration & Control [Nigeria]. Guidelines for production inspection of chemical manufacturing facilities in Nigeria 2023. Effective 19 January 2023. Accessed 18 May 2023.

https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/CHEMICAL_GUIDELINES/Guideline-For-Production-Inspection-Of-Chemical-Manf-Facilities.pdf

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/>

Legal documents

3. US District Court for DC. 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

News release

7. US FDA accepts new drug application for GSK's momelotinib for the treatment of myelofibrosis [news release]. GSK. 17 August 2022. Accessed 6 June 2023. <https://www.gsk.com/en-gb/media/press-releases/us-fda-approves-gsk-s-arexvy-the-world-s-first-respiratory-syncytial-virus-rsv-vaccine-for-older-adults/>

Package insert/ prescribing information (US)

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

Product information (EU)

32. European Medicines Agency. Aubagio [summary of product characteristics]. Last updated 22 August 2023. Accessed 29 October 2023. https://www.ema.europa.eu/en/documents/overview/aubagio-epar-summary-public_en.pdf

Podcast

22. Oliver A (host). The language of regulation [audio podcast episode]. Institute of Regulation. Released 3 November 2023. <https://ioregulationpodcast.buzzsprout.com/2163449/13901372-episode-4-the-language-of-regulation>

Presentation at a conference

21. Du X, et al. Orally available small molecule CD73 inhibitor reverses immunosuppression through blocking of adenosine production. Paper presented: American Association for Cancer Research Virtual annual meeting; 27 April 2020. Accessed 10 October 2022. <https://www.abstractsonline.com/pp8/#!/9045/presentation/10523>

Report to US Congress

19. 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>

Website article, agency

24. 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

Website article, news

16. Eglovitch JE. FDA officials offer CMC advice for gene therapies at OTP town hall. Regulatory Focus. Published online 25 April 2023. Accessed 26 April 2023. <https://www.raps.org/news-and-articles/news-articles/2023/4/fda-officials-offer-cmc-advice-for-gene-therapies>

TABLES AND FIGURES

Tables consolidate and/or summarize complex information in grid form so that it is accessible and easy for the reader to scan and comprehend. Figures depict information in graphic form for the same purpose as tables. Information in tables and figures should support aspects of the text rather than duplicate them.

A table should preferably be no longer or larger than an A4 or Letter-size page with normal margins and information presented in 10-pt Calibri in portrait orientation. If that is not possible for a table, then consider presenting the information in two or more smaller tables. The type size should not be reduced to fit the table on the page. Text-dense tables should be no more than four columns wide and always be in the portrait orientation.

Figures should also be simplified or split into smaller figures if they do not fit on a single print page. In general, there should be no more than one table or figure per 900 words of text.

Tables

Requirements for submission

Tables for a book chapter should be submitted in an editable Word document, separate from the chapter text Word document. Each table should start on a new page.

Tables with articles can be embedded withing the article body text. They must be editable.

They must not be submitted as images or PDFs.

Each table should:

- Be as complete and comprehensive as possible and include all elements outlined below; and
- Not include tabs and hard returns. If it does, it will have to be recreated, which will cause delays and increase the risk of errors being introduced.

Table style and elements

BASIC ELEMENTS OF A TABLE	
<i>Element</i>	<i>Style</i>
Table identifier 10-pt Calibri, bold	Table 10-6. 10 denotes the chapter number; 6, the order in which the table is placed in the body text. A table for an article would simply be Table 6 , if it is the sixth table placed in the article. Note the use of the period at the end.
Title (incl. table identifier) 10-pt Calibri, bold	Table 10-6. Acceptable Intake Limits for Elected Nitrosamines in Drug Products¹⁷ Title cased for books, sentence cased for articles; no period at end of title articles. If the table is sourced from a published article/book, it should have a superscripted citation number at the end of the title, and the source should be in the Reference list.

Body 10-pt Calibri	<p>Column headings – Title cased in bold; first column header is always flush left; second to final column headers are centered.</p> <p>Row headings – Title cased in roman, set flush left.</p> <p>Cell information – In roman, and, in general,</p> <ul style="list-style-type: none"> • If the cell information is in number form (e.g., data), it is centered across the column width. • If the cell information is in text form, it is set flush left.
End-of-Table/footnotes 9 pt Calibri	<p>Set flush left, with extra space between Abbreviations, Notes, and Source</p> <p>Abbreviations – Abbreviation first, with expanded version in roman. Comma after the abbrev; semicolon after the expansion.</p> <p>Notes – Denoted with superscripted lowercased letters. Notes run on consecutively and are not stacked:</p> <p>AAD, antibiotic-associated diarrhea; GI, gastrointestinal.</p> <p>^aLorem ipsum dolor sit amet consectetur adipiscing elit, sed do eiusmod tempor incididunt. ^bUt labore et dolore magna aliqua. ^cUt enim ad manim veniam, quis nostrud exercitation.</p>

Example of basic table

Table 8-4. Changes in Functional Claims for Health Foods

No.	Current Functional Claims	New Functional Claims
1	Immune regulation, enhances immunity	Helps enhance immunity
2	Delays aging, anti-oxidation	Helps anti-oxidation
3	Memory improvement, assists memory improvement	Assists memory improvement
4	Eyesight improvement, alleviates eye fatigue	Alleviates eye fatigue
5	Clears and nourishes the throat, clears the throat	Clears and nourishes the throat

Example of table with abbreviations, notes, and references

Table 32-3. Synopsis of Selected Reviews of Probiotics in Specific Fields

First Author Name	Review Description
<i>GI-related</i>	
McFarland, et al. ⁹	Strain-specific outcomes for IBS
Ford, et al. ¹⁰	Systematic review for IBS
Kaminski, et al. ¹¹	Systematic review of probiotics and usefulness in chronic constipation ^a
<i>Immune Support</i>	
Rashidi, et al. ²	Systematic review of probiotics on incidence of URTIs
Miller, et al. ⁶	Systematic review on immune function in healthy elders ^{a,b}
Farahmandi ¹³	20-year review of probiotic meta-analysis on disease prevention ^c

AAD, antibiotic-associated diarrhea; **IBS**, irritable bowel syndrome; **URTI**, upper respiratory tract infection.

^aLorem ipsum dolor sit amet piscing elit, sed do eiusmod tempor incididunt. ^bUt labore et dolore magna aliqua. Ut enim ad minim veniam, quis ullamco laboris nisi ut aliq. ^cEnim ad minim veniam, quis nostrud exercitation ullamco laboris nisi.

Table placement and first in-text mention

Each table will have a unique identifier denoting the chapter and the order in which the table is placed in the text, presented in the following sequence: Table 9-3. This is a table in chapter 9 of the book and is the third table placed in the chapter text.

Tables with articles are denoted simply as Table 1, Table 2, and so on, depending on the placement sequence in the text.

All tables must be mentioned in the text preceding the placement of the table. Tables should not be placed in the chapter text Word document when the manuscript is submitted. **They should be provided in a separate Word document and will be included in the text during layout and design stage.**

Example

Each of the violations noted within the five warning and six NoV letters that were analyzed (including those regarding Google) is summarized in **Table 16-7**. Some letters contained more than one violation.

Table 16-7. Violations Contained Within Warning and Notice of Violation Letters

Type of Violation	Violations in Untitled Letters	Violations in Warning Letters	Total Violations
False or misleading risk presentation	6	4	10
False or misleading claims about efficacy	3	1	4
Failure to submit under form FDA-2253	1	—	1
... [table continues]			

Use of the em dash. In the preceding table, note the use of the em dash in the last cell of Column 3 to denote that there are no data for this cell.

Tables with reference citations

Reference citations in tables should be:

- Flagged in bold in the first in-text mention of the table in the chapter Word document – see (Table 2-9¹⁰⁻¹⁵) in the example below.
- Assigned citation numbers in increasing numeric order following on from the last citation number in the text preceding the table; and
- Included in the Reference list in the chapter Word document in increasing numeric order, the same as for in-text citation numbers.

In the actual table in the separate Word document, reference citations are placed next to the relevant information, as shown in the following example.

Example of Table with reference citations

Sed ut perspiciatis unde omnis iste natus error sit voluptatem⁶⁻⁸ accusantium doloremque laudantium, totam rem aperiam, eaque ipsa quae.⁹ Ab illo inventore Veritatis, including health claims (Table 2-9¹⁰⁻¹⁵).

Table 2-9. EU Health Claims Status as of June 2022¹⁰

Type of Claim	Received	Withdrawn	Adopted	In Progress or Under Validation	Authorized by EU/Member State	% Authorized
Article 13.1 (general function) ¹¹	4,637	331	2,849	2,078 ¹²	229	5
Article 13.5 (new science/proprietary) ¹³	218	43 ¹⁴	163	3	12	6
Article 14.1a (disease risk reduction) ¹⁵	74	26	45	1	14	19

Nemo enim ipsam voluptatem quia voluptas.¹⁶ Neque porro quisquam est, qui dolorem.¹⁷⁻²¹ Enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi.

Figures

Requirements for submission

- Figures must be created in editable PowerPoint, Adobe Illustrator (.ai or .svg), Adobe InDesign (.indd), or Adobe Photoshop (.psd) formats.
- Actual data for plotting figures or charts must be provided in Excel.

The preceding requirements for submitting figures are preferable. However, images of figures can be sent as TIFF, JPEG, PNG, GIF, or BMP files provided they are high resolution, or hi-res, which is a minimum of A4 or Letter size if the resolution is 72 dpi. The following will not be accepted:

- Digital figures created in CAD, Visio, or other drafting programs.
- Figures embedded as graphics in a Word or multipage PowerPoint document.
- Figure image files that do not meet the stipulated requirements for hi-res.

Figure style and elements

BASIC ELEMENTS OF A FIGURE	
<i>Element</i>	<i>Style</i>
Figure identifier 10-pt Calibri	Figure 12-9. 12 denotes the chapter; 9, the order in which the figure is placed in the body text. A figure for an article would be Figure 9 , if it is the ninth table placed in the article. Note the use of the period at the end.
Title (incl. figure identifier) 10-pt Calibri	Figure 12-9. Social Media Platforms Noted in Issued Warning Letters¹⁷ Title cased for figure, sentence cased for article; no period at end of title. If the figure is sourced from a published article/book, it should have a superscripted citation number at the end of the title, with the source noted in the Reference list.
Body text, headings 10-pt Calibri	Headings should be title cased
Legend 10-pt Calibri	A legend should describe and explain a figure and should not repeat information in the text. It should be: <ul style="list-style-type: none"> • In bold; • No longer than 50 words, including spaces; and • Written in sentence format as a single paragraph.
End-of-Table/footnotes 9-pt Calibri	Set flush left, with extra space between Abbreviations, Notes, and Source line. Abbreviations – Abbreviation first, with expanded version in roman. Comma after the abbreviation; semicolon after the expansion. Notes – Denoted with superscripted, lowercased letters. Notes run-on.

