

Medical Communicators'
Guide to
Regulatory Writing



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Regulatory medical writers are key personnel in the regulatory environment for pharmaceutical products, providing valuable insight, clarity, and organization to documents that are submitted to regulatory agencies.

Regulatory writers' ability to analyze, organize, and distill complex scientific information makes reviewers' jobs easier, clearing the path for important scientific discoveries. They also provide leadership, project management, collaboration, and diplomacy to the work environment, which makes them indispensable team members.

Yet few formal opportunities exist for standardized training of regulatory writers.

This guide introduces medical communicators to the rich opportunities that exist in regulatory writing. It describes the regulatory writing ecosystem, providing details about breaking into the field and about the core skills and knowledge needed to help launch or advance a career in regulatory writing. It also outlines the most common types of regulatory documents and the role of regulatory writers in creating them. The guide examines the critical "soft skills" that are

needed in today's team-oriented work environments. Finally, it includes resources you can use to explore opportunities in regulatory writing further.

What Is Regulatory Writing?

Regulatory writing is, of course, much more than writing. Regulatory writers are often key members of cross-functional teams that study the safety and efficacy of pharmaceutical products and move them through the regulatory process.

Regulatory writing is primarily concerned with addressing the needs of regulatory agencies and reviewers who are tasked with determining whether a drug or medical device meets the requirements to reach the marketplace. Regulatory writers are also involved with the required disclosure of trial results to the public.

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Medical devices are a growth area in the pharmaceutical arena, and regulations for medical device applications and approvals can be quite different than for drugs, especially in the EU. This guide will focus broadly on the regulatory writer's role in the drug development process.

In most cases, regulatory writers are tasked with writing clinical regulatory documents, not nonclinical or Chemistry, Manufacturing, and Controls (CMC) documents. Examples of clinical regulatory documents include investigator brochures, informed consent forms, clinical study reports, and clinical safety reports, to name a few. However, the scope of responsibilities varies, depending on the size of the organization. In larger companies, safety documents are written by the clinical safety group, not regulatory writers. In smaller biotech companies or startups, regulatory writers may be asked to create documents for other functional areas.

A Team Effort

Teamwork is an integral part of regulatory writing. The intricate process of drug development requires regulatory writers to have both core knowledge and “soft skills,” such as shepherding documents through multiple iterations and review by many stakeholders. The document development process includes cross-functional teams that require input from subject matter experts within clinical, biostatistics, regulatory affairs, pharmacology and safety departments. Some documents require the involvement of team members from CMC and pre- or nonclinical research.



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Regulatory writers are communicators, and although the primary audience is familiar with the terms and acronyms used in the industry, regulatory writers employ their editorial skills in order to make the reviewers’ jobs easier to understand the main messages by using understandable language, limiting the use of jargon, and defining and limiting the use of acronyms. Many documents submitted to regulatory agencies become available to the public after a product is approved, so readability is key.

Regulatory writers should stay up to date on global and regulatory guidelines for documents, demonstrating their value to the team and the company.

Establishing a Career in Regulatory Writing

Regulatory writers are vital players in the drug development process, yet the lack of formal, standardized training in regulatory writing can make it challenging to break into the field. Success in the niche requires a specific set of technical and soft skills.

The pharmaceutical industry generally seeks experienced regulatory writers and therefore provides limited in-house training. Clinical research organizations (CROs) also hire regulatory writers, but they are often looking for seasoned professionals.

As is the case in other technical writing areas, hands-on training is important for regulatory writers. However, the proprietary nature of the content makes it difficult for external or third-party groups to provide specific training.



As the demand for excellent regulatory writers is growing, so is the need for more regulatory writing training. The pharmaceutical industry seeks to replace experienced writers who are retiring, and opportunities (including apprenticeships) do exist.

How can motivated regulatory writers get established in this rewarding career? One resource is AMWA's [Regulatory Writer Training eBook](#). This training report provides a foundation in 3 areas: core knowledge and skills, soft skills, and regulatory documents.

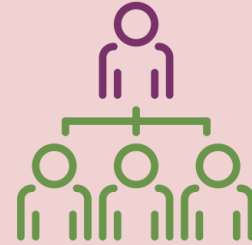
Core Knowledge and Skills

Success as a regulatory writer requires training in the areas of core knowledge and skills, the building blocks of a career in regulatory writing. Regulatory writers are expected to understand statistical concepts and know how to analyze and interpret data. They must write clearly and concisely. They are expected to understand and advise on the latest regulatory requirements and know the best practices, clinical trial transparency and public disclosure, and other aspects of the regulatory process.

They need to confidently lead project teams, even at the early stages of document development, in order to create documents that are ready for regulatory submission.

All regulatory writers should possess a high-level knowledge of the product development process and understand how regulatory documents fit into that process.

