



MEDICAL WRITING CERTIFICATION EXAMINATION  
APPLICANT AND CANDIDATE  
**HANDBOOK**

For questions about the Medical Writing  
Certification Examination, contact

Medical Writing Certification Commission  
American Medical Writers Association (AMWA)  
30 West Gude Drive, Suite 525  
Rockville, MD 20850

240-238-0940 • [certification@amwa.org](mailto:certification@amwa.org)

[www.amwa.org/mwc](http://www.amwa.org/mwc)

March 2017

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## About the Medical Writing Certification Program

Established by the American Medical Writers Association (AMWA), the Medical Writing Certification Commission (“the Commission”) is responsible for developing and overseeing a credentialing program for professional medical writers. AMWA and the Commission created the certification program to advance medical writing as a professional discipline by identifying and testing the knowledge, skills, and abilities (KSAs) that are essential to this type of work and by encouraging continued professional growth of medical writers. The certification program was developed in a deliberate and evidence-based manner, with input from individuals with a broad range of medical writing backgrounds and specialties. To learn more about the program, visit [www.amwa.org/mwc](http://www.amwa.org/mwc).

## About the Medical Writer Certified Credential

The Medical Writer Certified (MWC®) credential is awarded by the Commission to medical writers who pass the Medical Writing Certification Examination (“the exam”). Certification is voluntary and is not required for a medical writer to be employed in the field, but it offers many advantages.



The results of the exam are not intended to predict how well an individual may perform as a medical writer or to assess the relative level of that person’s medical writing skill or ability. However, the results can provide insight into each candidate’s level of knowledge in core content areas specific to medical writing. Therefore, some employers may consider certification in hiring decisions, job promotions, salary increases, recognition, or other considerations. In addition, certification will allow employers and clients to identify competency areas in the field; as a result, companies may be encouraged to promote professional development and, thus, improve the competency of their employees.

## Why Become Certified?

By obtaining the Medical Writer Certified (MWC®) credential, medical writers not only enhance their professional credibility but also give an employer or client increased confidence in their knowledge in core content areas specific to medical writing, as certified by a third party. Certification also shows a high degree of commitment to continued professional development in the field of medical writing. Those who earn the MWC® credential are required to adhere to a code of ethics and professional standards. These factors may increase an individual’s marketability and opportunities for career advancement and higher earnings. Also important is the personal satisfaction medical writers can derive from passing the exam and earning the MWC® credential.

## Applicant Eligibility Requirements

The Commission provides equal opportunity to all applicants without regard to race, color, religion, age, sex, national origin, sexual orientation, physical or mental disability, veteran status, or other legally protected categories.

To apply for the exam, individuals must have the following qualifications:

- a bachelor’s degree in any field of study.
- a minimum of 2 years of full-time work experience or equivalent (eg, 4 years of documented part-time work at 20 hours/week) within the past 5 years. Experience must be in a paid capacity in the field of medical writing.

Exceptions to the requirement for a bachelor’s degree may be granted for individuals with at least 5 full-time years (or equivalent) of verifiable work experience in the field. Experience must have been in a paid capacity within the past 10 years.

## Application Process

1. Complete the application form.
2. Provide a current résumé or curriculum vitae with

a short description of duties carried out in each job position.

3. Provide an official university transcript sealed in its original envelope. If the transcript is not in English, provide an English translation for Commission review.
4. Provide 2 letters of reference from individuals who can document the applicant's previous or current relevant medical writing work experience. Please provide the *Request Form for Letter of Reference* to each of your references. This form may be found on the certification website ([www.amwa.org/mwc](http://www.amwa.org/mwc)).
5. Answer background questions regarding any professional disciplinary proceedings. If applicants answer affirmatively to any of the background questions, their application will be subject to review by the Ethics and Appeals Committee of the Commission.
6. Read the *Adapted AMWA Code of Ethics and the Terms and Conditions of Certification* that are included in the application form. By signing the application, the applicant agrees to abide by these documents.
7. Pay the required application fee online through AMWA's website ([www.amwa.org/mwc](http://www.amwa.org/mwc)).

All original application materials must be sent to AMWA headquarters in 1 packet to the address on the application form. All submitted materials become the property of the Medical Writing Certification Commission. Once the submitted materials have been reviewed, the applicant will be notified regarding eligibility status.

**IF ELIGIBLE:** Within approximately 20 business days after receipt of materials at AMWA headquarters, applicants will receive an email notice of candidacy, along with instructions about how to register for the exam.

