Regulatory Requirements White Paper

Is your Software Project Meeting its Regulatory Requirements?

Is your software project meeting its regulatory requirements? Does your software development life cycle employ industry best practices? Will your design history file contents be correct and of the quality needed for FDA submission? How do you know?

Assessments are powerful business tools that can identify the current state of what is being assessed and identify opportunities for improvement. Assessments can be performed on many aspects of a software project, ranging from measuring a project's success to evaluating the quality of a specific project deliverable. One technique for performing an assessment is a gap analysis.

A gap analysis is used to determine steps that need to be taken to move from the current state to a desired, future state. Gap analysis consists of identifying characteristics of the current state ("where you are"), identifying factors needed to achieve the desired, future state ("where you want to be"), and then highlighting the gaps that exist and need to be filled. The deltas between "where you are" and "where you want to be" are the gaps, also considered deficiencies.

A common approach that is especially suited for assessing compliance to FDA's Quality System Regulations and international standards like IEC 62304 utilizes a checklist. The checklist starts with a column representing the desired, future state. This column contains the requirements of the regulations or standards, the "shall" statements. The next column is used to capture information about the current state. When capturing the current state, quality management system (QMS) procedures, work instructions, forms, and resulting project documentation should be considered, as well as information obtained via meetings and discussions with subject matter experts.

Once data representing the two states is captured, the gaps are identified. A rating system of red, yellow, and green can be used. Green indicates no gap; yellow indicates that the requirement is partially met; and red indicates that the requirement is not met at all. The yellow rating or “partial gap” is used for example, in cases where common practice meets the requirement, but QMS procedures do not accurately document that the activity is required. Having two levels for not meeting requirements can facilitate the prioritization of the gap filling work; for example, red gaps may be worked on first, followed by the yellow gaps.

Next, stake holders gather to discuss and evaluate options to address the gaps. Industry best practices should be considered, as well as the risks associated with each option. Assign estimated work effort, further refine priorities, find resources, and start implementing the improvements.

A primary benefit of performing a gap analysis is that when deficiencies are brought to light, it is easier to identify, quantify, and prioritize the work needed to fill the gaps. However, real success come as the identified gaps are filled, especially for gaps identified during regulations and standards gap analyses. When procedures are not robust or compliant to regulations and standards, it is difficult and time consuming to correct the deliverables those procedures produce. Using procedures that ensure that the correct activities occur and the correct information is captured saves times in the end and produces higher quality deliverables.

The RND Group has worked with the leading companies in the medical device industry since 1997. The RND Group fully understands the rigor required in designing, developing, documenting, and testing products that are regulated by the FDA. The RND Group has applied that rigor to the software engineering support it has provided for countless product development efforts, and The RND Group can point with pride to products that have been successfully introduced into the medical device marketplace.