

PQ Forum #10: Technical Writing for Validation



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“PQ Forum” provides a mechanism for validation practitioners to share information about Stage 2 Process Qualification PPQ in the validation lifecycle. Information about supporting activities such as design and development, equipment, and analytical validation will also be shared. The information provided should be helpful and practical so as to enable application in actual work situations. Our objective: Useful information.

Previous PQ topics discussed in this series include the following:

- 1. Is it Validated?, published in Journal of Validation Technology (JVT), V 16, #3, Summer 2010.*
- 2. Validation Equals Confirmation, JVT, V 16, #4, Autumn, 2010.*
- 3. Responsibilities of the Validation Approval Committee, JVT, V 17, #1, Winter 2011.*
- 4. Lifecycle Approach to Process Validation, JVT, V 17, #2, Spring 2011.*
- 5. PQ Documentation – Three Simple Rules, JVT, V 17, # 3, Summer 2011.*
- 6. Original Data Supporting PQ, JVT, V 17, # 4, Autumn 2011.*
- 7. Sampling Pages, JVT, V 18, #1, Winter 2012.*
- 8. Results Pages, JVT V 18, #4, Autumn 2012*
- 9. PQ Initiation – What, Why, How, and What Else? JVT V 20, #4, 2015.*

Comments from readers are needed to help us fulfill our objective for this column. Suggestions for future discussion topics are invited. Readers are also invited to participate and contribute manuscripts for this column – please share your successful practices with others. We need your help to make “PQ Forum” a useful resource. Please contact column coordinators Paul Pluta at paul.pluta@comcast.net or Melissa Carella at melissa.carella@cbinet.com with comments, suggestions, or topics for discussion.

ABSTRACT

The writing of validation documents is often a problem in pharmaceutical and related organizations. This discussion describes accepted general technical writing principles and then applies them to writing for validation. High level objectives for validation documents are discussed. A structured validation document series minimizes redundancy and repetition. A writing sequence is described including preparatory activities

and document outlines. Detailed recommendations such as sentence length and paragraph length are suggested. Recommendations for document authors and validation managers are proposed. The role of the site Validation Approval Committee (VAC) as an internal regulatory auditor is vital. Knowledge of technical writing basics, policies and procedures to provide document formats, ongoing training to associated personnel, and internal VAC review with the perspective of a regulatory auditor are keys to development of high quality PQ validation documents. Validation documents must be excellent documents for the personal credibility of the author, the reputation of the organization, and the success of the site validation function.

INTRODUCTION

The topic of validation documents was the subject of several discussions among validation managers from multiple pharmaceutical and medical device companies at Validation Week in San Diego, CA, USA in October, 2018. The quality of validation documents – specifically the technical writing quality in validation documents -- is a universal problem. Managers described various problems they experienced with validation documents including technical deficiencies in content, inadequate explanations, illogical structure, substandard appearance, and errors in spelling, grammar, and punctuation.

Validation documents are critical documents. These documents are the permanent record of the validation effort, representing the specific validation work and supporting associated systems, procedures, and related performance. Validation records may be consulted during the entire lifetime of the equipment, process, utility, etc. – often over decades of time. Validation documentation is often the first thing to be reviewed in an audit and has been requested in advance to be immediately available for auditor review. Validation professionals must strive for excellence in the preparation of validation documentation.

Validation documents are technical documents and should be written following applicable principles of technical writing. Technical writing is a broad topic with numerous applications. Technical writers develop operating manuals for commercially available machines, equipment, appliances, and so on – literally everything that requires instructions for operation. Technical writers also prepare scientific papers, patents, research grants, and other science and technical documents. These documents are fact-based impersonal documents – the personality or personal style of the writer is not apparent in these documents. The focus of technical writing is the content of the validation topic. Validation documents including validation master plans, validation protocols, results documents, and other validation documents must exhibit technical writing properties and characteristics.

This discussion begins a series on technical writing applied to validation documents. It will build on previous higher level discussions on validation documents and provide more detailed technical writing principles and approaches. Its application should help to improve validation documents and correct the deficiencies expressed by validation and quality managers.

Validation Documents -- Three Simple Rules

PQ Forum (1) has previously addressed general objectives for validation documents. Three simple rules were proposed.