**IF NOT ELIGIBLE:** Within approximately 20 business days after receipt of materials at AMWA headquarters, applicants will receive an email notice of ineligibility, along with the reasons for the denial.

Approved applications will be good for 3 years after the receipt date of the application; the exam must be taken and passed in this timeframe. After 3 years, the individual must submit a new application, meet the eligibility requirements in effect for the new exam date, and pay an additional Application Fee.

## Denial of Eligibility

Eligibility to sit for the Medical Writing Certification Examination will be denied if any of the following conditions are present when an application is received at AMWA headquarters:

- eligibility criteria not met (eg, degree, years of experience).
- application incomplete or illegible (eg, failure to sign the application).
- verification documents missing or incomplete.
- correct fees not received.
- document(s) show evidence of tampering.

## Eligibility Appeals

Applicants may appeal a denial of eligibility to sit for the Medical Writing Certification Examination by emailing a written appeal and supporting documentation to AMWA headquarters within 10 business days from the date of the denial notification. If the 10-day mark falls after the withdrawal deadline for the exam (ie, within 15 days of the exam date), applicants submitting an appeal will not be able to take the exam on the date originally requested.

The appeal of the denial message **MUST** include the following:

- the reason for the appeal.
- documentation supporting the appeal or showing that the matter identified in the denial message has been corrected.

Failure to follow the directions in the *Applicant and Candidate Handbook* is not grounds for appeal. Appeals based on the failure of the postal system, other delivery methods, or a university transcript office will be considered only in documented extraordinary circumstances.

Once the appeal materials have been reviewed, applicants will receive an email notice of eligibility or continued ineligibility to sit for the exam.

AMWA headquarters will maintain files of all appeals and outcomes, including the complete documentation for each appeal, for a period of 5 years.

## Fees

MWC® Application Submission Fee: \$150 (includes non-refundable \$75 administration fee)

Examination Registration Fee: \$375 (includes non-refundable \$75 administration fee)

Manual Examination Rescore Fee: \$50 (nonrefundable)

Recertification Fee: \$375 (includes nonrefundable \$75 administration fee)

All fees are to be paid online through AMWA's website ([www.amwa.org/mwc](http://www.amwa.org/mwc)). Fees are subject to change over time.

## Refund Policy

Applicants, including those who have been denied eligibility to sit for the exam, may request a refund of the Application Submission Fee, minus the nonrefundable \$75 administration fee.

Candidates may request a refund of the Examination Registration Fee, minus the nonrefundable \$75 administration fee. To request a refund, candidates must cancel their registration in writing (via email) within 15 business days (3 weeks) before the scheduled exam.

Candidates who cancel less than 15 business days before the scheduled exam, fail to appear at the designated location, or come to the exam center without proper identification (ID) and/or the proper admission letter will not be allowed to take the scheduled exam and will forfeit the full Examination Registration Fee. Exceptions may be made, with proper documentation, in extraordinary circumstances such as a medical or personal emergency, death of an immediate family member, jury duty, active duty military assignment, or severe weather or a disaster that makes getting to the exam site impossible. The nonrefundable \$75 administration fee still applies in these extraordinary circumstances.

The Commission reserves the right to verify any information submitted regarding an absence on exam day. All absences will be reviewed on a case-by-case basis.

If a candidate taking the exam is dismissed for any reason, all exam fees will be forfeited.

The Manual Examination Rescore Fee and Recertification Fee are nonrefundable.

## Medical Writing Certification Examination

The Medical Writing Certification Examination is based on the results of a job analysis survey of medical writers that was completed in 2012 and on the definition of a medical communicator, which was developed by an AMWA task force and can be found on the AMWA website:

Medical communicators 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 also have communication expertise, awareness of ethical standards, and health care knowledge.

Materials prepared by medical communicators, collaborating with others or working independently, include the following:

- patient education brochures, news articles, web content, and books for the general public.
- journal articles and continuing education monographs for health care professionals.
- regulatory documents for government agencies.
- grant proposals for research scientists and institutions.
- sales training and marketing materials for the pharmaceutical industry.

From the job analysis, a content outline (**Appendix 1**) for the exam was developed that delineated the core competencies (ie, knowledge, skills, and abilities [KSAs]) of professional medical writers. The KSAs were divided into the 5 domains of AMWA's definition of a medical writer: Gathering, Evaluating, Organizing, Interpreting, and Presenting.