Authors must provide a source for each figure submitted with the chapter. If a figure is generated by the authors, then the source line should read:

Created by Firstname Lastname. Source: Medicines and Healthcare products Regulatory Agency.

Authors are responsible for obtaining permission to publish any figures or illustrations that are protected by copyright, including figures published elsewhere. This permission should be obtained **before** the chapter or article is submitted for review. Figures without appropriate permission for use cannot be published.

Figure placement and first in-text mention

Each figure will have a unique identifier denoting the chapter and the order in which the figure is placed in the text, presented in the following sequence: Figure 11-9.

All figures must be mentioned in the text preceding the placement of the figure, with the first mention in bold. They should not be placed in the chapter text Word document. **Figures should be provided in a separate, editable PowerPoint and will be included in the text during layout and design stage.**

Figures with reference citations

Reference citations in figures should be:

- Flagged in bold in the first in-text mention of the figure in the chapter text Word template;
- Assigned citation numbers in increasing numeric order following on from the last citation number in the text preceding the figure; and
- Included in the Reference list in the chapter Word document in increasing numeric order, the same as for in-text citation numbers.

In the actual figure in the PowerPoint, reference citations are placed next to the relevant information as superscripted Arabic numerals.

STYLE AND USAGE

Grammar describes how a language is structured. It provides the rules for grouping the components or elements of the language in a particular relational sequence to form clear, cohesive sentences, which are the basis of good, accessible writing. The grammatical elements of English include nouns, verbs, pronouns, adjectives, adverbs, prepositions, conjunctions, and articles or determiners. This section aims to address certain elements of grammar and language usage to help authors avoid common errors and ambiguities that can diminish content quality and, ultimately, its value to the reader. Punctuation is a component of grammar and is addressed in a separate section on pp. 26-35.

Grammar and correct and preferred usage

Contractions

Avoid use of contractions, such as *don't* and *isn't* in body text, unless they are used in a direct quotation. Instead, write out the contraction in full – for example, *do not* instead of *don't*, *is not* instead of *isn't*, *we will* instead of *we'll*, and *I would* instead of *I'd*.

It's and its. The use of an apostrophe in a contraction indicates that letters are missing. This is particularly helpful in understanding the difference between *its* and *it's*.

It's best practice for a company to update **its** policies regularly.

In this example, *its* is the possessive form of the pronoun *it*, which refers to the company. Note that the rule of grammar stipulating that possessives be denoted with an apostrophe *s* does not apply in this case. That is so the *'s* construction can be used for *it's*, the contraction of *it is*. Here, the apostrophe indicates the *i* in *is* has been left out.

Pronouns and gender-specific and gender-neutral language

A **personal pronoun** is a word that can be used instead of a noun (e.g., woman/*she*) or noun phrase (to the woman/*to her*; of the woman/*hers*). It can be singular or plural. There should be pronoun-verb agreement, the same as with nouns and verbs, though there is an exception to the latter rule with certain uses of *they*, *them*, *their*. Some pronouns are gender specific, and others, gender neutral. **Always use a person's stated choice of pronoun.**

PERSONAL PRONOUNS	
<i>Gender specific</i>	
Third person, singular	She [subject] her [object, possessive]
	he, him, his
<i>Gender neutral</i>	
Singular	
First person	I, me, mine
Second person	you, your, yours
Third person	it, its/one, one's
Plural	
First person	we, us, their
Second person	you, your
Third person	they, them, their Can also be used as singular pronoun of choice

***they, them, their* as a singular pronoun.** Some individuals use the gender-neutral pronouns *they, them, their* as their pronouns, along with the plural form of the verb:

The commissioner said they plan to oversee the revision of the guideline.

The singular *they/their* construction. In addition to the preceding example of the singular use of *they*, the words *they* and *their* can also be used as singular pronouns when the plural form could be unwieldy or unclear.

Pronouns for transgender individuals. A transgender person's gender identity differs from the sex the person was assigned at birth. Always refer to a transgender person in accordance with their choice of pronoun.

Avoiding use of gender-specific pronouns. Sentences can often be constructed so that no gender-specific pronoun is necessary.

Use Regulatory professionals can make important contributions to their employers' organizational strategies ...

Instead of A regulatory professional can make an important contribution to his/her/their employer's organizational strategy ...

Avoiding the *you* construction. Use *one* instead of the *you/yours* construction unless it is in a quotation.

Use One should check with the agency before submitting one's application.

Instead of You should check with the agency before submitting your application.

There may be some flexibility in using the *you* construction in how-to content or in writing that focuses on recommendations and/or coaching, but such efforts to directly address the reader should be judiciously applied.

A **relative pronoun** is used to introduce a relative clause. Relative clauses modify – that is, describe or expand upon – a word or phrase elsewhere in a sentence.

RELATIVE PRONOUNS AND RELATED FUNCTION IN SENTENCE		
<i>Pronoun</i>	<i>Function</i>	<i>Example</i>
who/whom	Subject/object of verb or preposition, used for a person	The regulators who reviewed the application ... The regulator to whom it was addressed ...
whoever/whomever		
that	Refers to a specific object/institution/animal/condition	The agency that submitted the application ...
which [preceded by comma]	Adds information about an object/institution/animal/condition	The company, which also manufactures devices, had to resubmit ... The application was resubmitted to the agency, which gave it a priority review designation.

Spelling

Use standard American spelling, for example, *organize*, not *organise*; *legalize*, not *legalise*; *labor*, not *labour*; *standardization*, not *standardisation*; *aging*, not *ageing*; and *center*, not *centre*.

However, if a word is used in a quotation; in the name of an organization, law, or regulation; or as part of a book, chapter, article, or newspaper title or headline, it should be spelled the same as it is in the original text:

- International Council for **Harmonisation**
- **Organisation** for Economic Co-operation and Development
- Japan's Ministry of Health, **Labour** and Welfare
- European **Centre** for Disease Prevention and Control
- Data Analysis and **Real World** Interrogation Network (DARWIN EU)

Preferred spelling

Payer (not payor)
 Adviser (not advisor)
 Inquiry (not enquiry)
 controlling, controlled
 labeled, labeling

One word – eyedrops lifecycle healthcare caregiver flowchart

Two words – end point decision making decision maker

Write out in full

Examination (not exam)
 Influenza (not flu)
 Laboratory (not lab)
 pharmaceutical industry (not pharma)

One or two words, depending ...

Postpartum, when used attributively (before a noun)
 ... diagnosed with postpartum depression

Post partum, when used predicatively (after a noun)
 ... diagnosed with depression post partum

Postmortem, post mortem
 A postmortem examination revealed ...
 An examination post mortem revealed ...

Non-English words or phrases

Non-English or Latin words or phrases should not be set off in italics: ad hoc, in vitro, in vivo, post hoc, prima facie.

The phrases are not hyphenated when used adjectivally: prima facie evidence, post hoc testing

Vocabulary and correct and preferred usage

Instead of ...	Use ...
be granted access to	have access to
compared to, as compared to/with, in comparison to/with	compared with
each of the	each
electronic health record (EHR)	electronic medical record (EMR)
employs [a template]	uses [a template]
experts say	data show (always include supporting references)
for the treatment of	for treating
have an effect on	affect
have an impact on	impact, or affect
in order to, so as to, in an effort to	to
need for having	need for
normal range	reference range
postmarketing	postmarket
prior to	before
risk-benefit	benefit-risk (with a hyphen, not colon or virgule)

subject	participant, patient
takes care of planning and creating	plans and creates
there exists	there is
to provide clarity	to clarify
to utilize	to use
to author	to write
utilization	use
we are now seeing a change	there is a change

Distinctions in meaning

Word/term	Meaning
goal/aim/objective/purpose	<i>goal</i> refers to something one works toward achieving <i>aim</i> refers to something one tries or plans to achieve <i>objective</i> refers to something one plans to do or achieve <i>purpose</i> refers to the reason for doing something
normally vs. usually usually vs. generally typically vs. normally, usually, generally	Can be used interchangeably as indefinite adverbs, although: <i>normally</i> is used if there is an associated standard or norm <i>usually</i> is used if something is customary or habitual <i>generally</i> is used if something is considered universal or common, “as a whole,” or in a collective sense – in every case <i>typically</i> is used if something is representative of an example
deem vs. consider	<i>deem</i> means to think or judge <i>consider</i> means to have an opinion
appears vs. seems	<i>appears</i> is used in reference to facts and events <i>seems</i> is used in reference to facts as well as feelings and ideas
range vs. variety	<i>range</i> refers to sequence or scale between certain limits <i>variety</i> refers to a collection or grouping of different things
about vs. approximately	<i>about</i> – reasonably close to <i>approximately</i> – nearly correct or exact
past 15 years vs. last 15 years	<i>past 15 years</i> refers to the period of time that began 15 years ago, in 2008, and continues until the present (2023) <i>last 15 years</i> refers to the final portion of time in a longer period of time(e.g., the last 15 years of the 20th century)
clinical trial vs. observational study	<i>clinical trial</i> – participants are assigned to one or more intervention <i>observational study</i> – participants are not assigned to an intervention; researchers collect information from participants or from existing records

Defining stakeholder and sponsor in a text

The words *sponsor* and *stakeholder* should always be defined within the context of a given chapter or article.

A *sponsor* can be an individual, an academic institution, a pharmaceutical or medical device company, a government agency, or private or public organization. It is therefore important to clarify at the first mention of the word in the text which of those entities are implied when the word *sponsor* is used throughout the chapter or article.

The same logic applies to use of the word *stakeholder* or *stakeholders*. Companies, academic institutions, suppliers, manufacturers, investors, employees, management, patients, customers, and government entities could be considered stakeholders. Authors should clarify which entities or groups are implied in reference to stakeholders.

Editors should request these clarifications at the editing stage if they are missing from the text.

