AMWA REPORT

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RECOMMENDED TRAINING OUTLINE FOR REGULATORY WRITERS

AMWA.org

AMERICAN MEDICAL WRITERS ASSOCIATION

The Resource for Medical Communicators

RECOMMENDED TRAINING OUTLINE FOR REGULATORY WRITERS

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Overview

At AMWA's inaugural Medical Writing Executives Forum: Preparing for the Future of Medical Writing in Pharma and Biotech, participants identified several challenges in training and retaining skilled regulatory writers. Forum participants noted that the baseline experience of regulatory writers is uneven or absent due to the lack of formal, standardized training in many organizations. Such training is needed but is difficult to create because it consists of intensive structured education with different components, including hands-on training, and covers multiple years.

To address this lack of standardized training, AMWA established the AMWA Workforce Training Committee, which was charged with identifying the educational content needed to prepare medical communicators for a successful career in regulatory writing. Drawing on their professional experiences as writers and managers, the Committee members reviewed a list of training topics drafted by AMWA and the 2018 DIA Competency Model[1] to create a list of recommended training topics as well as set priorities for training, from entry level to more advanced levels. AMWA will review this training outline periodically to ensure that it conforms with current industry requirements and trends.

In developing this outline, the Committee recognizes that strong medical writing skills and knowledge of the drug development process are only two aspects of a successful regulatory writer. Rather, professional success, especially at advanced levels, depends on a host of other skills and proficiencies that enhance the value of regulatory writers and make them vital members of the team (Figure 1).

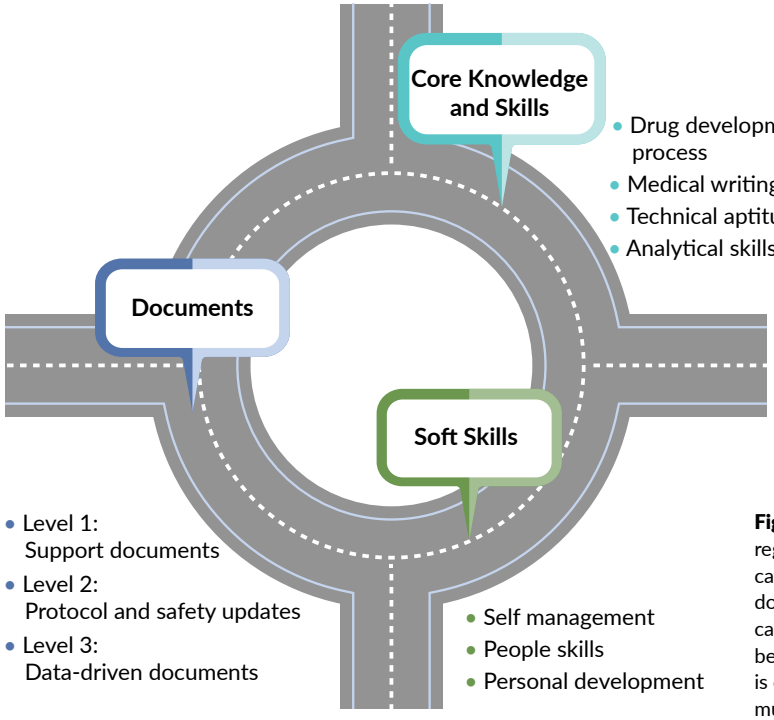

Figure 1. AMWA's recommended training topics for regulatory writers are organized under three primary categories—core knowledge and skills, soft skills, and documents. All three areas are crucial for a successful career in regulatory writing. Training is not intended to be linear; rather, concurrent training across the categories is encouraged, as a regulatory writer will typically require multiple skills when managing live projects.

In addition to the outline, the Committee also compiled a list of independent reading that provides essential background knowledge that regulatory writers need while developing their skills in the recommended training topics. Also included is a template checklist for recommended training that medical writing managers and mentors can use to customize training to fit the unique needs of their regulatory writers and company.

Categories of Topics

The training topics are organized under three primary categories—core knowledge and skills, soft skills, and documents, with the order of topics representing what the Committee believes is the order in which an entry-level regulatory writer should master the training topics in these three areas. Regulatory documents are listed according to how new regulatory writers typically train on documents and the frequency with which the documents are developed. Note that nonclinical documents, pharmacokinetic reports, medical device documents, and other specialized documents are not included in the list. Specialized documents can be added when customizing the training checklist to reflect the needs of specific regulatory writers and/or companies.

