Medical Writing Professionalism: Competency Modeling, Application, and Examination

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Eli Lilly and Company

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Renaissance Washington DC Downtown Hotel Congressional B

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Medical Writing Professionalism – Agenda

- Competency Model
- Application of Competency Model
- Certification Examination

Abbreviations:
DIA = Drug Information Association
KSABs = knowledge, skills, abilities, behaviors
MW = medical writer
MWC = Medical Writer Certified
Medical Writing Competency Model Content – Agenda

- Introduction to competency
- Background on model
- Content organization
- Work functions
- Knowledge, skills, abilities, behaviors (KSABs)
- Additional information
Introduction – What is Competency

The ability of an individual to perform a job successfully

A competent professional
- Is qualified to perform a specific role
- Has ability to perform a specific role
- Uses combination of KSABs to perform job successfully

Hanging a plaque on the wall that says medical writer
- No; thus,
  - Competency model (define the profession)
  - Certification development (test individual on competency)
Introduction - What is a Competency Model

- Defines what competence looks like for a given profession
- Outline of functions (tasks, activities) that person in role must perform to be successful
- Professionally agreed upon list of KSABs that define successful job performance
Background – Model History

- Developed by Drug Information Association (DIA) Medical Writing (MW) Community Working Group
  - Edition 1 approved 2009
  - Edition 2 approved 2017
  - Breadth of experienced MW professional contributors
    - 27 contributors/reviewers to edition 2
    - 419 cumulative years combined professional MW experience
    - Multiple global regions, companies, industry sectors, role settings
Background – Model Scope

Purposely inclusive to include scope/breadth of profession
- Covers competencies across wide range of situations
- All content is not relevant for an individual
- Focus on what applicable to individual based upon need

<table>
<thead>
<tr>
<th>Situation</th>
<th>Example 1</th>
<th>Example 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of writer</td>
<td>Regulatory</td>
<td>Publication</td>
</tr>
<tr>
<td>Setting (niche)</td>
<td>Industry</td>
<td>Freelancer</td>
</tr>
<tr>
<td>Information need</td>
<td>Role Communication</td>
<td>Training Plan</td>
</tr>
</tbody>
</table>

- Does not distinguish competencies of novice from experienced
  - Can be used to develop secondary tools to delineate
Background – Get a Copy

- DIA MW Community collaboration site: file library
- Email: davidclemow@lilly.com
- Published
Content Organization

- Work Functions
  - Tasks/Activities
- Knowledge
  - Skills/Abilities/Behaviors
- Additional Information

3 distinct but overlapping ways to show competencies
Content Organization – Additional Information

Additional Information

- General Abilities
  - All Medical Writers
- Certification
  - Competency Domains
- Abbreviations
Work Functions with Selected Task Examples

- **Scientific communication strategy**
  - Develop strategic plans for key message development and mapping
    - Continuity, alignment, synergy across documents, products, regions, functions
  - Develop strategic plans for key message dissemination

- **Document preparation, development, & finalization**
  - Author document, integrate cross-functional input, and ensure document communicates necessary information
  - Revise document while facilitating issue resolution
Work Functions with Selected Task Examples

- **Document project management**
  - Develop, coordinate, oversee work plans for both individual and multiple-document delivery, with all the needed tasks and subtasks, timelines, and assigned roles and responsibilities
  - Proactively establish a cohesive team to facilitate document delivery
  - Demonstrate leadership during conflict, disagreement, timeline delays

- **Document template, standard, format, & style development & maintenance**
  - Gather, review, and analyze resources to produce templates/guides
Work Functions with Selected Task Examples

- **Outsourcing, alliance partner, & client management**
  - Ensure governance and communication infrastructure in place, including operational principles and associated tools
  - Develop partner assessment program

- **Knowledge, skill, ability, & behavior development / sharing**
  - Elicit and respond to competency-related feedback

