1 Good Documentation Practices

Jenny Grodberg, PhD, RAC-US; Jocelyn Jennings, MS, RAC-US, RAC-Drugs, RAC-Devices, FRAPS

Introduction

Documentation is often a regulator's first, and sometimes only, impression of a research group or organization. A robust documentation system serves as the foundation from which a healthy compliance program can be built and, once in place, will remain a source of first impressions during audits and inspections. The documents themselves, individually and collectively, represent the face of a company's operations.

Good Documentation Practices (GDPs), essential in any professional setting, are critical in regulated medical device, drug, and biological product environments. In general, GDPs encompass all written activities, processes, studies, and results associated with product development, approval, maintenance, and improvement. Good documentation serves as evidence of product development decisions and provides a basis for all activities required throughout the product's lifetime. Given the dynamics of product development and the potential timeline for realizing commercialization, good documentation allows consistent information transfer among parties, functional groups, and regulatory authorities. Some organizations refer to GDPs to encompass Good Recordkeeping Practice, an essential component of overall Pharmaceutical Quality Systems (PQS) and Quality Risk Management strategies (QRM).

A sound documentation system also allows regulatory agencies to conduct a complete and efficient review of marketing applications and other communications necessary for product evaluation and approval. GDPs help regulators understand the product's history, assess the adequacy of studies, verify data integrity, and assess the appropriateness of intended use and the validity of claims about the product's safety, efficacy, and quality.

Ensuring the safety of approved products is critically important; GDP compliance should be applied from the product's conception and throughout its development. From prototype through clinical trials and up to postmarket surveillance, GDPs should be developed, implemented, and maintained.

GDPs apply to the following:

- Procedures (e.g., standard operating procedures [SOPs])
- Documentation during product development (e.g., formulation development reports, drug master files, device master files or design history files)
- Documentation for purposes of product clearances, approvals, and licenses (e.g., premarket notification [510(k)s], premarket approval applications, new drug applications, and biologics license applications)
- Pharmacovigilance and medical device reporting documentation
- Assembly of justification files to support an organization's decision-making process and conclusions reached
- Regulatory authority meeting packages and meeting minutes
- Regulatory interaction correspondence
- Postmarket documentation

Regulatory authorities can provide a GDP framework that is incomplete. Most guidance documents and defined regulatory standards contain GDP elements, and each stage of product development has its nuances as to how documentation should be approached. Although guidance documents issued by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), or other regulatory authorities do not establish legally enforceable responsibilities. Their influence is limited to a regulatory authority's current thinking on a topic and their recommendations should be applied when possible and supplemented with existing available statutory requirements. An organization should consult the expectations of all applicable regulatory authorities, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF), and the World Health Organization (WHO).

Being well-versed in regulations is merely the first step in creating a healthy compliance profile, producing documentation, maintaining a robust quality system, and meeting

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

regulatory requirements. GDP adherence is highly focused on postmarket documentation, such as medical information communications, promotional materials, and user operation manuals. These documents should not stray from the approved indications or safety and efficacy claims. Supporting documentation should be kept on file.

This chapter explores the components of GDPs. Although not exhaustive, the discussion highlights the best efforts to provide a thorough understanding of the principles and concepts necessary to develop, maintain, or improve an existing documentation system. The fact that regulatory authority expectations and industry best practices will continue to evolve underscores the importance of regularly monitoring internal systems and implementing value-added changes.

Goals of Documentation

It is best to start organizing documentation with the end purpose in mind. Documentation is essential for effective and efficient operations and serves the following purposes:

- Making internal processes and procedures clear and consistent
- Assisting in personnel training and cross-training
- Creating a reference for conducting evaluations
- Creating standards upon which continual improvements can be fostered
- Tracking product changes and the reasoning behind them
  - Centralizing important concepts related to business development
  - Creating a foundation for risk assessments and quality systems' maintenance
  - Incorporating global regulatory considerations, as necessary
  - Allowing internal and external product knowledge transfer
  - Complying with quality and regulatory expectations
  - Supporting premarket applications
  - Supporting postmarket commitment requirements and surveillance activities
  - Assisting in putting the product into and maintaining it in commercial distribution

An organization must understand its documentation system's goals, define its components, review its requirements, implement its execution, train for incorporating it into organizational culture, and maintain it and its results periodically.