Document titles – Laws/acts, regulations, directives, and guidance

Laws and acts. The title of a US law or act should be written out in full the first time it is cited in a text. It should be title cased and followed with the abbreviated or shortened form if it is used more than once in the text. The first mention of the law or regulation should be cited as a reference.

The title must not be italicized or placed within quotation marks.

Examples of US law titles

Affordable Care Act (ACA)¹²
 Federal Food, Drug, and Cosmetic Act (FDCA)⁴
 Federal Trade Commission Act (FTCA)⁹
 Medical Device User Fee Amendments (MDUFA)¹¹
 Prescription Drug User Fee Act (PDUFA)⁴

But

21st Century Cures Act (Cures Act)¹⁶
 Biologics Price Competition and Innovation Act (BPCI Act)¹⁹
 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)²³
 Agriculture Improvement Act of 2018 (2018 Farm Bill)³¹

Directives and regulations. Titles of EU regulations and directives present challenges because the same piece of legislation can be referred to in three different ways, using:

- The long title of the original European Commission document verbatim and which includes related repeals and amendments and the date. This version is not used in the text but is included in the Reference entry for the legislation (see p. 9);
- The EU bureaucratic code for the legislation, for example, Regulation (EU) 2017/746 for the EU IVDR; or
- A shorter, more informal and descriptive form of the title, which can be abbreviated and more easily incorporated into text and is used more widely in conversations and presentations, for example, EU CTR.

Examples of EU regulation and directive titles

EU Medical Devices Regulation (EU MDR), also known as Regulation (EU) 2017/745,³ ...
 EU Medical Devices Directive (EU MDD), also known as Directive 93/42/EEC,⁹
 EU Active Implantable Medical Devices Directive (EU AIMDD), also known as Directive 90/385/EEC, ...

EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR), also known as Regulation (EU) 2017/746,⁶ ...
 EU In Vitro Diagnostic Medical Devices Directive (EU IVDD), also known as Directive 98/79/EC,¹²

[not IVD, which is the abbreviation for in vitro diagnostic medical device]

EU Clinical Trials Regulation (EU CTR), also known as Regulation (EU) No. 536/2014,²
 EU Clinical Trials Directive (EU CTD), also known as Directive 2001/20/EC,¹⁰

EU Clinical Trials Regulation (EU CTR), also known as Regulation (EU) No. 536/2014,²
 EU Clinical Trials Directive (EU CTD), also known as Directive 2001/20/EC,¹⁰

EU Paediatric Regulation, also known as Regulation (EC) No 1902/2006,⁷

[no abbreviation -- subsequently referred to as the EU Paediatric Regulation in full or the regulation, if it is the only regulation mentioned in the chapter or article.]

EU Artificial Intelligence Act (EU AI Act), also known as Regulation (EU) 2024/1689,¹⁵

Guidance documents. The full titles of guidance documents must not be written out in full on first mention. These titles can be long, unwieldy, and awkwardly structured. They are intrusive when written out in full, especially if they are italicized or in quotation marks, and seldom fit with the flow or meaning of particular sentence. The first mention of a guidance can be an edited version of the full title, presented as a shorter, easily understood descriptive phrase that flows easily with the sentence.

Use The FDA has also released new guidance **on using RWD and RWE to support regulatory decision making**,¹⁵ which includes clarification of its evidentiary expectations for clinical study designs that use RWD.

Instead of The FDA has also released new guidance titled, “**Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products,**”¹⁵ including clarification of its evidentiary expectations for clinical study designs that use RWD.

ICH guidelines. The full titles of ICH guidelines need not be written out in full on first mention. ICH has an established naming convention for its guidelines, and it would be sufficient to follow that convention and name the category into which the guideline falls – quality, safety, efficacy, or multidisciplinary.

Use The ICH Q11 quality guideline on the development and manufacture of drug substances, which was implemented in May 2012, applies to small molecules and biologicals.³

Instead of The “Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities) Q11” guideline was implemented in May 2012 and applies to both small molecules and biologicals.³

Quotations from laws and regulations

Avoid using lengthy, verbatim block quotes from laws or regulations that are offset by quotation marks. These texts can be grammatically convoluted and repetitive and are intrusive in the chapter/article context. Such language is acceptable in original legal or regulatory documents, where the purpose is to document requirements and expectations that will need to be followed and enforced. In chapters and articles, the purpose is to inform readers accurately and clearly. The author is an intermediary between the complex legal text and the reader and should distill the information and present it to the reader in a succinct, easy-to-understand form. In these cases, it is preferable to provide a brief description or synopsis of the quotation, along with a citation to the original source.

Use The EU CTR requires special considerations for vulnerable populations (e.g., pediatric, pregnant or breastfeeding women, women of childbearing age), including that individuals who assess applications for authorization of clinical trials in these populations should be experts in those fields.¹²

Instead of The special considerations for vulnerable populations (pediatric, child-bearing-age women, pregnant or breastfeeding women) are elaborated further in the EU CTR as summarized in this section of this article.

1. “Where human subjects are minors, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of pediatric expertise or after taking advice on clinical, ethical and psychosocial problems in the field of pediatrics.
2. Where the subjects are incapacitated subjects, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of expertise in the relevant disease and the patient population concerned or after taking advice on clinical, ethical and psychosocial questions in the field of the relevant disease and the patient population concerned.
3. Where the subjects are pregnant or breastfeeding women, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of expertise in the relevant condition and the population represented by the subject concerned.
4. If according to the protocol a clinical trial provides for the participation of specific groups or subgroups of subjects, where appropriate, specific consideration shall be given to the assessment of the application for authorisation of that clinical trial on the basis of expertise in the population represented by the subjects concerned.
5. In any application for authorisation of a clinical trial referred to in Article 35, specific consideration.”¹²

This guideline should also apply to shorter quotations (**bold** is used to highlight the distinctions – it is not a reflection of style):

Use Additionally, ICH Q11 reinforces the same principle, stating that **the GMP provisions in ICH Q7 apply to each branch at the first use of a starting material.**¹

Instead of Additionally, ICH Q11 reinforces the same principle, stating that “**The Good Manufacturing Practice (GMP) provisions described in ICH Q7 apply to each branch beginning with the first use of a starting material.**”¹

Use These considerations, which should be combined with ICH Q11’s **requirement that the application describe the manufacturing process for the drug substance so that regulatory bodies will understand how impurities are formed during manufacturing; how process changes might affect the formation and purging of impurities; and the suitability of the proposed control strategy.**¹

Instead of These considerations, which should be combined with ICH Q11's claim that “**enough of the drug substance manufacturing process should be described in the application for regulatory authorities to understand how impurities are formed in the process, how changes in the process could affect the formation, fate, and purge of impurities, and why the proposed control strategy is suitable for the drug substance manufacturing process,**”¹ explain the tendency from regulatory authorities to push the designation of RSMs as backward as possible in the overall route of synthesis.

Note that in the second example, the rewritten version is not much shorter than the original, but it fits better with the sentence flow and still conveys the necessary information.

Highlighting a word or phrase when defining it

Italicize a word or phrase when defining its meaning. Do not use quotation marks.

Examples

The term *commercially confidential information* refers to any information included in the CTA or shared throughout the trial lifecycle that could potentially harm the legitimate economic interests or competitive position of the sponsor (or later the applicant/holder of the marketing authorization) of the trial.

The term *label* refers to any information provided with medicines according to country-specific regulations.

In the EU, the term *electronic product information*, or ePI, describes ...

Collective nouns

Data, media, and criteria take the plural form of the verb – *the data/media/criteria are*

However, *team, staff, committee, audience, company, agency, hospital, industry, and profession* all take singular verbs.

Use of a and an

The rule for using *a* or *an* before a noun is literally to “play it by ear.”

If the first letter of the word or abbreviation is an aspirated h or a consonant sound (e.g., *historic, digital, UN*), then use the article *a*:

- a historic event
- a digital publication
- a UN motion

If the first letter of the word or abbreviation is unaspirated h or a vowel sound (e.g., *honor, NDA, application*), then use the article *an*:

- an honor
- an NDA submission
- an application

Emphasis

Do not use uppercase, boldface, italics, underscore, or exclamation marks to emphasize a point. Also avoid use of words such as *dramatic* and *very* – words such as *notable* or *significant* may be better suited to writing in the regulatory setting.

Drug and biologics names

Drugs have a brand or proprietary name and a generic or nonproprietary name, for example, Keytruda (pembrolizumab). The brand name is the manufacturer's assigned name for the drug and is always capitalized; the generic name usually refers to the drug's active ingredient and is always lowercased and written in parentheses after the first mention of the brand name. After the first mention of the combined brand and generic names, use only the brand name, for example, Neulasta (pegfilgrastim) and then Neulasta alone thereafter.

Some drug names are stylized in all capital letters. Do not apply this treatment to brand drug names; the initial capitalization of the proprietary name will be sufficient for RAPS publications.

Different manufacturers can produce and market the same generic drug and each can assign their drug a unique brand name. The generic name is always the same for a given drug, even if the brand names vary, because the chemical composition of the generic's active ingredient does not change – it is consistently identical to that of the original reference drug.

However, the same does not apply to biosimilars. They are made from living organisms and there is some inherent variation across lots. They are therefore not identical to the reference drug but are sufficiently similar to it to achieve the same therapeutic and clinical effects in patients. Both the brand and generic names of a biosimilar are different from the reference drug and its generic. The FDA has stipulated a specific nomenclature for a biosimilar generic – a combination of the reference drug's generic name and a distinguishing suffix of four lowercased letters that has no meaning, separated by a comma:

- Stimufend (pegfilgrastim-fpgk) – reference drug, Neulasta (pegfilgrastim)
- Fylnetra (pegfilgrastim-pbbk) – reference drug, Neulasta (pegfilgrastim)
- Cimerli (ranibizumab-eqrn) – reference drug, Lucentis (ranibizumab)
- Rezvoglar (insulin glargine-aglr) – reference drug, Lantus (insulin glargine)

Patented products may have different brand names for different indications. NovoNordisk's semulglutide, for example, is marketed in the US under three different brand names, depending on the indication:

- **Rybelsus** is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- **Ozempic** is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
- **Wegovy** is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in:
 - Adult patients with obesity or who are overweight with at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes); or
 - Pediatric patients aged 12 years or older with obesity.