- **Process improvement**
  - Identify, collect, evaluate quantitative metrics to optimize performance in a data-driven manner
# Work Functions with Selected Task Examples

## Example

<table>
<thead>
<tr>
<th>F2</th>
<th>Document Preparation, Development, &amp; Finalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>Thoroughly gather, review, analyze, and evaluate pertinent resources and data to produce a high-quality document that meets internal/external customer needs</td>
</tr>
<tr>
<td>A1</td>
<td>Learn and understand the relevant medical/scientific background and treatment/therapeutic area intricacies</td>
</tr>
<tr>
<td>A2</td>
<td>Obtain and review applicable guidelines (eg, regulatory, publication, company, and industry) and document-specific templates for project applicability</td>
</tr>
<tr>
<td>A3</td>
<td>Obtain, compile, and organize the appropriate data, research literature, background information, and other materials needed to compose the document and make the document fit-for-purpose (eg, messaging, context, audience, output type, outlet/venue type)</td>
</tr>
<tr>
<td>A4</td>
<td>Ensure all information required to create the entire document and its various sections are valid, final, and representative as well as easily accessible by the authors</td>
</tr>
<tr>
<td>A5</td>
<td>Analyze, distill, and interpret data and other information to determine the best approach to composing the document</td>
</tr>
</tbody>
</table>
KSABs with Selected Examples

All medical writers
- Industry guidelines
- Project management techniques
- Science
- Communication techniques

Deliver written/visual communications that tell a scientific narrative
- Author content for cascade-level messaging
- Act with the highest ethical standard
- Demonstrate judgment-based thinking

Regulatory writers
- Standardization initiatives (eg, ICH)
- Regulatory authority regulations and guidance

- Prepare regulatory submission communication strategy
- Prepare documents for e-publishing
KSABs with Selected Examples

Publication writers
- Publication guidelines (eg, GPP3)
- Reporting guidelines (eg, CONSORT)

Managers of writers
- Business planning process
- Resource management

• Prepare publication plan strategy
• Prepare publication documents

• Create quality and compliance plans
• Provide risk management
• Strategically develop writing function

• Influence without authority
• Provide cultural sensitivity and manage across cultures
**Knowledge, Skills, Abilities, & Behaviors**

<table>
<thead>
<tr>
<th>All Medical Writers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
</tr>
</tbody>
</table>

1. Customer needs (e.g., information wanted in requested format)
2. Industry guidelines and regulations, including:
   - Copyright law and associated contracts
   - Life sciences regulatory: device, pharmaceutical/drug, biologic, vaccine, genetic, and immunologic therapies
   - Professional, pharmaceutical, health, and other life sciences organization/association
   - Publisher, journal, editor
   - SDO standards (e.g., CDISC, HL7, PhUSE)
3. Functional roles of other document development team members (e.g., role of statistics, clinical research, medical, safety, regulatory, and legal)
4. Policies, procedures, and processes of company, company suppliers/vendors, and customers (internal/external)
## General Abilities

<table>
<thead>
<tr>
<th>Ability</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive abilities</td>
<td>attention to detail</td>
</tr>
<tr>
<td>Communications skills</td>
<td>written expression</td>
</tr>
<tr>
<td>Work habits</td>
<td>time management</td>
</tr>
<tr>
<td>Soft skills</td>
<td>openness to feedback</td>
</tr>
</tbody>
</table>

