RAPS Author Style Guide

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Manuscript 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.”

Use only one space at the end of a sentence.

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article (the publisher assumes no liability) Anything accepted for publication becomes the publisher’s property and may not be published elsewhere without the written permission of both the author and publisher.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

Acronyms
Acronyms should follow the full spelling in parentheses upon first reference. Example: The Federal Bureau of Investigation (FBI) is looking into the matter. For each subsequent reference, use only the acronym. If the name is to be referenced only once, do not use the acronym at all—spell out the name completely.

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
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., 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.

**Hyphen**
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
- 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
- multi-center
- multi-site
- 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, Endnotes and Bibliographies**
RAPS follows the *American Medical Association Manual of Style* for reference, endnote and bibliography content. Titles of articles and book chapters should be spelled out and enclosed within quotation marks. 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.
6. Op cit. 3.
7. Ibid.

When including a url, please add the date the website or web page was accessed.