Drug names and information should always be checked and verified against the most recently updated information for the product from the agency that approved it. Some sources for doing this would include:

- US, [Food and Drug Administration](#)
- EU, [European Medicines Agency](#)
- UK, [Medicines and Healthcare products Regulatory Agency](#)
- Japan, [Pharmaceuticals and Medical Devices Agency](#)
- Canada, [Health Canada](#)
- Australia, [Therapeutic Goods Administration](#)

There is no direct link for a list of approved drugs in China ([National Medical Products Administration](#)).

RAPS follows the AMA style guideline regarding use of the trademark or registered trademark symbols, which is that the symbols are not used because the capitalization is indicative of it being proprietary.

Medical devices

Classifications. Medical device classes are identified using Roman numerals with *Class* capitalized, as in *Class I*, *Class II*, etc.

510(k) clearance. When referring to the FDA's clearance of medical devices through the 510(k) process, always use the term *clearance* or *cleared*. Do not use approval or approved.

Country names

PREFERRED USE AND NEW NAMES	
Country	Notes
Preferred use	Official title, but not used
Laos	Lao PDR
North Korea	Democratic People’s Republic of Korea
South Korea	Republic of Korea
Taiwan	Republic of China
New name	Original name
Bosnia–Herzegovina	Bosnia
Czechia, Slovakia	Were known together as Czechoslovakia; Czechia was initially known as Czech Republic
Democratic Republic of the Congo (DRC)	Zaire
Kosovo	Formerly part of Serbia
Montenegro, Serbia	Were known together as Yugoslavia
Myanmar	Burma
South Sudan, Sudan	Republic of South Sudan seceded from Sudan in 2011.

Country names after the dissolution of the former USSR – Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan

RAPS global geopolitical regions

The following global regional breakdown reflects the regions denoted in the 2024 Global Regulatory Affairs Professionals Workforce Report. The RAPS’ regions closely align with the United Nations’ geoscheme. Geographically, Russia spans Europe and Asia and is not usually assigned to one or the other region. RAPS has elected to include Russia as part of Europe.

BREAKDOWN OF RAPS GLOBAL REGIONS	
Region	Countries included
Africa	Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Djibouti, Ethiopia, Egypt, Eritrea, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland (Eswatini), Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe
Asia	Includes China, Japan, India, Singapore, Indonesia, South Korea, Taiwan, Philippines, Armenia, Azerbaijan, Georgia, and Turkey, among others
Europe	<p>EU Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden</p> <p>Non-EU European countries – Albania, Andorra, Belarus, Bosnia–Herzegovina, Iceland,^a Kosovo, Liechtenstein,^a Moldova, Monaco, Montenegro, Norway,^a Russia, Serbia, Switzerland,^b and Ukraine</p> <p>UK – England, Scotland, Wales, and Northern Ireland Great Britain – England, Scotland, and Wales</p>
Latin America (LATAM)^c and the	Central America – Belize, Honduras, Costa Rica, El Salvador, Guatemala, Mexico, Nicaragua, and Panama

Caribbean	<p>South America – Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela, the Falkland Islands (Malvinas), South Georgia and the South Sandwich Islands</p> <p>Caribbean – Cuba, Haiti, Jamaica, and Dominican Republic, among others</p>
Middle East	Includes Bahrain, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, the Palestinian territories, Qatar, Saudi Arabia, Syria, United Arab Emirates, and Yemen
North America	US and Canada; Puerto Rico and other US territories [Mexico is part of the LATAM region; see above]
Oceania	Australia, New Zealand, and the islands of Melanesia, Micronesia, and Polynesia

EU, European Union; EEA, European Economic Area; UK, United Kingdom.

^aIceland, Liechtenstein, and Norway are not EU member states but participate in the EU's single market. See notes on EEA on p. 25. ^bSwitzerland, Iceland, Liechtenstein, and Norway make up the European Free Trade Association (EFTA; p. 25). ^cLatin America (LATAM) includes Central and South America).

Regional economic and/or geopolitical groups

ASEAN, Association of Southeast Asian Nations – Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam

BRICS, Brazil, Russia, India, China, South Africa – This is an economic grouping of nations comprising Brazil, Russia, India, China, South Africa, and its most recent new members, Iran, Egypt, Ethiopia, and the United Arab Emirates. BRICS is not a regional geopolitical grouping because the member countries are not neighboring nations. Their commonality is that they are developing countries with expanding emerging national economies that are becoming increasingly active in global markets. Some of these developing economies may have certain features of developed economies, which makes them unique.

The name was originally coined in 2001 as BRIC (referring to the founding countries of Brazil, Russia, India, and China) and was changed to BRICS in 2010, when South Africa was included. Iran, Egypt, Ethiopia and the United Arab Emirates have subsequently joined the group, but the name BRICS has been retained as of October 2024.

It is a challenge to establish a broad style for using this term. The abbreviation is for a list of countries and the expanded version does not describe the group's activity or purpose, as is often the case with organization names (e.g., Regulatory Affairs Professionals Society, or RAPS). In addition, many readers are likely not familiar with BRICS or why it exists. There is also confusion about when to use BRICS and BRIC.

Regarding the BRICS-versus-BRIC question: always use the current, post-2010 abbreviation, BRICS, as we do for all other organizations that have changed their names – for example, ASEAN used to be ASA. (See next section for style for references to the BRIC era.)

Regarding general and first mentions of the abbreviation, note the following:

- Use the abbreviation mostly as an adjective qualifying “country” or “economy,” rather than a standalone noun;
- Always include a boilerplate description of BRICS after the first mention in a text. A starter boilerplate might be:

The economies of the rapidly developing nations of Brazil, Russia, India, China, South Africa, Iran, Egypt, Ethiopia, and the United Arab Emirates (UAE), are collectively referred to as BRICS. The group was previously known as BRIC (Brazil, Russia, India, China) and was changed to BRICS after South Africa joined in 2010. Iran, Egypt, Ethiopia and the UAE have subsequently joined the group, but the name BRICS has been retained.

- After the first mention and accompanying boilerplate, the abbreviation may be used more frequently as a noun if there is no ambiguity of meaning.

Example

The pharmaceutical industry is growing rapidly in the BRICS nations, which are becoming increasingly active in global markets.

MENA, Middle East and North Africa – includes Algeria, Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, the Palestinian territories, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates, and Yemen.

The Palestinian territories include the West Bank and the Gaza Strip, including East Jerusalem.

Unless there is a specific regulatory collaboration among these countries that is being addressed in an article or book chapter, the primary assigned global region for these countries should be:

- **Middle East** – Bahrain, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, the Palestinian territories, Qatar, Saudi Arabia, Syria, United Arab Emirates, and Yemen
- **Africa** – Algeria, Egypt, Libya, Morocco, Tunisia, as part of Africa

EU, European Union – Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden

EEA, European Economic Area – Includes the EU countries, plus Iceland, Liechtenstein, and Norway, which are not EU member states but participate in the EU’s single market.

Note that the European Economic Community (EEC) and European Community (EC) no longer exist and have been replaced by the EU. Under the EU, the European Commission, which is also abbreviated to EC, serves as the EU’s main executive body and proposes new laws and manages most EU policies. Authors should be careful to not confuse the commission with the now-defunct community when writing the expanded version of the abbreviation for EC on the first mention in a text.

EU institutions:

- European Parliament
- European Council
- Council of the EU
- European Commission
- Court of Justice of the EU
- European Central Bank
- European Court of Auditors

EFTA, European Free Trade Association – This is the intergovernmental organization of Iceland, Liechtenstein, Norway, and Switzerland.

UK, United Kingdom – England, Scotland, Wales, and Northern Ireland

Great Britain, or Britain – England, Scotland, and Wales

The **island of Ireland** comprises Ireland (Republic of Ireland), an EU member state, and Northern Ireland, which is part of the UK.

Countries designated to Latin America, Middle East and North Africa (MENA), and Oceania regions are listed the table on p. 24.

Global health and regulatory agencies

Some national or regional health agencies include the name of the country in their titles (e.g., Saudi Food and Drug Administration or European Medicines Agency), whereas others do not (e.g., Australia’s Therapeutic Goods Administration and Japan’s Ministry of Health, Labour and Welfare).

To help readers easily situate agencies whose titles do not include the name of the country/region, use one of the following style options. Note the accompanying abbreviations.

Scheme 1. If the country/region name is not part of the title, then include the name in the possessive form before first mention of the agency and do not include the geographic name in the abbreviation :

- **Australia's** Therapeutic Goods Administration (TGA)
- **Japan's** Ministry of Health, Labour and Welfare (MHLW)
- **China's** National Medical Products Administration (NMPA)
- **Nigeria's** National Agency for Food and Drug Administration and Control (NAFDAC)
- **Indonesia's** National Agency of Drug and Food Control (NADFC)

The possessive is not used for UK and US agencies:

- UK Medicines and Healthcare products Regulatory Agency (MHRA) [note the lowercased *products*]
- US Food and Drug Administration (FDA) [note *US* is used only when the name is written out in full for the first time to introduce the abbreviation. *US* is never used with the abbreviation]

Scheme 2. If the country/region name is part of the title, then write the title as the agency does on its website and include the title letters of the country/region as part of the abbreviation, according to style:

- Saudi Food and Drug Administration (**SFDA**)
- Ministry of Health Malaysia (**MHM**)
- South African Health Products Regulatory Authority (**SAHPRA**)
- Icelandic Medicines Agency (**IMA**)
- Egyptian Drug Authority (**EDA**)
- Tanzania Medicines and Medical Devices Authority (**TMDA**; note the noun, and not adjectival, form of the country name)

Scheme 3. If the name of the agency is in a non-English language, and the abbreviation reflects the non-English language title, then use the following format on first mention of the agency and the abbreviation alone thereafter:

- Mexico's health regulatory agency, COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), ...
- Brazil's health regulatory agency, ANVISA (Agência Nacional de Vigilância Sanitária), ...
- Argentina's health regulatory agency, ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), ...

Exception. In Israel, the Ministry of Health's Pharmaceutical Division is responsible for regulating medical and pharmaceutical products. The Medical Device Division (AMAR) is responsible for medical device registration, submissions, supervision, and control over the manufacture, assembly, sterilization, import, and marketing.