## Example

<table>
<thead>
<tr>
<th>Communication Skills and Abilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Oral comprehension:</strong> understand what others are saying and understand the true meaning;</td>
</tr>
<tr>
<td>listen to and understand the meaning of words, phrases, sentences, and paragraphs, without judgment</td>
</tr>
<tr>
<td>2. <strong>Oral expression:</strong> deliver information in a clear, efficient, and interesting manner that fits</td>
</tr>
<tr>
<td>the audience; communicate the meaning of ideas, using correct diction, syntactic construction,</td>
</tr>
<tr>
<td>semantic usage, common sense, and economy of communication</td>
</tr>
<tr>
<td>3. <strong>Written comprehension:</strong> understand written material; read and understand the meaning of</td>
</tr>
<tr>
<td>words, phrases, sentences, and paragraphs; discern the potential unwritten subtext of the</td>
</tr>
<tr>
<td>communication</td>
</tr>
<tr>
<td>4. <strong>Written expression:</strong> use English (and other regional language for those who work in</td>
</tr>
<tr>
<td>non-English native countries) words and sentences in writing so others can understand;</td>
</tr>
<tr>
<td>communicate information and ideas in writing; know grammar, the meaning of words, the</td>
</tr>
<tr>
<td>distinctions between words, and how to organize sentences, paragraphs, and the ongoing flow of</td>
</tr>
<tr>
<td>ideas; write documents and correspondence, including email and instant messaging, that are</td>
</tr>
<tr>
<td>well organized, technically correct, and demonstrate brevity in communication</td>
</tr>
</tbody>
</table>
### Certification Core Competency Domains

Gathering – Evaluating – Organizing – Interpreting – Presenting

#### Example

<table>
<thead>
<tr>
<th>4. Interpreting</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Comprehend relevant medical and scientific content</td>
</tr>
<tr>
<td>a. Understand terminology</td>
</tr>
<tr>
<td>b. Understand concepts (i.e., at molecular, cell, organism, and population levels)</td>
</tr>
<tr>
<td>c. Understand study design (e.g., clinical trial, case-control, longitudinal)</td>
</tr>
<tr>
<td>d. Understand statistical concepts (e.g., P value, confidence interval, power)</td>
</tr>
<tr>
<td>B. Interpret clinical and numerical data</td>
</tr>
<tr>
<td>C. Derive key message(s)</td>
</tr>
<tr>
<td>D. Determine inferences, implications, and clinical relevance</td>
</tr>
<tr>
<td>E. Synthesize and integrate information</td>
</tr>
<tr>
<td>F. Revise or repurpose content</td>
</tr>
<tr>
<td>G. Comprehend review processes (e.g., peer review, grant review, regulatory review)</td>
</tr>
<tr>
<td>H. Respond to reviewer’s comments</td>
</tr>
<tr>
<td>a. Interpret feedback from reviewers</td>
</tr>
<tr>
<td>b. Determine appropriate responses</td>
</tr>
</tbody>
</table>
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>351(K)</td>
<td>351(k) Biologics License Application (for biological biosimilar or interchangeable)</td>
</tr>
<tr>
<td>510(k)</td>
<td>Premarket Notification 510(k)</td>
</tr>
<tr>
<td>ACCME</td>
<td>Accreditation Council for Continuing Medical Education</td>
</tr>
<tr>
<td>ADaM</td>
<td>Analysis Data Model</td>
</tr>
<tr>
<td>ADME</td>
<td>Absorption, Distribution, Metabolism, &amp; Excretion</td>
</tr>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>AMCP</td>
<td>Academy of Managed Care Pharmacy</td>
</tr>
<tr>
<td>AMWA</td>
<td>American Medical Writers Association</td>
</tr>
<tr>
<td>ANDA</td>
<td>Abbreviated New Drug Application</td>
</tr>
</tbody>
</table>
Medical Writing Competency Model Application – Agenda

Managers
- Hiring
- Training
- Setting goals / expectations
- Performance evaluation
- Retention
- Career ladders
- Vendor / sponsor management

Writers
- Professional development
- Training
- Developing best practices
- Coaching / mentoring
Hiring – Job Description

Responsibilities

• Write a variety of regulatory documents
• Coordinate quality review of documents
• Provide input on data analysis planning and interpretation

Qualifications

• Strong computer and project management skills, and a high attention to detail
• Strong oral and written communication skills
Revised responsibilities:

- Write and edit protocols, clinical study reports, and integrated summaries of safety and efficacy