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Understanding the Drug Development Process

No discussion of regulatory writing is complete without an understanding of [ethics and Good Clinical Practice \(GCP\)](#).

Ethics and Good Clinical Practice

Regulatory writing supports pharmaceutical research from start to finish, and regulatory writers follow ethical guidance for clinical (human) research. The GCP guidelines are not just for personnel conducting clinical studies; regulatory writers need to understand patients' rights and the responsibilities of investigators and sponsors who conduct research on humans.

For example, regulatory writers should be aware of subtle yet problematic phrases in a protocol that could possibly jeopardize research participants or produce biased results.

When facing ethical questions, medical communicators should refer to the [AMWA Code of Ethics](#), 8 principles that guide “the profession of medical communicators so as to engage only in activities that bring credit to their profession, to AMWA, and to themselves.”

Global Regulatory Agencies

A vast network of regulatory agencies around the world oversees the development and marketing of pharmaceuticals. In an attempt to streamline the process and avoid duplicate efforts, the [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use \(ICH\)](#) keeps a database of guidelines that apply to drug development in many regions. The founding regulatory members of the ICH are the US Food and

Drug Administration (FDA), the European Commission (EC), and the Ministry of Health, Labour and Welfare (MHLH/PMDA) in Japan.

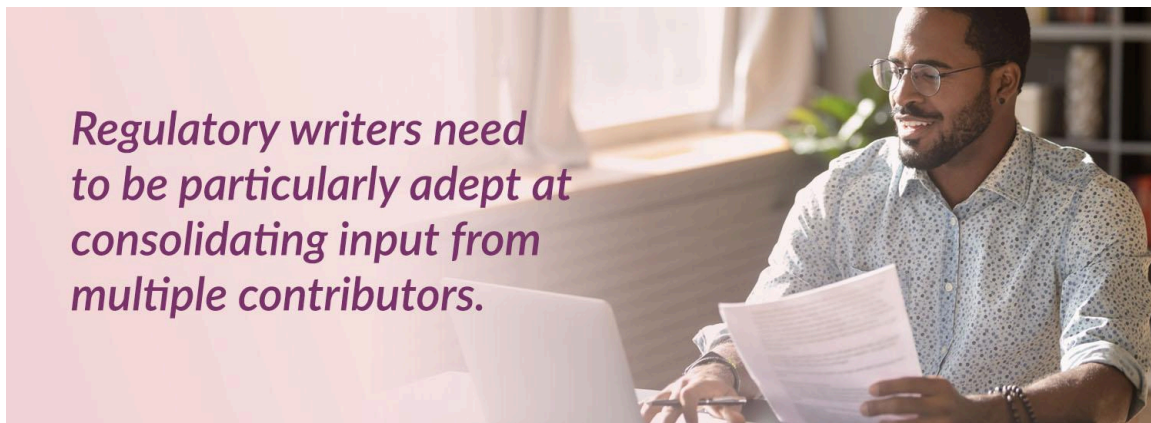
The ICH created the [Common Technical Document \(CTD\)](#), which is actually a dossier of documents that includes the Quality, Safety, and Efficacy information in all drug applications.

The CTD became the mandatory format for drug applications in the EU and Japan in July 2003. For new drug applications (NDAs) submitted to the FDA in the United States, it is the “recommended format of choice,” according to the ICH.

Several other regulatory agencies mainly follow ICH rules, but they may have separate or additional requirements.

Medical Writing Skills

Writing skills are essential for all medical communicators. However, regulatory writers need to be particularly adept at consolidating input from multiple contributors. In addition, regulatory writers should excel at basic writing and editing mechanics and understand the principles of writing for specific audiences. The regulatory environment also requires clear communication of complex concepts, analytical skills, and technical aptitude.



Technical Aptitude

The technical knowledge and skills required for regulatory writing vary across companies and positions. However, all regulatory writers should be adept at working with common programs and systems used in the regulatory writing environment.

AMWA's [Regulatory Writer Training eBook](#) lists the following as examples of basic technical skills and tools that are used in regulatory writing.

Basic Technical Skills

- Microsoft Word
- Collaborative/coauthoring tools
- Document management systems
- Adobe Acrobat
- Document review systems
- Creating and formatting tables
- Managing references and bibliographies
- Quality review and management of appendices
- Secure file and information transfer methods

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Advanced Technical Skills

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

Analytical Skills

Regulatory writers must be able to understand and analyze emerging research concepts, processes, and clinical trial designs. They need to master basic statistical concepts, pharmacokinetics and pharmacodynamics, data handling, and concepts of lean authoring. They need to create and link key messaging to study outcomes to ensure that reviewers get an efficient and accurate report of the data that emerges. As they advance in the field, regulatory

writers also grow in their understanding of advanced statistical concepts and their ability to interpret data.

