About the Medical Writing Certification Program

In collaboration with the American Medical Writers Association (AMWA), the Medical Writing Certification Commission (MWCC) developed the Medical Writer Certified (MWC®) credential, which helps document the proficiency of professional medical writers. The MWC credential is a rigorous, examination-based professional certification. Professionals with this credential have demonstrated their broad understanding of core competencies associated with medical writing and an ability to apply these competencies. The MWCC developed the certification program in an evidence-based manner, with input from professionals from a broad range of medical writing backgrounds and specialties. To learn more about the program, visit the following sites:

- Overview of the MWC program:
  - Medical Writer Certified – [click here](http://www.amwa.org/mwc) or visit www.amwa.org/mwc
- Applicant eligibility:
  - MWC FAQ – [click here](http://www.amwa.org/page/mwc_faq/#Eligibility)
- Qualifying work experience:
  - Qualifying Work Experience document – [click here](http://www.amwa.org/mwc)
- Application:
  - Apply to become an MWC – [click here](http://www.amwa.org/page/MWC_Apply)
- Examination registration information:
  - MWC Applicant and Candidate Handbook – [click here](http://www.amwa.org/page/MWC_Apply) or visit www.amwa.org/page/MWC_Apply
Examination Preparation Recommendations

The MWCC developed this study guide to help candidates prepare for the MWC Examination. We recommend that you read the guide thoroughly before starting your preparation. This guide includes the following:

- A content outline to help candidates identify topics covered in the examination and recognize unfamiliar areas that require extra study
- A few example questions to acquaint candidates with types of questions in the examination and to provide opportunity for practice
- A resource list to help candidates identify study materials

The content outline delineates the core competencies—knowledge, skills, and abilities (KSAs)—of professional medical writers. Carefully studying this outline will help you:

- Know the approximate percentage of the examination devoted to each content area
- Identify the topics and medical writing tasks that are associated with each content area and that may be tested for on the examination
- Assess your current knowledge related to each content area
- Build a study plan based on your current knowledge (For example, candidates unfamiliar with regulatory writing may want to study materials in that area.)

An example of an examination preparation sequence that may be helpful is to:

- Use the examination content outline and the example topic and subtopic categories in this study guide to help identify areas of medical writing
- Identify competencies and related topics that are unfamiliar
- Study materials about the identified unfamiliar topics (The section in this guide on examination preparation resources has materials that may be helpful.)

You are not expected to have detailed knowledge of all topics. However, you should be familiar with major concepts and guidelines within the topics. The MWC Examination is a robust test of professional competency. Important aspects of examination preparation include having at least 2 years of full-time or 4 years of part-time medical writing experience, possessing a broad understanding of medical writing competencies, and filling knowledge gaps before taking the examination. However, these items do not guarantee a passing score.
Medical Writing Certification Examination Content

Content in the MWC Examination is based on the definition of medical writer shown below and in the content outline that follows. The 125-question multiple-choice examination is completed via computer-based answer entry at a testing center. The examination is in English and taken over a 2.5-hour period. All questions are weighted equally. There is no penalty for incorrect answers; therefore, candidates should try to answer every question.

Medical Writing Definition

The MWCC defines medical writing based on AMWA’s definition of a medical communicator.

*Medical writers write, edit, or develop materials about medicine and health. They do this by gathering, evaluating, organizing, interpreting, and presenting information in a manner appropriate for the target audience. Professional medical writers have communication expertise, awareness of ethical standards, and health care knowledge.*

Examination questions cover several types of medical writing, including:

- Patient education brochures, news articles, web content, and books for the public
- Journal articles for health care professionals and biomedical researchers
- Continuing education monographs for health care professionals
- Regulatory documents for government agencies
- Grant proposals for funding agencies
- Sales training and marketing materials for the pharmaceutical, biotech, and device and diagnostic industries

Examination Content Outline

To guide preparation, candidates should use the content outline (see below). The KSAs of the outline are divided into 5 domains associated with the definition of a medical writer: gathering, evaluating, organizing, interpreting, and presenting. The questions address all 5 domains, with the approximate percentages of questions per domain shown in parentheses.