- Participate in document strategy sessions, including messaging, document flow, logic, and consistency for assigned projects

- Gather, review, analyze, and evaluate sources of information with appropriate guidance from products teams

- Interpret and explain data generated from a variety of sources, including research documents and tables, figures, and listings
Revised qualifications:

- Has strong written, verbal, and data visualization communication skills to convey scientific narrative

- Able to accurately interpret data and communicate scientific concepts and numerical data in a clear and concise manner

- Has strong Microsoft Office skills (especially Word, PowerPoint, Excel, and SharePoint)

- Knows global regulatory requirements and guidance associated with clinical regulatory document preparation and submissions
Create checklists/screening tools to
• Assess skills and abilities of potential job candidates
• Ask competency-linked interview questions
# Hiring – Checklists and Screening Tools

## Abilities Checklist

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Score</th>
<th>Skill</th>
<th>Score</th>
<th>Behavior</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competency 1</td>
<td></td>
<td>Competency 1</td>
<td></td>
<td>Competency 1</td>
<td></td>
</tr>
<tr>
<td>Competency 2</td>
<td></td>
<td>Competency 2</td>
<td></td>
<td>Competency 2</td>
<td></td>
</tr>
<tr>
<td>Competency 3</td>
<td></td>
<td>Competency 3</td>
<td></td>
<td>Competency 3</td>
<td></td>
</tr>
</tbody>
</table>

## Knowledge

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Score</th>
<th>Skill</th>
<th>Score</th>
<th>Behavior</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of global regulations and guidances</td>
<td></td>
<td>Prepare regulatory submission communication strategy</td>
<td></td>
<td>Communicate effectively</td>
<td></td>
</tr>
<tr>
<td>Scientific communication techniques and principles</td>
<td></td>
<td>Author quality, compliant documents specific to audience needs</td>
<td></td>
<td>Manage multiple tasks</td>
<td></td>
</tr>
<tr>
<td>Expertise in Microsoft Word, Excel, and PowerPoint</td>
<td></td>
<td>Interpret data results from statistical outputs</td>
<td></td>
<td>Adapt to changing, complex environment</td>
<td></td>
</tr>
</tbody>
</table>
Training

- Identify training needs based upon model content
  - Metrics
  - Audit findings
  - Client feedback
  - Writer feedback

- Use model to develop trainings
  - Onboarding
  - Back to the basics
  - New processes and new technology
  - Advanced courses
Setting Goals and Expectations

- Writer and manager agree on expectations
  - MW competencies
  - Assessment: self, supervisor, peers, customers
  - Setting goals in Professional Development Plan

- Explain how will writer be measured against these expectations
  - Writer competencies
  - Metrics / key performance indicators
  - Formal and informal feedback
# Performance Evaluation

## Work Function:

<table>
<thead>
<tr>
<th></th>
<th>5 Excellent</th>
<th>4 Good</th>
<th>3 Average</th>
<th>2 Below Expect</th>
<th>1 Unacceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity 2</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Activity 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Feedback Survey

- Total: 31
## Performance Evaluation

### Work Function: Document Project Management

<table>
<thead>
<tr>
<th>Work Function</th>
<th>5 Excellent</th>
<th>4 Good</th>
<th>3 Average</th>
<th>2 Below Expect</th>
<th>1 Unacceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop, coordinate and oversee a completed work plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discuss tasks, subtasks, and roles and responsibilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop timelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordinate cross-document and task delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage the tasks, roles, responsibilities, and timing of the authoring team</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Feedback Survey
Retention

Retain good employees
• Base assignments on writer’s competencies and interests
• Clear expectations
• Provide resources and training
• Facilitate environment of knowledge sharing
Vendor / Sponsor Management

- Use model to aid successful collaborations
  - Expectation setting and alignment
  - Work plan development
Career Ladders

- Update job descriptions
- Create technical ladder
  - Increasing level of skills, abilities, and experience across roles or levels

