

Secrets to a Successful Validation Project

by **Rey Hernandez and Judith Echevarria**

Three major elements comprise validation projects in the biopharmaceutical industry: cost, schedule, and quality. If you can work within a budget, complete activities on time, and maintain regulatory-compliant documentation, then you significantly increase your chances for a successful validation project. Here we suggest ways you can improve these essential measurements with the help of a third-party validation team to achieve favorable outcomes.

TEAM SELECTION

The first key is building a validation team. Cohesion is critical for successful project management. All members must pull in the same direction and fully understand their colleagues' concerns and responsibilities for a project to run smoothly.

The size of a validation group will depend on project scope. This can be determined by developing a preliminary project schedule and carefully evaluating the times at which activity levels will peak during the course of it. The scope of a project can also influence selection criteria used in determining and selecting the number of supervisors that report to a validation manager.

The manager's first step is preestablishing selection criteria. This largely depends on the project type and associated budget, which helps a



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validation manager decide what skills and relevant experience are most applicable or necessary. Once the pool of potential team members is narrowed down, managers should choose people who are compatible both with one another and with the project. Their goals, objectives, and working styles should align to create an efficient workflow process.

Those teammates also should be dedicated and steady throughout the validation project. A team can't have one person working on two different projects, which creates conflicts of interest around job priorities. This

approach maintains continuous working styles and helps keep a project on schedule. In addition, a highly functioning team understands each member's roles and expectations. As such, it works to prevent gaps and/or overlaps in responsibilities so that no critical project element will be overlooked or duplicated. One way to accomplish this goal is to create a matrix of defined tasks (e.g., standard operating procedures, protocols, and foundation plans). The validation team then goes through each deliverable and double-checks it against that matrix to quickly identify any gaps or overlaps.

UNDERSTAND YOUR PROJECT

The next key is understanding your project. Meet with all participating teams, lay out the project's purpose, and establish a timeframe. You should also define what your project needs are, what work will be contracted out, what will be accomplished internally, and what kind of support is available.

If you decide to outsource your validation project, it's imperative to fully involve the validation team in this project's lifecycle. Integrate its members from the outset, especially in the production of user requirement specification (URS), functional requirement specification (FRS), software development specification (SDS), traceability matrix (TM), and other critical documents that support protocol development for each activity. It's also important to outline the schedule, deadlines, and expected timeframes for the validation team to execute qualification. The team should in turn provide other groups with input, concerns, and needs for the project.

Communication is essential. Set a standard for transmitting all decisions and data to the entire team so that relevant information reaches the right people at the right times. Design reviews are one example of providing input. Including the validation team in such reviews establishes validation-specific requirements and methodologies up front. And it helps the design team account for those details in their project planning.

The last step is building a project plan, also known as a validation master plan (VMP). Strong plans are clear, concise, and comprehensible. Anyone coming in cold should be able to quickly grasp all project details by looking at the VMP.

VALIDATION PROJECT PHASES

Initiation: If you decide to contract your project out to a validation service company, invest well in your proposal evaluation and selection process. The latest trend is toward sponsor companies giving contract organizations only one week to submit their proposals, then taking one week to select among them. But that's the

opposite of what should be occurring. One week is not enough time to let a company define, understand, and clarify the scope of a project. Instead, it forces submitting companies to operate on assumptions, which will affect change orders later. And this approach gives the sponsor company only a week to evaluate proposals — certainly not enough time to make a qualified, thoughtful decision. This increases the risk that you'll pick the wrong company, need to repeat the process, and ultimately delay your validation project.

We recommend taking up to a month to complete selection. Tackle the proposal process in stages. For example, map out your document handling process and rules from the start. Ask for a proposal in two weeks. Then review your plan with all applicants to address any questions they might have. After that, evaluate the quality and experience of the proposed team. Finally you can ask for a final price, secure in the knowledge that the costs were not generated from assumptions but rather from specific facts about your project.

Once your team is selected and gathered, initiate team-building exercises to gauge the team's "temperature." It can ultimately help you determine when conflict is rising or communication is waning. Use this insight throughout your validation process to catch problems early and keep the team on track.

Planning is the second project phase. Create a master plan with your validation team, and adhere to it as closely as possible. Frequent changes can signal disorganization, so evaluate each change as it comes up, and proceed only with those that are imperative. Establishing a realistic schedule from the start will help you stick to your timeline. If you must comply with a specific milestone then go back, be creative, and come up with different ways to manage the project without disrupting a realistic schedule.

In addition, make certain your schedule follows a logical order of events. This leads to scientifically based risk management. Use good

judgment by taking schedule or cost risks — rather than quality risks — wherever possible. For example, if one team hasn't finished qualification of a clean steam system, someone decides not to begin the next step (SIP runs) until that qualification is 100% done. The riskier choice would be to conduct a one-week sampling and then immediately start SIPs. Even if this risk fails, it will affect only schedule and costs. The worst that could happen is repeating those SIP runs, increasing cost and interrupting schedules. Through it all, however, quality remains uncompromised.

Setting expectations is equally important at this stage. Include support teams in all communications. Get everyone to approve the schedule. Tell all team members exactly what is needed, by when, and at what values. This keeps everyone fully involved and engaged, and it also fosters teamwork. One tip is to establish monthly acceleration sessions, depending on schedule duration. They prompt members to compress or accelerate the schedule however they can to save time and money. Further motivate your team to cut time frames by offering incentives (such as extra vacation days) whenever possible.

Finally, establish period milestones throughout the validation project, and measure your team against them consistently. Break this down by different portions in the schedule, and evaluate progress and compliance at each marker.

Implementation: Once a validation project is mapped out, you can tackle its implementation. Here the key is to manage the project without letting it



manage you. Predict the results of your decisions instead of reacting to them. Regularly examining metrics and periodic reports will help you forecast. And monitor yourself continuously against the schedule. Prevent slippage as much as possible because a day here or there can significantly affect a schedule by month's end. It's easier to fix a one-day or two-day slippage than a four-month slippage on a schedule.

Establish a simple and trustworthy corrective action, preventive action (CAPA) program as well. In the event of deviations, the team should understand exactly how to quickly, efficiently, and safely resolve and prevent future occurrences.

As with risk management during the planning phase, take a scientific approach to your schedule rather than relying on old project habits. Review documents using a meaningful process and with rationale that truly supports what you're pursuing in validation.

Overall, be careful not to overwork or pressurize your staff. Otherwise, you risk sacrificing quality. To maintain strong output, provide your validation team with extra support whenever necessary. Also, replace dysfunctional employees as quickly as possible to prevent strain on dependable team members.

Close-Out: When implementation is complete, you've reached a validation project's close-out stage. End your project with a "lessons learned" activity, which can help team members reflect on their work and glean insight from their experiences. This activity *must* occur. It's imperative to share takeaways and recommendations with the rest of your company. It will help everyone better prepare for the next validation project.

Performance reviews are also critical at this stage. Conduct them immediately, while a project is still fresh in your mind. Sit down with each associated staff member for a one-on-one interview. Evaluate what each person did right or wrong at each step, and identify what needs to improve for the next project. Finally, reward those who deserve to be rewarded. This will provide incentive for your top performers to work even harder on the

next project while increasing their loyalty to your projects.

Following these recommendations — particularly in partnership with an experienced validation provider — can help you reap significant rewards: namely a successful validation that qualifies your systems, maintains regulatory compliance, and ensures quality for your business now and in the future. 🌐

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