1. **Gathering** (16% of content)
   - A. Determine the purpose of the document
   - B. Identify the context for the document
   - C. Identify the target audience
     - 1) Assess needs
     - 2) Identify knowledge gaps
D. Select appropriate output type (eg, publications, regulatory documents, continuing medical education materials, patient education)

E. Identify appropriate outlet (eg, target journal, other print media, web)

F. Apply effective processes to gather information
   1) Conduct a literature search (eg, PubMed/ MEDLINE)
   2) Elicit information from collaborators and stakeholders (eg, interview researchers, statisticians, clinicians, patients, regulators, thought leaders)
   3) Identify other relevant sources (eg, websites, databases, data outputs, clinical guidelines)
   4) Identify relevant writing guidelines, instructions, and ethical standards (eg, journal instructions for authors, grant application instructions, regulatory requirements)
   5) Identify relevant document models and templates
   6) Identify necessary forms and supporting materials (eg, permission to reprint, disclosures, copyright)

2. **Evaluating** (19% of content)
   A. Evaluate collected information with regard to
      1) Content (ie, quality and relevance, level of evidence)
      2) Audience (ie, appropriate and relevant to needs)
      3) Context (ie, credibility of sources and suitability for purpose)
   B. Perform fact or data check
   C. Identify inconsistencies in data or other content presented
   D. Conduct critical review of a draft
      1) Assess quality of writing (eg, clarity, readability, usability, logic, organization, consistency)
      2) Provide constructive criticism
         a) Provide options for solutions
         b) Craft appropriate queries
      3) Evaluate representation and description of data
      4) Recognize ethical considerations with respect to self and others (eg, conflict of interest, disclosure, authorship, plagiarism, duplicate publications)
   E. Evaluate the document for completeness, fair balance, and absence of bias
   F. Determine the appropriate levels of editing (eg, proofreading, microediting, macroediting)
   G. Implement best approaches to resolve issues (eg, author disagreements, scope change, unexpected delays)

3. **Organizing** (19% of content)
   A. Determine correct organization of a document (eg, IMRAD)
   B. Identify and prioritize key elements of content
   C. Structure content to communicate message
   D. Develop an outline
   E. Apply templates and guidelines to documents (eg, CONSORT, ICMJE, FDA, ICH, PRISMA, ACCME, HIPAA, health literacy)
F. Determine structure of tables and figures to best communicate data
G. Determine which references to cite in a document
H. Comprehend processes of developing and disseminating documents (eg, news releases, publications, grant and regulatory submissions)
I. Design project work plan
   1) Determine deliverables
   2) Develop timeline
   3) Recognize roles, responsibilities, and processes
J. Track progress and status of project
K. Determine process for tracking changes and version control
L. Recognize and apply appropriate software and technology to use in developing the document

4. **Interpreting** (19% of content)
   A. Comprehend relevant medical and scientific content
      1) Understand terminology
      2) Understand concepts (eg, cellular and molecular level, organism level, and population level)
      3) Understand study design (eg, clinical trial, case control, longitudinal study)
      4) Understand statistical concepts (eg, \( P \) value, confidence interval, power)
   B. Interpret clinical and numerical data
   C. Derive key messages
   D. Determine inferences, implications, or clinical relevance
   E. Synthesize and integrate information
   F. Revise or repurpose existing content
   G. Comprehend review processes (eg, peer review, grant review, regulatory review)
   H. Respond to reviewers’ comments
      1) Interpret feedback from reviewers
      2) Determine appropriate responses