- Clear, complete, concise, and consistent. The respective content of validation documents must be direct and clearly related to the objective of the document. They must completely describe their topic and leave no unanswered questions. They must be concise in explanation – complete with minimum wording. There must be consistency and continuity between validation documents in a specific project and within each document. The content of validation documents – validation initiation, risk analysis, and plan; protocol, and results/report -- must demonstrate knowledge and understanding relevant to their topic objective.
- “Stand-alone” documents written for the reader. Validation documents must be written for the future reader of the document without any supplemental explanation. Writers and management of validation

projects will have likely changed jobs and will not be available to provide explanation for validation document during the extended lifetime of the validation documents. Validation documents will be read by a wide variety of readers over many years; authors must write documents understandable to all future potential readers. Documents that clearly require additional verbal explanation to be understood are not acceptable.

- Short sentences and simple words. Validation documents must be correctly written following conventional rules of language, grammar, and punctuation. Sentences should be short and simple. Too many phrases or and an excessive number of commas in a sentence likely indicates a poorly constructed sentence. Simple words should be used whenever possible. The reader will not be impressed with complex words if the content is not understandable. A recent book by Luntz (2) listed ten recommendations for presentations; his first two recommendations were “Simplicity: Use Small Words” and “Brevity: Use Short Sentences.”

Technical Writing Definition and Characteristics

Blake and Bly (3) have defined and generally characterized all technical writing. “Technical writing is defined by its subject matter: It is writing that deals with topics of a technical nature. By technical we mean anything having to do with specialized areas of science and technology.” Technical writing now includes all areas of physical, natural, and social science such as biology, chemistry, archeology, botany, ecology, and other disciplines. Technical writing is objective and focuses on technical content – its focus is accuracy. Technical writing is impersonal – there is no indication of the author’s feelings or opinions in technical writing. In contrast, non-technical writing is personal, creative, and intended to entertain, advertise, motivate, sell, or other non-technical objectives.

The authors described specific technical writing characteristics as follows:

- Technically accurate. The purpose of the document is technical information for making decisions, operating equipment, or drawing conclusions. It must be accurate.
- Useful. The document is being used for a specific purpose. It must meet objectives.
- Concise. The shorter, the better -- while still meeting objectives. Tell the entire story in the fewest possible words.
- Complete. An incomplete document is not useful. Important content must not be missing.
- Clear. The document must be understandable. Suggestions by the authors to improve clarity include:
 - “Keep writing short and simple”
 - “Avoid jargon”
 - “Present your story in a logical orderly fashion, one step at a time”
 - “Use visuals.”
- Consistent. An inconsistent document in style, punctuation, capitalization, and other details is sloppy and unprofessional.
- Correct spelling, punctuation, and grammar is mandatory.
- Targeted. The document should be written to the technical level of the expected reader.
- Well organized. An organized document is clear and easy to follow. Before you write, plan and prepare a rough outline.
- Interesting. Do not bore your readers.

The above Blake and Bly technical writing definition and listing of characteristics are directly applicable to validation documents.

Technical Writing Approaches

Lindsell-Roberts (4) has provided specific detailed and practical suggestions for technical writing.

- Adequate white space (margins and open space on page) helps the readability of the document. Sentences and paragraphs must be constructed into managing bits of information for the reader.

- Maximum sentence length = 25 words
- Maximum paragraph length = 8 lines
- Double-space between paragraphs.
- Headlines: Titles of sections help readability and categorize information.
- Lists: Use lists when warranted.
 - Use numbered lists to prioritize content
 - Use bulleted lists when list order is not important
- Graphs and charts: Pictures are often preferable to conventional sentences. Line charts, bar charts, pie charts, pareto charts, Gantt charts, and others.
- KISS principle. Keep it short and simple. Use clear and simple wording.
- Simple words. Do not use multiple words when one simple word will do. For example, use “investigated” instead of “conducted an investigation;” use “consider” instead of “give consideration to.”
- Use contractions (I’m, can’t, don’t) for a more conversational style.
- Accentuate the positive and avoid the negative. Deliver a positive message whenever possible. “We expect you’ll be pleased...” rather than “We hope you won’t be disappointed...”
- Use an active voice (“I love you.”) rather than a passive voice (“You are loved.”). “Dr. Salk discovered the polio vaccine” rather than “The polio vaccine was discovered by Dr. Salk.”
- Consistency and clarity. Use consistent wording; do not replace technical terms with synonyms; do not be ambiguous; be precise with terms such as “top,” “bottom,” “left,” or “right.” Use “clockwise” or “counterclockwise” to describe turns.
- List technical terms definitions in a tabular format.
- Humor and jargon. Be cautious with use of humor. Technical jargon may be understandable to experts only.

