PHARMACEUTICAL MEDICAL WRITING COMPETENCY MODEL*

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In 2009, members of the Drug Information Association (DIA) Medical Writing (MW) Special Interest Area Community (SIAC) Competency Model Working Group developed a competency model to describe the work functions, activities, knowledge, skills, and behaviors deemed necessary to perform successfully as a medical writer in the pharmaceutical industry.

To understand the basis behind the content of the medical writing competency model, it is important to define competency. Competency is the ability of an individual to perform a specific role successfully; a competent professional is one who has a combination of knowledge, skills, and behavior qualifying him or her to perform a particular role or job successfully.[1,2]

A competency model defines what competence looks like for a given profession and contains a professionally agreed-upon written list of the skills, knowledge, and behavior (competencies) that defines successful job performance. The model typically includes an outline of activities that a person in the role must perform to be successful.

The content of this competency model encompasses the diverse skills of a pharmaceutical medical writer, including the essential, but not sufficient, core skill set (writing) that differentiates a medical writer from other pharmaceutical professionals. The model has 2 main structural components, the first focusing on 9 work functions deemed to be activity areas where competency is needed. For each of these work functions, there are associated behavioral benchmarks; and for each benchmark, there are several related critical activities. The second structural component of the model describes technical knowledge, skills and abilities, and behaviors deemed necessary for competent medical writers. This section is divided into subsections for all medical writers, regulatory writers, and publication writers. Presented here is the core content of Version 1.4 of the Competency Model that was made available to DIA membership in June 2009. Only some introductory text and text related to supervisors of medical writers and additional general abilities was excluded to adjust for space limitations.

**The content expressed in this model is based solely on the opinion of the individual contributors and should not be attributed in any way to the Drug Information Association (DIA) or any of the companies/organizations (or employees or departments within the companies/organizations) with which the contributors are employed or affiliated. The DIA Medical Writing Special Interest Area Community was used as a conduit for members to gather medical writing professionals to develop the model. The Working Group Members are listed on the last page.*

***Editor's note:** The model is presented here as submitted, without editing.*

WORK FUNCTIONS, CRITICAL BEHAVIORS, & ACTIVITIES

› Work Function: DOCUMENT PREPARATION

Behavioral Benchmark 1: Thoroughly gather, review, and analyze pertinent resources or data to produce a high-quality document that meets internal and external customer needs.

Critical Activities:

1. Review applicable guidelines (eg, regulatory, publication, company, and industry), templates, and/or research literature.
2. Obtain, compile, and organize the appropriate data, background information, and other materials needed to compose the document.
3. Analyze and interpret data and other information in order to determine the best approach to composing the document.

Behavioral Benchmark 2: Plan document architecture and content with cross-functional areas by bringing the team to consensus, thus ensuring that the document contains the information necessary to meet internal and external customer needs.

Critical Activities:

1. Meet with cross-functional team (eg, statistics, clinical development, medical, and regulatory) members to review gathered information and guidance to plan for a high quality document that meets industry and company requirements, standards, regulations, and development (eg, clinical, nonclinical, biopharmaceutic, clinical pharmacology, and CMC) needs.
2. When applicable (eg, clinical study reports or manuscripts), participate in planning sessions for statistical output; ensure output content meets regulatory or publishing requirements and clinical development needs.
3. Work with cross-functional team and external consultants (eg, regulatory affairs or publication planning) to determine the purpose of the document (eg, support an indication or other label claim).

Behavioral Benchmark 3: Author document, integrating cross-functional input, to ensure that the document communicates the information necessary to satisfy internal and external audience needs.

Critical Activities:

1. Compose the initial draft of a document by referring to all information compiled in preparation for composition.
2. Integrate into the initial draft the input, expertise, and opinions from members of the authoring team and internal/external experts and business partners.
3. Build persuasive and scientific-based arguments when drafting documents that will support the regulatory, publication, or other purpose of the document.
4. Provide advice, support, and composition for designing content that can be reused in other deliverables (content reuse; eg, summary document to label).

Behavioral Benchmark 4: Revise document while facilitating issue resolution among team members to deliver a document with quality, speed, and value.