Scheme 4. As noted in Scheme 1, numerous global health agency titles do not include the country name. If a document from one of these agencies is included the references list, then add the country name in brackets after the title of the agency:

6. National Agency for Food & Drug Administration & Control [Nigeria]. Guidelines for production inspection of chemical manufacturing facilities in Nigeria 2023. Effective 19 January 2023. Accessed 18 May 2023.
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/CHEMICAL_GUIDELINES/Guideline-For-Production-Inspection-Of-Chemical-Manf-Facilities.pdf

Notified bodies. A notified body is an organization designated by an EU member state to assess the conformity of certain products with prevailing legislation before the product goes to market.

The European Association of Notified Bodies (Team-NB) focuses on promoting high standards and protecting the interests of member notified bodies active in the medical device sector.

Punctuation

Punctuation comprises a set of codes used in writing to group together or separate the components of a sentence to make it easier to read and understand. Think of punctuation marks as visual guides or “pointers” that help readers understand and absorb the author’s meaning. Good punctuation is integral to good writing. It facilitates text accessibility, readability, and comprehension.

With few exceptions, punctuation marks are always placed inside quotation marks.

Period

The period is the most-used punctuation mark. It is used:

- To denote the end of a sentence;
- In some abbreviations, such as e.g., vs., i.e., et al., etc., p. (page), pp. (pages), No. (number – used in a table or figure), although most abbreviations do not include periods (CMC, Britain’s MHRA); and
- As a decimal point with numbers, for example, 36.9% or $P < .03$ (note the space before the decimal, and there is no zero before the decimal).

Periods precede closing quotation marks and superscripted text citations:

... cross labeling the separately provided constituent parts, where the constituent parts have “mutually conforming labeling.”

... and the FDA withdrew its proposal in 2020.⁷

See pp. 34-35 for use of periods in a Bulleted List.

Periods are not used:

- At the end of chapter or article titles and subheads;
- After authors’ names at the beginning of the chapter or article;
- After a URL or email address;
- For degrees (MSc, PhD, BSc Hons); and
- After the components of abbreviated journal titles using the NLM title abbreviation system for references, although there is a period at the end of the abbreviated title, for example, Eur J Pharm Sci. (for European Journal of Pharmaceutical Sciences).

Comma

Commas are used most commonly to separate a sequence of three or more words or phrases:

... healthcare facilities such as pharmacies, operating theaters, clinics, and military field hospitals.

However, there is no need to use a comma for fewer than three words or phrases, especially if the noun and modifiers can be read as a single entity:

randomized placebo-controlled trial

Use the serial (or Oxford) comma. The serial comma is helpful for eliminating any possibility of ambiguity in technical and/or complex text. It is placed before the conjunction (*and*, *or*) when it precedes the last word or term in a multiterm or multiphrase sentence.

The guidance applies to approved products, those with pending applications, **and** over-the-counter marketed monograph drugs.

Identify major CMC goals for current program stage, for example, new product registration, new formulation, **or** significant manufacturing process change.

The comma with and or but

Use a comma if a sentence is made up of two independent clauses (i.e., they have different subjects), and the clauses are connected by *and* or *but*. In the following examples, the subjects of the respective clauses (in bold) are different, so commas are used before the conjunctions between them:

The principles were tested in a pilot project, **and** **the final report** highlighted several complex challenges in applying these principles.

The principles were tested in a pilot project, **but** **the final report** did not highlight the challenges in applying these principles.

The same use of the comma would apply for *or*, *nor*, *for*, *yet*, *so*.

Offsetting appositives

An appositive is a noun or noun phrase that renames or describes a preceding noun or noun phrase. The appositive and initial noun/noun phrase refer to the same person or entity in slightly different ways but name it in different ways. In the example below, the appositive is highlighted and has been offset by commas before and after it.

Emer Cooke, **the executive director of the EMA**, said the agency would make adjustments for similar types of emergencies.

In keywords (articles only)

Note the respective uses of commas and semicolons in the following article keyword lists:

Keywords – advertising, co-promotion, MLR, promotion

Keywords – advertising; co-promotion; medical, legal, and regulatory; promotion

In the second example, semicolons are used because the basic structure of the phrase *medical, legal, and regulatory* already uses commas. That means that when the phrase is part of a list in which the other words would usually be separated by a so when it is part of a list, semicolons

Offsetting nonrestrictive subordinate clauses

These are clauses – usually introduced by *which*, *that*, *who*, *whom*, or *whose* – that modify a preceding noun or noun phrase:

The final guidance, **issued in July 2022**, also clarifies that review divisions should provide a justification for not conducting these studies.

With author names and degrees

Note the use of commas and semicolons in the following examples:

For an individual

Jorge Carrão, MSc, MPH

Amy Wang, MB BCh, RAC-EU

Joanne Weiss, PhD, RAC (US, EU, Global)

David Olejede, PharmD, RAC-Drugs

For listing author names for a chapter or article (see *Semicolons*)

Jorge Carrão, MSc, MPH; Amy Wang, MB BCh, RAC-Devices; and David Olejede, PharmD, RAC-Drugs

When name and degree(s) are part of a sentence

David Olejede, PharmD, RAC-Drugs, is senior manager in commercial regulatory affairs ...

The construction in the latter example could be used in an author biography. Placing a comma after the final degree provides a visual break between the individual's degrees and the rest of the sentence, making it easier to read. Another way of looking at this construction is that the "PharmD, RAC-Drugs" is used as the appositive, as described on p. 28.

Offsetting in-text use of for example and that is

A combination product is a combination of two or more different types of medical products, for example, a drug and a device, a device and a biological product, or a drug and a biological product.

RWD can be used to guide clinical outcomes research, that is, patient-reported outcomes development.

Colon

When a colon is used within a sentence, the first word following a colon is lowercased, with the following exceptions.

In chapter or article titles

Brexit, three years on: Opportunities and challenges for UK medicines regulation

Introducing a quotation (whether blocked or in running text)

In the Federal Register notice announcing the meeting and calling for public comments,³ the FDA stated:

When the new product is intended to be used with the approved product in a way that is significantly different from ways described in the current labeling of the approved product (e.g., for a different indication, route of administration or dose), refusal by the sponsor of the approved product to submit a supplement may preclude mutually conforming labeling.

Introducing two or more sentences

Yolanda faced a conundrum: She could finish the soup, pretending to enjoy it. She could feign satiety and thank the host for a good meal. Or she could assert her preference for a vegetarian diet.

Introducing a complete question

The question occurred to her at once: What if I can't do this?

Introducing a list

The five elements of the NIST framework core are: identify, protect, detect, respond, and recover.

See pp. 34-35 for use of the colon with a Bulleted List.

With numbers

Use the colon to separate the two numbers in a ratio and the hours, minutes, and seconds in stating time.

The participants were randomized in a 3:1 ratio to receive the study drug or placebo.

The workshop ran from 10:30 am to 1:00 pm.

In references (see pp. 7-11)

Semicolon

With independent clauses

A semicolon denotes a slightly stronger break in a sentence than a comma and is usually used between two long independent clauses.

Nutrition inadequacy remains an issue in certain regions and subpopulations; however, a more prominent problem now is overnutrition, which has contributed to the rapid increase of noncommunicable chronic diseases such as obesity and Type 2 diabetes.

The final rule does not require specific records or forms; customary or reasonable records generated in the normal course of business may suffice.

However, try to avoid overusing the semicolon in this context as it can become intrusive and affect the flow of the text and pace of reading. Often, the clauses can be presented as two self-contained sentences, separated by a period.

For clarity in long and/or complex sentences

However, micronutrient deficiency is still a problem in certain subpopulations, for example, iron deficiency and resulting anemia in children and pregnant women; vitamin D deficiency in school children; and calcium deficiency in all ages and gender groups throughout the country.

For clarity in sentences with serial commas

The lack of clear principles to determine when the labeling of an approved product must be changed to reflect its concurrent use with another product has led to uncertainty in the regulatory process; ad hoc, case-by-case, and/or subjective regulatory decision making; and inconsistent outcomes.

See pp. 34-35 for use of semicolons in a Bulleted List.

Hyphen

Hyphens are used to connect certain words or phrases to facilitate their comprehensibility.

Hyphenate

Asia-Pacific	Likert-type scale
benefit-risk*	online-only
check-in, follow-up, make-up (used as nouns)	pre-2008, post-2016
double-blind	<i>P</i> -value
e-labeling, e-book, e-consent (but email)	real-time assessment (when used adjectivally; two words as a noun phrase – <i>in real time</i>)
false-positive	up-classify, down-classify (preferred use: <i>assigned to a higher/lower risk class</i>)
goodness-of-fit	Wi-Fi (note uppercase use)
governor-elect	
half-life	
HIV-AIDS	

*Always use **benefit-risk** with the word *benefit* first and with a hyphen. Do not use a colon or virgule between the two words, and do not use “risk-benefit.”

Do not hyphenate

One word

caregiver	postauthorization, postapproval, postmarket, postsubmission
email	preapproval, preclinical, presubmission (but pre-authorization)
eyedrops	roundtable
flowchart	subsection
healthcare	website
lifecycle	
online	
onsite inspection (but <i>on site</i> if a noun)	

Two words

check in, follow up, make up (used in the verb form)
 decision making, decision maker
 end point
 real time (as a noun phrase, in real time)
 shelf life
 two thirds of the participants (but *two-third majority*)
 end point

Latin phrases used adjectivally

in vitro diagnostics
 prima facie evidence
 post hoc testing

Compound adjectives before a noun

Adjectives used before a noun are attributive adjectives, and those used after a noun are referred to as predicative. A compound adjective, that is, a descriptive phrase of two more words, is hyphenated if it is used attributively – before the noun it qualifies:

FDA-approved drug or biologic
 FDA-cleared medical device
 direct-to-consumer drug advertising
 first-in-human clinical trial (not *first-in-man*)
 high-risk device types; medium-sized company; low-risk patients
 over-the-counter drug sales
 third-party review
 two-thirds majority (but *a majority of two thirds*)
 well-known author (but *the author is well known*)
 consumer-use studies (but *approved for consumer use*)
 actual-use conditions

Number ranges (p. 8, for references; pp. 41-42, for dates)

Prefixes and suffixes with and without hyphens

PREFIXES	
<i>Without hyphens</i>	
anti	Antithesis, antitrust, but anti-intellectual
bi	bilateral
co	cosponsor, coordinate, cooperate, coauthor, cochair, cosponsor, coworker, but co-owner, co-occur
cyber	cybersecurity
hyper	hyperfocused, hypersensitive, hypercompetitive
inter	international
macro	macroeconomic
mega	megawatt
meta	metastatic, metabolite, but meta-analyses
nano	nanometer
mid	midsized
multi	multinational, multicenter, multisite
non	noncompliance, nonbinding, nonclinical, noninferiority
over	overstate
post	postapproval
pre	preapproval
semi	semiconductor
socio	socioeconomic
re	reevaluate, unless to avoid ambiguity(e.g., <i>resent</i> and <i>re-sent</i>)
super	superconductor
under	underestimate
un	unbiased
<i>With hyphens</i>	
all	all-encompassing
cross	cross-labeling (noun and adjective), cross-functional
ex	Use <i>former</i> instead (e.g., <i>former director</i>)
self	self-report, self-assured
Suffixes	
<i>Without hyphens</i>	
able	manageable
gram	echocardiogram
meter	nanometer
cede/ceed/sede	secede, concede, precede, succeed, proceed, supersede
<i>With hyphens</i>	
elect	president-elect
like	Hyphenate if the root word is three syllables or more (e.g., emulsion-like, business-like) or if the root word ends in <i>L</i> (e.g., trial-like, bell-like); but without hyphens for one- or two-syllable words (e.g., lifelike).
free	dairy-free
type	influenza-type symptoms

Dashes

A hyphen separates two or three standalone words, or an abbreviation and a word, whereas a dash separates a group of words composing a phrase or introduces a break in a sentence for clarity or emphasis.