The Committee acknowledges that real-world training needs vary across companies. Although the order of topics within each of the three primary categories appears to be linear, training across the categories may be concurrent based on an individual's learning abilities and corporate needs and work opportunities. For example, training on a topic within soft skills can occur before or be concurrent with training on topics within core knowledge or documents. This is, in fact, encouraged, as a regulatory writer will typically require multiple skills when managing live projects.

Levels of Topics

The list of training topics also includes levels, with Level 1 indicating foundational skills and Level 2, advanced skills. These skills follow an order that matches the skills needed for the deliverables in each level in the document category. For documents, the levels align with the level of the regulatory writer, starting with support documents and moving to protocols and safety updates and data-driven documents that require interpretation and messaging. The level of a specific document may change according to its complexity. For example, a protocol that is simple will be a Level 1 document, whereas a complex protocol may be a Level 2 document.

The AMWA Medical Executives Council and the AMWA Board of Directors reviewed the list of recommended training topics and provided feedback.

AMWA Recommended Training Outline

Core Knowledge and Skills

Training in the area of core knowledge and skills is fundamental to success as a regulatory writer. Writers are expected to know and advise on the latest requirements and best practices for regulatory writing, disclosure, etc. They should be able to confidently lead project teams to produce documents that are submission ready, even at the early stages of development (ie, protocols), as the initial development writing has downstream effects. Although the knowledge and skills noted here focus on clinical documents, the list should be modified for situations in which regulatory writers work in other areas (eg, preclinical).

Drug Development Process

All regulatory writers should have a high-level knowledge of the drug development process and understand how regulatory documents fit in that process.

- Ethics and Good Clinical Practice (GCP)
- Overview of global regulatory agencies
- Transparency and disclosure
- Key documents in the drug lifecycle
  - Clinical development plan
  - General investigational plan
  - Common technical document (CTD) (overview)
  - Clinical trial initiation documents (eg, Investigational New Drug [IND] application, Clinical Trial Application [CTA] and registration applications (New Drug Application [NDA] and Marketing Authorisation Application [MAA]) (overview)

Medical Writing Skills

Strong medical writing skills are a core competency for all medical communicators. Consolidating contributions and input from project teams into focused and clear deliverables will demonstrate the value of a writer and facilitate his or her integration into a matrix team.

- Basic writing and editing mechanics
- Principles of writing
- Writing to specific audiences
- Clear communication of complex concepts

Technical Aptitude

Regulatory writers must be proficient with technology and adept at working with a variety of programs and systems used in the regulatory writing environment. Frequently, team members are hesitant to work within required systems and rely on the writer to do so. The knowledge and skills needed for software and other tools will be company-specific and will vary.

Level 1

- MS Word
- Collaborative/Coauthoring tools
- Document management systems
- Adobe Acrobat
- Document review systems
- Table creation and formatting
- Reference/bibliography management
- Appendices quality review and management
- Secure file and information transfer methods

Level 2

- Clinical Data Interchange Standards Consortium (CDISC) Glossary
- Structured authoring
- Template creation and formatting
- Project management
- Visual communication: figures and graphs

Analytical Skills

Training in analytical knowledge and skills is necessary to enhance regulatory writers' understanding of the context of their writing and to help them remain current with emerging research concepts and processes. In addition, writers need to create and link key messaging to study outcomes for reviewers to efficiently digest and validate a substantial amount of trial data.

Level 1

- Evolving clinical trial designs
- Quality control review
- Basic statistical concepts
- Pharmacokinetics and pharmacodynamics
- Basic data interpretation
- Lean authoring

Level 2

- Advanced data interpretation
- Advanced statistical concepts

Soft Skills

Soft skills are crucial for working efficiently, gaining trust, communicating and collaborating effectively with colleagues, and achieving personal and company goals. As regulatory writers become proficient in soft skills, their teams' confidence (as well as their own) will enable them to be a valued and integral member.

Self-Management

Level 1

- Time management
- Developing connections and maintaining high productivity
  - —Remote working
  - —Working cross-functionally

Level 2

- Critical thinking, decision-making, and problem-solving

People Skills

Level 1

- General project management (leading the document development process)
- Interpersonal communication (includes email)
- Leading meetings
- Leading teams through document review: best practices (includes editing, publishing, and quality control at the end of the document process)
- Working within a multifunctional team structure (matrix environment)
- Collaborating virtually and in person
- Working across cultures
- Dealing with difficult/unexpected situations or personalities

Level 2

- Leading without authority
- Influencing and persuading
- Project management negotiation
- Managing conflict
- Demonstrating the value of the medical writer
- Managing a team of writers (for complex projects, such as submissions)

Personal Development

- Stress management
- Resilience and flexibility
- Self-confidence
- Composure under pressure
- Empathy
- Saying 'no' while maintaining positive relationships