Basic Principles of GDPs

When developing GDPs, it is important to:

- Look at the consequences of including or omitting information:
  - If information is not documented, it does not exist; retrospective documentation is not recommended.
  - Overkill in reporting minor details or repeating information may impede transparency.
  - Templates are a good start, but customization is crucial and should be specific to each organization and internal group within an organization.
  - Do not make reviewers look too hard to verify the organization's compliance.
- Make required actions and expectations attainable:
  - Avoid requiring actions that existing personnel cannot support.
  - Budgetary constraints may exist that limit implementation of the ideal system.
  - If current operations do not allow for compliance with stated requirements, do not document them as requirements.
- Implement robust change control procedures to capture all changes made to documentation and review periodically:
  - Corrections to hand-written documentation should be made with a single line, signed and dated.
  - White-out should never be used for corrections.
  - The reason(s) for any documentation corrections or changes should be stated.
- Remain current on quality and regulatory rules and regulations, and update documentation as needed:
  - Document compliance clearly and reference supporting guidelines and resources used.
  - If applicable, justification for any necessary noncompliance resulting from business decisions or changes in rules, regulations, or policies should be documented.
- Write clearly, using consistent practices and language:
  - Stick to technical writing basics; this is not creative writing.
  - Use established words, references, and acronyms. Define acronyms on first usage in a document.
  - Avoid discrepancies within and between documents. While many groups may contribute to a document, finalization should be centralized within the quality, regulatory, medical writing, or labeling group.
  - Adopt an appropriate style for each document. Bench science, manufacturing, and regulatory affairs writing styles differ and should be used as appropriate.
  - Avoid the use of arrows and ditto marks.
- Maintain control of contents and records:
  - Documentation should be attributable, legible, contemporaneous, original, and accurate (ALCOA). (ICH E6(R3) Section 2.12.2)[1]
  - Verify what is documented to the extent practicable.
  - In the event of an audit or inspection, the audit trail should be clear and complete; where it may lead, or where it may fail to lead, should be anticipated and defensible.
  - Do not destroy records; keep them as accessible as possible for internal use while protecting them from public access.
  - Ensure data Integrity with validated, protected, secure and backed-up data systems.

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Documenting Procedures

When creating documentation, the questions of what, when, why, and how should be addressed and a format created to memorialize the outcome of documented processes or procedures. With increasing emphasis being put on quality management systems and risk management during agency inspections and audits, an organization must pay careful attention to its SOP documentation. Procedures established to maintain quality operations are of little value if not followed, and when such documentation is not followed, it creates a trail of noncompliance. Any deficiency in adhering to the specifications, procedures, or recordkeeping requirements impacts an organization's compliance profile. One must adhere to SOPs, validated specifications, other controlled documents as well as work instructions or study plans (when applicable) referenced within the system. The documents containing validated product specifications are most important since any deviation could compromise product quality and potentially pose a danger to consumers.

Consistency, Clarity, and Completeness. A primary goal of GDP is to avoid conflicting provisions, ambiguous statements, incompatible requirements, and unattainable compliance goals. Consistency is important among related documents, regulatory requirements, and agency documents so that readers can find needed information.

A documentation system often involves many cross-functional groups, sometimes with overlapping areas of responsibility. Hence, an organization may develop documents with similar business goals but diverging execution pathways. Internal communication is key when documenting roles, responsibilities, and expectations while avoiding conflicting or inconsistent information.

A lack of specificity and detail can result in unanticipated vulnerabilities by inviting subjective interpretations. Achieving consistency involves carefully defining the terms used, abbreviations employed, and unifying individual writing styles. A focus on the documentation's goal and understanding the targeted audience is also important.

Clearly Delineate Processes and Relationships. Writing style and language use also are important in maintaining consistency and clarity. The following questions apply:

- Is the terminology used consistently throughout the documentation system?
- Does the language cater to the intended reader's level?
- Is the document easy to read and follow?
- Do the processes and/or procedures identified lead the user to the desired result efficiently?
- Is the document's information compliant with regulatory expectations?
- Will the document's contents and relevance be easy to explain during an inspection?
- Is the information included in the document all relevant to the subject matter under discussion?

Organizations should create document inventory lists, so they are readily available to users and regulators upon request. An electronically based documentation system should include copies of historic documents and a robust change control process. Connecting the documentation and any changes to it with the training program would be optimal. The more coordinated these good documentation system elements are, the smoother the transition between product development phases and across different functional groups. The consistent capture of specifications, procedures, records, and data, and this information's accessibility are key to successful operations and a healthy regulatory compliance profile.