Lindsell-Roberts also proposes a general approach to the actual sequence of writing technical documents.

1. See” your target so you know where to aim. Know the audience who will read the document.
2. Create structure with bones. Prepare an outline.
3. Add meat to the bones. Add content to your outline.
4. Make the bones visually appealing. Use headings, subheadings, bulleted lists, tables, figures, and charts.
5. Hone the tone. Use as few words as possible, positive tone, and active voice; avoid humor and jargon.
6. Proofread ‘til your eyes pop out.” Proofread to eliminate mistakes.
7. Give the document the litmus test. Get a second opinion on your document.

The above Lindsell-Roberts writing sequence is directly applicable to writing validation documentation.

In brief: Preparation --> Outline --> Write --> Enhance --> Revise --> Proof --> Peer review.

Garner (5) has provided useful information for business writing that is generally consistent with technical writing principles described above. He also described a chronological approach to writing and associated writing skills. A technique described by Flowers (6) in which the writing process is divided into four separate tasks – MACJ – is proposed:

- a) Madman. The madman gathers information and generates ideas
- b) Architect. The architect organizes information by making an outline. Garner recommends jotting down your three main points in complete sentences. This forces a focus on main points in a logical order of presentation.
- c) Carpenter. The carpenter put thoughts into words following the architect’s plan

d) Judge. The judge polishes the writing, fixes language, and corrects grammar and punctuation.

The Garner-Flowers writing sequence of writing is consistent with Lindsell-Roberts and is directly applicable to validation documentation.

Discussion Topics

The above technical writing principles may be directly applied to writing validation documents. Specific topics this first discussion are as follows:

- Recommendations for validation authors. Considerations for validation writers in the actual writing of validation documents are proposed.
- Recommendations for management. Considerations for managers who support validation authors are proposed.
- Validation Approval Committee (VAC) responsibilities. The site VAC has a critical responsibility regarding validation documentation.

RECOMMENDATIONS FOR VALIDATION AUTHORS

Validation and quality managers proposed several suggestions for authors of validation documents to help with the preparation of validation documents. These are categorized as follows:

- Document initiation – Preparing to write
- Prepare outlines – Organizing thoughts
- Document writing – Multiple suggestions for actual writing.
- Peer review – Document review by others.

Document Initiation – Preparing to Write

The first step in writing validation documents is preparatory work “before putting pen to paper.” Validation managers opined that this step is often overlooked – writers simply start writing without giving sufficient thought to the entire validation project content or the individual document content. They simply want to start writing or may be under project time pressure. Validation authors should have a definite approach to preparation of their document that includes activities before actual writing. Writers should assemble site procedures, templates, outlines, or other formats available for validation documents. Reviewing recent approved similar validation documents should also be done before writing. What is the level of detail expected, how are references handled, are defined sections expected, are graphs or other visual displays expected, is there a standard bulleted format expected, and so on. Writing references cited above describe a preparatory phase prior to actual writing. To summarize: Understand expectations and make use of what is already available before starting to write.

Prepare Outlines – Organizing Thoughts

After preparatory work, preparation of appropriate outlines is recommended. Validation managers commented that they rarely see authors preparing outlines before they start writing. Again, human nature is to start writing and create content without much foresight; project timeline goals may also force premature writing. Preparing outlines forces the author to organize thoughts and develop a logical presentation. Outlines are recommended for the overall validation project – what documents are required for the entire project -- and for individual validation documents.

Validation Project Outline. Writers should have an outline of all validation documents (initiation, plan, protocol(s), results, etc.) to be written in support of their validation project. Often organizations have required formats, templates, or document structures available in approved procedures. Figure 1 presents a document outline for all phases in a simple manufacturing process validation project. This outline lists

References		Conclusions
		Validation Final Statement
VAC Approvals	VAC Approvals	VAC Approvals

Figure 1. Document Outline: Validation Initiation, Risk Analysis, Validation Plan, Protocol, and Results