<table>
<thead>
<tr>
<th>Role</th>
<th>Abilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Writer</td>
<td>Write documents within a team environment</td>
</tr>
<tr>
<td>Senior Medical Writer</td>
<td>Evaluate, analyze, and interpret medical literature with minimal supervision</td>
</tr>
<tr>
<td>Principal Medical Writer</td>
<td>Serve as a medical writing lead for submission-related documents</td>
</tr>
</tbody>
</table>

- Educate writers on possible career paths
Professional / Career Development

- Self assess own competencies
- Seek assessment from others
- Identify new work functions, tasks, activities
- Identify new KSABs
- Use to create development plans and careers maps
- Seek opportunities based on interest or growth
- Discuss regularly with supervisor
Professional / Career Development

- Think internally / locally
  - In-house training
  - Best practice sharing

- Think externally / globally
  - Professional organization conferences / workshops (eg, DIA, AMWA)
  - Volunteer activities (DIA Communities and work groups)
Use competency model content to perform gap analysis
  • Roles
  • Functions, tasks, activities
  • KSABs
    • Process
    • Technology
    • Technical skills
    • Soft skills

Use gap analysis to decide on training plans to enhance skill sets

Use competency model to create training and drive content for others
Best Practices

- Use model content to aid development of best practices
- Align on practices with team and alliance partners
- Share with customers
  - Denote what level of value professional medical writers (medical / scientific communicators) bring to the table
Coaching and Mentoring

- Use competencies to assign subject matter experts (SMEs) to topics for training, coaching, and mentoring
  - Maintain SME list
  - Pair junior writers with senior writers

- Create a library of shared learnings linked to competency topics
Medical Writing Certification – Agenda

- What is certification
- Certification commission
- Certification exam backbone
  - Competency domains and KSAs
  - DIA MW Competency Model link to MWC® exam backbone
- Competency and its Testing
What is Certification

<table>
<thead>
<tr>
<th>Certification</th>
<th>Certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td>For individual</td>
<td>For individual</td>
</tr>
<tr>
<td>Assessment process</td>
<td>Education process</td>
</tr>
<tr>
<td>Professional experience needed</td>
<td>Newcomers and experienced</td>
</tr>
<tr>
<td>Awarded by 3rd party standards organization</td>
<td>Awarded by educational program</td>
</tr>
<tr>
<td>Competency measured by standardized test</td>
<td>Complete a course(s)</td>
</tr>
<tr>
<td>Standard set via defensible job analysis process outlining required knowledge/skills</td>
<td>Variety of ways content set (eg, instructor)</td>
</tr>
<tr>
<td>Designation to use with name</td>
<td>Documented certificate</td>
</tr>
<tr>
<td>Ongoing requirements to maintain</td>
<td>Demonstrates knowledge at given time</td>
</tr>
</tbody>
</table>

Medical Writer Certified = MWC®
Certification Commission

- Manages development and execution of certification policies and procedures
  - Adheres to best practices and legally-defensible guidelines

- Supported currently by American Medical Writers Association (AMWA)
  - But goal is to be independent

- Guided by Schroeder Management Technologies (SMT), a credentialing service vendor
Certification Commission

- Responsible for administration of reliable & content-valid credentialing program
  - Oversees certification application, examination, and recertification
  - Represents professional diversity and stakeholder voice
  - Develops and revises the certification examination

Initiate – Develop – Implement – Maintain – Monitor – Evaluate – Oversee

<table>
<thead>
<tr>
<th>Activities</th>
<th>Job analysis</th>
<th>Exam assembly and administration</th>
<th>Standard setting and scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item writing</td>
<td>Item analysis and banking</td>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>Policies &amp; procedures</td>
<td>Address appeals</td>
<td>Eligibility requirements</td>
<td></td>
</tr>
</tbody>
</table>
Job Analysis
- Survey
- Defines the profession (practices, expertise, expectations)
- Establishes assessment content and standardized testing foundation
- Ensures accuracy of KSA exam backbone
- Links assessment and practice
- Provides legal defensibility of certification process