Critical Activities:

1. Revise document drafts based on the review comments from authoring team or extended team members to ensure inclusion of all relevant input from the team.
2. Compose the final document by referring to reviewers' input and other information compiled.
3. Ensure data consistency and document integrity across the document by critically evaluating comments and incorporating them appropriately.
4. When authoring team or reviewers are in disagreement, facilitate and negotiate issue resolution and decision-making and incorporate outcomes into the draft/final document.
5. Document resolution and the rationale of significant decision.

Behavioral Benchmark 5: Edit documents within the expectations of the level of edit (format, proofread, microedit [copy edit or line edit], macroedit [substantive or content edit], rewrite, or translation edit) needed for the deliverable based upon document type, stage of development, and request from authoring team.
[Editing may fall to a medical or scientific editor role rather than the medical writer depending upon the organizational situation.]

Critical Activities:

1. Ensure expectations from authoring team are understood and discern what 'level of edit' (specific editorial tasks) is needed (wanted) for the document.
2. Edit document to ensure document quality in regard to correctness of structure, content, language, and/or style.

› Work Function: DOCUMENT MANAGEMENT

Behavioral Benchmark 1: Develop an agreed upon and complete work plan, with all needed tasks and subtasks, as well as assigned roles and responsibilities that enable the team to work efficiently and effectively.

Critical Activities:

1. Discuss tasks (eg, plan, data production, write, review, edit, quality check, and publish), subtasks, and roles and responsibilities of authoring team members and reviewers in advance of the document preparation plan.
2. Coordinate and manage the tasks, roles, responsibilities, and timing of the authoring team and internal/external reviewers to facilitate document completion.
3. Determine which document review monitoring method(s) is optimal (eg, formal meeting or e-mail) to reach document completion with high quality.
4. Determine the best format (document management system) and tools (eg, draft with changes tracked and comments providing context/rationale for changes) for documents to be reviewed by team members in order to complete document with consensus.
5. Ensure appropriate plan, process, and tools are in place for content editing, formatting, independent quality checking, and publishing.

Behavioral Benchmark 2: Develop an agreed upon timeline to ensure that all work plan milestones are met to achieve team objectives.

Critical Activities:

1. Using task and timeline tools, draft timelines that detail the steps and associated time intervals in document preparation, each authoring team and review team member's responsibilities, and due dates in the process.
2. Obtain timeline buy-in from authors and reviewers to facilitate on-time completion.

Behavioral Benchmark 3: Proactively establish a cohesive team dynamic to facilitate delivery of work-plan tasks without delays.

Critical Activities:

1. Schedule authoring team project meetings to evaluate progress on tasks and timelines as well as to identify issues and monitor resolutions.
2. Communicate with review and authoring team members to maintain focus and awareness of expectations, project steps, milestones, and deliverables; keep team members informed of any changes to timelines or milestones.
3. Facilitate team meetings in order to make progress with the document and achieve consensus.
4. Partner with other members of the authoring team to manage and drive the timeline.

5. As document preparation progresses, assess and prioritize needs (eg, information, input, and resources) in order to stay on track with work plan.

Behavioral Benchmark 4: Demonstrate leadership during conflict, disagreement, or timeline delays, thereby facilitating document completion in a professional and timely manner.

Critical Activities:

1. Maintain awareness of potential delays, problems, or gaps of information that exist in the team effort of document preparation in order to effectively manage the process.
2. Mediate conflict among team members and others by negotiating, compromising, persuading, and facilitating the open exchange of ideas and opinions in order to come to consensus.
3. When necessary, influence or negotiate change of the timeline with other team members in order to have a viable back-up plan when the document preparation process has delays.
4. When necessary, enlist the aid of project management and/or functional management to ensure progress on document preparation and completion.

Behavioral Benchmark 5: Facilitate document approval, finalization, electronic publishing and submission, as applicable to the job function.
[Submission and publishing may fall to a separate submission or publishing group.]

