Independent, third-party blood bank validations

BC Solutions explains why third-party blood bank validations might be right for your laboratory in this Q&A.

Congratulations! Your lab is finally installing or upgrading your new blood establishment computer system (BECS). Your team spent months determining the best plan for installation, and you have painstakingly configured the system and data tables to account for all your facility's unique workflows and processes. But how can you be confident that the system is capable of consistently operating within established limits and tolerances? Validation. There is no question that it must be done. The question is: Who should be tasked with doing the job?

You could assign your own staff to this task, but this is often impractical since they already have full workloads and their productivity is key to patient safety and your lab's success. The BECS software vendor might do it, but some perceive that scenario as the fox watching the henhouse. Your best option is clear: An independent, third-party validation.

Q: Can I trust the quality of the work done by a third party?

A: Higher quality is often achieved by using external resources who bring not just more validation knowledge, but more specialized processes as well. In addition, having an outside opinion on workflows and SOPs can provide a fresh perspective on ideas for efficiency and quality. An experienced vendor will have the expertise necessary to provide you with the quality your validation deserves. Look for a vendor that employs trained, licensed medical technologists with practical blood bank experience and knowledge of the legal, regulatory, and compliance standards.

Q: Are auditors and assessors satisfied with third-party validations?

A: Absolutely. Third-party validations are superior to in-house validations because vendors can work objectively, without bias or predisposition, while keeping the focus on patient safety. A reputable validation vendor like BC Solutions will also guarantee their work and provide post-validation support in the case of an inquiry or audit. The vendor shares the risk in such an instance, which helps ensure they will provide a comprehensive, well documented validation. Hiring an experienced validation vendor will put you, and any potential auditors, at ease.

Q: Our facility is limited by both time and budget constraints. How will using a third-party help me?

A: Outsourcing your validation allows your lab to concentrate on your core business. When organizations go outside their expertise, they can be drawn into unfamiliar functions and processes and could potentially take away from their main focus – patient safety. Many facilities are unaware of the intensity and extent of the validation process. In addition, they usually do not have the resources to perform the validation, either due to limited staffing or tight project timelines. And although a software installation is technically an IT project, it's unlikely the IT staff can assist with the validation. This is meticulous work that requires laboratory personnel who are familiar with the workflow and regulatory requirements. Regarding cost, there can be significant savings when a business function is outsourced. Employee compensation costs, office space expenses, and other costs associated with providing a workspace are eliminated and free up resources for other purposes. A qualified third-party vendor can give you the time, the experience, and the cost control your facility needs.

Q: If I choose to use a third party to validate my software, will my staff still need to be involved?

A: Yes, to varying degrees, depending on the vendor. For example, vendors require access to system configurations and some initial Q&A in order to understand the client's system parameters, background info, and workflows. There is also the review of the validation documentation. By regulation, the validation of the system software is ultimately the client's responsibility, regardless of whether a third-party was used. The client must be familiar with the validation in order to answer any inquiries.