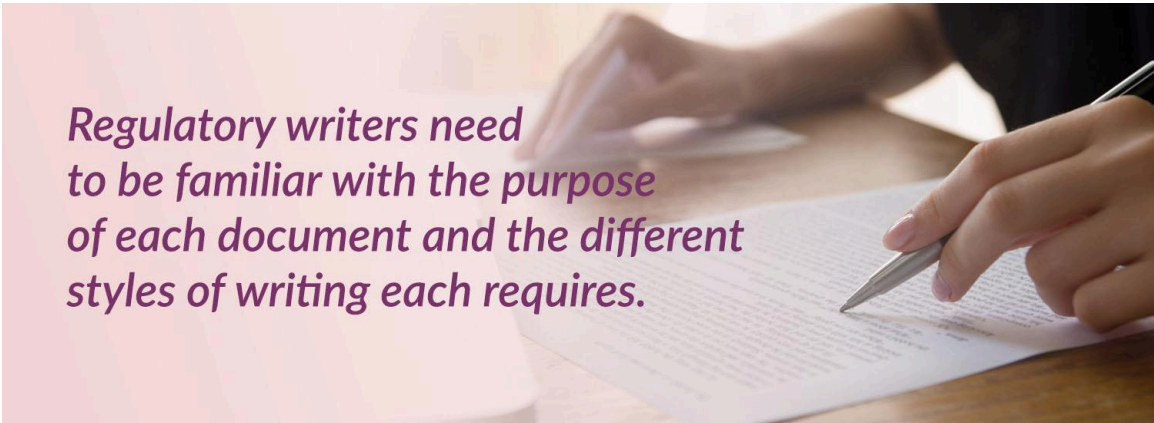
Regulatory Documents

Regulations keep patients safe and hold corporations accountable. Regulatory writers are critical for creating, shepherding, and compiling key documents that are required during the life cycle of the drug.

Regulatory writers interact closely with the internal publishers who work to ensure that documents meet the precise technical specifications of regulatory agencies; thus they should have a basic understanding of this internal publishing process. They also need to be familiar with document management standards and document management archival systems.

Key Documents in the Drug Life Cycle

Regulatory writers are often involved in creating vital documents in the life cycle of a drug's development from discovery all the way to marketing and trial disclosure. Regulatory documents require various levels of experience and analysis, as well as a knowledge of the needs of the audience for each document. While most of the documents and dossiers that regulatory writers prepare are developed specifically with the regulatory agency as the audience, others are designed to be read by clinical trial personnel or by patients and the public. Regulatory writers need to be familiar with the purpose of each document and the different styles of writing each requires. Regulatory agencies review and approve all documents, regardless of the audience. Some common documents in the drug life cycle include:



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Documents for Regulatory Authorities

- Clinical development plan
- Clinical study report (CSR)
- Common Technical Document (CTD) summaries
- Clinical trial documents (eg, Investigational New Drug [IND] application, Clinical Trial Application)
- Registration applications (New Drug Application [NDA] and Marketing Authorisation Application [MAA])

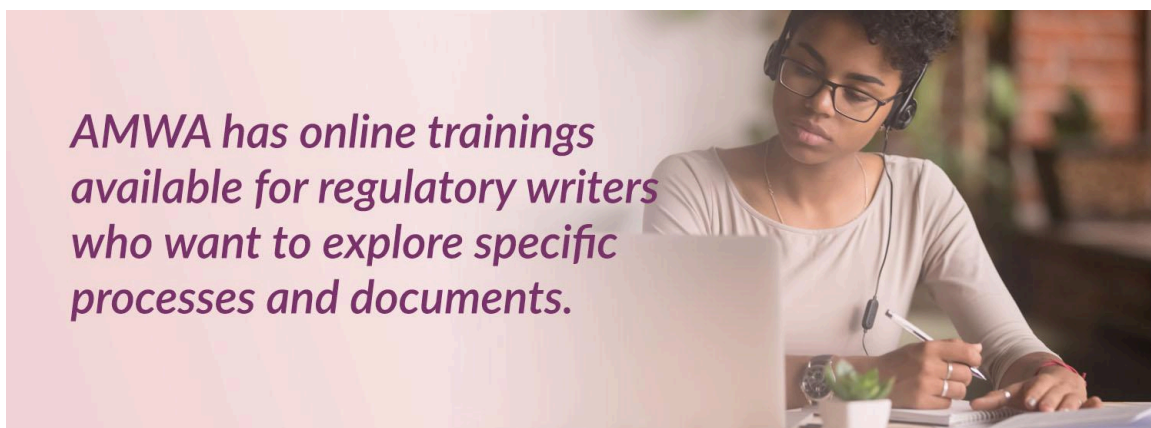
Documents for Clinical Investigators

- Investigator's brochure and updates
- Simple and complex protocols
- Protocol amendments

Documents for Clinical Study Participants and the Public

- Informed consent forms
- Lay summaries
- Basic results and trial disclosure reporting

AMWA has [online trainings available](#) for regulatory writers who want to explore specific processes and documents.