5. **Presenting** (27% of content)
   A. Present the message logically and coherently (ie, tell the story)
   B. Retain the intended meaning of source materials or original document
   C. Communicate scientific content appropriately
   D. Communicate statistical content appropriately
   E. Develop clear, concise prose
   F. Write an abstract (eg, for presentation or publication) or executive summary
   G. Tailor prose to the audience
   H. Build logical and science-based arguments
   I. Apply proper mechanics
      1) Apply rules of grammar, spelling, and punctuation
2) Apply proper word usage (general and medical), correct nomenclature, and nondiscriminatory language
3) Construct effective sentences
4) Construct effective paragraphs (eg, topic sentences, transitions, repetition of key terms)
5) Apply techniques for cohesion between paragraphs and sections
J. Apply principles of proofreading
K. Apply basic principles of design and layout (eg, document, slide, poster, web)
L. Apply principles of visual presentation of data (eg, tables, figures)
M. Write document to adhere to standardized formats, guidelines, instructions, and ethical standards
Example Topic and Subtopic Categories

To provide a more concrete sense of what the examination will cover, examples of core topics and sample subtopics are provided below. Although the list indicates the main scope of the examination, it is not exhaustive, and the examination may also address other relevant topics and subtopics.

- Continuing medical education
  - Needs assessment
  - Learning objectives
  - Independence from commercial interest

- Epidemiologic and other research
  - Bias, confounding, and interaction
  - Incidence vs prevalence
  - Phases of drug development
  - Study design (for example, clinical trial, cohort, case-control, cross-sectional)
  - Systematic review and meta-analysis

- Ethical and legal principles
  - Authorship criteria
  - Conflicts of interest
  - Copyright
  - Fair/balanced content
  - Privacy/confidentiality

- Mechanics of writing
  - Grammar
  - Parallelism
  - Punctuation
  - Sentence structure
  - Paragraphing
  - Proofreading

- Patient/health education
  - Lay words for medical terms
  - Definition of plain language
  - Suitable medium for the target audience
  - Techniques for assessing understandability
  - Writing for reading comprehension levels

- Project management
  - Coordinating authors and/or reviewers
  - Managing document development timelines
  - Using document management tools and processes

- Publication practices
  - Author guidelines
  - Consolidated Standards of Reporting Clinical Trials
  - Good Publication Practice
  - Journal selection
  - Prepublication embargo
  - Publication planning
  - Responding to reviewers
• References and literature searching
  o Use of search terms
  o Fair/balanced searching
  o Source credibility

• Regulatory submissions
  o Structure of the Investigator's Brochure
  o Content of the Clinical Study Report
  o Structure of the Common Technical Document
  o Data Safety Monitoring Plan
  o New Drug Application vs Investigational New Drug application
  o Regulatory document types and purposes
  o Documentation of substantial evidence of effectiveness

• Research grant applications
  o The purpose of grant proposals vs other scientific documents
  o Application process
  o Strategic techniques in writing and editing grant proposals (grantsmanship)

• Statistical concepts and analysis reporting
  o Confidence interval
  o Effect size
  o Measures of central tendency and variability
  o Multiplicity (multiple testing)
  o Risk ratios, odds ratios, and relative risk
  o Sensitivity and specificity
  o Statistical tests and statistical significance
  o Type I and II errors (false-positive and false-negative studies)

• Terms and their usage—for example:
  o Clinical research terms
  o Medical communication terms
  o Medical terms
  o Other terms—for example:
    ▪ Digital object identifier
    ▪ International System of Units (Système International)
    ▪ Institutional review board
    ▪ Protocol deviation
    ▪ Publication bias
Example Questions
The questions listed below are representative examples of those on the MWC Examination. An answer key appears in the next section.

1. The beginning of the Discussion section in a scientific article should
   A. answer the question(s) posed in the Introduction.
   B. review the literature related to the field.
   C. state the strengths and limitations of the study.
   D. explain the significance of the results.

2. A medical writer receives an assignment to produce a multimedia project that will involve multiple vendors. The client wants the project to be rolled out in conjunction with a new product, for which there is a firm deadline. Which task is MOST appropriate for the medical writer to undertake first to complete the project?
   A. Given the deadline, propose alternatives to a multimedia project.
   B. Monitor the budget weekly and send vendors weekly invoices.
   C. Create a timeline for each vendor’s deliverable items.
   D. Begin to create a draft script for the project.