Critical Activities:

1. Facilitate document management activities to ensure that the document is approved and ready for publishing/submission in a timely manner according to agreed-upon time lines.
2. Ensure appropriate formatting and hyperlinking for e-publishing and submission.
3. Facilitate publishing and submission activities to meet final document delivery timelines by acting as a liaison between publishers, submission experts, and the authoring team.
4. Ensure quality document submission to regulatory bodies, congresses, or journals (acceptance by target audience), following applicable guidelines (eg, instructions to authors for a manuscript), formatting, and hyperlinking for e-publishing.
5. Ensure appropriate document life-cycle management (eg, short- and long-term storage, archiving, and retrieval).
6. Contribute to the development, implementation, and maintenance of document management system.

› Work Function: STRATEGIC COMMUNICATIONS AS INTEGRAL PROGRAM (PROJECT) TEAM MEMBER

Behavioral Benchmark 1: Analyze proposed programs, individual studies, and related documents for their ability to deliver the information required by the target audience (eg, regulatory authority) with accuracy and consistency.

Critical Activities:

1. Understand issues affecting design of product strategy, and understand how study design, data capture, and statistical analysis plan design will affect downstream documents.
2. Critique ability of product strategy (eg, submission or publication plans) to deliver to business objectives or meet regulatory needs, and identify where new, additional, or alternative arguments are needed.
3. Understand where all intended messages will be located across individual documents within a program, and ensure alignment of messages across documents.
4. Ensure that study designs and document designs will contribute the necessary information to meet audience needs.

Behavioral Benchmark 2: Align, coordinate, and build consistent information and messages across all individual documents (eg, multiple document components of a New Drug Application; eg, documents for same compound developed separately over time [eg, protocol 1, protocol 2, study report 1, and study report 2]), starting with initial strategic plans, continuing through study-level documents to final program-level deliverables (eg, prescribing information for a regulatory submission or publication of key journal articles for a publication plan).

Critical Activities:

1. Lead cross-functional teams to develop a messaging strategy across a program of work (eg, building a clinical submission or data disclosure plan).
2. Develop prototypes or key message language for key documents to aid in consistent and integrated messages. Help ensure alignment of these development documents with down-stream documents (eg, study report, submission document, manuscript, and intended product label).
3. Manage issues that impact messaging strategy (eg, highlight impact of unexpected results or data quality issues).
4. Set program-level standards (eg, style conventions).
5. Build convincing clinical or regulatory arguments in the absence of direct data, using logic, analogy, and therapeutic area science.
6. Ensure that data and the way data are described are consistent across documents.

Behavioral Benchmark 3: Act as a document and cross-document specialist, providing intellectual leadership and contributing document knowledge and expertise.

Critical activities:

1. Ensure historical records are kept electronically (eg, regulatory rationale or rationale for agreed upon variation).
2. Ensure that the project team plans are consistent with

targeted audience (eg, regulatory authority) document requirements; provide alternatives and suggestions based upon experience.
3. Ensure that the project team's arguments and strategy are sound, consistent, and in alignment with strategy (eg, do not present an argument to a regulatory body inconsistent with a previously sent argument) and audience requirements.
4. Act as a document content historian for program/project team and proactively provide insight, ensuring that team decisions, key messages, issue resolution, and positioning are reflected within and across all program documents.

› Work Function: MULTIPLE DOCUMENT COORDINATION (eg, SUBMISSION OR PUBLICATION PLANNING AND OVERSIGHT)

Behavioral Benchmark 1: Develop an agreed upon and complete work plan, with all needed tasks, subtasks, timelines, and assigned roles and responsibilities that enables the team to work efficiently and effectively to meet all tasks.

1. Discuss tasks (eg, plan, data production, write, review, edit, quality check, and publish) and subtasks (eg, deliverables, table-figure-listing delivery, and literature compilation) and how the tasks relate across documents, subtasks, and roles and responsibilities of authoring team members and reviewers.
2. Utilize competencies, behaviors, and activities outlined for the Document Preparation, Document Management, and Strategic Communication Work Functions, but use multiple-document-based project management tools and strategies, to coordinate document and task delivery.
3. Identify resource constraints that may affect timely delivery.