Completeness matters. When filling out forms or documenting results, each required element should be addressed and every blank filled with either the appropriate answer or, if not applicable, N/A. During inspections, the agency will not assume a blank space means a requirement was N/A; it will presume the requirement was overlooked. During pre-inspections, any use of not applicable are scrutinized carefully and blank spaces eliminated.

Transparency and Disclosure

A culture of honesty and openness is an essential component of GDPs and achieving a healthy compliance profile. In addition to an organization's willingness to communicate, such a culture can open the door to more efficient product review processes, audits, inspections, and compliance dispute resolution efforts. The FDA emphasizes the importance of data integrity during inspections, particularly current Good Manufacturing Practice inspections.[2]

An organization must consider and make decisions carefully about what content should be captured in which documentation. For example, it is inadvisable to address overall product development strategy in a protocol or Investigator's Brochure, even though this information is included in an Investigational New Drug application or background package. Internal planning and clear upper management direction are necessary, so an organization's documents remain meaningful, relevant, and applicable to its actual operations.

Identifying Documentation Guidelines and Resources

Although no single regulation or policy defines GDP, its components are cited by federal and international agencies, including FDA, ICH, IMDRF, and WHO, as well as institutional policy. Professional groups, such as Pharmaceutical Research and Manufacturers of America (PhRMA) and TransCelerate, also collaborate with industry partners to provide guidance that, such as the ICH guidelines, help bridge content development and ethical concerns with requirements for reporting and other types of documentation. Additionally, country-, region-, and therapeutic area-specific guidelines exist for many different purposes. For example, guidance such as the PhRMA Code,[3] the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist,[4] and various works on the Enhancing the Quality

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

and Transparency of Health Research Network (EQUATOR Network)[5] may be helpful to ensure appropriate data are collected to meet reporting requirements.

The ICH has been instrumental in the global initiative to standardize pharmaceutical product development and regulation. In realizing its vision, ICH has taken the lead on preventing duplication of efforts, reducing product development timelines, streamlining product approvals, and contributing to human health protection.

The ICH created and implemented the Common Technical Document for the assembly of all the quality, safety, and efficacy information into a comprehensive dossier for regulatory reviews in each member region. It consolidated the documentation necessary for a product to be adequately reviewed and approved efficiently. Regulatory authorities, industry sponsors, and the public have benefited from this important ICH initiative.

Elements of Good Clinical Practice, Good Manufacturing Practice, and Good Laboratory Practice requirements can be employed when establishing an effective GDP system. **Table 1-1** includes some available resources for developing a GDP system.

Using Form FDA 483 Observations to Refine a Good Documentation System

Form FDA 483 is issued to firm management after any inspection when an FDA investigator has observed any condition they believe may constitute violations of the Federal Food, Drug, and Cosmetic Act and related acts.[6] Often, the deficiencies cited include the lack of GDPs (i.e., design controls, certificates of analysis/conformance, calibrations or validations, postmarket studies, and pharmacovigilance or complaint handling.)

The most constructive way to approach a Form FDA 483 observation is to consider each deficiency cited as an opportunity to take corrective action and improve operational processes and procedures.

Some of the most recent Form FDA 483 findings can be found on the FDA website and are made available to the public through the Office of Inspections and Investigations Freedom of Information Act (FOIA) Reading Room.[7] The lessons learned, preferably at the expense of other organizations, are invaluable. They include the following documentation-related observations that organizations should take the time to review, understand, and avoid proactively. The following are some sample findings from the FOIA Reading Room:

- The organization failed to maintain complete data from all laboratory tests conducted to ensure compliance with established product specifications and internal quality standards.
- Laboratory records did not contain all raw data generated during each test for active pharmaceutical ingredient batches.
- A sample failed the purity specification limit, but the failure was not documented.
- Sample preparation information was not documented, and quality control records used to support the Drug Master File and batch disposition decisions did not include all testing results.
- None of the explanations justifies the failure to maintain complete records; neither do they support the practice of substituting repeat tests for failed results.
- The organization failed to prevent unauthorized access or changes to data and provide adequate controls to prevent data omission; no passwords are required to log into the databases, credentials are unverified, and there is no electronic or procedural control to prevent data manipulation.
- The software lacks an audit trail feature to document all activities related to the analysis performed; staff cannot demonstrate records include complete and unaltered data or verify there have been no alterations or deletions.
- The organization has no raw data for the test limits reported on the Certificates of Analyses; the release of these batches was approved without data to support that release specifications were met.
- The organization is responsible for having controls to prevent data omissions and recording any changes made to existing data, including the date of the change, the identity of the person who made the change, and an explanation or reason for the change.[4]

