



LIMS Validation Projects: Critical Considerations for Successful Execution

by Gina Guido-Redden

This article will present a lean approach to planning a successful Laboratory Information Management System (LIMS) validation project. It will utilize a Six Sigma project management approach, focusing on the following project milestones; defining the project, gathering specifications, defining requirements, establishing the validation approach and plan, constructing quality procedures and protocols, training execution personnel and organizing the execution plan.

ARTICLE EXCERPT BEGINS

“...The process of defining user requirements in a usable way must always begin with direct communication with the intended user group, and an indepth evaluation of the processes that will be automated. This author recommends organizing formal user group meetings that encourage discussion, and deepen the understanding of the potential technologies and the users’ routine processes. The information obtained will produce a User Requirements Specification [URS] document that is easily traceable through development. The following is a high-level procedure for organizing, managing and controlling these communication meetings;

1. Conduct these discussions in a group environment, allowing the discussion to promote the differences between processes, which are often more critical to the definition of user requirements than are the similarities.
2. Recognize that the means of data generation, manner of storing, reporting and grouping data, and metrics that may be calculated using the data, will vary widely by user group/data type (e.g., release, in-process, environmental monitoring, process validation, lot management/release and equipment calibration/maintenance).
3. Recognize that in order to understand all of the implications of the discussions, IT, LIMS users and the recipients of LIMS reports must participate in the discussions.
4. Prepare and circulate a questionnaire designed to identify major areas of potential system use; circulate it to users prior to the meeting in adequate time to receive and collate responses.
5. Structure the roles of the LIMS project team prior to initiating the meeting. Elect a leader, scribe, process checker, and provide daily meeting agendas based on the responses submitted prior to the meeting.
6. Announce the LIMS team roles to the attendees and ensure that the team leads group discussions, which focuses the subject matter. Users will often express themselves with examples, and maintaining focus will enable the LIMS team to extract the need from the example. This exercise will grow in productivity over the course of the meeting, as few examples represent unique needs, the users will begin to recognize redundancy.
7. While extracting needs, refocus the group by drawing attention to the fact that requirements should be able to follow the words “Require the ability to...” Employing this communication technique will aid the LIMS team and the users in identifying redundant statements.



Acquiring and Evaluating Vendor Responses to User Requirements.

Once the user requirements have been identified and represented formally within a specification document, circulate the approved specification to potential vendors, and require the submission of a formal response (brief abstract of mechanisms for meeting user requirements). Reviewing responses in a comparative manner will aid dramatically in the comparison between, and the selection of, vendor/product by immediately demonstrating the following:

- Attentiveness and thoroughness of vendors
- Ability of the vendor to comprehend requirements (clear indication of familiarity with your business practices)
- General abilities/limitations of the software..."

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