Behavioral Benchmark 2: Lead other writers (as project lead writer, submission coordinator, or publication coordinator) to deliver on work plan with quality and timeliness.

Critical activities:
1. Manage contribution of other writers working on individual documents.
2. Ensure that appropriate (right person at right time) input and decision making occurs within program team.
3. Ensure that key information received in project or program meetings gets appropriately disseminated such that that project strategy is maintained and that data or key wording changes are incorporated appropriately across documents (eg, changes to safety text mirror label text updates).

› Work Function: DEVELOPMENT & MAINTENANCE OF DOCUMENT & PRESENTATION TEMPLATES, STANDARDS, FORMATS & STYLES

Behavioral Benchmark 1: Thoroughly gather, review, and analyze pertinent resources needed to produce high quality document templates and standards.

Critical Activities:
1. Obtain and review current/new regulatory, publication, and industry organization document guidelines, as well as industry initiatives (eg, publications on regulatory websites or information gathered at professional conferences).

Behavioral Benchmark 2: Create and implement agreed upon presentation and document templates and associated guidance tools to allow authoring teams to quickly author quality documents that meet regulatory, corporate, and industry needs and requirements.

Critical Activities:
1. Create document style, format, and writing guides and presentation and document templates to meet regulatory, corporate, and industry needs and requirements.
2. Lead review and obtain approval of new or updated guides and templates, gaining input from local and global stakeholders (eg, regulatory affairs).

Behavioral Benchmark 3: Maintain document style, format, and writing guides, and presentation and document templates.

Critical Activities:
1. Facilitate adherence to and maintenance of guidelines, standards, and templates through interactions with department, corporate, global, CRO, and alliance partners.
2. Proactively determine the needed creation of new or changes to existing guidelines, standards, and templates.

› Work Function: OUTSOURCING, ALLIANCE PARTNER, & CLIENT MANAGEMENT

Behavioral Benchmark 1: Ensure that a governance structure is in place with the partner, including guiding and operational principles and associated tools.

Critical Activities:
1. Develop a governance structure that includes operational oversight, whether for one document or an entire development program to ensure a successful relationship.
2. Develop communication plans to ensure continued partner alignment and satisfaction.

Behavioral Benchmark 2: Build and maintain collaborative relationships with partner (CRO, vendor, alliance partner, client, etc) for an effective, efficient, productive, and professional working relationship.

Critical Activities:

1. Use relevant tools and resources to determine whether to use own or partner tools, standard operating procedures, and templates.
2. Participate in bid defense, contract development, work alignment, and/or operation meetings.
3. Build a relationship with the partner in order to enhance communications and effectiveness.
4. Be responsive and available to answer questions from the partner as needed.

Behavioral Benchmark 3: Together with the partner (CRO, vendor, alliance partner, client, etc), develop and implement a complete timeline and work plan that enable the team to work efficiently and effectively.

Critical Activities:

1. Negotiate with partner to determine the author, plan, data production, write, review, edit, quality check, and publishing processes, roles, and mutual expectations.
2. Consult with partner to determine the specifications of document flow and archiving.
3. Negotiate with partner to determine the timeline that will be used for documents.
4. Provide input into work plan.

Behavioral Benchmark 4: Review document, consult with relevant functions, facilitate issue resolution with partner, and maintain general project oversight to deliver a document with quality, speed, and value.

Critical Activities:

1. Review work products from partner as needed.
2. Mediate disagreement and conflict among team and partner by negotiating, compromising, persuading, and facilitating the open exchange of ideas and opinions in order to come to consensus.

Behavioral Benchmark 5: Develop partner assessment program and associated tools to ensure quality deliverables and a maintained positive partner relationship.

Critical Activities:

1. Develop feedback system for checking and maintaining quality document delivery and client/vendor satisfaction.
2. Conduct training and regular lessons learned sharing.

› Work Function: CONTINUOUS DEVELOPMENT OF KNOWLEDGE & SKILLS

Behavioral Benchmark 1: Complete training and development activities while eliciting and responding to competency-related feedback to maximize the development of skill sets that benefit the company, client/partner, and career objectives.