Building a Robust GDP System

Consider all Applicable Documentation

The following documents should be considered in regulated industry environments:

- Research and development
  - o Conception plans
  - o Prototype designs
  - o Engineering drawings
  - o User requirements
  - o Specification requirements
  - o Drug and formulation development reports
  - o Nonclinical study reports (both non-GLP and GLP)
  - o Clinical study protocols
  - o Investigator's Brochures
  - o Informed consent forms
  - o Case Report Forms
  - o Clinical study reports
  - o Design history file
  - o Development Safety Update Reports
- Sponsor narratives
- Commercialization
  - o FDA presubmission communications
  - o Supportive documentation for regulatory submissions
  - o Manufacturing SOPs
  - o Validation and stability reports
  - o Batch records
  - o Certificates of Analyses
  - o Labeling justifications and finalization
  - o Regulatory applications or dossiers
- Postmarket

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Table 1-1. Developing a GDP System

Resource	Website	Comments
Guidance/Guidelines		
ICH E3: Structure and Content of Clinical Study Reports (30 November 1995)	https://database.ich.org/sites/default/files/E3_Guideline.pdf	Helpful in developing a complete, unambiguous, and organized clinical report.
ICH E6(R3): Guideline for Good Clinical Practice (6 January 2025)	https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf	Outlines a unified standard (GCP) for documenting, recording, and reporting human clinical trials and ensuring data integrity.
ICH Q9(R1) Quality Risk Management (18 January 2023)	https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2025_0115.pdf	Outlines the principles of risk management and processes.
Design Control Guidance for Medical Device Manufacturers: Guidance for Industry (March 1997)	https://www.fda.gov/media/116573/download	Provides an in-depth review of the design control principles.
Guidance for Industry: Electronic Source Data in Clinical Investigations (September 2013)	https://www.fda.gov/media/85183/download	Provides information on maintaining electronic source data from computerized systems used in clinical trials
Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff (3 February 2003)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-system-information-certain-premarket-application-reviews	Provides an overview of quality information needed for premarket applications.
ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (10 November 2000)	https://database.ich.org/sites/default/files/Q7%20Guideline.pdf	This guideline provides an overview of GMPs for Active Pharmaceutical Ingredients and the required documentation.
ICH Q10 Pharmaceutical Quality System (4 June 2008)	https://database.ich.org/sites/default/files/Q10%20Guideline.pdf	This guideline provides an in-depth examination of a quality system for pharmaceutical products.
Guidance for Industry: Process Validation: General Principles and Practices (January 2011)	http://www.fda.gov/downloads/ Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM070336.pdf	This guidance provides an overview of the process validation process and the required documentation.
Guide to Good Manufacturing Practice for Medicinal Products Part 1, Chapter 4 Documentation: PIC/S PE 009-8 (Part I)(15 January 2009)	https://www.medsafe.govt.nz/regulatory/guideline/PE_009-8_GMP_Guide%20_Part_I_Basic_Requirements_for_Medicinal_Products.pdf	This guide provides an overview of the documentation requirements for use during GMP manufacturing.
Regulations		
21CFR812.140	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-G/section-812.140	Records
21CFR11	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11?toc=1	Electronic Records; Electronic Signatures
21CFR211.68(b)	https://www.ecfr.gov/current/title-21/part-211/subpart-D#p-211.68(b)	Appropriate controls
21CFR211.100(b)	https://www.ecfr.gov/current/title-21/part-211/subpart-F#p-211.100(b)	Written procedures; deviations
21CFR211.160(b)	https://www.ecfr.gov/current/title-21/part-211/subpart-I#p-211.160(b)	Laboratory controls
21CFR211.180(d)	https://www.ecfr.gov/current/title-21/part-211/subpart-J#p-211.180(d)	Records and Reports; general requirements
21CFR211.188	https://www.ecfr.gov/current/title-21/section-211.188	Batch production and control records
21CFR211.194(a)	https://www.ecfr.gov/current/title-21/part-211/subpart-J#p-211.194(a)	Laboratory records
21CFR212.60(g)	https://www.ecfr.gov/current/title-21/part-212/subpart-G#p-212.60(g)	Test records
21CFR212.110(b)	https://www.ecfr.gov/current/title-21/part-212/subpart-L#p-212.110(b)	Record quality