There are four types of dashes, of which two are commonly applied in writing:

- The em dash (—), which is used for introducing a break in a sentence to emphasize a point or include information that expands on a point already made in the sentence; and
- The en dash (–), which is used for separating words in a noun or adjectival phrase.

En dash

With a noun or adjectival phrase. In the following examples, the phrase associated with the en dash is highlighted in yellow. Note that there is no space before or after the dash:

European Medicines Agency–approved device, but hyphenate EMA-approved
 the then–Ministry of Health and Welfare (now Health Canada)
 non–small cell carcinoma
 lung cancer–like symptoms
 sponsor agency–focused approach
 high-quality machine-learning–enabled medical devices

For introducing a break in a sentence. RAPS also uses the en dash, with spaces before and after the dash, to denote a break in sentence for emphasis or clarity. This is a deviation from conventional use, which advocates the em dash be used without spaces before and after the dash.

RAPS style

Those large clinical sites also present another **problem – stiff** competition for a relatively small potential participant pool.

RAPS elects to use the en dash with spaces because it is less intrusive visually and does not seem to slow down the reader as much as does the closed-up em dash, promoting a more fluid reading of the sentence.

In bulleted lists. Use the en dash, with spaces before and after the dash, for emphasis in a bulleted list. The dash is bold because it follows text in bold:

- **Risk assessment** – Manufacturers must conduct risk assessments to identify potential cybersecurity risks and vulnerabilities.
- **Security controls** – Manufacturers must implement appropriate security controls to mitigate cybersecurity risks.
- **Incident response** – Manufacturers must have procedures in place to detect, respond to, and report cybersecurity incidents.
- **Continuous monitoring** – Manufacturers must continuously monitor the security of their devices and take action to address any new threats or vulnerabilities.

For a minus sign. –273 °C.

Em dash

The only time an em dash is used in book or article text is to denote an empty cell in a table.

Parentheses

To offset additional or supplementary information within a sentence

In writing statistics –

A significantly higher proportion of COVID-19 infections occurred in the vaccinated cohort during omicron dominance ($P < .001$), compared with unvaccinated people.

A P -value more than the significance level (typically, $P > .05$) is not statistically significant.

In-text reference to tables, figures, and pages within an issue –

In all, 239 participants (87%) confirmed that poor document quality impedes regulatory assessment (**Figure 10-4**) and that they encounter issues related to document quality during the review process either sometimes or often (**Figure 10-5**).

Omae and colleagues have reported that drug approval under the program has been expedited by approximately 4.5 years (**Table 10-6**, p. 32).

Offsetting information after the *e.g.*, *i.e.*, or *vs.* abbreviations –

These would include comprehensive promotional pieces (e.g., sales aids, journal advertisements, and websites) directed at healthcare professionals and other materials (e.g., patient brochures, magazine advertisements, and websites) for patients.

Avoid “doubling up” on Latin abbreviations within the same parenthetical information.

Use Products intended for self-testing (e.g., for pregnancy, fertility, and cholesterol) are Class C.

Instead of Products intended for self-testing (e.g., for pregnancy, fertility, cholesterol, etc.) are Class C.

To offset abbreviation after first mention of a term

software as a medical device (SaMD)
real-world data (RWD)
Australia’s Therapeutic Goods Administration (TGA)

With drug generic name after first mention of brand name

Leqembi (lecanemab-irmb)
Wegovy (semaglutide)
Zoryve (roflumilast)

To indicate the possibility of a plural when singular or plural could apply, for example, *Author(s)*

Back-to-back parentheses

Note use of the comma and semicolon used in the following examples to avoid back-to-back parentheses.

Based on all included trials and patients, there were clear benefits of docetaxel on overall survival (HR, 0.79, 95% CI, 0.70 to 0.88; $P < .0001$) and progression-free survival (0.70, 0.63 to 0.77; $P < .0001$).

In references (see p. 9)

Brackets

To denote clarifying or explanatory insertions in a quotation or text

FDA benefit-risk guidance [draft].²⁵ Includes significant information about how PROs and patient-preference information has become an important part of benefit risk assessment.

“Challenges around navigating the post-Brexit transition and supply chain disruptions and the status of Northern [sic] Ireland have been addressed.”

Within parentheses

... submissions (e.g., new drug approval [NDA], biologic license application [BLA])

Brackets in references (see pp. 9-11)

Quotation marks

Always use double quotations marks, except in:

- A quotation within a quotation,
- Chapter or article titles,
- Table or figure titles, and
- Subheads.

The general rules for using punctuation and quotation marks together are:

- 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.

Do not use any quotation marks (or italics) to offset the titles of laws, books, guidances, or songs. They are title-capped as they are established titles:

Fundamentals of Pharmaceutical and Biologics Regulations: A Global Perspective
Federal Food, Drug, and Cosmetic Act
Purple Haze

Ellipses

An ellipsis is a series of three dots used to signal the omission of a word, phrase, line, paragraph, or more from a quoted passage. These dots – sometimes called suspension points – must appear together on the same line.

RAPS style is to use three periods to denote an ellipsis and to have spaces before and after it.

This has meant that a myriad of EU-level guidance and training documentation has been created and released ... and countless draft and temporary documents released at the member state level have not always been consistent with the EU-level guidance.

Virgule

The virgule, or forward slash, can be used with words to mean *per*, *and*, or *or*. It is also used with numbers to separate the numerator and denominator in fractions, for example, *6/10* for *six out of 10*.

Do not use the virgule in dates.

Avoid overusing virgules. It often is not clear if a virgule is supposed to mean *and* or *or* and it is therefore preferable to write out the exact word – *and* or *or* – whenever possible.

Showing duality

hematologist/oncologist
and/or
either/or

In general, the virgule is used between nouns that are similar and not between nouns that are not the same. These examples from the Centers for Disease Control and Prevention are helpful:

The physician/patient experience (implies physician and patient are one and the same)
The physician-patient relationship (implies two different persons)

HIV/TB co-infection (because they equally describe the co-infection)
HIV-AIDS is the noun form (because they are not the same; avoid HIV/AIDS)

In the per construction

Use the virgule with Arabic numerals and units of measure:

a BMI of 18 m²/kg
92 ml/kg of body weight
a pulse rate of 68/min

Do not use the virgule if there are no associated numbers, for example, *The units for BMI are meters squared per kilogram*.

In regulation titles

Some regulation titles include virgules, often to offset the year or other information in the title. Those virgules should always be retained: Directive 2001/83/EC, Regulation (EC) No. 178/2002, and Regulation (EC) No. 1223/2009.

Bulleted list

A bulleted list is a useful way of helping readers quickly scan and better retain information in a long text containing specialized and/or complex content. It can also introduce a visual element to what might otherwise be a text-heavy page, making it easier for readers to engage with the content.

Bulleted lists should not be overused. They should be used only in specific instances for the above reasons and not as a pro forma way of presenting content. In general:

- A bulleted list is introduced with a colon;
- The first word of each bullet point should be capitalized;
- Punctuation at the end of each bullet point varies, depending on the structure of the list;
- The penultimate bullet point has *and*, *or*, or *and/or* after the end of the point; and
- There is a period at the end of the last point.

Use commas at the end of each bullet point if there is no other punctuation in the list, for example:

- Requirement for the cross-departmental review process and timelines aligned with the finalization of the education affiliation agreement,
- Preceptor requirements,
- Use of the core experiential-learning management system software to manage student evaluations, and
- Varying block schedule start/end dates across each institution.

Use semicolons if there is existing punctuation (see highlight), for example:

- Good academic standing;
- Demonstrated interest in the biopharmaceutical industry, particularly regulatory science;
- Leadership skills and experiences (e.g., FDA/industry, but not required);
- Strong leadership, communication, and interpersonal skills; and
- Successful interview with Pfizer GRA program administrators.

If the bulleted points read as a list of items, then capitalize the first word, but do not use punctuation, for example:

- New drug application
- Accelerated new drug application
- Postmarket surveillance
- Emergency use authorization

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.

Levels of bulleted items

Try as much as possible to use only one level of bulleted items, as in the preceding examples. Should there be a need for a second level, use the following formatting:

These steps include a number of stages that explain, in more detail, the status of an entity's implementation and adherence:

- **Before implementation**
 - Not yet implemented – There is no guideline or the national/regional guideline deviates from the ICH guideline; or there is national/regional guideline, but the process for replacement or amendments for alignment with the ICH guideline has/have not yet started.
 - In the process of implementation – The process for the implementation of the ICH guideline has started and reached a specified milestone with process monitored by the regulatory agency and progress reported regularly to the ICH management committee and assembly.

Third and fourth level subheads should be avoided.

Capitalization

Capitalize the US Cabinet, US Congress, US House, US Senate, US Federal Register, European Commission, European Parliament, European Council, Court of Justice of the EU, and European Central Bank.

