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CHOOSING THE RIGHT WRITER FOR YOUR DOCUMENTATION PROJECT

Understanding the differences between writers for optimal results.

Aligning Writer Expertise to Project Objectives is an Important First Step!

Pharmaceutical technical writers are a broad collection of technical people including engineers, biologics, chemists, microbiologists, and even a few liberal arts majors. Nearly all writers share a passion for:

- Accuracy
- Completeness
- Robustness
- Compliance
- Clarity

But what pharmaceutical companies need from their writers differs across projects, products, departments, and maturity. Some companies need document processors to manage redlines and facilitate approvals. Other companies need an expert to identify and address compliance or procedural gaps. Some companies need writers to compile, analyze, and summarize data for reports. And others need authors who can leverage data to tell a story, inform and instruct readers, or present a scientific perspective for a submission.

Matching writer skills to project objectives is an important first step. Why?

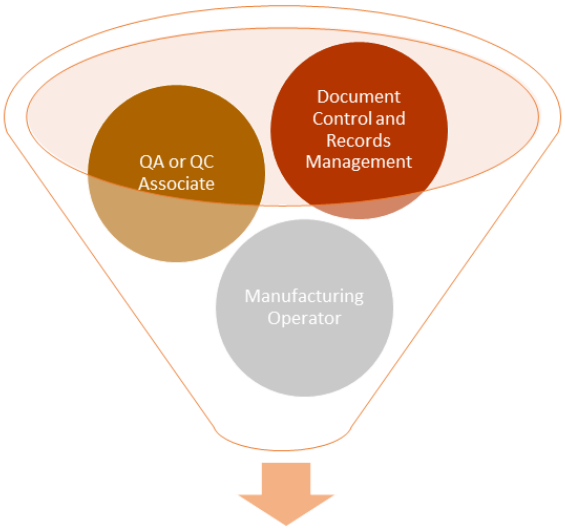
Hiring a document processor for a GMP facility commissioning project could result in poorly written, inaccurate, or incomplete documentation that requires significant rework to achieve GMP production success.

Engaging a quality consultant to develop CMC modules for a license application may result in improperly interpreted or presented data that could lengthen submission time and result in missed milestones.

Hiring a CMC regulatory writer for a large SOP reformatting project may result in excessive word-processing time and higher costs.

What are the required skills needed for your documentation project? How do documentation professionals differ? How can you secure the right writer?

Document Processors



Focus on Document Management:

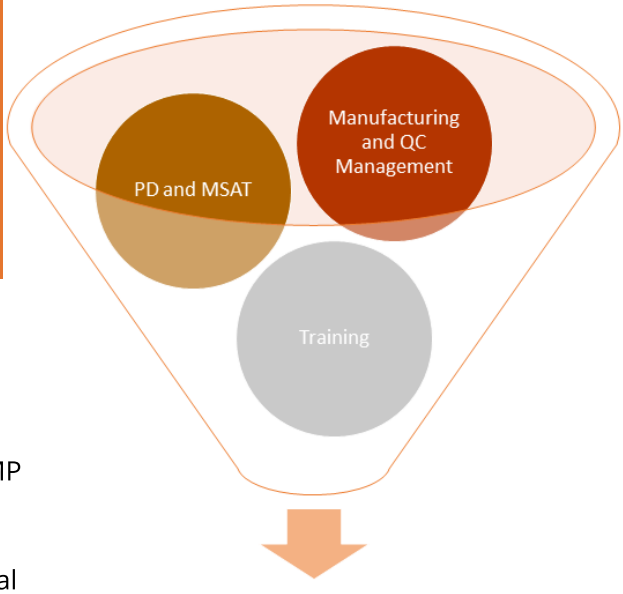
- Formats
- Finite edits, redlines
- Management of document approval
- Tracking document status
- Minimal subject matter expertise or contribution

Who are they and what is their background?

- Strong clerical or administrative skills
- Skilled word-processing capabilities
- Detail-oriented, rule-following, autonomous when trained
- Organized, task-oriented, completes work on time
- Career path may include roles in manufacturing, administration, document control, records management, assay history

Projects for Document Processors	Typical Deliverables and Responsibilities
▸ Formatting projects associated with document control system implementation or migration to new systems ▸ Large volume, minor document formatting projects ▸ Document approval management; review and approval of documents ▸ Document issuance and/or reconciliation projects: logbook, lab notebooks, batch records, test forms, etc. ▸ Records inventory management projects	▸ Document approval or EDMS workflow management ▸ Document formatting ▸ Document control ▸ Records management ▸ Document status tracking and reports ▸ Management of periodic reviews

GMP Technical Writers



Focus on Operations:

- Tailored to manufacturer, product, site, department
- Executability and robustness of written procedures
- Documentation as ecosystem working together in cGMP environment
- cGMP compliance and traceability
- Moderate to significant manufacturing and/or analytical subject matter expertise

Who are they and what is their background?