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

- Market and launch documentation
- Proof of compliance with acceptable practices and International Organization for Standardization requirements
- Pharmacovigilance reports
- Periodic safety update reports
- Medical information communications
- Annual reports
- Supplemental application filings
- Benefit-risk evaluation reports
- Postmarket study requirements/commitments
- Advertising and promotional materials and references

Good Practices for Signatures, Change Control, Validation, and Dating

If records are kept electronically, the system must be validated and backed up, and access should be limited to maintain control over any changes. Under GDPs, only the most current document may be used for any given purpose, and change control is a must. Each document should be assigned an internal control number, and revisions should be tracked. Originators, reviewers, and approvers should be identified and have appropriate qualifications to support their respective decisions.

Documentation should be dated in real-time and never pre-or postdated. Any retrospective additions, modifications, or deletions should be signed and dated; having these changes witnessed should be considered.

The time an organization should retain any given documentation can vary, so care should be taken before destroying any records. Maintaining a records retention schedule for the different types of records produced should be considered. SOPs on record retention, destruction of records and long-term storage of records are a must. Documents often require signatures. No document should be signed unless it is understood, and the contents are supported.

An organization's documents can be pivotal in a product liability or personal injury case, and it is possible they will be demanded during court proceedings. Likewise, any person within an organization responsible for that documentation also may be called into court. The credibility of a witness or a product's quality can be influenced greatly by implementing GDPs. In today's increasingly litigious environment, all documentation should be viewed through the lens of could this document be explained, justified, or defended in a court of law?

Recordkeeping, Review, and Training

Organizations are understandably focused on getting a product to market, but good documentation improves processes and, ultimately, the bottom line. An organization's quality system is based on its documentation system. Even with the best intentions, individual differences in execution or interpretation can result in inconsistencies and compromise product quality. That is why it is best to implement a GDP system at the earliest stages to minimize subjective interpretation.

Good documentation is a significant investment that may not bring immediate returns but provides important protection against internal inconsistencies, adverse regulatory actions, and legal liabilities. The human resources required to respond to a Form FDA 483 warrant the upfront investment in a documentation system that will mitigate communication, performance, and recordkeeping failures. Any findings of deficiencies are on the public record, available to competitors and customers alike.

Any documentation system should contain clear, consistent, and focused documents, including SOPs, work instructions. and training materials. Inconsistencies or ambiguities can have devastating effects on an organization's operations. Thus, documents should be reviewed periodically and reconciled with each other to minimize confusion among users. The organization should determine which are specific to its operations and customize policies and procedures accordingly. For example, processes and procedures not currently in place, even if they were previously, should not be documented.

Change control will ensure all users are using the most up-to-date version of a document, and an organized change control procedure should be developed and followed. A document change control system is intended to capture changes made to existing documentation and provide a means of tracking these changes and communicating them throughout an organization.

If an organization's operations deal with medical devices and pharmaceuticals, documentation for each product type should be maintained separately. Likewise, specific provisions may be necessary for documents related to an organization's pharmaceutical products if they are Drug Enforcement Administration (DEA)-controlled substances, biologics, generics, etc.

Once the documentation system is in place, it should not be neglected or abandoned. Changes should be considered regularly, following schedules mandated in regulations or in conjunction with other appropriate events. Additionally, the system should be kept in a validated state at all times. Meaning that any changes to the system should be assessed using risk management tools and if needed those changes should be validated. The documentation from this process must be maintained to ensure compliance with all regulations and internal procedures. In the event of an audit, the trail of the changes made, the dates of those changes, and the parties responsible for them should be identified easily, and support for those changes should be kept on file accordingly. Documenting the obvious can make short work of inspections. One test for whether updates are required is to answer the question, can you explain how this (i.e., the subject matter of the document) all works? It is not unreasonable for an auditor or inspector to expect a document user to explain the contents or their relevance to business operations. If a document, as written, cannot translate information to the reader to allow informed decisions to be made, reworking the document is advisable.