Documents*

*Practical application in developing regulatory documents is the cornerstone of the overall training of a regulatory writer. (*The complexity of a specific document is a factor in assigning a level. If a Level 1 document is complex, it should be categorized as Level 2.)*

Level 1

- Patient narratives
- Investigator's Brochure and updates
- Informed consent forms
- Simple protocols and clinical study reports (CSRs)

Level 2

- Lay summaries and other patient- and public-facing documents
- Basic results and trial disclosure reporting
- Simple study initiation document sections
- Simple CTD modules (5.2, 2.7.5, 2.7.6)
- Safety updates: Risk Management Plans (RMPs), Drug Safety Update Reports (DSURs), Periodic Adverse Drug Experience Reports (PADERs), and Periodic Benefit-Risk Evaluation Reports (PBRERs)
- Complex protocols

Level 3

- Complex CSRs
- Complex study initiation document sections
- CTD efficacy summary (module 2.7.3) and Integrated Summary of Efficacy
- CTD safety summary (module 2.7.4) and Integrated Summary of Safety
- CTD clinical overview (module 2.5)
- Health authority response documents
- Briefing documents

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References

1. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model—Section 2: knowledge, skills, abilities, and behaviors. *Ther Innov Regul Sci*. 2018;52(1):78-88.

About the American Medical Writers Association

Founded in 1940, the American Medical Writers Association (AMWA) is the leading professional organization for writers, editors, and other communicators of medical information. AMWA serves as a resource for professional medical communicators, promoting excellence in medical communication and providing educational resources in support of that goal. AMWA represents more than 4,000 members in the US, Canada, and 30 other countries who are committed to accurately and ethically making information about health and medicine clear and meaningful.

AMWA is committed to the overall value of continuous learning and offers a variety of educational resources, including workshops, onsite training, monthly webinars focusing on practical topics, and interactive online learning activities designed to enhance medical communication skills. AMWA's premier event, the Medical Writing & Communication Conference, offers more than 100 learning opportunities through its education sessions, roundtable discussions, and posters. You can learn more about AMWA at www.amwa.org.

Recommended Independent Reading*

Core Knowledge and Skills

Overview

Handbook for Good Clinical Research Practice (GCP). Guidance for Implementation; World Health Organization, 2005

E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). Guidance for Industry; US FDA, March 2018

World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. *JAMA*. 2013;310(20):2191-2194.

CDISC Global Regulatory Requirements (https://www.cdisc.org/resources/global-regulatory-requirements)

External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (EMA policy 0070), version 1.3; European Medicines Agency, February 2018

"What you need and when—the key documents in the drug lifecycle" [includes documentation roadmap]

M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use. Guidance for Industry; US FDA, October 2017

Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. Guidance for Industry (revision 6); US FDA, January 2019

FDA: Investigational New Drug (IND) Application (https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application)

FDA: New Drug Application (NDA) (https://www.fda.gov/drugs/types-applications/new-drug-application-nda)

Analytical Skills (Level 1)

Guidance for Industry. E9 Statistical Principles for Clinical Trials; US FDA, 1998

Documents

Level 1

CDISC Glossary (https://www.cdisc.org/standards/glossary)

Chen A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207.

TransCelerate Common Protocol Template (https://transceleratebiopharmainc.com/initiatives/common-protocol-template/)

McNally T, Whitsell R. The TransCelerate Clinical Protocol Template. *AMWA J*. 2018;33(4):170-177.

Level 2

Guidance for Industry. E2F Development Safety Update Report; US FDA, 2011.

Summaries of Clinical Trial Results for Laypersons, version 2; Expert Group on Clinical Trials for the Implementation of Regulation (EU) No. 536/2014 on Clinical Trials on Medicinal Products for Human Use, February 2018

Federal Plain Language Guidelines; Plain Language.gov, May 2011

Level 3

TransCelerate CSR Template (https://www.transceleratebiopharmainc.com/wp-content/uploads/2018/11/CPT_ImplTK-How-was-Common-CSR-Developed_V001.pdf)

Hamilton S, Bernstein AB, Blakey G, et al. (on behalf of the Budapest Working Group [BWG]). Critical review of the TransCelerate Template for clinical study reports (CSRs) and publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. *Res Integr Peer Rev*. 2019;4:16.