3. A study comparing the risks of postoperative complications for 2 surgical procedures showed a 2-fold difference. An analysis stratified by patient smoking status found a risk ratio of 4.75 among smokers and 1.0 among nonsmokers. Which term BEST explains these results?
   A. Confounding
   B. Interaction
   C. Information bias
   D. Selection bias

4. When conducting a needs assessment for an accredited-provider continuing education activity for nurses, a medical writer should identify the
   A. gap between best practice and the nurses’ current practice.
   B. gap between the nurses’ interests and current knowledge deficits.
   C. nurses’ rank-ordering of their current learning needs.
   D. nurses’ self-identified current practice interests.
5. A medical writer recognizes that abbreviations are
   A. universally used across languages.
   B. used only in titles and headers.
   C. avoided in lengthy publications.
   D. to be defined when first used.

6. When submitting a regulatory marketing application for a new drug, the medical writer needs to know that the Common Technical Document format includes
   A. the summary and overview documents in Module 2.
   B. the Clinical Overview in Module 3.
   C. the Clinical Study Reports in Module 4.
   D. the Nonclinical Study Reports in Module 1.

7. Which is the BEST title for a grant proposal based on preliminary studies showing that microRNA-based therapy may reverse right ventricular hypertrophy and improve pulmonary arterial hypertension and survival in rats?
   A. MicroRNA-based therapy reverses right ventricular hypertrophy and improves pulmonary arterial hypertension and lifespan.
   B. Studies of microRNA-based therapy in rats with pulmonary arterial hypertension.
   C. Improvement of right ventricular hypertrophy, of pulmonary arterial hypertension, and of lifespan after microRNA-based therapy.
   D. MicroRNA-based therapy for treating right ventricular hypertrophy and improving survival in a rat model of pulmonary arterial hypertension.

8. When evaluating a commercial website as a potential resource for information, which of the following items is MOST important for the medical writer to consider?
   A. The reputation and background of those who have created the website
   B. Whether the treatments discussed have been approved by regulatory authorities (eg, FDA)
   C. The number of references and patient testimonials cited to support the potential treatment claims
   D. Potential conflict of interest if the products being discussed are sold by the website sponsor
9. A researcher asks a medical writer to review a draft manuscript and provide critical comments and suggestions. The medical writer notices that the narrative describing a table is not consistent with the data presented in the table. What should the medical writer do?
A. Ignore it since the scientific peer reviewers did not see it as a problem.
B. Query the author about the apparent discrepancy.
C. Correct the discrepancy in the text so that it matches the table.
D. Evaluate the data in the table to determine the problem.

10. The results from a placebo-controlled clinical trial of a new antihypertensive treatment are mean difference in blood pressure=1.2 mm Hg (P<.001). Which BEST describes these results?
A. Clinically important and statistically significant
B. Clinically important but not statistically significant
C. Not clinically important but statistically significant
D. Not clinically important and not statistically significant

11. To assess the potential effect of drinking wine on the risk of fatal myocardial infarction, researchers collected the cardiac mortality rate and per capita wine consumption for 30 countries and found a correlation coefficient of −0.75. What type of study design is this?
A. Cohort
B. Case-control
C. Ecologic
D. Cross-sectional

12. In the following sentence, which word or words are used incorrectly?
The patient died of pneumonia, which was due to immune suppression from a large dosage of azathioprine.
A. Died of
B. Which
C. Due to
D. Dosage
**Answer Key**

References are noted for each answer listed. The full citations for references are provided in the Selected Examination Preparation Resources section.

1. **The correct answer is A.** The opening of the Discussion should succinctly answer the research question(s) posed at the end of the Introduction, i.e., state the conclusion that can be drawn from the data presented in the Results. This is the author’s chance to frame the discussion of the results. In the middle section of the Discussion, the author should explain the significance of the results in light of others’ work and mention any limitations of the study. The Discussion is not the place for a literature review. Only literature directly related to the results of the author’s study should be discussed.