Do not capitalize the following unless they are part of an agency, organization, or law title:

agency
 abbreviated new drug application
 biologics license application
 congressional
 cannabis, unless it is written as *Cannabis sativa*
 [EU] member state
 good manufacturing practice
 good clinical practice
 good distribution practice
 good documentation practice
 good laboratory practice
 investigational new drug [application]
 institutional review board
 managing director, chief operating officer, etc.
 marketing authorization
 mark, marked, marking in reference to the CE Mark
 ministry, parliament, government, department
 new drug application
 premarket approval application
 quality assurance
 risk management
 treaty, act, regulation, federal

Clinical trial phases

Use uppercase for phases of clinical trials – Phase 1, Phase 2, Phase 3.

Note the use of Arabic numerals for identifying the phase.

Drug schedules assigned by the DEA

Use uppercase for assigned schedules of drugs – Schedule I, Schedule II, Schedule III, etc.

Note the use of roman numerals with the classification.

Day specifications in a timeline

When referring to the timeline for approval, such as for a product labeling submission to the EMA, capitalize *day*:

Detailed review of the mock-ups will parallel the scientific assessment, with comments issued by Day 120.

Book, chapter, and article titles and subheads

Book and chapter titles and subheads use title case: **Medical Device Labeling in the US**

In the title case option, the first letter in most words and abbreviations is uppercase, as in the preceding example.

Use title case for:

- All nouns, pronouns, adjectives, verbs, and adverbs, irrespective of their length: **All, Any, Approves, He, New, Regulation, She, Be, Is, That**
- Prepositions of four or more letters: **Above, Between, Over, With**
- The second part of a hyphenated word: Real-**World** Data Quality

Use lowercase for:

- Prepositions of three or fewer characters, for example, *out, in, up, on*, when used on their own. However, prepositions in prepositional verbs should be title cased, for example, **Voted Out**
- Articles *an, a, the*
- Conjunctions *and, but*

Article titles and subheads use sentence case: **Medical device labeling in the US**

Abbreviations in titles for books, chapters, and articles follow the same rules for upper- and lowercased use as they would if they were used in the chapter or article body text.

Levels of subheads

There should be no more than three levels of subheads, formatted as follows for articles:

Subhead Level 1: Calibri 11, bold, roman; text begins on line below the subhead

History of software safety risk management

Sed ut perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam, eaque ipsa quae ab illo inventore veritatis et quasi architecto beatae vitae dicta sunt explicabo. Nemo enim ipsam voluptatem quia voluptas sit aspernatur aut odit aut fugit.

Subhead Level 2: Calibri 11, bold, italics, text begins on line below the subhead

1985-1987 – Software controlling a therapy device

Quia consequuntur magni dolores eos qui ratione voluptatem sequi nesciunt. Neque porro quisquam est, qui dolorem ipsum quia dolor sit amet.

Subhead Level 3: Calibri 11, bold, roman; subhead is short, ends with a period; text continues on same line as subhead

Consequences. Consectetur, adipisci velit, sed quia non numquam eius modi tempora incidunt ut labore et dolore magnam aliquam quaerat voluptatem

Root causes. Ut enim ad minima veniam, quis nostrum exercitationem ullam.

Abbreviations

RAPS publications use the generic term *abbreviation* to refer collectively to abbreviations, acronyms, and initialisms. An abbreviation is a shortened or contracted form of a word or phrase; acronyms and initialisms are abbreviations with distinctive properties.

- An **abbreviation of a word** is commonly formed using the first letters of the word, for example, Sen., Rep.
- An **abbreviation of a phrase** is commonly formed using the first letters of each word in the phrase, for example, AI, SaMD
- An **acronym** is pronounced as a word, for example, AIDS, COVID-19, NASA
- An **initialism** is pronounced one letter at a time, for example, FDA, HIV, ATMP

Use and related style in text

Abbreviations should be used sparingly. Their overuse can be confusing, especially for readers who are not familiar with the subject matter. If, for example, the European Medicines Agency (EMA) is referred to many times in a text, one can avoid overuse of *EMA* by occasionally substituting *the agency*, provided it is the only agency mentioned in the text.

Use only established abbreviations – ad hoc, author-originated abbreviations will not be retained.

In general, words or phrases should be abbreviated only if they are used three times or more in the text. However, if an agency or organization is mentioned only twice, the abbreviation can be used the second time to avoid repeating the full agency title. If the two uses of the agency name are close together in the text, it might be possible to use the *agency/organization* on the second mention.

The word, phrase, or agency/organization name should be written out in full at the first mention, followed by the abbreviation in parentheses:

The US Food and Drug Administration (FDA) has issued guidance ...

... sponsors must submit a clinical trial application (CTA) for authorization.

Commonly used terms should not be title-cased when written out in full before an abbreviation or when used one their own:

- new drug approval (NDA)
- good manufacturing practice (GMP)
- well-established technology (WET)
- chemistry, manufacturing, and controls (CMC)
- priority review voucher (PRV)
- regenerative medicine advanced therapy (RMAT)
- postmarket surveillance (PMS)
- electronic common technical document (eCTD)
- additional condition for nonprescription use (ACNU)
- medical devices document (MEDDEV)

If the first mention of a word or phrase that has to be abbreviated is a plural, then the abbreviated form should also be in the plural:

... approvals for advanced therapy medicinal products (ATMPs), classified as ...

However, avoid using the possessive form of an abbreviation for the first mention even if the expanded form is possessive:

Use The International Council for Harmonisation (ICH) revised its quality guidance ...

Instead of The International Council for Harmonisation's (ICH's) quality guidance was revised ...

In most cases, letters in an abbreviation are uppercase and are not separated by periods, as in the preceding examples. However, some abbreviations:

- **Can include periods** – The following are used only in parentheses, tables, and figures and not in the body text, where they should be written in full:

e.g. (for example)	i.e. (that is)	et al. (and others)
p. (page)	pp. (pages)	vs. (versus)
No. (number, in a table/figure)		Nos. (numbers, in a table/figure)
- **Do not use uppercase or periods** – am, pm, mph, ppm, km, m, ml, jpeg, html
- **Include a mix of upper- and lowercased letters** – PhD, kDa, Tdap, mRNA, cCMC, NBOp (notified body opinion), eCTD (electronic common technical document – not dossier), EudraCT (European Union Drug Regulating Authorities Clinical Trials database)
- **Need not be spelled out at first mention because they are widely used** –
 - US, EU, UK (used as nouns and adjectivally)
 - HIV-AIDS, COVID-19, DNA, RNA, mRNA, rDNA, ANCOVA, PDF, Excel, URL, DOI, IQ, ISSN, ISBN, LGBTQ, NSAID, UV, Ltd, Inc
 - x-ray
 - Units of measure (e.g., 3.2 mg, 6 ml – note space between number and abbreviation)
 - For temperatures (e.g., 98.6 °F or 37.5 °C – note space before degree sign)
 - Degrees and certifications. Periods are not used in abbreviations for degrees or certifications, for example, PhD, MBA, RAC. Professional prefixes are not included in text, including Dr., Prof.
- **Use lowercase for *and* and prepositions** – software as a medical device (SaMD), software in a medical device (SiMD), AI as a medical device (AIaMD), level of concern (LoC), end of life (EoL), and Department of Justice (DoJ)

Abbreviations in subheads

If a word or phrase that has to be abbreviated is used for the first time in a subhead, use the abbreviated form in the subhead and introduce the expanded and abbreviated forms in the paragraph immediately after the subhead:

Health Canada's SGBA Plus Action Plan

In 2021, Health Canada's Health Products and Food Branch developed a Sex- and Gender-Based Analysis Plus (SGBA Plus) Action Plan to address barriers and challenges to equitable health product development.

If the abbreviation has already been introduced in the text, then it can be used in the subhead, as in the rest of text, provided it is in combination with other words:

... Patient-reported outcomes (PROs) are outcomes that are directly reported by the patient and considered without interpretation of the patient's response by a clinician or anyone else ...

PROs in oncology and clinical outcome assessments

Developing PRO measures that satisfy US Food and Drug Administration (FDA) standards can take years ...

However, if the abbreviation has already been introduced in the text and the subhead is the standalone expanded form of the abbreviated phrase, then it should be written out in full for the subhead:

Today, the most successful ML models use artificial neural networks, which have been applied to the fields of natural language processing (NLP) and computer vision.

Natural language processing

NLP is a branch of artificial intelligence ...

Likewise, when US, UK, and EU are used alone as subheads, they should be written out as United States, United Kingdom, and European Union.

Academic degrees and professional certifications

Generally, include an individual's credentials for all postgrad degrees: master's (MA, MBA, MPH, MS), doctorates (PhD, DSc), medical degrees (MD, MBBS), and doctor of pharmacy and jurisprudence (PharmD, JD).

Degrees should be presented in the following order after the author's name:

- Doctorate
- Master's
- Bachelor's
- Fellowship (FRAPS only)
- Credentials and certifications

The RAPS Regulatory Affairs Certification

Certifications – Regulatory Affairs Certification (RAC) and the Regulatory Compliance Certification (RCC) –should also be included:

- RAC-Devices and RCC-Devices for regulatory professionals working with medical devices and in vitro diagnostics; and
- RCC-MDR for those working with the EU Medical Device Regulation and RCC-IVDR for those working with the EU In Vitro Diagnostic Devices Regulation

Additional historic, and still valid, RAC designations include:

- RAC-US for those working with US Food and Drug Administration (FDA) regulations;
- RAC-EU for those working with EU regulations;
- RAC-CAN for those working with Canadian regulations; and
- RAC-Global for those working with regulations from multiple regions and countries.

(Note: Since fall 2019, the preceding options are no longer available as a first-time option for certification after the society determined that regulatory professionals tend to focus on a product area rather than geographic regions. RAC holders who took regional versions of the RAC examination will be equally recognized by the RAC program and can continue maintaining their RAC status for as long as they wish, as long as they continue to recertify.)

Note that:

- The degree or degree listing is offset with a comma after the person's last name.
- There are no periods in the degree and credential abbreviations, for example, PhD, JD, MD, RAC:
Author1 Lastname1, PhD, MBA, RAC-Drugs
Author2 Lastname2, RAC
Author3 Lastname3, BPharm, RCC-IVDR
- Some abbreviations are a mix of upper- and lowercased letters and those conventions should be followed.
- The order for listing multiple degrees and credentials should be in decreasing order, from highest to lowest: medical, doctorate, master's, fellow, selected certifications.
- Editors should independently verify RAC, RCC, and FRAPS status for all RAPS publications.

