astrix

TECHNOLOGY GROUP

Optimizing Laboratory Software Vendor Selection with Strategic Planning

The digital revolution is rapidly changing the landscape for scientific organizations by making readily accessible information and data ubiquitous. In order to capitalize on this abundance of data, industry-leading enterprises are investing heavily in laboratory informatics technologies (e.g., LIMS, ELN, SDMS, CDS, Advanced Analytics, reporting tools, etc.) enabling accelerated product development, improved quality and compliance, enhanced customer safety, and reduced cost.

Unfortunately, IT project are notorious for failure. While the root causes of failed IT projects are diverse, a lack of a comprehensive and proven vendor selection methodology is a common source of failed implementations. With many different informatics vendors now available to choose from, an increase in vendor specialization in terms of targeted laboratories and/or industries, and increasing demands for cloud-based applications, selecting the best system for your organization has become more difficult than ever. In fact, there really is no such thing as "the best system." The focus instead should be on selecting the system that is best fit for your *unique* laboratory and organization.
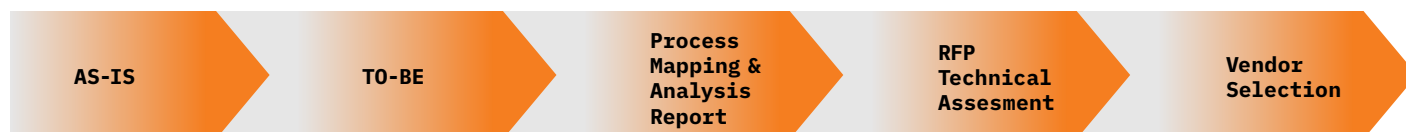
In this white paper, we will outline a comprehensive vendor selection methodology that, when applied properly, will serve to ensure that you select the technology that will provide the most business value for your organization.

Business Process Analysis

In a recent survey, over 50% of IT professionals revealed they had a project fail over the last year. Laboratory informatics projects can be especially challenging, considering the many different aspects of the enterprise that laboratory operations touch. Given this high failure rate, it is imperative to adopt a proven methodology providing a solid project foundation and ensures success in selecting the best system for your enterprise.

One of the most common mistakes companies make during informatics projects is to not conduct Business Process Analysis (BPA). Many organizations try to select and implement a system without first performing the due diligence necessary to align laboratory functional needs with the strategic needs of the business – an error that is magnified if more than one site is involved. Towards this end, the first step in any laboratory informatics project should always be a thorough workflow and business analysis.

The BPA process can be broken into five distinct phases, each of which will be described in detail below.

| AS-IS | TO-BE | Process Mapping & Analysis Report | RFP Technical Assesment | Vendor Selection |

AS-IS Process

Onsite Interviews	Render AS-IS Visios	Review AS-IS	Update AS-IS

The first step in BPA is to perform a current state (AS-IS) assessment of work processes. The intention is to accurately capture the current state environment – warts and all. When completed, these AS-IS workflow maps should fully document the current state of laboratory operations, including sample and data flow, work assignment, reporting and review.

The AS-IS assessment begins by determining the relevant teams that need to be interviewed and developing an interview schedule. Initially, the management team is interviewed to understand the goals, aspirations and objectives of the desired future state. The BPA team then conducts interviews with representative end users in each identified functional area with a focus on understanding and documenting the AS-IS workflows. As such, it is important to interview the people who actually do the work, although team supervisors can often provide valuable information as far as data review and approval as well.

During the interviews, the BPA team will determine how each team fits in the overall landscape of the company, as well as the granular details of their workflow(s).

One common mistake that companies make when trying to conduct their own BPA is to capture the AS-IS process at too high a level (figure 1), such that identifying process improvements and/or delineating meaningful system requirements is virtually impossible.

Samples Arrive	Samples Tested	Results Generated	Results Reviewed	Samples Released	End

Figure 1: AS-IS process flows captured at too high a level

A high level of granularity is required for the AS-IS workflow diagrams in order to utilize this information effectively in the next step of the BPA process. AS-IS workflow diagrams that are documented at the wrong level lead to system requirements that are too high-level to effectively identify meaningful differentiation of systems in the vendor selection process.