2. **The correct answer is C.** Creation of a timeline before beginning work will allow the writer to understand what needs to be delivered and communicate with the client about potential scheduling constraints, which is important given the firm deadline and the complexity of typical multimedia projects. This step will help the writer, in collaboration with the client, determine an appropriate scope for the project.

   References: Project Management Institute (2011: 1)

3. **The correct answer is B.** “Two explanatory variables are said to interact if the effect of one explanatory variable on the response variable depends on the level of the second explanatory variable. Interaction implies that the explanatory variables should be considered together, not separately” (Lang & Secic, 2006: 98). In this question, smoking status influences the effect of the independent variable (surgical procedure) on the outcome/dependent variable (postoperative complications) because the risk is present (risk ratio=4.75) only for smokers, i.e., not for nonsmokers (risk ratio=1.0).

   References: Lang & Secic (2006: 98, 112), Fletcher (2020:).

4. **The correct answer is A.** According to the updated ACCME criteria, continuing education for health care professionals must focus on the educational needs that underlie the professional practice gaps of the targeted learners (formerly Criterion 2). A practice gap is defined as the difference between current practice and best practice. Thus, in writing a needs assessment, which justifies the need for a continuing education activity, a medical writer must first identify the practice gap and describe how the proposed activity will provide the education to bridge that gap.
5. **The correct answer is D.** The normal practice in medical writing is to define abbreviations on first mention (except, for instance, if they are standard abbreviations for units of measure).


6. **The correct answer is A.** As defined in the ICH CTD guidelines, Module 2 contains the overviews and summaries of information contained in Modules 3, 4, and 5.


7. **The correct answer is D.** Answer D is best because it is specific, indicates the research area and goals of the project, and includes the variables and species. Answer A claims too much for a project that is based on preliminary studies (i.e., …reverses right ventricular hypertrophy) and does not mention the species or population of the study. Answer B mentions the species, but the title is vague. Answer C has too many prepositional phrases and a nominalization as the first word.


8. **The correct answer is D.** The information being presented should be considered by the writer in the context of potential bias stemming from the commercial purpose of the commercial website. For choice A, reputation is subjective and although background may give insight into qualifications, it is not always a reliable indicator of information quality. Similarly, for choice B, the regulatory status of a treatment being discussed does not guarantee the quality of the information being presented. Regarding choice C, the number of cited references or anecdotes alone would not be a sufficient indicator of information quality; these would need to be verified and considered in terms of level of evidence.


9. **The correct answer is B.** Even if medical writers believe they know how to correct the discrepancy, this decision is the responsibility of the authors. According to widely accepted
international guidelines for scientific manuscripts, authors must approve the final version of the document. They must also agree to be accountable for all aspects of the work and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Querying authors about an apparent discrepancy will allow the authors to fulfill their responsibility.


10. The correct answer is C. While the result presented indicates that it is unlikely to have arisen by chance (ie, it is statistically significant given that $P<.001$), the magnitude of the average effect anticipated ($1.2 \text{ mm Hg}$) is quite small (not clinically important).


11. The correct answer is C. This is an ecologic study because the exposure variable (drinking wine) and outcome variable (fatal myocardial infarction) are measured/characterized by the average of the group (in this case, by country), rather than being measured on individual study participants as they would be in the other 3 listed study designs.

Reference: Fletcher (2020: 212)

12. The correct answer is D. Dosage would imply the regimen of azathioprine prescribed rather than the individual quantity given. The wording “died of” is preferred according to the AMA Manual of Style. “Which” is used correctly (answer B) to introduce a nonrestrictive clause. “Due to” is an adjectival phrase, modifying pneumonia. The words “caused by” or “attributable to” can be substituted for it, which is another way to know that it is used correctly in this instance.

Selected Examination Preparation Resources

Although work experience should provide much of the knowledge needed to pass the examination, the examination will cover many aspects of medical writing. Thus, MWC candidates should assess their knowledge base related to the content outline and focus on filling perceived gaps in knowledge and experience. Below are examples of study materials that may aid in this regard.