Training, vital to success, is only as good as the documentation on which it is based. High-quality documents are

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

the basis for high-quality training. For smaller organizations with limited resources, consultants specializing in GDPs are available.

Good documentation not only supports and advances an organization's quality system but also safeguards public health and can enhance employee retention. When everyone in an organization understands what is expected, product quality will be ensured, which enhances customer experience.

Acknowledgements

This chapter builds on the work of Joanne Rupprecht, Esq, RAC whose coauthorship in the prior edition of this book is deeply appreciated.

References

1 International Council for Harmonisation. Guideline for good clinical practice-E6(R3). Dated 6 January 2025. Accessed 17 March 2025. https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
2 Food and Drug Administration. Data integrity and compliance with drug CGMP: Questions and answers [guidance]. Current as of 13 December 2018. Accessed 23 March 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers
3 Pharmaceutical Research and Manufacturers of America. Code on interactions with healthcare professionals. Dated 1 January 2021. Accessed 23 March 2025. https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA%20Code%20-%20Final.pdf
4 Standard Protocol Items Recommendations for International Trials. SPIRIT 2013 checklist. Accessed 23 March 2025. https://spirit-statement.org/publications-downloads/
5 Enhancing the Quality and Transparency of Health Research-Equator Network. Accessed 23 March 2025. https://www.equator-network.org/
6 Food and Drug Administration. Form FDA483 frequently asked questions. Current as of 9 January 2020. Accessed 23 March 2025. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions
7 Food and Drug Administration. OII FOIA electronic reading room. Current as of 11 March 2025. Accessed 23 March 2025. https://www.fda.gov/about-fda/office-inspections-and-investigations/oii-foia-electronic-reading-room

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

2 General Considerations for Quality Regulatory Writing

E. Mitchell Seymour, PhD, RAC-US

Introduction

Regulatory writing – which interweaves language, science or engineering, medicine, and law – creates communications deliverables that advance medical, scientific, and manufacturing objectives. In biopharmaceutical, vaccine, and device development, a regulatory writer's principal goal is to produce documents for submission to health authorities that are scientifically and editorially accurate, a reflection of regulatory strategy and corporate goals, compliant with applicable regulations and guidelines, and clearly worded concerning key messages.

Regulatory documents often feature multiple authors across several subject matter areas. This practice presents challenges to producing writing in one consistent voice. Well-designed documents provide information that the audience can easily understand and interpret. When producing regulatory deliverables, authors, reviewers, and editors should consider the following questions:

- Does the document present one clear, consistent representation or narrative of the data?
- Are the safety information and risks disclosed and discussed adequately? Is adequate information included to support safety conclusions?
- Is all information and terminology consistent?
- Are previous discussions with the health authority addressed and consistent with all prior meeting minutes?

Regulatory writers must always keep their intended readers in mind, particularly in terms of word choice and level of detail.

Teamwork for Success

The team should clarify expectations and roles early in the writing process and ensure team members understand the importance of their editorial and writing tasks. Rapport-building and communication are critical to promoting this understanding. One editorial team member and one content expert team member could be responsible for assessing and presenting key messages and conclusions within documents

Barriers to Effective Communication

Effective regulatory communication must produce clear, accurate exchange of key medical, scientific, and quality messages and explain complex data. Recipients of regulatory documents include health authority reviewers, including the US Food and Drug Administration (FDA), the European Medicines Agency, European notified bodies, physician investigators, study coordinators, Institutional Review Board members, pharmacists, and insurance providers. As readers, these groups have varying needs.

Poor communication can have real and costly consequences. Some examples include the following:[1]

- Health authorities may misunderstand a submission and be unable to complete the review or give the sponsor a timely answer.
- Submission content may not support the key messages or desired label indications.
- Health authorities may question the content, raising more issues than it answers.
- Health authorities may refuse to review dossiers that seem deficient in content or format.
- Reviewers may spend more time searching for relevant sections and information than reviewing them.

Sloppy submissions can create a negative impression of the submission and the organization that wrote it. And once that stage is reached, the reviewer may be more disposed to identify deficiencies because of low expectations for the overall submission. If the regulator loses faith in the organization, deficiencies may be more difficult to resolve because addressing technical issues is not the only action needed to redeem the company in the regulatory reader's opinion.

Text that is too dense or written mainly in the passive voice is challenging to read, comprehend, and assess. Inconsistent information can raise questions that delay or confound a regulatory decision.

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org