Inputs
- Job descriptions
- Educational curricula
- Articles
- Guidelines
- Expert opinion
- Competency model

Certification Exam Backbone – Link to Competency Model

Competency Model Linked to Certification Exam

DIA MW Competency Model

Certification Competency Domain / KSAs

Exam Backbone

MWC Exam Questions

Contributed

Equal

Linked

Informed
Certification Exam Backbone – Domains

**Competency Domains**

- **Presenting**: 27%
- **Gathering**: 16%
- **Interpreting**: 19%
- **Evaluating**: 19%
- **Organizing**: 19%

**Focus from DIA Comp Model**

- WF2: Document preparation, development, & finalization
- WF3: Document project management
- But also pulls tasks/activities from other model areas

**Content**

- Focused on frequency of applicability across settings
- Focused on testability

**KSAs**

- All medical writers
- But also pulls KSAs from regulatory and publication
## Certification Exam Backbone – Selected KSAs

### Link Exam with Competency Model

<table>
<thead>
<tr>
<th>Exam Backbone</th>
<th>Excerpts from Competency Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Gathering</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Determining purpose of document | Thoroughly gather...pertinent resources  
| Identify context for document | Establish...strategic purpose  
| Identify target audience | Evaluate...quality, including relevant content, context  
| Select appropriate output type | Ensure team plans will meet target audience...requirements  
| Identify appropriate outlet type | Make the document fit-for-purpose (eg...output type, outlet/venue type)  

**2. Evaluating**  
| Evaluate information | Evaluate pertinent resources and data  
| Perform fact or data checks | Quality review...fact or data check  
| Identify inconsistencies in data or other content presented | Ensure team messaging...do not present an...inconsistent...argument  
| Conduct critical review of a draft | Disseminate good quality check and review practices  
| Evaluate for completeness, fair balance, and absence of bias | Evaluate... for...completeness and fair balance  

Learning competency model content is helpful preparation for certification exam!
## Certification Exam Backbone – Selected KSAs

### Link Exam with Competency Model

<table>
<thead>
<tr>
<th>Exam Backbone</th>
<th>Excerpts from Competency Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3. Organizing</strong></td>
<td></td>
</tr>
<tr>
<td>Develop an outline</td>
<td>Organize the appropriate research literature</td>
</tr>
<tr>
<td>Apply templates and guidelines to documents</td>
<td>Organize and outline document architecture</td>
</tr>
<tr>
<td>Determine structure of tables and figures to best communicate data</td>
<td>Train writers/authors on the use of templates, guidelines</td>
</tr>
<tr>
<td>Design project work plan</td>
<td>Design appropriate stand-alone, caption-styled figures and tables</td>
</tr>
<tr>
<td>Track progress and status of project</td>
<td>Develop, coordinate, and oversee completed work plans</td>
</tr>
<tr>
<td></td>
<td>Hold regular meetings...provide status updates</td>
</tr>
<tr>
<td><strong>4. Interpreting</strong></td>
<td></td>
</tr>
<tr>
<td>Comprehend relevant medical and scientific content</td>
<td>Analyze, distill, and interpret data</td>
</tr>
<tr>
<td>Interpret clinical and numerical data</td>
<td>Comprehend, interpret, and communicate scientific concepts</td>
</tr>
<tr>
<td>Derive key message(s)</td>
<td>Draft medical messages that address data interpretation</td>
</tr>
<tr>
<td>Revise or repurpose content</td>
<td>Develop product and disease state key messages</td>
</tr>
<tr>
<td>Respond to reviewer’s comments</td>
<td>Author content for repurposing</td>
</tr>
<tr>
<td></td>
<td>Facilitate...author-reviewer disagreement resolution</td>
</tr>
<tr>
<td><strong>5. Presenting</strong></td>
<td></td>
</tr>
<tr>
<td>Present the message logically and coherently</td>
<td>Deliver written, visual, and oral presentations</td>
</tr>
<tr>
<td>Communicate statistical content appropriately</td>
<td>Communicate statistical concepts in...clear, and concise manner</td>
</tr>
<tr>
<td>Build persuasive and science-based arguments</td>
<td>Use persuasive presentation and communication techniques</td>
</tr>
<tr>
<td>Apply proper mechanics</td>
<td>Edit documents...style and mechanics</td>
</tr>
<tr>
<td>Apply principles of visual presentation</td>
<td>Data visualization to improve message understanding</td>
</tr>
<tr>
<td>Domain / KSA</td>
<td>Patient Education</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td><strong>Gathering:</strong> Elicit info.</td>
<td>interview clinical experts, patients</td>
</tr>
<tr>
<td>from stakeholders</td>
<td></td>
</tr>
<tr>
<td><strong>Evaluating:</strong> Evaluate info.</td>
<td>ensure information suitable for patients</td>
</tr>
<tr>
<td>with regard to audience, context</td>
<td></td>
</tr>
<tr>
<td><strong>Organizing:</strong> Apply templates and guidelines</td>
<td>use factsheet, Q&amp;A, news article template</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interpreting:</strong> Synthesize and integrate information</td>
<td>summarize condition, treatment information</td>
</tr>
<tr>
<td><strong>Presenting:</strong> Develop clear, concise prose and visuals</td>
<td>write, edit, review content</td>
</tr>
</tbody>
</table>
Competency and its Testing