CORE (Clarity and Openness in Reporting: E3-based). An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies; CORE, 2016

Guideline for Industry. Structure and Content of Clinical Study Reports; ICH3, 1996

Guidance for Industry. E3 Structure and Content of Clinical Study Reports. Questions and Answers (R1); US FDA, January 2013

21 CFR Part 312 (IND)

Guide for Industry. M4S: The CTD—Safety; US FDA, August 2001

Schwartz DN, Umen MJ, Nomides K, Vanderhoof M. Understanding the differences and effectively transitioning between the US Integrated Summaries of Effectiveness and Safety (ISE/ISS) and the CTD Summaries of Clinical Efficacy and Safety (SCE/SCS). *Drug Inform J*. 2010;44:641-648.

European Medicines Agency. Human medicines: regulatory information (www.ema.europa.eu/en/human-medicines-regulatory-information)

*All readings in this list are available in the AMWA Member Resource Library.

AMWA Recommended Training Outline Checklist

Customize this checklist to fit the needs of an individual regulatory writer and/or your specific company.

	Training Completed		
Topic	**External**	**In-house**	**Hands-on**
Core Knowledge/Skills			
Drug development process			
Ethics and GCP			
Overview of global regulatory agencies			
Transparency and disclosure			
Key documents in the drug lifecycle			
Clinical development plan			
General investigational plan			
CTD (overview)			
Study initiation documents (eg, IND application, CTA) and registration applications (eg, NDA, MAA) (overview)			
Medical writing skills			
Basic writing and editing mechanics			
Principles of writing			
Writing to specific audiences			
Clear communication of complex concepts			
Technical aptitude[a]			
Level 1			
MS Word			
Collaborative/Coauthoring tools			
Document management systems			
Adobe Acrobat			
Document review systems			
Table creation and formatting			
Reference/bibliography management			
Appendices quality review and management			
Secure file and information transfer methods			

Level 2			
CDISC Glossary			
Structured authoring			
Template creation and formatting			
Project management			
Visual communication: figures and graphs			
Analytical skills			
Level 1			
Evolving clinical trial designs			
Quality control review			
Basic statistical concepts			
Pharmacokinetics and pharmacodynamics			
Basic data interpretation			
Lean authoring			
Level 2			
Advanced statistical concepts			
Advanced data interpretation			
Soft Skills			
Self-management			
Level 1			
Time management			
Developing connections and maintaining high productivity			
Remote working			
Working crossfunctionally			
Level 2			
Critical thinking, decision-making, and problem-solving			

People skills			
Level 1			
General project management (leading the document development process)			
Interpersonal communication (includes e-mail)			
Leading meetings			
Leading teams through document review: best practices (includes editing, publishing, and quality control at end of document process)			
Working within a multi-functional team structure (matrix environment)			
Collaborating virtually and in person			
Working across cultures			
Saying "no" while maintaining positive relationships			
Dealing with difficult/ unexpected situations or personalities			
Level 2			
Leading without authority			
Influencing and persuading			
Project management negotiation			
Managing conflict			
Demonstrating the value of the regulatory writer			
Personal development			
Stress management			
Resilience and flexibility			
Self-confidence			
Composure under pressure			
Empathy			
Documents[b]			
Level 1			
Patient narratives			
IBs and updates			
Informed consent forms			
Simple protocols and CSRs			

Level 2			
Lay summaries and other patient-and public-facing documents (as well as plain language and health literacy principles)			
Basic results and trial disclosure reporting			
Simple study initiation document sections			
Simple CTD modules (5.2, 2.7.5, 2.7.6)			
Safety updates: RMPs, DSURs, PADERs, PBRERs			
Complex protocols			
Level 3			
Complex CSRs			
Complex study initiation document sections			
CTD efficacy summary (module 2.7.3) and ISE			
CTD safety summary (module 2.7.4) and ISS			
CTD clinical overview (module 2.5)			
Health authority response documents			
Briefing documents			

[a]The software and tools a regulatory writer will use will be company-specific and will vary.
[b]Add specialized documents as appropriate to meet the unique needs of your company. For example, if regulatory writers develop nonclinical documents or documents for medical devices, add those documents to the list. Also, move documents to a different level depending on their complexity. For example, a simple yearly update to an Investigator's Brochure may be a Level 1 document, but a substantial revision may be a Level 2 document.
GCP = Good Clinical Practice, CTD = Common Technical Document, IND = Investigative New Drug, NDA = New Drug Application, CTA = Clinical Trial Application, MAA = Marketing Authorisation Application, CDISC = Clinical Data Interchange Standards Consortium, IB = Investigator's Brochure, CSR = Clinical Study Report, RMP = Risk Management Plans, DSUR = Drug Safety Update Report, PADER = Periodic Adverse Drug Experience Report, PBRER = Periodic Benefit-Risk Evaluation Report, ISE = Integrated Summary of Efficacy, ISS = Integrated Summary of Safety.

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