Critical Activities:

1. Maintain familiarity and compliance with company and industry competency maps, curriculum maps, technical ladder guidelines, and/or performance management processes in order to establish, pursue, and achieve behavior, outcome, and individual development needs and goals.
2. Perform self-assessment of one's knowledge and skill set regarding technical and soft-skill areas in order to note gaps and needs for personal development planning.
3. Elicit formal and informal feedback regarding one's knowledge, skills, and abilities (technical and soft-skill) in order to note gaps and needs for personal development planning.

Behavioral Benchmark 2: Identify and pursue developmental opportunities from a variety of sources (training classes, readings, subject matter experts [SMEs], coaches, professional organizations [meetings, conferences, or seminars], or colleagues), both internally and externally, enhancing critical competencies in a manner that benefits company, client/partner, and career objectives in order to continuously improve skills and knowledge.

Critical Activities:

1. Maintain and enhance technical knowledge, skills, and abilities.
2. Continually improve non-technical knowledge, skills, and abilities.

› Work Function: SHARING KNOWLEDGE & EXPERIENCE

Behavioral Benchmark 1: Share knowledge and experience internally and externally to increase competencies, thereby enhancing effectiveness in meeting function, company, client/partner, and career objectives while being resource-focused, service-oriented, and promoting knowledge sharing.
[Coaching (shared learning) activities are particularly important when medical writing "teams" are constructed with "lead writers" assigned to deliver on more complex deliverables (eg, regulatory submission packages); in such situations the lead writer may review multiple documents and coach other writers to ensure quality and timely deliverables that are accurate and consistent across documents.]

Critical Activities:

1. Anticipate and proactively assist individuals (particularly those new to medical writing) by assessing their needs and then providing formal or informal coaching to aid in their development: share technical information, give guidance (eg, best practices), answer questions, and direct them to appropriate resources and contact persons.
2. Review documents and provide meaningful feedback to medical writers on both form and content of documents.
3. Provide assistance (mentor) and help to others in the

areas of soft skills, people interactions, and how things get done with customers/business partners.
4. Provide informal and/or formal feedback on performance, skill, and knowledge-related issues in order to help individuals improve in these areas.
5. Participate in professional association activities (eg, Drug Information Association, American or European Medical Writers Association).

› Work Function: PROCESS IMPROVEMENT

Behavioral Benchmark 1: Identify best practices and anticipate the need for change in current or future processes, driving efforts to ensure that medical writing processes remain aligned with changing requirements.

Critical Activities:
1. Evaluate critically the current processes, practices, and technologies used by medical writers to find more effective and efficient approaches.
2. Proactively identify and evaluate changes occurring in the internal and external environment to determine ways that processes, technologies, or guidelines can be adjusted to meet changing environment, and then implement and adapt to those changes to improve quality, efficiency, and effectiveness.

Behavioral Benchmark 2: Develop, implement, and communicate best practices that increase quality, consistency, efficiency, and effectiveness of processes and deliverables.

Critical Activities:
1. Participate on process improvement teams, committees, or similar initiatives in order to partner with others in the effort to improve processes.
2. Through appropriate channels, develop and introduce new processes, methods, or technologies in order to enhance medical writing operations.
3. Communicate process improvements through multiple internal (eg, across departments) and external (eg, professional groups) channels to promote consistency and facilitate their widespread use.