- **Competency is demonstrated through...**
  - Action in variable situations and context
  - Outcome of getting job done with quality, speed, value

- **Certification exam does not...**
  - Have a written portion (currently)
  - Test ability to execute KSABs
  - Prove competence, expertise, or guarantee future success
Competency and its Testing

- Novice
- Beginner
- Knowledgeable practitioner
- Expert

Demonstrated by action and documented in performance review.

Figure concept: Karen Woolley, ProScribe
Competency and its Testing

- **Value**
- **Experience**
- **Competency**

- **Unconsciously Incompetent**
- **Consciously Incompetent**
- **Consciously Competent**
- **Unconsciously Competent**

**Practitioner**

- Certification exam tests knowledge not execution
- 2 years experience and letters of recommendation before can apply for MWC
Certification does...

- Test core foundational knowledge of KSAs via examination
  - Essential knowledge for success in work place (but not sufficient)
- Demonstrate breadth of knowledge
  - Understanding of fundamental principles in medical writing field
- Require continuing education for recertification
  - Knowledge of current best practices
- Identify professional medical writer vs someone just looking for job
  - Benchmark for practitioners
  - Roadmap for beginners or those changing specialization area
- Show commitment to profession
- Build resume
Testimonials…

• “Whether you are an experienced medical writer or just entering the profession, obtaining the MWC credential is a worthwhile endeavor. Anyone can hang out a shingle and call herself a medical writer, but having the MWC identifies you as a professional who has demonstrated medical writing core competencies.

• I proudly display the MWC credential in my email signatures, and I feel strongly that it enhances my credibility as a medical writer with new and existing customers.

• MWC certification is a manifestation of my expertise; it gives my work credibility and distinguishability. Moreover, credentials garner respect for our profession. People do notice.

• I believe that earning the MWC credential does reflect having core medical writing skills.”
How to become certified...

• Have bachelor’s degree
• Minimum of 2 years full-time paid work experience or equivalent
  ▪ Review Eligibility FAQs and Qualifying Work Experience
• Review website
  ▪ http://www.amwa.org/certification
  ▪ Review applicant/candidate handbook
• Resume, transcripts, 2 x letters recommendation
• Application and examination fee
• Prepare (study)
  ▪ Review Candidate Study guide
  ▪ Review Help You Prepare video
• Take exam
  ▪ 125 multiple choice exam in English
• Recertify every 5 years
  ▪ Continuing education credits or re-examination

Competency and its Testing

Not dependent on region, niche, or AMWA affiliation
Activities that constitute 2 years of paid medical writing experience...