Other Critical Documents

It is important to note that some key regulatory documents are written by cross-functional team members other than regulatory writers. They are included here because regulatory writers need to be familiar with all documents contributing to a drug's life cycle. They include the following:

- Statistical Analysis Plan (SAP) – written by biostatistics

- Data management plan – written by data management plus biostats and clinical research
- Case report form (usually electronic these days) – written by data management plus biostats and clinical research
- Clinical development plan (and update) – written by clinical research

Critical Soft Skills

It takes more than technical proficiency to succeed as a regulatory writer. Often the difference between a successful regulatory writer and a struggling one is the area known as [soft skills](#) – a constellation of qualities that are developed internally or by working in collaboration with others. Soft skills are as important as technical skills. For example, the multidisciplinary, collaborative nature of regulatory writing requires high levels of self-management, time management, and people skills.

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When regulatory writers demonstrate their ability to communicate and work well as part of a team, they quickly become valued, trusted members.

The following are some soft skills that are particularly valuable for regulatory writers.

Self-Management

The pharmaceutical industry can be a high-pressure environment, and regulatory writers must have exemplary time management skills. They must also be adept at relationship building and maintaining a high level of productivity. Additionally, since the COVID-19 pandemic, regulatory writers have had to master the art of self-discipline and working remotely but also and working cross-functionally at the same time.

In addition, successful regulatory writers excel at critical thinking, decision-making, and problem-solving.

People Skills

Regulatory writers are often leading the document development process using general project management skills. They need to master interpersonal communication, including emailing, leading meetings, and leading teams through document review. The document review process often requires familiarity with best practices in editing, quality control, and internal publishing.

Regulatory writers work as part of cross-functional teams, so they must be excellent collaborators, both virtually and in person, and across cultures. They also need to be able to cope with difficult or unexpected situations or personalities.



As they advance in the fast-moving and high-pressure pharmaceutical industry environment, regulatory writers establish themselves as leaders, adept at influencing, persuading, negotiating, and managing conflict. These skills become very important as they find themselves managing project teams or teams of writers for complex projects such as submissions.

Personal Development

Good regulatory writers have learned to manage stress, in part, by exhibiting resilience and flexibility under pressure. They can stay composed, self-confident, and empathetic, and they have learned the art of saying “no” while still maintaining positive relationships.

Proving Your Value as a Regulatory Writer

The work of regulatory writers should speak for itself. However, if the need arises for regulatory writers to prove their value, they don’t need to reinvent the wheel as. AMWA’s Value of Medical Writing Work Group has been conducting literature searches, surveys, and interviews exploring this topic. Three articles have been published in the [AMWA Journal](#).

In addition, the findings were also presented as educational sessions at the 2021 AMWA Medical Writing & Communication Conference. The sessions are available for complimentary viewing in AMWA Online Learning.

- [Value of Medical Writing: The Regulator's Perspective](#)
- [Value of Medical Writing: The Regulatory Writer's Perspective](#)

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Regulatory Writing Resources

Because of the lack of formal, standardized training, aspiring regulatory writers need to seek out appropriate training and mentorship opportunities.

AMWA has a number of resources available to help steer regulatory writers toward success.

- The [Regulatory Writer Training eBook](#) provides an overview of the field, exploring the core knowledge and skills, soft skills, and documents that regulatory writers will need to succeed and advance in their careers.
- [AMWA Certificate in Regulatory Writing Core Knowledge.](#)
This program is organized into 3 content areas - the drug development process, core knowledge and skills, and analytical skills. In total, the 10 activities provide a comprehensive overview of the knowledge and skills you need to succeed as a regulatory writer.
- A number of AMWA webinars explore [regulatory writing topics](#) and dive into specific documents.
 - [Clinical Study Report Development Pt. 1](#) and [Clinical Study Report Development Pt 2](#) explore one of the most common regulatory documents.

[To read this article online, click here.](#)

- [Effective Project Management for Regulatory Documents During the Document Process](#) helps regulatory writers tackle the management of the process, timelines, and people involved in the regulatory process.

The Value of Medical Writing

How valuable are regulatory writers? In 2021, AMWA's Value of Medical Writing Work Group published the results of a year's worth of literature searches, surveys, and interviews in the [AMWA Journal](#).

- [Optimizing the Value of Regulatory Medical Writers](#)
- [Value of Medical Writing: The Regulator's Perspective](#)
- [Value of Medical Writing: The Regulatory Writer's Perspective](#)

These articles provide additional evidence to the lived experience of AMWA's experts: Trained regulatory medical writers are vital to the process of developing and marketing products that improve health and longevity.

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