TO-BE Process

Develop TO-BE	Customer Review	Review Workshop	Update TO-BE

Once systems and workflows have been documented in the AS-IS stage, business analysts develop a strategic plan to align business processes, business goals, and technology to ensure that the laboratory informatics system selected and implemented will maximize business value. In this stage, analysts create a model of the future state (TO-BE) workflows based on their experience and the company's strategic needs as expressed by the management team. There should be a clear business rational behind every step of the TO-BE business processes.

Many customers implementing informatics systems end up simply implementing their current state workflows, or even modifying their current workflows to fit the technology. This is obviously not ideal – why not take the opportunity to optimize workflows and select the vendor based on those optimized workflows? "Electrifying" a poor work process, after all, simply yields a faster-moving poor process. Organizations get the most out of any system solution when business processes are optimized and then mapped in the informatics system solution.

Of course, vendors often believe they have developed the "ideal" one-size-fits-all workflow in their product, and customers should yield to the wisdom of their product design. Some vendors go so far as to offer "pre-configured" systems. Such an approach may gain favor with the Purchasing Department who may interpret pre-configured systems as less expensive because they might reduce consulting hours. In reality, system workflow that is forced upon the user community often results in missed targets, unwieldy functionality with unnecessary encumbrances, and passive-resistance from those who are saddled with a poorly-fit system.

The truth of the matter is that complex systems require user ramp-up time. Problems with informatics deployments, may not manifest for up to 6 months after the system goes live. At that juncture, system configuration changes take on a disruptive tone, businesses suffer, and users are frustrated. So, the attraction of an "Off-the-Shelf" system gives ways to possibly expensive retrofitting, and any imagined savings earlier in the project continuum vanish.

Instead, the future-state TO-BE workflows should be designed to fulfill agreed-upon business needs. Well-designed TO-BE workflows will seek to exploit available technologies while eliminating/minimizing wait states, redundancies, and other identified inefficiencies to maximize productivity in the laboratory.

Depending on the complexity of your environment, a single workflow may range from a dozen to hundreds of steps. Complex environments and/or highly regulated industries can require several dozen TO-BE models, broken down by functional area. Examples of functional areas include:

- Raw Materials Receipt & Release
- Manufacturing Lot Creation & Release
- Environmental Monitoring
- Shelf Life / Stability Studies
- Equipment Management

- Work Assignment
- Microbiology Testing
- Analytical Testing
- Peer Review
- Analyst Qualification

In addition to the areas discussed in the interviews, TO-BE models may also include related support processes that can be addressed through laboratory automation or by interfacing with other client-owned systems. This may include functions such as analyst qualification or instrument certification, both vitally important in regulated environments. When multiple sites are involved, the TO-BE models represent a harmonized environment across all sites, with minimal to no site variation.

Once completed, the TO-BE models should undergo a thorough review process with the user community, as agreement and consensus on TO-BE models are important for user buy-in and adoption. Once the TO-BE state has been finalized, what remains is a firm, fundamental system design that works for the company—not the vendor.

Finally, a detailed Requirements Matrix with prioritized opportunities is developed directly from the TO-BE workflow. The final result of the TO-BE process is a set of optimized future state requirements that will be used to guide laboratory IT architecture, technology/vendor selection, project planning task prioritization, and system development and deployment. Note that, utilizing this approach, system requirements become *vendor* requirements and have been constrained to business improvements, not bells and whistles vendors love to present during demos that may have no practical utility.

It is important to note that the business analyst(s) (BA) conducting the TO-BE process should ideally have a scientific background, extensive industry knowledge, an understanding of laboratory environments, IT knowledge, as well as expertise in the candidate informatics systems being evaluated. These qualifications will allow the BPA team to gain a thorough understanding of what might be possible for your unique laboratory environment when designing the TO-BE process maps. A third-party consultant can add significant value during this stage due to their exposure to hundreds of customer project initiatives and expertise with many different systems. Although it may seem counterintuitive at first, investment in a thorough BPA process typically saves project budget in the long run, and increases the prospect of user acceptance.