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 for health care professionals and biomedical researchers.
- 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.

“This criterion excludes individuals from other professions... and other research and medical professionals for whom medical writing is not the core focus of their job. However, applicants may qualify even if their job title is not Medical Writer.”
### Competency and its Testing

### Activities that constitute 2 years of paid medical writing experience...

<table>
<thead>
<tr>
<th>Qualifies Toward 2-Year Experience</th>
<th>Does Not Qualify Toward 2-Year Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical, clinical research organization, or freelance medical writer who writes drug development publications (eg, abstracts, posters, and manuscripts), regulatory documents (eg, clinical study reports, and Common Technical Document clinical summaries and overviews), medical information documents (eg, medical letters), or continuing medical education materials (eg, medical education slide decks)</td>
<td></td>
</tr>
<tr>
<td>Medical writer who writes clinical research manuscripts at a medical communication company</td>
<td>Physician who writes patient notes or insurance claim reports</td>
</tr>
<tr>
<td>Medical education content developer who writes continuing medical education content for a medical communications company or agency</td>
<td>Physician who assembles lecture materials to teach a medical course</td>
</tr>
<tr>
<td>Medical writer who writes journal articles for a research institution</td>
<td>Physician, scientist, or statistician who writes articles as a product of his or her scientific or medical research</td>
</tr>
<tr>
<td>Medical editor who contributes substantive, macro-level reworking of journal articles, clinical research grant proposals, or protocol text to aid authors in document refinement</td>
<td>Researcher who helps colleagues or students refine manuscripts or other clinical research documents as part of his or her research role</td>
</tr>
<tr>
<td>Medical journalist, public health information writer, medical marketing content developer / writer, or freelance writer who prepares medical information documents to inform lay audiences about medical topics</td>
<td>Health professional whose clinical work includes preparing materials informing patients about medical topics</td>
</tr>
<tr>
<td>Writer of online medical content for a medical information company providing comprehensive clinical information to physicians and other health professionals</td>
<td>Educator who, as part of his or her teaching role, prepares materials for students about medical topics</td>
</tr>
<tr>
<td>Health outcomes writer who prepares clinical content for health economic/outcome journal articles or health technology assessments</td>
<td>Physician or medical consultant who works for a payer organization (eg, insurance or government) and as part of his or her role writes claimant medical record case reports</td>
</tr>
</tbody>
</table>


Competency and its Testing

Study tips from testimonials...

• Attend AMWA workshops and review notes
• Set up a multi-week self-study syllabus based on content outline
• Tag Candidate Study Guide topics based on level of knowledge and review recommended preparation resources, particularly for those topics less familiar

  ▪ Example topics:
    ✓ Continuing medical education
    ✓ Epidemiology / research
    ✓ Ethical principles
    ✓ Mechanics of writing
    ✓ Medical writing competency
    ✓ Patient / health education
    ✓ Project management
    ✓ Publication practices
    ✓ References and literature searching
    ✓ Regulatory submissions
    ✓ Research grant application
    ✓ Statistical concepts and analysis reporting
    ✓ Terms and their usage

  Example – stat subtopics:
  Confidence interval
  Effect size
  Measures of central tendency and variability
  Multiplicity (i.e., multiple testing)
  Risk ratios, odds ratios, and relative risk
  Sensitivity and specificity
  Statistical tests and statistical significance
  Type I and II errors (false-positive or negative studies)

Leave time to study because the test covers content that may be outside one’s area of specialization.
MWC Certification launched September 2015
As of October 1, 2018:

**MWC Certifications:**
- 75 MWC® certified medical writers

**MWC Applications:**
- 60 applicants who have not yet passed the MWC exam
- 34 new applications in 2018
- Increasing each year