KNOWLEDGE, SKILLS, ABILITIES & OTHER CHARACTERISTICS

ALL MEDICAL WRITERS

Technical Knowledge
1. Techniques of scientific writing and editing
2. Software and systems, including but not limited to:
   - Document management (including associated version control principles, Electronic Records and Electronic Signatures [ERES], records retention, and best practices and approaches)
   - Word processing or authoring (eg, Word)
   - Spreadsheets (eg, Excel)
   - Presentations (eg, PowerPoint and Visio)
   - Databases (eg, Access)
   - E-mail/calendaring (eg, Outlook)
   - Table/figure creation (eg, SigmaPlot)
   - Adobe Acrobat
   - Reference or bibliography management (eg, Reference Manager or EndNote)
   - Publishing
   - Literature searching (including best practices and approaches) and other internet and intranet portals (eg, SharePoint), resources, and search tools
   - Other (eg, file conversion - one format to another)
3. Company policies, procedures, and tools (eg, style guides, templates, and project management worksheets)
4. Functional roles of other members of the authoring team (eg, role played by statistics, clinical research /medical, regulatory, and legal)
5. Industry guidelines:
   - Pharmaceutical regulatory
   - Applicable professional, pharmaceutical, health, and journal organization/society guidelines
   - Clinical trial registry and results posting (eg, FDAAA and State of Maine)
   - Copyright laws and application of those laws, publisher guidelines, or contracts
   - Standards Developing Organizations and their developing standards
6. Science:
   - Therapeutic area, including the safety and efficacy profile of the compound being studied and the associated disease state of interest. [Medical writers should be able to write across therapeutic areas when they have access to drug and therapy area experts on their authoring/project teams.]
   - Biological sciences (from tertiary studies, academics, or other experience)
   - Chemistry, Manufacturing, and Controls
   - Biopharmaceutics
   - Pharmacology (including pharmacokinetics and pharmacodynamics)
   - Absorption, Distribution, Metabolism, & Excretion (ADME)
   - Drug (eg, phases of drug development) and clinical (eg, clinical trial design) development (eg, compound-specific information), including drug development

techniques and approaches
    - Scientific method, including hypothesis testing and clinical research methodologies
7. Statistics: accepted methods of data analysis (descriptive and inferential statistics) and techniques for communication of statistical results
8. Publishing standards, including e-publishing
9. Training (eg, lead writer trains junior writer): adult learning concepts; instructional design (planning the content or delivery of instruction) and communication design (planning the content and delivery of messages for a given purpose)

Technical Skills and Abilities

1. Interpret and communicate clinical and numerical data, verify consistency in data, calculate with data (eg, basic math formulas/concepts), and collect data (eg, chart reviews)
2. Comprehend and communicate scientific concepts; interpret and communicate clinical, nonclinical, biopharmaceutic, pharmacology, ADME, and CMC data and information
3. Learn, understand, and communicate statistical concepts, terminology, and analyses within text and tables/figures; interpret results from statistical tests and understand level of significance results; utilize appropriate statistical terminology in tables, figures, and text; present scientific concepts and statistical analyses in a clear and concise manner, making the concepts as simple as possible to fit the targeted audience; express statistical issues as text
4. Author quality documents:
    - Prepare a well written and well thought out structural outline
    - Write with the intended audience in mind; determine document organization and content (within and across documents) that meets project purpose and audience needs
    - Prepare text that is credible and compelling
    - Prepare text that is simple, plain, clear, concise, and correct, with the correct use of spelling, grammar, and punctuation
    - Prepare a correct and complete reference list
    - Prepare table of contents, indexes, hyperlinking, and other document organizational components
    - Design and prepare appropriate figures and tables
5. Conduct an effective literature search
6. Create and layout slides and posters
7. Project manage deliverables; ensure appropriate sponsorship/accountability assigned, work, contingency, timeline, roles/responsibilities, and communication planning and implementation, issue resolution, change control, and meeting organization and facilitation
8. Manage information; manage scientific information flow and accuracy and consistency of that information
9. Edit documents (revise, correct, or rearrange content, language, style, or structure) based upon 'level of edit', with each level of edit containing the tasks associated with the previous level of edit:
    - Format: align with template, company, journal, congress, or regulatory guidelines
    - Proofread (read and mark corrections):
        - Noncomparison proofread (mark absolute errors): internal consistency (text, numbers, and language), reference validation, and style and mechanics (spelling, grammar, punctuation, capitalization, word use, use of units, and abbreviations)
        - Comparison proofread (compare 2 versions of the same document or similar content from 2 related documents [eg, protocol and study report])
    - Microedit (language, copy, line, or mechanical edit): review of text at or below level of paragraph to improve grammar, word choice, flow, voice, syntax, style, logical inconsistencies, clarity, and reduce duplication (eg, text vs table)
    - Macroedit (substantive edit): evaluate content and organization of document at level of document section ensuring congruency, tone, structure, consistency, logic, and completeness, and that needs of audience are met (manage a document's concept and intended use)
10. Quality check documents (check document against source); fact or data check (verify one set of data against another; verifying the accuracy of claims)
11. Rewrite existing documents
12. Interview for information (obtaining needed information from spoken conversations); Focus-group test (obtaining verbal feedback from readers on the qualities of a text)
13. Report information (render an accurate account of a verbal presentation) and summarize (condense someone else's text)
14. Review document content (analytically edit and critically appraise); evaluate statistical presentations and general research methods; peer review (assess the quality and completeness of scientific content and specific research methods based upon personal knowledge); regulatory review (verify adherence to requirements and standards)
15. Translate (transcription) documents from one language to another, appropriately and accurately expressing the content of a text written in one language in another [This is a specific skill that may (likely will) fall to a professional scientific translator rather than a medical writer; however, translation also refers to the need to conform to American, British, and Indian English, which is needed by medical writers; additionally, bilingual communication skills (English plus local language) is an important skill needed for medical writers in non-English speaking regions]