The exam questions address all 5 KSA domains according to rankings of importance indicated by survey data. The questions are presented in the context of different types of medical writing (eg, scientific manuscripts, patient-oriented content, regulatory).

The 125-question, multiple-choice exam is completed with paper and pencil, in English, over a 2.5-hour period. Example questions can be found in **Appendix 2**.

## Schedule, Location, and Deadlines for Medical Writing Certification Examinations

For information about upcoming exams, visit the Certification website ([www.amwa.org/mwc](http://www.amwa.org/mwc)).

## Delay or Cancellation of the Examination

The exam will be delayed or canceled only in emergencies (eg, if severe weather or a disaster makes the examination center inaccessible or unsafe). Notice of the same-day delay or cancellation will be posted on the Medical Writing Certification Commission's webpages on the AMWA website and relevant social media outlets. Every effort will also be made to formally notify scheduled candidates of a cancellation or delay individually via the email or phone contact information provided on their application forms.

## Security

Any candidate who gives or receives assistance with test questions or whose behavior is disruptive during the exam will be required to surrender the exam materials immediately and leave the exam room. The candidate's answer sheet will not be scored, and the situation will be reported to the Commission. The exam proctors, who are chosen by the Medical Writing Certification Commission, are authorized to make security decisions; there is no onsite appeal.

The entire item bank, the exam materials, and each form of the exam are the property of the Medical Writing Certification Commission. Distribution of exam content or materials through any form of reproduction,

including oral and written communication, is strictly prohibited and punishable by law. Any individual who removes or attempts to remove exam material from the exam site or in any other way to recompose an exam will be subject to prosecution. Discussion of exam content with other candidates after the test is also considered a breach of security and could cause revocation of certification.

## Day of the Examination

### Personal Identification

On the day of the exam, each candidate must present 2 valid (*primary* and *secondary*) forms of identification.

Valid *primary* forms of identification must be government-issued, current, and include the candidate's name, signature, and photograph. Examples of valid primary ID documents are a driver's license with photograph, state ID card with photograph, passport, and military ID card with photograph. A temporary ID card is not acceptable. Valid *secondary* forms of identification must display the owner's name and signature (eg, credit card with signature, social security card with signature, employment/student ID card with signature).

If the name on the exam registration list differs from that on the candidate's primary or secondary forms of identification, proof of name change (eg, marriage license, divorce decree, or court order) must be brought to the exam site. Candidates sitting for the exam also will be required to sign a roster to verify their identity.

### Restrictions

- No personal items or valuables should be brought to the exam room. Only a small purse or wallet and keys are permitted.
- No cameras, notes, or tape recorders are allowed in the exam room. Use of a cellular phone/smartphone or other electronic device is strictly prohibited and will result in dismissal from the exam.
- Pencils will be provided during check-in.
- No documents or notes of any kind may be removed from the exam room.

- No questions concerning the content of the exam may be asked during the exam.
- Eating and smoking will not be permitted during the exam; however, drinking of water is allowed.
- If a candidate taking the exam is dismissed for any reason, all exam fees will be forfeited.

## Accommodation for Disabilities

The Medical Writing Certification Commission is committed to the letter and spirit of the Americans with Disabilities Act of 1990 (ADA). Accordingly, special examination accommodations will be reviewed on an individual basis in compliance with ADA requirements.

- Special accommodations will be made only if previously requested and approved before the date of the exam.
- The Special Accommodations Request Form and a letter from a professional documenting the disability-related needs are required at the time of exam registration.
- Additional fees will not be charged to provide special accommodations.
- Information submitted to the Certification Commission about candidate disabilities and testing will be kept confidential unless required to be disclosed to provide the accommodation.

## Resources for Examination Preparation

The content outline for the Medical Writing Certification Examination appears in **Appendix 1**. The content outline lists the KSAs considered necessary for competency in the field of medical writing and the percentage of exam questions that will come from each area of the outline. Because the exam will include questions from all of the content areas (domains), the content outline can be used to guide candidate review in preparing for the exam. For example, if unfamiliar with a particular type of medical writing found on the content outline, such as regulatory writing or grant writing, potential

applicants can prepare themselves in those specific areas before taking the exam. They can choose to review content from the references listed in the *Select Resources* (**Appendix 2**) or from other resources in the content areas. Other opportunities for learning new content or reviewing material for the exam could include attending a workshop at an AMWA annual conference or chapter conference, or attending meetings of other organizations. As mentioned earlier, a few example questions that are representative of the types that may be included on the certification exam can be found in **Appendix 3**.