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Individual Document Outlines. Individual document outlines should be prepared providing section details consistent within the general project document structure described above. Figure 2 presents a document outline for a representative results document for a manufacturing process validation. An outline with defined sections facilitates writing of individual sections at different times or by different individuals. For example, it may be most efficient to write short sections apart from the normal written sequence of the document due to time constraints, or laboratory analysts may be asked to write test data sections apart from the normal written sequence. The outline also enables the author to focus on most important sections of the document. Managers commented that in usual beginning-to-end writing practice, the start of the document is thorough and complete, but the end of the document has minimal content as the author tires or has limited time to complete writing. In the Figure 2 example, results discussion and conclusions are the most important

before actual writing will save time in the future revising the document as changes are required. Preparing outlines helps to organize thoughts and present a logical discussion. Writing references cited above describe an outline phase prior to actual writing.

Document Writing

After preparatory work and outline development are completed, actual writing is started. The following recommendations are proposed:

- Three simple rules (listed above)
- Write most important sections first
- Revisions and improvements
- Fewest possible words.

Three Simple Rules. Document authors should follow the three rules listed above for every validation document:

- Clear, complete, concise, and consistent – fundamental document characteristics.
- “Stand-alone” documents written for the reader. Documents must be reasonable in length and explain content as best as possible. There must be no unanswered questions.
- Short sentences and simple words. There is no need to use complex language. Maximum understanding must be the author’s objective.

Write Most Important Sections First. Writing an outline for a validation document enables the author to have a total and complete perspective on the future document. The author can then identify the most important sections of the document, and put most energy and time into writing these sections. Writing the most important sections of the document first is recommended. For example, the results and discussion section of the validation results document should be the first section written. Managers described extensive projects with multiple pages of test data. After prolonged work compiling and formatting data, the results and discussion section comprised one very short paragraph – an insufficient discussion for what is the most important section of the document. The authors spent excessive time compiling data and were not able to adequately discuss results either due to time constraints or the author was simply “burned out” – resulting in a substandard discussion in the document.

Writing Specifics

Specific writing approaches recommended in above references should be followed whenever possible:

- Short sentences: Maximum sentence length = ~25 words
- Paragraph length: Maximum paragraph length = ~8 lines
- Double-space between paragraphs.
- Section headings. Titles of sections help readability and categorize information.
- Lists: Use numbered lists for chronological content
- Lists: Use bulleted lists when list order is not important
- Graphs and charts: Pictures are preferable to conventional sentences. Line charts, bar charts, pie charts, pareto charts, Gantt charts, and others. “A picture is worth 1000 words.”
- Avoid humor and jargon.

Revisions and Improvements. The first draft of a validation document is not likely to be the final document. An author who expects that his initial writing will be an acceptable final document is highly unrealistic. Validation managers complain about the number of amendments, deviations, and changes to approved documents – all on approved documents that are later determined to contain significant errors. The document should be revised, enhanced, and otherwise improved during a multiple revision phase. Sections, lists, graphics, may be added to enhance the readability and understanding of the document. These revisions and improvements must be made before submitting the document to the VAC for final approval.

Use Fewest Possible Words. One final revision of the document is recommended after the document is considered to be final. This final revision should comprise an attempt to minimize the number of words in the document. Content should be clear, complete, concise, and consistent, but stated in the fewest possible words. Long and complex sentences should be shortened and simplified. When you think your document is perfect, read one more time with the objective of using the fewest possible words.

Peer Review

Asking a respected colleague to review the document after it is finalized is very useful. This should be done before submitting the document for review and approval by the site VAC. Sometimes VAC members with appropriate technical expertise may be good preliminary reviewers of documents apart from their official VAC responsibility. A second person reviewing your document is always useful either to correct problems, enhance or better explain certain topics, or confirm the approach and content of the document – “different eyes” provide a different perspective. Ideally the peer reviewer should review the document as if they were a regulatory auditor. The peer reviewer must be mindful of the above three basic rules for validation documents. After peer review corrections and enhancements, the document should be ready for submission to the VAC.

RECOMMENDATIONS FOR MANAGEMENT

Improvements in validation documentation will not occur without proactive support from validation, quality, and site management. Validation managers can provide valuable assistance to authors of validation documents. Their activities will positively impact the quality of validation documents submitted to the VAC for review and approval. Discussion topics:

- Document policies and procedures
- Training
- Peer reviewers

Document Policies and Procedures

Validation managers should provide policies and procedures that standardize validation document structures. These may include templates such as for the validation initiation document, outlines as described in Figure 1, or model documents with acceptable structure, content, and presentation that have been previously approved by the site VAC. One manager described activities in which several previously approved documents were reformatted according to a new structure; this approach provided a visible example of the desired structure, format, and technical writing characteristics. After several revisions over several months, the new format was approved by the VAC and became expected practice. The reformatted documents provided a starting point for authors of new validation documents. All associated personnel must be trained on these procedures to institutionalize their routine use.