Once the TO-BE state has been finalized, what remains is a firm, fundamental system design that works for the company—not the vendor.

Similar to customer internally developed AS-IS models, TO-BE workflows also developed internally, in many cases lack the depth and detail required to effectively differentiate one informatics solution from another, or may be focused on functionality bringing no measurable business benefit to the company. It is common for companies developing future state models to use their current systems as a template because it is a comfortable frame of reference, but doing so forgoes any chance at exploiting the broad functionality available in today's modern systems.

Process Mapping and Analysis Report

Develop Report → Presentation →

Clear and frequent communication between stakeholders is critical to the success of any laboratory informatics technology selection and/or implementation project. Good communication helps convey critical information necessary to keep the project on track, and also engages all stakeholders so they feel part of the process. Disenfranchised users are a common cause for lack of system adoption, and a phenomenon sometimes referred to as "Black Market Workflow". This occurs when users revert to their pet systems, secret Excel spreadsheets, and other under-the-radar tools they feel allow them to work more effectively.

With this concept in mind, after the AS-IS and TO-BE process maps are complete, the BPA team should develop a Process Mapping and Analysis Report summarizing the observations and findings from the AS-IS process analysis and the process improvements gained from the TO-BE models. The report should address the following topics:

- **Statement of the client's objectives**
- **Description of the methodology**
- **Summary of current state findings**
- **Description of the future state**
- **Opportunities for business process improvement**
- **Recommendations for achieving the TO-BE environment**

This report should be submitted to the client for review and, after a sufficient period of time, followed up with a meeting between the BPA team and your organization to review the report and address any questions or concerns.

RFP Technical Assessment

| Develop RFP Technical Assessment | → | Customer Review | → | Send To Candidate Vendors | → | Vendors Respond | → |

Utilizing the finalized TO-BE models and information gathered during the interviews and discussions to date, the BPA team next works to develop a Technical Assessment for the Request for Proposal (RFP) document, along with the list of vendors who will receive the RFP. The Technical Assessment document is drawn from the TO-BE models and addresses the technical requirements for the system being selected. The nontechnical part of the RFP (e.g., vendor background, sales contact, project schedules, terms and conditions, etc.) can typically be prepared by the organization seeking to purchase the laboratory technology.

The technical assessment is divided into a series of functional areas (see above list) based on the client environment. Each of these functional areas is then subdivided into smaller units of functionality for which a series of questions is asked to determine if the candidate system can meet your organization's requirements. For each of these functional "snippets," the vendor is asked to rate their product in terms of its ability to meet requirements through configuration, customization, integration with a third-party product, or lack of ability. Vendors are also encouraged to provide a written response to each snippet.

It is never enough for a vendor to say they can meet the requirements; they must explain how they intend to meet the requirements. A significant point of friction exists in the disagreement between vendors and consultants/customers as to what constitutes "configuration" as opposed to "customization". It is commonplace for customers to state boldly to the candidate vendors that they do not want a "customized system". Of course, vendors rarely classify any action to deliver functionality as customization. There are two reasons for this. First, all vendors know their competitors are promising to deliver all requirements without a hint of customization. Second, customers never provide a definition of customization, so all vendors are free to strike the word from all responses. The BPA Team should provide strict definitions of what constitutes "customization" when preparing RFP documents. Such definitions may include terms such as "Any statements requiring IF-THEN logic is customization." A general rule of thumb is that simple configuration may be possible using non-programmers with software skills. This could be defined as using "pull-down" menus or "radio buttons". Developing user interface screens with tools such as Visual Basic or proprietary vendor-developed programming languages is not something that non-technical resources can easily accomplish.