## Notification of Examination Results

Candidates who complete the exam will receive notification of their results (passing/certified or not passing/not certified), from the Medical Writing Certification Commission, typically within 60 to 90 days after the exam date. Those who achieve the minimum required score will be mailed an official document attesting to their certification. During this process, candidates should notify AMWA of any contact information (email or mailing address) changes.

Note: Examination results will not be provided over the telephone or by facsimile under any circumstances.

## Examination Appeals

Individuals may appeal the exam results, citing and providing evidence of extraordinary circumstances. Failing the exam is not sufficient grounds for appeal. Appeals must include the reason for the appeal and supporting documentation. Appeals will be considered by the Ethics and Appeals Committee and must be submitted via email within 30 days from the date of notification of the exam score.

## Requests for Manual Scoring

Every answer sheet used for an exam is scanned by an optical mark reader, and errors are reviewed by the scanning operator. The possibility of a scanning error is negligible. However, after exam results are received,

candidates may request that the testing agency manually verify that the answers marked on their answer sheet match the answers recorded by the scanner. The Manual Examination Rescore Fee of \$50 is nonrefundable.

## Retaking the Examination

Once an applicant's eligibility to sit for the Medical Writing Certification Examination has been approved, the exam may be retaken without resubmitting original verification, as long as current eligibility requirements are fulfilled and remain current at the time of the subsequent exam. The exam may be taken an unlimited number of times until a passing score is obtained. However, Examination Registration Fees will apply for each exam attempted.

Certified medical writers who have earned the MWC® but whose certification has lapsed must retake the exam. They will need to reestablish eligibility under current requirements and submit a full application, with supporting documentation and appropriate examination fees.

## Use of the Medical Writer Certified (MWC®) Credential

Candidates who pass the Medical Writing Certification Examination will be considered certified as of the exam date and will be entitled to use the credential Medical Writer Certified or MWC® after their name. Before using the certification mark, candidates should review the *Terms and Conditions of Certification* agreed upon when the application form was signed. MWC® is a registered certification mark. It is not to be punctuated with periods. Certification will expire at the end of the calendar year in which the 5-year certification anniversary falls.

By granting a Medical Writer Certified (MWC®) credential, the Commission and its affiliates assume no responsibility for the actions or activities of the certified individual and are released from all liability.

## Misrepresentation of Certification

Inappropriate use of the credential will be referred to the Ethics and Appeals Committee for action. Individuals using the Medical Writer Certified (MWC®) credential without being duly certified by the Commission will be advised in writing by the Commission Chairperson of the seriousness of this offense and the legal ramifications of professional misrepresentation. Individuals found to be using the credential after receiving such notification will not be permitted to sit for the Medical Writing Certification Examination. If the individual persists in using the credential, legal action may be taken.

## Revocation of Certification

An individual's certification may be revoked at the Commission's discretion after review by the Ethics and Appeals Committee. Grounds for revocation include the following situations:

- falsifying an application for certification.
- falsifying any information requested by the Medical Writing Certification Commission.
- cheating on the exam.
- failing to maintain the confidentiality of the exam.
- failing to recertify.
- violating the *Terms and Conditions of Certification* or the *Adapted AMWA Code of Ethics*.
- being convicted of a felony or of a crime relating to the provision of medical writing services.

## Recertification

To maintain the Medical Writer Certified (MWC®) credential, individuals must recertify by the end of each 5-year certification period, before December 31 of the fifth year after certification was granted. (For example, if certified in October 2015, the individual must recertify by December 31, 2020.) Individuals may recertify by reexamination or by obtaining 50 continuing education (CE) credits related to the exam content outline. Those who choose to recertify by reexamination will be bound



by the Medical Writing Certification Examination policies and procedures in place at that time. To locate the current version of this *Handbook* and the *Recertification Handbook*, visit the Certification webpages ([www.amwa.org/mwc](http://www.amwa.org/mwc)). *The Recertification Handbook* also delineates the procedures to follow and the qualifying activities and credits required for recertification. Certificants can begin accruing MWC® recertification points once they have passed the exam.

## **Confidentiality and the Release of Testing and Certification Information**

AMWA staff will verify certification status to members of the public on request, and an online directory will be accessible on the AMWA website. To protect privacy, no individual results (test scores) will be made available.