16. Publish documents; visually design a publication; render (page design), web design, illustrate (drawing or painting biomedical images), photograph (taking photos of scientific images such as surgical procedures); technical draw (eg, rendering charts, graphs, and maps) [This is a specific skill that may (likely will) fall to a professional publisher rather than a medical writer; however, visual design also refers to slide design (layout) and poster design (layout), which is a skill needed for medical writers; additionally, medical writers often have to ensure documents are publish ready (eg, formatted appropriately)

Behavioral Skills for Technical Contributions

1. Organized
2. Manages time well
3. Pays attention to details
4. Manages multiple tasks
5. Builds positive and productive relationships
6. Makes effective decisions
7. Demonstrates learning agility (ie, is able to come up to speed on new projects quickly
8. Negotiates
9. Resolves conflicts
10. Copes with and adapts to change
11. Creates solutions and influences adoption
12. Strong leadership skills and teaming skills
13. Results and performance driven with bias for proactive action
14. Actions are commercially astute
15. Actions are ethical (eg, ensures appropriate copyright, authorship requirements, and acknowledgements are met; ensures that there is no plagiarism or falsifying and that the subject's and patient's best interest are met)
16. Ability to globally work share when working with global project teams
17. Cultural sensitivity and ability to efficiently and productively work in a multicultural teams

REGULATORY MEDICAL WRITERS

Technical Knowledge

1. Regulatory guidelines, such as:
    - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines and regional regulatory authority interpretation of guidance (every ICH guidance that is relevant to the required task or role, eg, Common Technical Document (CTD) guidance (ICH M4) or electronic CTD guidance (ICH M2)
    - Labeling guidance, including Structured Product Labeling (SPL) and Physician Labeling Rule (PLR)
    - Guidelines for interactions with prescribing physicians
    - e-Submission guidance (eg, ICH, Regulated Product Submission [RPS], and Study Tagging Files [STF])
    - Regional guidelines (multiple and topic specific):
        - United States (eg, Food and Drug Administration [FDA] Code of Federal Regulations [CFR])
        - European Union (eg, European Medicines Agency [EMEA]/ Committee for Proprietary Medicinal Products [CPMP]; Directive of the European Parliament and of the Council)
        - Japan (Ministry of Health, Labour, and Welfare [MHLW]/ Pharmaceutical and Medical Devices Agency [PDMA] guidance)
        - Other regions, including important differences in document-related and e-submission guidance.
2. Regulatory authority and global initiatives
3. Understanding of clinical, nonclinical, and CMC requirements to support major regulatory filings
4. Standardization initiatives, such as:
    - Clinical Data Interchange Standards Consortium (CDISC)
    - Clinical Data Acquisition Standards Harmonization (CDASH)