Another common approach used by vendors is to mention early on in the project sales effort that "We do not implement your system as much as we mentor you in implementing your system." It sounds good, and such language is both intoxicating and irresistible to the Purchasing Department, but in practice it is rarely practical.

Vendor implementers are highly experienced at system development. Customer resources, even those with advanced software skills, are rarely a fraction as effective as vendor professionals. What tends to happen is that vendor resources typically deploy X many functions/products/reports, and the remainder are left to the customer. When the project slips because those resources are not delivering in the defined time allotted, the vendors are asked to quote more expert developer time. In essence, the sale was made creating the impression that the system implementation was easier than it ended up being. There is another reason to imply that customers need to take on significant system development responsibilities: Elite vendor deployment resources are a prized commodity and are better optimized when they can get major projects moving and then move on to the next customer project.

Regardless, once the RFP is finalized and sent to the vendors on the list, the BPA team works with your organization to develop a scoring system and scoring sheet for the evaluation of responses. There are a number of options to quantify written responses, including:

- **Assigning a single rating per functional area**
- **Assigning a rating to each snippet**
- **Assigning weights to each functional area, or the underlying snippets**
- **Assigning a mandatory/nice to have priority**
- **Assigning personalized weights based on each team member's job responsibilities**

Vendor Selection

| Review Responses | Select Short List | Onsite Demos | Identify Finalist(s) |

Once vendor responses are received, team members will review and score the responses, with the BPA team providing the primary review and scoring of the Technical Assessment. Scores will then be tallied, and the top scoring vendors will be invited for onsite demos. Vendors will prepare their demos based on the Technical Assessment, which also serves as the demo script.

The BPA team attends the vendor demos in order to evaluate and helps to score candidate vendors and their products. The BPA team technically evaluates the validity of the vendor responses and ensures the vendor adheres to the demo script. This ensures that the demos stay focused on meeting requirements instead of devolving into a general vendor marketing session.

A few days after all demos have been completed, the team meets to select the first and second place candidates based on scoring as well as subjective aspects of the system (e.g., user friendliness, consistency of operation across modules, etc.). Project cost estimates will of course also play a role in the final system selection. Your organization's Purchasing Department will work with the remaining vendors to negotiate and finalize the purchase.

Note that sometimes the selected vendor solution will not be a perfect fit for the TO-BE processes. The "best" solution for any vendor is best thought of as the system meeting most of the requirements easily, while other requirements may require some level of configuration. Of course, the challenge is to identify those areas requiring configuration early on in the project so they can be planned and budgeted.

Business Process Analysis Benefits

An effective BPA conducted by an analyst with appropriate domain knowledge can lead to significant benefits for your organization and informatics projects. Some of these include:

Cost Savings. While adding a BA to the project team for your informatics project will add some costs in terms of resource hours, the cost savings will far outweigh the initial investment. When your project starts off with BPA, future state requirements are designed to include functional and operational improvements that serve to eliminate bottlenecks, streamline enterprise workflow, and provide agreed-upon business benefits for your company. This all translates into a more effective and efficient technology selection process and overall laboratory efficiency gains, ultimately reducing expenses for your organization. Requirements focused on agreed-upon business needs also reduce the scope and cost of the deployment as unnecessary bells and whistles are trimmed from the project plan.

Facilitates Good Communication Between Stakeholders. The combination of laboratory, IT and informatics software expertise of an experienced BA enables them to formulate and communicate the future state require-ments in a way that is understood by all stakeholders. The BA effectively serves as a bridge between all stake-holders (management, project team, IT, users, etc.) and helps the project proceed smoothly and effectively.

Effective Technology Selection. Without the optimized set of future state requirements that BPA produces, the project team has no effective basis to choose the best system for your organization. Companies often choose a system based on the flashiest demo or which system has the most bells and whistles. The ability to accurately capture optimized system requirements is the only metric by which software applications and/or platforms should be judged.

User Adoption. A good BA facilitates user adoption through effective communication and engagement with users. Users buy-in to the future state being implemented because they are consulted throughout the process and help to shape the TO-BE workflows. This collaborative approach ensures the implementation will address user needs and thereby facilitates user adoption.