## Appendix 1: Content Outline for the Examination

In 2012, Commission members were charged with developing an outline to determine the core knowledge, skills, and abilities (KSAs) for medical writers. To do so, the Commission assembled a set of profession-related materials and resources, including material from AMWA's workshops and the competency model developed by the Drug Information Association's Medical Writing Community. The Commission convened a Job Analysis Panel that met with the examination administration agency in March 2012 to create a final KSA outline, which was based on the results of a Job Analysis Survey. The Panel deliberated about the key domains of a medical writer's competencies, as well as the component KSA elements comprising each domain.

The resulting content outline, which was used to develop the Medical Writing Certification Examination, can be used to guide review and to ensure the appropriate knowledge and critical thinking skills necessary to earn the Medical Writer Certified (MWC®) credential. All areas of the content outline will be represented on the exam. Thus, the outline will allow individuals to

- become familiar with the emphasis (percentage of content) for each content area.
- know the topics and the appropriate medical writing tasks associated with each content area.
- inventory their current knowledge related to each content area.
- build a study plan based on their knowledge inventory (for example, those not familiar with regulatory writing will probably need to review materials in this area).

### Medical Writing Certification Examination Content Outline

#### 1. Gathering (16% of content)

- A. Determine purpose of document
- B. Identify context for document
- C. Identify 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 for completeness, fair balance, and absence of bias
- F. Determine appropriate level(s) of editing (eg, proofreading, microediting, macroediting)
- G. Implement best approach 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 message(s)
- 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

## Appendix 2: Select Resources

Reviewing the content outline (Appendix 1) is the best way for those interested to decide whether they have the knowledge, skills, and abilities (KSAs) addressed in the Medical Writing Certification Examination. Work experience should provide many of the needed skills. However, the exam will cover broad aspects of medical writing, so additional review may be necessary for medical writers who are unfamiliar with an area of the content outline. You should prepare based on your assessment of where you are stronger or weaker in knowledge or experience.

This list of resources is meant only to give examples of the types of study materials that may be used in exam preparation; other references and websites may also be helpful.

Alperin LM. *Punctuation for Clarity and Style*. Rockville, MD: American Medical Writers Association; 2011.

American Medical Association. *AMA Manual of Style: A Guide for Authors and Editors*. 10th ed. New York, NY: Oxford University Press; 2007.

Babler SD. *Pharmaceutical and Biomedical Project Management in a Changing Global Environment*. Hoboken, NJ: John Wiley & Sons; 2010.

Council of Science Editors. *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers*. 7th ed. New York, NY: The Council of Science Editors in Cooperation with Rockefeller University Press; 2006.

Day RA, Gastel B. *How to Write and Publish a Scientific Paper*. 7th ed. Greenwood; 2011.

Fletcher RH, Fletcher SW, Fletcher GS. *Clinical Epidemiology: The Essentials*. 5th ed. New York, NY: Lippincott Williams & Wilkins; 2014.

Gastel B. *Elements of Medical Terminology*. Rockville, MD: American Medical Writers Association; 2010.

Hamilton C. *Essential Ethics for Medical Communicators*. Rockville, MD: American Medical Writers Association; 2011.

Hamilton C. *Tables and Graphs*. Rockville, MD: American Medical Writers Association; 2012.

Harvey B. *Statistics for Medical Writers and Editors*. Rockville, MD: American Medical Writers Association; 2011.

Huth EJ. *Writing and Publishing in Medicine*. 3rd ed. Baltimore, MD: Lippincott Williams & Wilkins; 1999.

Institute of Medicine. *Health Literacy: A Prescription to End Confusion*. Washington, DC: National Academies Press; 2004.

International Committee of Medical Journal Editors (ICMJE). *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. December 2014. Available at <http://www.icmje.org/icmje-recommendations.pdf>. Accessed February 27, 2015.

Lang TA, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers*. 2nd ed. Philadelphia, PA: American College of Physicians; 2006.

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Schwager E. *Medical English: Usage and Abusage*. Phoenix, AZ: Oryx Press; 1991.

U.S. Food and Drug Administration. ICH Guidance Documents. [www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm).

U.S. National Library of Medicine. PubMed Tutorial. <http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/cover.html>.

Witte F. *Basic Grammar and Usage for Biomedical Communicators*. Rockville, MD: American Medical Writers Association; 2011.

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Wood LF, Foote M. *Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics*. Basel; Boston, MA: Birkhäuser; 2009.

Yang OO. *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application*. 1st ed. New York, NY: Springer; 2005.