Training

Managers should provide ongoing training to personnel associated with the validation effort and who directly contribute to validation documents. These include personnel who execute protocols, document authors, testing personnel, and the VAC. Suggested training modules should include basic validation,

writing validation documents including document structures, technical writing skills, good documentation practices, and VAC responsibilities. Periodic retraining is recommended to evaluate revisions as well as reinforce approaches. The most important outcome of these trainings is the development of a quality culture in which quality documentation is recognized as vital to the organization.

Peer Reviewers

Managers should encourage peer review of validation documents before official submission to the site VAC for final approval. Peer reviewers should be assigned for new personnel or to personnel who will likely require help in writing their documents. Some organizations utilize a writing team including an individual with technical writing expertise for specific projects.

VALIDATION APPROVAL COMMITTEE (VAC) RESPONSIBILITIES

PQ Forum has previously (7) identified specific responsibilities of the Validation Approval Committee regarding validation documentation. In brief, these include three primary responsibilities regarding validation documents as follows:

- **Technical / Scientific Justification.** The VAC must insure that the validation / qualification and all associated activities are conducted with consideration for scientific and technical principles, a generally consistent approach based on risk to patient, product, and process, and reference documentation as needed to support technical excellence.
- **Compliance With Regulations.** The VAC must insure that the validation / qualification is compliant with relevant policies, regulatory standards, local regulations, and industry expectations.
- **Document Quality.** The VAC must ensure that validation documentation must demonstrate the technical and compliance aspects of the validation in a logical and grammatically correct manner.

In addition to the above, VAC members should also serve as internal consultants on validation projects, and help site staff who are performing validation projects to prepare acceptable documents – documents that the VAC will ultimately review and approve. Finally – a key responsibility -- the VAC must function as an internal regulatory agency and review documents through the eyes of a regulatory auditor. Members of the VAC must have the wisdom, knowledge, experience, foresight, maturity, and training to fulfill responsibilities of the VAC position. VAC membership is not appropriate for new or inexperienced personnel. If a regulatory auditor finds deficiencies in a validation document, VAC members have not done their job.

The VAC must have a basic understanding of technical writing principles to ensure document quality in validation documents. Fundamental principles as described above – Clear, complete, concise, and consistent; “stand-alone,” and correct grammar and punctuation – are obvious requirements. The VAC represents the final reading and approval of validation documents before eventual reading by regulatory auditors – a critical responsibility that must be embraced by all VAC members for organizational success.

SUMMARY

This overview has initiated a discussion of technical writing principles applied to preparation of validation documents. The referenced technical and business writing publications provide common characteristics and approaches to technical writing. Discussions with validation and quality managers indicate these fundamental considerations are often overlooked by validation authors. Key points discussed:

- Authors should approach writing with a defined approach. In brief:

Prepare ? Outline ? Write ? Enhance ? Revise ? Proofread.

- Technical writing principles should be utilized in writing: Simple words, short sentences, short paragraphs, section titles, bullets, graphs and charts.

- Management must support authors with procedures explaining expectations, templates, and model documents. A standard document format is helpful to validation authors. Example acceptable documents are also helpful.
- Training should emphasize document expectations and develop a culture whereby quality validation documentation is a site expectation
- VAC should maintain above standards and approaches and review documents as a regulatory auditor.

Validation documents are critical documents. They are the sole lasting documented record of a technical project at a manufacturing site. They are of major importance in regulatory audits. Validation documents represent the author and the organization. A substandard validation document tells the reader (auditor) that the organization does not value the work of validation. Validation documents must be excellent documents for the personal credibility of the author, the reputation of the organization, and the success of the site validation function.

FUTURE PQ FORUM TECHNICAL WRITING DISCUSSIONS

Future discussions on topics related to technical writing are planned. Writing approach, punctuation errors, grammar, and related topics relevant to validation documentation will be discussed. Comments, suggestions, and other input from readers are most welcome.

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