Requirements Development and Prioritization. A good BA will interview your management team to discuss the project at a high level and understand the goals, aspirations and objectives of the desired future state before designing future state requirements. Business objectives and goals must be clear and measurable in order to be able to validate project ROI and develop accurately targeted requirements. These business objectives will also be used to prioritize the requirements into must-haves, should-haves and wish list items in a collaborative fashion, ensuring the most important requirements are implemented first.

Provides an Accurate Assessment of the Vendor Responses and Demos. Experienced BA resources have reviewed a great number of vendor RFP responses. As such, experienced BA resources are comprehensively knowledgeable of the operation of vendor systems and can provide perspective on what is stated in the RFP, as well as help evaluate responses for accuracy and completeness. Experienced BA resources have also witnessed many vendor demos and are particularly adept at ensuring vendors answer any and all questions posed and stay focused on the demo scripts.

Facilitate Management Buy-In. By interviewing the management team to discuss the desired future state goals, BAs facilitate management understanding, resulting in greater buy-in to the project.

Provide an Accurate Measurement of ROI. A good BA will establish a baseline by precisely capturing the current state in terms of process time, sample turnaround, completed tests, released results, etc. This allows an accurate measurement of ROI for a project. From these captured metrics, the success of the future state can be properly measured.

Conclusion

Selection, implementation and rollout of an enterprise-class laboratory technology is an expensive, high-risk endeavor for many companies, because success or failure in the lab often translates into success or failure of the product being brought to market in terms of data quality and manufacturing productivity, both of which play a major role in establishing consumer credibility while enhancing margins. Without a clear strategic plan, companies often select and implement solutions in ways that do not support the business's future goals. To rectify this problem, Business Analysts (BA) work to create this strategic plan by serving as a bridge between all stakeholders – IT, the project team, corporate management, software suppliers, scientists and users. Additionally, the BPA process can be scaled to accommodate your organization's unique environment, needs, and budget.

Gone are the days when vendors deployed a system and expected a customer to conform to its workflow. With the proven methodology described in this white paper, Business Process Analysis is conducted at the beginning of your project to ensure that:

- **The best system for your unique laboratory and organization is selected**

- **your laboratory workflows are optimized**

- **project plan design time is reduced**

- **prioritization of functionality is established**

- **the system deployment rollout is laser-targeted**

- **the implemented technology generates significant business value for your organization**

---

[1] **"Innotas Survey Reveals That 55% of Respondents Had a Project Fail in the Past Year: Up From 32% Last Year," Available at: www.marketwatch.com/press-release/innotas-survey-reveals-that-55-of-respondents-had-a-project-fail-in-the-past-year-up-from-32-last-year-2016-06-01**

· ·

About the Author: Randy Hice is Managing Director of Astrix Technology Group in the Business Process Analysis Practice. Randy is recognized worldwide as a leading authority in laboratory informatics, specifically focused on complex, large-scale customers implementing Laboratory Information Management Systems (LIMS), Laboratory Information Systems (LIS), ELN, and sophisticated Cloud architectures. Randy has developed global laboratory automation and harmonization strategies for leading pharmaceutical, biotechnology, medical device, and Contract Research Organization companies, identifying opportunities to share and utilize critical laboratory data across corporate locations in Europe, Asia, and the US.

About Astrix: Astrix Technology Group is a full-service global laboratory informatics consulting, regulatory advisory and professional staffing firm focused on serving the scientific community since 1995. Our experienced professionals bring together technical, strategic, regulatory and content knowledge to provide the most effective solutions to problems faced by scientific organizations. We provide Business Analysts with appropriate domain knowledge that work to align business processes, business goals, and technology to ensure your laboratory informatics project maximizes business value for your organization. If you would like to have Astrix conduct Business Process Analysis for your laboratory informatics project, or if you would like to discuss your laboratory informatics strategy, please contact us at www.astrixinc.com.