COMMON DEGREES AND CERTIFICATIONS USED BY RAPS	
Medical degrees	MD, doctor of medicine MBBS, bachelor of medicine, bachelor of surgery MB BCh, bachelor of medicine, bachelor of surgery
Doctorates	PhD, doctor of philosophy DSc, doctor of science EdD, doctor of education PharmD, doctor of pharmacy JD, doctor of jurisprudence
Master's degrees	MA, master of arts MBA, master of business administration MPH, master of public health MPharm, master of pharmacy MS, master of science MSc, master of science
Bachelor's/undergrad degrees	BA, Bachelor of Arts BS, Bachelor of Science BPharm, Bachelor of Pharmacy
Fellowship designations	FRAPS only
RAPS certifications	RAC and RCC
Other certifications	<i>Nursing</i> APRN, advanced practice registered nurse CNM, certified nurse midwife CNMT, certified nuclear medicine technologist CNP, certified nurse practitioner CNS, certified nurse specialist CRNA, certified registered nurse anesthetist GNP, gerontologic or geriatric nurse practitioner LPN, licensed practical nurse LVN, licensed visiting nurse; licensed vocational nurse NP, nurse practitioner PMHNP, psychiatric mental health nurse practitioner PNP, pediatric nurse practitioner RN, registered nurse RNA, registered nurse anesthetist RNC, registered nurse, certified <i>Pharmacy</i> RPh, registered pharmacist
Project management	PMP, project management professional CAPM, certified associate in project management PMI-RMP, Project Management Institute risk management professional DASM, Disciplined Agile scrum master DASSM, disciplined agile senior scrum master

Editors: When listing author names for a chapter or article, use the following structure with a bullet point between the author names, and a double space before and after the bullet point:

Author1 Name2, PhD, RAC • Author2 Name2, DPharm, MPH • Author3 Name3 PhD, FRAPS

Numbers and percentages

Cardinal and ordinal numbers – Arabic and written out

Cardinal numbers from one to nine should be spelled out unless they are used with a unit or are reporting data:

There are two stages to the process ...
 ... titrated to 2 mg ...
 ... decreased from 6% to 2% ...

Cardinal numbers for 10 onward should be written as Arabic numerals whether they are used with a unit or not.

Ordinal numbers (first, 25th, etc.) should be written out for first to ninth, but numbers should be used for 10th onward. Note that the ordinal number suffix *-th* is not superscripted. The same applies to *-st* and *-nd*.

If there is a mix of numerals and spelled-out numbers within the same sentence, then both numbers should be written as numerals:

The turnaround period decreased from 11 days to 9 days.

If a number begins a sentence, it is always spelled out:

Thirty-six patients reported adverse reactions ...

Roman numerals

Do not use Roman numerals for:

- Text citations of the Reference list;
- To denote notes in a table or figure (instead, use superscripted, lowercased letters separated by commas (^{a,b,c}); or
- To denote a clinical trial phase (instead, use Arabic numerals – Phase 1, Phase 2, Phase 3).

Use Roman numerals for:

- Drug schedules assigned by the DEA -- Schedule I, Schedule II, Schedule III, and so on (note that Schedule is uppercase); and
- Medical device classes – Class I, Class II, and so on (note that Class is uppercase).

Dates

In **text and references**, use the international format and sequence for dates: 16 February 2021. Note that:

- The basic order of information in the date sequence is Date Month Year,
- There is no comma after the month,
- The month is spelled out in full,
- The date and year are expressed as Arabic numerals, and
- The date numbers do not have ordinal number suffixes (*-st*, *-nd*, *-th*).

This format is preferable because it is visually uncluttered and fits easily within the flow of the sentence, making it easier to skim read and comprehend, especially if there is other grammar-related punctuation in the sentence. For example,

Use The guidance was issued on 18 July 2022, which coincided with the expiration of
Instead of The guidance was issued on July 18, 2022, which coincided with the expiration of

Write out the names of months in **tables and figures**: *February 2021*.

Always write out the year in full to avoid confusion with the date. (In the preceding example, using *Feb 21* to denote the year, 2021, could be confused with 21 February, which denotes the day).

However, do not use numerical dates with virgules or hyphens, such as 2/16/2021 or 2-16-2021 in the body text.

Use the hyphen to express ranges as in the following examples:

- **Days** – 21-26 October 2020
- **Months** – July-August 2022, Jul-Aug 2022
- **Years** – During 2020-2023, but,
From 13 March to 25 October 2022
From 13 March 2022 to 18 November 2023
From March 2020 to October 2022

Time

Use Arabic numerals with the unit abbreviation when denoting time, for example, 3:15 *pm*.

Use the colon to distinguish hours, minutes, and seconds: 4:06:52 *am*.

Use *am* and *pm* – lowercased, in roman, no periods, and with a space before and after – for *morning* and *afternoon*.

Use *noon* for 12:00, and *midnight* for 00:00.

Currencies

Currencies are expressed in decimal or whole number form and are written as Arabic numerals preceded by the internationally accepted symbol or abbreviation for the referenced currency.

The comma is used to denote currency values of 1,000 or more, for example, \$7,500 or ¥8,000,000.

If a country other than the US uses the dollar as its currency unit, then the dollar sign should be preceded by the abbreviation for referenced country:

- Australian dollar, AU\$
- Canadian dollar, CA\$
- Hong Kong dollar, HK\$
- New Taiwan dollar, NT\$
- New Zealand dollar, NZ\$
- Singapore dollar, SG\$
- Zimbabwe dollars, ZW\$

It should be noted that the dollar symbol is also used for the peso and is preceded by an abbreviation indicating the reference country, for example, UY\$ for the Uruguayan peso.

The following table includes the currencies from selected countries and regions covered in RAPS publications. Most of the countries are mentioned in the sections on global geopolitical regions and regional economic and/or geopolitical groups on pp. 25-28. The information is partly adapted from the American Medical Association.

Country	Currency name	Symbol/abbreviation/ example of written out form
Australia	Australian dollar	AU\$
Argentina	Argentine peso	ARS\$
Brazil ^a	Brazilian real	R\$
Brunei Darussalam ^b	Brunei Darussalam dollar	BN\$
Cambodia ^b	riel	Write out, e.g., 6.72 million riel
Canada	Canadian dollar	CA\$
Chile	Chilean peso	CL\$
China ^a	yuan renminbi	CN¥
Colombia	Colombian peso	CO\$
Cuban peso	Cuban peso	CU\$
Dominican peso	Dominican peso	DO\$
Egypt	Egyptian pound	EG£

EU member states ^c	euro	€
Hong Kong	Hong Kong dollar	HK\$
Iceland ^{d,e}	krona	ISKr
India ^a	rupee	Write out, e.g., <i>1,750 rupees</i>
Indonesia ^b	rupiah	Write out, e.g., <i>6 rupiah</i>
Israel	sheqel	Write out, e.g., <i>12.4 million sheqels</i>
Japan	yen	¥
Kenya	Kenyan shilling	Write out, e.g., <i>100,950 shillings</i>
Laos ^b	kip	Write out, e.g., <i>150 kip</i>
Lebanon	Lebanese pound	LBE
Liechtenstein ^{d,e}	Swiss franc	CHF
Malaysia ^b	ringitt	RM
Mexican	Mexican peso	MX\$
Myanmar ^b	kyat	Write out, e.g., <i>650,000 kyat</i>
New Zealand	New Zealand dollar	NZ\$
Nigeria	naira	Write out, e.g., <i>15,000 naira</i>
Norway ^{d,e}	krone	NOKr
Philippines ^b	Philippine peso	PH\$
Russia ^a	ruble	Write out, e.g., <i>10.4 million rubles</i>
Saudi Arabia	riyal	Write out, e.g., <i>4 million riyal</i>
Singapore ^b	Singapore dollar	SG\$
South Africa ^a	rand	R
Switzerland ^e	Swiss franc	CHF
Sweden	krona	SEKr
Tanzania	Tanzanian shilling	Write out, e.g., <i>280,000 shillings</i>
Taiwan	New Taiwan dollar	NT\$
Thailand ^b	baht	Write out, e.g., <i>20,000 baht</i>
Turkey	Turkish new lira	Write out, e.g., <i>150 lira</i>
Ukraine	hryvnia	Write out, e.g., <i>750 million hryvnia</i>
United Kingdom	pound	£
Uruguay	Uruguayan peso	UY\$
Vietnam ^b	dong	Write out, e.g., <i>2.6 million dong</i>
Zimbabwe	Zimbabwe dollars	ZW\$

^bMember of the Association of Southeast Asian Nations. ^aBRICS [Brazil, Russia, India, China, South Africa] member. ^cMember states are Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. ^dMember of the European Economic Area (includes the EU countries, plus Iceland, Liechtenstein, and Norway).

^eMember of the European Free Trade Association, which includes Iceland, Liechtenstein, Norway, and Switzerland.

If the US dollar is the only dollar value mentioned in a text, then the dollar symbol need not be preceded by *US*:

In 1997, \$1.3 billion was spent in the US on DTC promotion of prescription products.² By 2021, the total amount of spending had increased to \$6.88 billion.

However, if US dollars and dollars from another country, for example, Canada or New Zealand, are mentioned in the same article, then the US dollar values should be written as US\$.

For cryptocurrencies, keep the names lowercased: bitcoin, libra, kin, ether, litecoin.

PRESUBMISSION CHECKLIST for ARTICLES

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

- Formatting of the Word document:
 - 11 pt Calibri
 - Paragraphs set flush left (no paragraph 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, including spaces
- Byline – FirstName LastName, degrees and certifications (lead author or first)
- Abstract, a brief summary of the article – 70-75 words
- Keywords or phrases – 3-5, in alphabetic order, all lowercased, 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), first in-text mention in bold
- Figures – heading, legend, abbreviation list, source (if applicable), first in-text mention in bold
- Level 1 subheads – **bold typeface**
- Level 2 subheads – ***bold, italic typeface***
- Bulleted lists (not numbered)
- Abbreviations list in alphabetical order – after article body text, before author bios
- Brief bio for each author – no more than 100 words, bios should be in alphabetic order by last name. Each bio should include the author’s 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 RCC holder and/or RAPS member; contact email.
- Corresponding Author – state clearly which author is the Corresponding Author and provide their email. Ghostwriters or communications staff should not be assigned as corresponding authors.
- References are complete, as per the 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

Resources and references

Last checked and verified on 4 November 2024.

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