- Technical subject matter experts in manufacturing, quality control, process, and/or analytical subject matter expertise
- Adept in MS Office Suite and a range of document management systems
- Comfortable developing documents from scratch, such as master batch records, SOPs, test methods, data forms and logs, protocols and reports, work instructions, and more
- Handles large volumes of documents at any given time, layering and managing time effectively
- Advocates and defends content, negotiates conflicting inputs
- Highly interpersonal, excellent communicators
- Career path may include roles in manufacturing or QC laboratory leadership, process or manufacturing technology engineers, training, and quality assurance

Projects for GMP Technical Writers	Typical Deliverables and Responsibilities

▸ New facilities or facility modifications
▸ New product and technical transfer GMP documentation
▸ Batch records improvements and redesign
▸ Development and validation protocols and reports
▸ Significant document impacts such as global CAPAs, critical process improvements, new quality or manufacturing systems implementation
▸ Controlled document development and consensus building
	▸ Spectrum of controlled documents:
	  ▸ SOPs
	  ▸ Master batch records
	  ▸ Data forms and logs
	  ▸ Test methods
	▸ Protocols and summary reports
	▸ Annual product quality reviews
	▸ Work instructions and process flow diagrams

Quality Consultants Who Write

Focus on Quality:

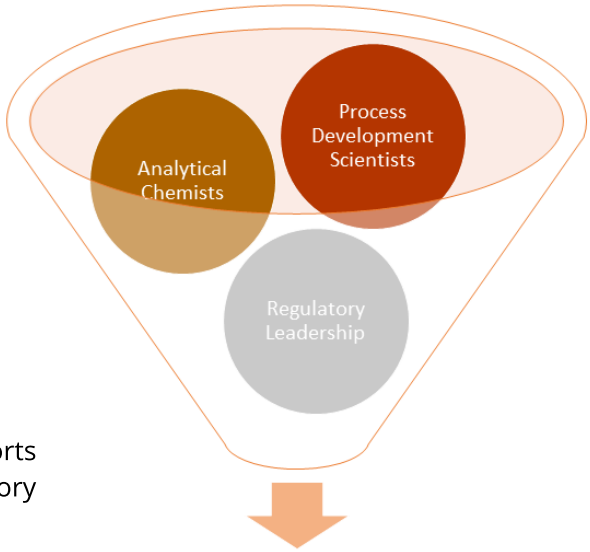
- cGMP compliance and alignment to industry standards
- Alignment with regulations and guidances
- Adherence to internal written procedures and policies
- Audit and remediation of gaps - minimal to significant
- Quality systems focus
- Strong quality subject matter expertise

Who are they and what is their background?

- Quality consultants typically advance from manufacturing, quality control, or development areas
- Technically strong and a good complement to internal subject matter experts
- Adept at reviewing/auditing processes and documents against internal procedures and regulations for compliance
- Able to sift through large volumes of information across different systems to identify gaps and areas for improvement
- Detail-oriented, compliance-minded, able to suggest compliant alternatives and solutions
- Career path may include roles in manufacturing and QC, operations leadership, compliance or inspection management, corporate and product quality assurance

Projects for Quality Consultants Who Write	Typical Deliverables and Responsibilities
▸ Compliance audits and remediations ▸ Regulatory responses and CAPAs ▸ Large volumes of investigations reports, trend reports, validation reports ▸ Next generation maturity to quality systems from early stage development to late stage development or to commercial ▸ Preapproval inspection readiness ▸ Quality Control (QC) review of regulatory submissions and responses	▸ Quality manuals and policies ▸ Audit reports and recommendations ▸ Mock inspections ▸ Quality systems and procedures ▸ Audit responses ▸ Investigations ▸ Compliance and Quality Training

CMC Writers



Focus on Regulatory Submissions:

- Highly customized within submission formats
- Content development traceable to source data and reports
- Compilation of product and analytical development history for product story
- Strategic input to assist to support, defend, justify, or minimize development data anomalies, trends, or other unexpected outcomes
- Communicate thorough and well-planned product development approach
- Specialized, in-depth subject matter expertise

Who are they and what is their background?

- Strong analytical and process development expertise, including design of experiments, data analysis and trending, and validation
- Understanding of product technical life cycle and development requirements
- Comfortable in laboratory and production environments with all levels of staff and executives
- Able to evaluate raw data, reports, trend data, and protocols to develop content and piece together a complete product picture and story
- Adept at identifying issues, proposing potential solutions and risks, and facilitating decisions
- Highly organized; easily navigates technical and operational work product
- Career path may include roles in product and process development, analytical and method development, stability, quality, and regulatory affairs

Projects for CMC Writers	Typical Deliverables and Responsibilities
▸ INDs, BLAs, and NDAs ▸ Complete Response Letter responses ▸ Technical report development and data review/analysis ▸ Peer review of regulatory submissions and responses ▸ Specification setting and justification ▸ Preparation of regulatory agency briefing materials and questions ▸ Filings for different geographies and regulations	▸ CMC modules in CTD Format ▸ Quality control/verification of CMC data to source ▸ Stability protocols and reports ▸ Technical reports: Method and process development, validation, stability ▸ Comparability reports ▸ Specification setting

A Word on Interpersonal Skills

A critical factor for technical writer success is interpersonal skills. Documentation professionals must be able to work with a variety of personalities, skillsets, professions, and education levels to be effective. They need to be flexible in how they meet the company's needs, team structure, and culture.

In our experience, people sometimes have emotional reactions to documents. Bad documents can create frustration and anger. Major document changes can be scary and generate resistance. Elegant documents convey confidence and control. Writers may elicit similar reactions.

Strong interpersonal skills are critical to building partnerships and trust with team members. Bluntness, coarseness, or shutting people down can be distancing. Isolationism or protectionism impedes communication and creates silos. Inability to take feedback or consider new ideas can lead to stonewalling or disengagement.

Therefore, consider your company culture when hiring a writer. Is the company social? Does it value humor? Or is the environment serious or intense? Do people work remotely or are they in a communal office environment? Which behaviors get results and which don't? Writers that have the greatest impact are aligned with your company's expectations and ways of working.

In Summary

When evaluating the documentation professional needed for your project, consider the following:

- Scope and impact of the project
- Subject matter expertise and autonomy required from writer
- Risk of failure and consequence to company
- Company culture and soft skills

What may seem affordable at first could prove pricey over time and, conversely, what may seem expensive at first could prove cost-effective when done well. Because writers differ greatly, evaluate the most critical skills required for your project, and then consider the secondary requirements for added value.