RAPS Author Style Guide

Publications

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Mission

In an ongoing effort to fulfill RAPS’ strategic priorities, the society aims to develop a wide range of books, publications, and resources to address the wants and needs of regulatory professionals who deal with a diverse range of healthcare product types, lifecycle phases, and geographic locations. These books include the gold standard Fundamentals series and topical books, including global medical device regulatory strategy, regulatory writing, regulatory intelligence, due diligence and more. The Editorial Advisory Committee (EAC) assists RAPS in determining new topics that will be of most interest and use to regulatory professionals and helps identify potential authors, reviewers, and subject matter experts.

Strategic Priorities

1. Proactively address evolving regulatory competencies required for the global profession
2. Deliver valuable and accessible learning and professional development experiences
3. Inform regulatory professionals of complex and evolving healthcare product regulatory developments
4. Empower a community focused on interactions, relationships and knowledge-sharing
Chapters

Chapter Format

All text and tables should be prepared using MS Word, single-spaced. Please provide figures in their raw format (Excel, PowerPoint, etc.); do not convert them to image files.

Please do not use automatic numbering or the automatic endnote/footnote tools in Word.

If any website links (URLs) are included, please confirm they are correct. Try to avoid links that require registration fees. If multiple sources for a document exist, use the source most likely to remain unchanged, e.g., for an FDA guidance, FDA’s website instead of a link to a copy of the document on a consulting firm’s website.

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

Chapter Presentation

Format

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

Elements

- Headline – no more than 75 characters
- Byline – e.g., By First Author, PhD, Second Author, MSc, and Third Author, MD
- Introduction to chapter – provides background information and states goals of chapter
- Subheads
  - Level 1 subheads – **bold typeface**
  - Level 2 subheads – **bold, italic typeface**
- Bulleted points – not numbered unless text specifically indicates a series of number (see below, under Punctuation, Bulleted lists)
- Tables and Figures – in increasing numeric order (see below, under Tables and figures)
- Text citations – superscripted numbers (e.g., 1) in increasing numerical order (see below, under References)
• Conclusion summary
• References in increasing numerical order, corresponding to text citations (see below, under References)

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

Correctness and Accuracy
Authors are responsible for the correctness and accuracy of all statements contained in the article (the publisher assumes no liability) Anything accepted for publication becomes the publisher’s property and may not be published elsewhere without the written permission of both the author and publisher.

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

Abbreviations

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

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

The United Kingdom
Use UK, without periods, rather than spelling out United Kingdom.

The European Union
Use EU, without periods, rather than spelling out European Union.

Acronyms and Abbreviations
Abbreviations and acronyms should follow the full spelling of the term in parentheses after first reference, for example, “The US Food and Drug Administration (FDA) is looking into the matter.”

For each subsequent reference, use only the abbreviation. If the name is referenced only once, there is no need to include the abbreviation after that single reference.
Acronyms are abbreviations that can be pronounced as words, for example, AIDS, COVID, and NASA. RAPS style is to use uppercase for acronyms as well, although some publications use title case for acronyms of four letters or more, as with a proper noun.

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

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

**Capitalization**

**Commonly Used Words**

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

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

Clinical Trial Phases
Phases of clinical trials are identified using Arabic numerals and capitalize “Phase,” i.e., Phase 1, Phase 2, etc.

Contractions
Limit the use of contractions, such as “don’t” and “isn’t,” except in direct quotations. Spell out “do not,” “is not,” etc., since RAPS’ audience is global and includes non-native English speakers who may be less familiar with contractions. Note: It is best to avoid regional idioms for the same reason.

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

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

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

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

Gender-Specific Pronouns
Often sentences can be constructed so that no gender-specific pronoun is necessary, e.g., Regulatory professionals make important contributions to their employers’ organizational strategies, instead of a regulatory professional makes an important contribution to his or her employer’s organizational strategy. Use “his or her” or “he or she” only when absolutely necessary. Avoid using a construction such as “he/she.” When referring to an individual, never use “their.”
Medical Device Classifications
Medical device classes are identified using Roman numerals, and “Class” is capitalized, i.e., Class I, Class II, etc.

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

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

Punctuation

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

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

Commas
Use the serial comma.

Use only one space at the end of a sentence.

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

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

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

**Quotation Marks**
Periods (.) and commas (,) always go inside the quotation marks.

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

References and Text Citations
In Reference lists, please do not use endnotes or footnotes; auto-numbering; or italics or quote marks for titles. If there are multiple sources for a document, use the source most likely to remain unchanged, e.g., for an FDA guidance, use the agency website instead of linking to a copy of the document on a consulting firm’s website.

- All statements of fact within the text sourced from an original document must be noted next to the corresponding text using a superscripted number and listed in the reference section, using the same number as the text citation.

- The superscripted text citation numbers (e.g.,1-6) should be presented sequentially, in increasing numerical order.

- The superscripted number should go after the punctuation, e.g., ... risk strategy.45

- The sources listed in the reference section should be presented sequentially, in increasing numerical order, reflecting the order in which the references are cited in the text.

- References with URLs should include the date of publication or of last update (e.g., Last updated 7 April 2019. or Published 3 March 2020.), as well as the date on which the author last accessed the article through the URL (e.g., Accessed 14 July 2020.)

- Where possible, use PubMed abbreviations for journal titles. The titles are not italicized and take a single period at the end of the full title, not after each abbreviated word in the title.

- A reference entry for a source should generally include the following elements, in this order:
  - Name of content originator, e.g., author or organization.
  - Title of document, sentence case – no italics or quotation mark.
  - Abbreviated journal name – single period at the end of the title, not italic.
  - Year;Volume(Issue):page range
  - Page range numbers are separated with a hyphen; don’t repeat duplicate numbers, e.g., pages 103 to page 109, would be 103-9; pages 1175-1190, would be 1175-90.
  - URL, if applicable – hyperlinked to source.
  - If a URL is used, include the date the item was published/posted/last updated or revised, e.g., Published 16 November 2019. Last updated 16 November 2019.
  - Also include the most recent date on which the article was accessed through the URL, e.g., Accessed 15 January 2020.
References should be sequentially numbered. Any repeat references should utilize Ibid (“in the same place”) for a repeat immediately following the original reference, or Op cit for repeated use of an earlier reference. Do not use endnotes or footnotes. Do not use auto-numbering. Titles of articles and book chapters should be spelled out and enclosed within quotation marks. When including a URL, please add the date the website or web page was accessed.

Sample Reference List


3. Ibid.


15. Ibid.

For directives, regulations standards and guidelines covered in each chapter, please include a list of these at the beginning of each chapter with numerical, sequential citations. Follow the number sequence in the chapter for magazine or journal articles, books and book chapters.

**Style for Specific References**

**Report to Congress**


**Act**


**Draft Guidance**


**Final Guidance**


**Code of Federal Regulations (CFR) Part**

CFR Section

Federal Register; Final Rules

Legal and Laws

Journal article, print journal

Journal article, online

For website URLs

Presentation at a conference


Example

Directives, Regulations, Standards and Guidelines Covered in This Chapter


Following on this example, the next reference in the body of the article will be number 6.