



## Regulatory Documents Explained: The Basics

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In this article, we set out to define the basic types of regulatory documents related to matters of quality assurance and computer system validation and attempt to characterize their anatomy, structure, organization, and content, so they may be better understood by those who use them. Hopefully, once we have a better understanding of our documents and the purpose they serve, we will find them more useful and easier to create, review, modify, and maintain.

### ARTICLE EXCERPT BEGINS

#### Background

“...Experience shows that far too many industry professionals are confused about Food and Drug Administration (FDA) required documents. This is apparent from the blank stares on people’s faces when they are asked to write a specification, update a procedure, or execute a protocol. Another sure sign of lack of understanding can be observed when a document includes the word *Plan* or *Policy* in the title, and the document is clearly a Procedure; or when a system requirement states: The system should perform operations correctly. Perhaps no one has explained the differences (and similarities) between document types or what information the document is supposed to contain. If so, this is a training issue.

Another situation that we encounter when dealing with regulatory documents is push-back from colleagues and management. It is true that projects often spend too many resources on producing and maintaining documentation, and it is understandable that some people see the effort required to produce documentation as a waste of time. Our processes are not always as efficient as they could be, and clearly some streamlining is in order. However, the claim that developing quality documents and validating regulated computer systems interferes with operational objectives shows a lack of appreciation regarding the fundamental purpose that these documents serve.

Industry professionals commonly ask why FDA regulations require so much documentation. The truth is, regulations do not specify documents based on quantity, but rather quality. The FDA has repeatedly stated that they are not looking at the thickness of documents, but rather their content. Again, the root cause for the indifference industry professionals exhibit toward regulatory documents can be traced to a general lack of understanding regarding the true purpose of documentation.

As an industry, we need to do a better job of explaining why certain documents are needed and their purpose. Only then can we begin to convince the naysayers, the push-backs, and the confused of the value that regulatory documents provide. With some guidance and direction, it is our belief that industry professionals will find that what is being requested is not only appropriate, but well-justified. Please see *Figure 1* on page 82...”

### ARTICLE EXCERPT ENDS



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