RAPS Author Style Guide

Publications

Last updated: 25 September 2020

RAPS Regulatory Affairs Professionals Society

CONTENTS

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

sponsor
treaty, act, regulation, federal (unless in title)

Clinical Trial Phases

Phases of clinical trials are identified using Arabic numerals and capitalize "Phase," i.e., Phase 1, Phase 2, etc.

Contractions

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

Dates

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

Degrees and Certifications

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

To Hyphenate or Not: Commonly Used Words

Asia-Pacific
benefit-risk
co-sponsor
e-book
email
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

1. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. (OJ L 120, 7.4.2004, p. 48). EUR-LEX website. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF. Accessed 30 July 2020.
2. 21 CFR Part 820, Quality System Regulation (QSR). Revised April 2019. FDA website. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1. Accessed 10 June 2020.
3. Ibid.
4. Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC). Last amended November 2007. EUR-LEX website. https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31990L0385 . Accessed 10 June 2020.
5. EN ISO 13485:2016. Medical Devices: Quality Management Systems: Requirements for Regulatory Purposes. Last updated December 2019. ISO website. https://www.iso.org/standard/59752.html. Accessed 10 June 2020.
6. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Last updated June 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505. Accessed 10 June 2020.
7. Op cit 3.
8. Schaible S. Making the call to test in-house or outsource. Regulatory Focus. May 2020. Regulatory Affairs Professionals Society (RAPS) website. https://www.raps.org/news-and-articles/news-articles/2020/7/a-military-civilian-perspective-on-real-world-evid. Accesses 30 July 2020.
9. Brass E. Changing the Status of Drugs From Prescription to Over-the-Counter Availability. N Engl J Med 2001; 345:810-816. NEJM website. https://www.nejm.org/doi/10.1056/NEJMra011080. Accessed 30 July 2020.
10. Leboffe MJ and Pierce BE. 2010. Microbiology: laboratory theory and application. Englewood (CO): Morton Publishing Company.
11. Regulatory Affairs Professionals Society (RAPS). 2020. Fundamentals of EU Regulatory Affairs. Ninth Edition. Rockville, MD.
12. Rapley R. 2010. Recombinant DNA and Genetic Analysis. In: Wilson K, Walker J, editors. Principles and Techniques of Biochemistry and Molecular Biology. 7th ed. New York (NY): Cambridge University Press. p. 195–262.

13. Op cit 10.
14. Bos G. 2020. Medical Device Conformity Assessment Procedure. In: Regulatory Affairs Professionals Society (RAPS). 2020. Fundamentals of EU Regulatory Affairs. Ninth Edition. Rockville, MD. P. 257-269.
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

1. US Food and Drug Administration, Fiscal Year 2014 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. FDA website. https://www.fda.gov/media/128892/download. Accessed 9 July 2020.

Act

1. Safe Medical Devices Act (SMDA) of 1990. Last updated January 1990. http://congress.gov/bill/101st-congress/house-bill/3095#:~:text=Safe%20Medical%20Devices%20Act%20of%201990%20-%20Amends%20the%20Federal%20Food,or%20contributed%20to%20a%20death%2C. Accessed 9 July 2020.

Draft Guidance

1. Draft Guidance for Industry and FDA Staff: Interpretation of the Term "Chemical Action" in the Definition of Device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act. June 2011. Last updated July 1990. FDA website. https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Gray%20Sheet/38/40/chemical_action_guidance.pdf.

Final Guidance

2. Current Good Manufacturing Practice Requirements for Combination Products: Guidance for Industry and FDA Staff. January 2017. Final. Last updated July 2020. FDA website. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-requirements-combination-products. Accessed 8 July 2020.
3. Postmarketing Safety Reporting for Combination Products: Guidance for Industry and FDA Staff. July 2019. Last updated June 2020. FDA website. https://www.fda.gov/media/111788/download. Accessed 9 July 2020.
4. Guidance for Industry: How to Write a Request for Designation (RFD). April 2011. Last updated February 2020. FDA website. http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm. Accessed 9 July 2020.

Code of Federal Regulations (CFR) Part

1. 21 CFR Part 820, Quality System Regulation (QSR). Revised April 2019. FDA website. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1. Accessed 10 June 2020.

CFR Section

1. 21 CFR §3.2(o). FDA website. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=3.2. Accessed 9 July 2020.

Federal Register; Final Rules

2. Assignment of Agency Component for Review of Premarket Applications, Final Rule, 68 Fed. Reg. 58,754 (23 June 2003). Federal Register website. https://www.federalregister.gov/documents/2003/06/23/03-15698/assignment-of-agency-component-for-review-of-premarket-applications. Accessed 30 July 2020.

Legal and Laws

3. Letter from Thomas A. Kraus, Associate Commissioner for Legislation, to The Honorable Joseph R. Pitts, Chairman, Subcommittee on Health, Committee on Energy and Commerce, House of Representatives (12 November 2014).
4. Prevor v. U.S. Food and Drug Administration, No. 1:13-cv-01177-RMC, Status report by United States Food and Drug Administration, Attachment A, Prevor—Remand Decision (D.D.C. 13 January 2015).
5. Genus Med. Techs., LLC v. U.S. Food and Drug Administration, No. 19-544 (JEB), Memorandum Opinion (D.D.C. Dec. 6, 2019). https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv0544-19. Accessed 9 July 2020.

Journal article, print journal

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

Journal article, online

7. Zhou P, Zhou J. The primary cilium as a therapeutic target in ocular diseases. Front Pharmacol. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7333185/. Published online 26 June 2020. Accessed 17 June 2010.

For website URLs

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

Presentation at a conference

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

Book (Whole)

10. Venables WN, Ripley BD. Modern applied statistics with S. 4th ed. New York, NY: Springer Publishing Co; 2003.

Book Chapter

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

Package Insert

12. Qinlock [package insert]. Waltham, MA: Deciphera Pharmaceuticals; 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213973s000lbl.pdf. Accessed 21 July 2020.

Example

Directives, Regulations, Standards and Guidelines Covered in This Chapter

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[1]
- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells[2]
- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells[3]
- Commission Directive 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells[4]
- Commission Directive 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells[5]

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