Technical Skills and Abilities

1. Prepare communication strategy for a project (eg, key message map for a regulatory submission or publication plan)
2. Prepare (write/author) regulatory documents, such as:
    - Advisory Committee documents (eg, briefing document and presentations)
    - Annual Safety Reports (eg, European Annual Report, Development Safety Update Report (DSUR), and Periodic Safety Update Report [PSUR])
    - Annual IND and NDA Reports
    - Bioanalytical Report, as applicable to the writing situation (often written by scientist not medical writer)
    - Briefing Document (eg, for FDA PDUFA meetings and Europe or Canada's expert advice meetings)
    - Clinical Development Plan
    - Clinical Study Report (CSR; Phase 1-4, including clinical pharmacology study report)
    - Clinical Trial Application (CTA; see also IMPD)
    - Clinical Trial Notification (CTN; Chiken-Todoke)
    - Clinical Trial Registry (CTR; results posting)
    - Common Technical Document (CTD; all subcomponents: Modules 1-5, including FDA required Integrated Summaries of Safety and Efficacy [ISS and ISE]), including Overviews (eg, Overview of Efficacy) and Summaries (eg, Summary of Safety)
    - Country specific documents and responses
    - Investigator's Brochure (IB)
    - Investigational Device Exemption
    - Investigational Medicinal Product Dossier (IMPD)
    - Investigational New Drug Application (IND)
    - Label (eg, package insert), including labeling supplements and European Union (EU) variations.

- New Drug Application (NDA; Marketing Authorization Application [MAA]), New Drug Submission [NDS], Supplemental NDA [sNDA], and Supplemental NDS [sNDS])
- non-eCTD Electronic Submissions (NEES) or other modified e-CTDs, and regulatory submission documents for countries that do not accept ICH CTD format
- Nonclinical Study Report
- Pediatric Investigational Plan (PIP)
- Periodic Safety Update Report (PSUR)
- Premarket Approval Application (PAA)
- Premarket notification (510k)
- Protocol (Phase 1-4)
  - Clinical Pharmacology Trial Protocol
  - Clinical Trial Protocol
  - Observational Study Protocol
  - Protocol Amendment
  - Protocol Addenda
- Regulatory Response documents (responses to regulatory agencies; eg, submission inquiries, Japan and EU LOQ, and Canada Clarifax)
- Regulatory submission for countries that do not accept ICH CTD format
- Risk Management Plan (RMP; Risk Evaluation and Mitigation Strategy [REMS])
- Risk Profile
- Safety Narratives
- Safety Updates
- White Paper

3. Prepare documents suitable for e-publishing and that are publishing ready

PUBLICATION MEDICAL WRITERS

Technical Knowledge

1. Publication guidelines, such as:
   - Good Publication Practice for Pharmaceutical Companies
   - Uniform Requirements for Manuscripts Submitted to Biomedical Journals
   - Position Statements from medical writing organizations (eg, AMWA, EMWA, and ISMPP)
   - Interactions with prescribing physicians, investigator-authors
2. Publication Planning and Coordination
3. Publication planning systems/software
4. Reporting guidelines, such as:
   - Consolidated Standards of Reporting Trials (CONSORT) – for randomized trials
   - CONSORT for Abstracts
   - CONSORT Harms
   - STAndards for the Reporting of Diagnostic accuracy studies (STARD)
   - Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA); previously Quality of Reporting of Meta-Analyses (QUOROM)
   - Meta-analysis Of Observational Studies in Epidemiology (MOOSE)
   - Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)

Technical Skills and Abilities

1. Prepare a publication plan (publication strategy: what publications to where, when, and why, with subsequent implementation and tracking of plan) [Publication planning is a specific skill that may fall to a professional publication planner; however, this is also a general skill needed for publication medical writers]
2. Prepare (write/author) publication documents, such as:
   - Manuscript for a peer-reviewed journal
   - Review article (narrative or systematic review)
   - Abstract for a conference
   - Poster for a conference
   - Slide presentation
   - Response to reviewer document
   - Conference report
   - Journal article summary
   - Tables and figures suitable for publication
3. Prepare documents that are journal publication ready (meet journal guidelines)

Application of the Model

Because the model defines what competencies a professional should have, it can be a tool for organizational structure; recruiting and hiring; onboarding, training, and development; setting expectations and aligning to assignments; performance evaluation and staff retention; and defining the profession. An article on how to apply the model is scheduled for the September issue of the *AMWA Journal*.

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