Zeiger M. *Essentials of Writing Biomedical Research Papers*. 2nd ed. New York, NY: McGraw-Hill, Health Professions Division; 2000.

## Appendix 3: Example Questions

The following questions are representative examples of those that will be on the certification examination. The full citations for references can be found after the answer key.

Remember that you are not expected to know every answer in order to pass the exam.

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 found 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 of the following **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 (CTD) 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 that showed 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 specific website as a potential resource for information, which of the following criteria is **MOST** important for the medical writer to consider?
- The reputation and background of those who have created the website
  - Whether the treatments discussed have been approved by regulatory authorities (eg, US Food and Drug Administration)
  - The number of references and patient testimonials cited to support the potential treatment claims
  - 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?
- Ignore it since the scientific peer reviewers did not see it as a problem.
  - Query the author about the apparent discrepancy.
  - Correct the discrepancy in the text so that it matches the table.
  - 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 mmHg ( $P < .001$ ). Which of the following **BEST** describes these results?
- Clinically important and statistically significant
  - Clinically important but not statistically significant
  - Not clinically important but statistically significant
  - 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?

- Cohort
- Case-control
- Ecologic
- 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.

- died of
- which
- due to
- dosage

### Answer Key

1. **The correct answer for this question is A.** The opening of the Discussion should succinctly answer the research question(s) posed at the end of the Introduction, ie, state the conclusion that can be drawn from the data that were presented in the Results. This is the author's chance to frame the discussion of the results. The rationale is that readers remember best what comes first and last, so the author needs to take advantage of the beginning of the Discussion to state what was found. In the middle section of the Discussion, the author will explain the significance of the results in light of others' work and mention any limitations of the study. The Discussion is never the place for a literature review. Only literature directly related to the results of the author's study should be discussed.

References: Huth (1990: 67), Lang (2010: 161), Mallia (2001: 110), Zeiger (2000: 183-184)

2. **The correct answer for this question 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 collabora-

tion with the client, to determine an appropriate scope for the project.

References: Project Management Institute (2011: 1), Rieger (1997: 224)

- 3. The correct answer for this question 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 affects 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, ie, not for nonsmokers (risk ratio=1.0).

References: Lang & Secic (2006: 98, 112), Fletcher, Fletcher, & Fletcher (2014: 76).

- 4. The correct answer for this question is A.** According to the updated Accreditation Council for Continuing Medical Education (ACCME) criteria, continuing education for health care professionals must focus on the educational needs that underlie the professional practice gaps of the targeted learners (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.

Reference: Massy (2010: 6-9)

- 5. The correct answer for this question 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).

References: American Medical Association (2007: 357), Day & Gastel (2011: 210), Gastel (2010: 42), Huth (1999: 214), Lang (2010: 38)

- 6. The correct answer for this question is A.** As defined in the International Conference on Harmonization (ICH) guidelines on Organization of the Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use, Module 2 contains the overviews and summaries of information contained in Modules 3, 4, and 5.

References: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2004: 2-4), Wood & Foote (2009: 148)

- 7. The correct answer for this question is D.** Answer A claims too much for a project that is based on preliminary studies (ie, ...reverses right ventricular hypertrophy) and doesn't 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. Answer D is best because it is specific, indicates the research area and goals of the project, and includes the variables and species.

References: Gerin (2011: 152-153), National Institutes of Health: National Institutes of Allergy and Infectious Disease (March 25, 2015), Lang (2010: 143-147), Zeiger (2000: 300-302)

- 8. The correct answer for this question 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 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.

References: American Medical Association (2007: 168), National Library of Medicine (April 19, 2012), UC Berkeley (May 8, 2012)

**9. The correct answer for this question is B.**

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. Even if a medical writer believes he or she knows how to correct the discrepancy, this decision is the responsibility of the authors.

References: International Committee of Medical Journal Editors (2015: 2), Einsohn (2011: 41)

**10. The correct answer for this question 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 mmHg) is quite small (not clinically important).

References: Lang & Secic (2006: xvii–xix), Glantz (2012: 125)

**11. The correct answer for this question 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, Fletcher & Fletcher (2014: 202)

**12. The correct answer for this question 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*, although some publications may allow “die from.” “Which” is used correctly in answer B to introduce a nonrestrictive clause. “Due to” is an adjectival phrase, modifying pneumonia. The words “caused by” can be substituted for it, which is another way to know that it is used correctly in this instance.

References: American Medical Association (2007: 109–110, 318, 391–392), Witte (2003: 82, 109–110), Huth (1987: 266)

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