It is important to understand the following:

- Not all examination content is specifically covered in the listed resources.
- As shown by the sample questions, much of the examination requires applying knowledge. Therefore, only memorizing content from the resources may not suffice. Candidates also should know how to use the learning.
- The number of resources listed for a topic does not indicate the amount of examination content related to that topic. The amount of content for each topic on the examination is shown in the content outline.
- Some resources may contain information that contradicts information in other resources. Although it is valuable for medical communicators to be familiar with various industry resources, any contradictions among resources will not affect questions on the MWC Examination.
- The content domains tested on the MWC Examination—gathering, evaluating, organizing, interpreting, and presenting—are italicized and in brackets after each numbered category.
- Resources, including websites, were last tabulated/updated and/or accessed on November 30, 2023.
- For resources with multiple editions, it is best to consult the most recent edition.

A. General References Applicable to All Areas of Medical Writing

1. Epidemiology and statistical concepts and analysis reporting [Evaluating, Interpreting, presenting]


2. Ethical principles [Gathering, Evaluating, Interpreting, and Presenting]

   i. Online version: http://www.amamanualofstyle.com/


   i. Online version: http://www.amamanualofstyle.com/

   i. Online version: http://www.scientificstyleandformat.org/Home.html


4. **Medical writing competency** [Gathering, Evaluating, Organizing, Interpreting, Presenting]

5. **Project management** [Organizing]

6. **References and literature searching** [Gathering and Evaluating]

7. **Terms and their usage** [Presenting]

B. **Resources for Specific Areas of Medical Writing**

1. **Continuing medical education**


2. Patient/health education


i. Paling J. Strategies to help patients understand risk. BMJ. 2003;327:745–748. (free)
3. Publication practices [Presenting]


b. Gastel B, Day RA. How to Write and Publish a Scientific Paper. 9th ed. Greenwood; 2022. 348 pages. (Includes chapters on writing grant proposals and writing for the public)


4. Regulatory submissions


https://www.ich.org/page/ctd (free)

i. Wood LF, Foote M, Eds. Targeted Regulatory Writing Techniques: Clinical 
Documents for Drugs and Biologics. Birkhäuser; 2009. 238 pages.

5. Research grant application

a. National Institute of Allergy and Infectious Diseases. Writing a Winning 
January 22, 2024. https://www.niaid.nih.gov/grants-contracts/winning-
application-excite (free).

b. National Institute of Allergy and Infectious Diseases. Apply for a Grant. 

c. Yang OO. Guide to Effective Grant Writing: How to Write a Successful NIH 
Grant Application. 2nd ed. Springer; 2012. 90 pages.

C. Additional Resources on the AMWA Website

1. AMWA Education, Online Learning. Includes documents, interactive learning 
resources, and on-demand videos, many complimentary for AMWA members.  
http://amwa.mycrowdwisdom.com/diweb/catalog/t/5259/c/184/n/0.

2. Guidelines for Document Designers is a short, practical, evidence-based handbook 

   a. A cleaner PDF is available for AMWA members:  

(free).

4. The complete list of AMWA Essential Skills Workbooks. (Self-Study).  
Definitions of Acronyms

ACCME: Accreditation Council for Continuing Medical Education
AMA: American Medical Association
AMWA: American Medical Writers Association
CONSORT: Consolidated Standards of Reporting Clinical Trials
CSE: Council of Science Editors
EMWA: European Medical Writers Association
EQUATOR: Enhancing the Quality and Transparency of Health Research
FDA: United States Food and Drug Administration
HIPAA: Health Insurance Portability and Accountability Act
ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMJE: International Committee of Medical Journal Editors
IMRAD: Introduction, Methods, Results, and Discussion
ISMPP: International Society for Medical Publication Professionals
KSA: Knowledge, skills, and abilities
MWC: Medical Writer Certified
MWCC: Medical Writing Certification Commission
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses