Introduction

An implementation is the process of putting a plan or decision into effect. The outcome of the execution can range from a great success to a disastrous failure — and every variation in between — depending on how well each phase of the implementation is planned and carried out. Success, whether it is a system, process, or program being implemented, is far more likely when a documented, time-tested process is followed. With a proven methodology in place, preparation, evaluation, integration, and eventual sustainability are all appropriately contemplated throughout the project and can then be applied to initiatives of any size and complexity.

At QPharma, we’ve been implementing projects and programs for more than 20 years — and in various roles, from overseer and project manager, to one of many stakeholders engaged by a client as part of a larger initiative. In that time, we’ve had the opportunity to identify what works, and what doesn’t; what common missteps and obstacles can be avoided; and which pivotal steps should never be overlooked. Is it always a cookie-cutter approach? Definitely not. But any “recipe for success” always begins with having the right recipe.

Understanding the desired end result of a project, and the implications of this result, are key goals of this methodology. For example, when implementing a Customer Relationship Management (CRM) system, the business may identify field sales as the end user, but consideration must also be made for where data from the CRM will reside, and how data will flow to another system, or systems, for reconciliation, transparency reporting, and validation of practitioner sample eligibility. Understanding critical data flows and how that data will ultimately be used must be considered throughout the span of the implementation.
QPharma followed our implementation methodology in a collaborative process with the client business owner, IT team, validation group, and other stakeholders.

From kick-off and the establishment of business rules, all the way to final onboarding, the implementation team encountered only minimal obstacles — and afterwards, the client commented that it was the smoothest, easiest implementation of a high-visibility, complex program they had ever experienced.

- Thanks to proactive monitoring and automatic watchlist alerts, the client is now able to identify potential issues with sales representatives two to three weeks sooner than previously.
- The reconciliation process, which would previously take the client two to three months, was reduced to an industry-standard thirty days.
- All annual inventories and inspections, which the client would perform over the course of approximately six months, were also reduced to thirty days.
- The successful pilot program helped create “power users” that ensured faster, smoother onboarding due to a train-the-trainer approach.
- The client has streamlined its sales operation costs and now employs one experienced home-office compliance analyst who serves as a liaison to the QPharma team.
- The same experienced Account Executive who oversaw the implementation continues to manage the program and conduct Quarterly Business Reviews, ensuring continuous improvement and ongoing client satisfaction.

<table>
<thead>
<tr>
<th>Step 1 — Preparation: Before any project can even begin, taking the time to appropriately prepare is crucial. Questions will always arrive over the course of an implementation, but asking the right ones early in the process will increase the chances of success.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Scope Review</strong> – Prior to setting timelines and expectations, it is important to confirm the scope of the implementation and clarify the requirements. Requirements may include any applicable regulations that are expected to be met, how a system is expected to work, or what problems or issues are expected to be resolved.</td>
</tr>
<tr>
<td>• <strong>Identify Key Stakeholders</strong> – Before a timeline can be established, key stakeholders must be identified and responsibilities assigned for the implementation, as well as any areas of the business being impacted. The roles and responsibilities may expand depending on the complexity of the implementation; however, it is critical that key decision makers and stakeholders are a part of the implementation from the onset, and that the success of the implementation is dependent on a shared commitment to the process. Just as it’s important not to engage certain stakeholders too late, it’s equally important not to waste time by engaging nonessential personnel long before their input is needed.</td>
</tr>
<tr>
<td>• <strong>Set Goals</strong> – A program can run indefinitely, but an implementation is a project; once all goals are successfully met, the implementation is complete. The project goals should be able to answer the question, “At the end of the project, what will have been accomplished?” Project expectations and goals should be realistic, practical, and sustainable, and since a long-term implementation can sometimes seem to take on a life of</td>
</tr>
</tbody>
</table>
its own, well-documented project goals ensure that all stakeholders keep their eye on the prize.

- **Establish Timelines** – Once the project expectations, requirements, roles and responsibilities are appropriately documented, realistic timelines are much more likely. While many implementations are worked against a set timeline, even backing into a timeline will be more realistic after appropriate preparation. Keeping in mind that key tasks are often reliant on the successful completion of other tasks and milestones, it is important that key stakeholders are included when establishing the timeline or the initial plan may not be practical.

**Step 2 — Initiation:** After appropriate preparation, initiation of the implementation can begin. Circumstances can change over the course of an implementation, but an established plan will allow for changes to be appropriately documented and addressed.

- **Establish Project Governance** – Some of the first, and key, steps to a successfully initiating any implementation are identifying the roles and responsibilities of the team and confirming the decision makers. Those decision makers need to be well informed of the timelines, the impact decisions will have on the project, and the overall goals of the implementation.

- **Collect Critical Input** – Once the key stakeholders are identified, collecting input from impacted business areas ensures that all critical concerns and needs are addressed in the implementation, and allows for prioritizing process improvements that may not be driven by a regulatory or corporate requirement, but which would make things more efficient or cost effective.

When considering the requirements, it is important to ensure any compliance concerns are appropriately contemplated. Are there compliance ramifications stemming from the business requirement? For a system implementation, is validation required? Do the requirements align to internal policies? Will the implementation require additional training, and if so, who will be impacted by the training requirements?

Prior to finalizing the definition of requirements of the business, it is important to determine how the requirements
will be translated effectively for the other members of the team and how realistic the stakeholder expectations are. Do the requirements reflect a regulatory need, or are they a “nice-to-have” set of features that will strain the technology team and possibly compromise the timeline?

When finalizing the documentation of the critical input on the implementation, each key stakeholder should be included in this process, including a review of the assigned tasks and the timeline, making it clear what the expectations are from each stakeholder and decision maker; the impact those tasks and expectations have on the timeline; and an explanation of how each stakeholder should prepare for the project.

Reviewing the tasks and timelines also allows key stakeholders to identify any resources that may be needed for special tasks or feedback. Aligning everyone’s responsibility in the implementation plan will not only allow for incorporating key tasks and expectations, but it will also ensure that vacations, holidays and other ongoing projects are factored in and that the timeline remains realistic and practical.

While collecting critical input from key stakeholders can have a direct correlation to the success of an implementation, so can making the mistake of gathering too much input. Having too many cooks can give rise to conflicting expectations, which is why project leaders should always be prepared to refer back to the goals and project governance to stay on track.

Lastly, when collecting critical input, include discussions on previous missteps in recent or similar projects, implementations, or goals. Lessons learned and identified best practices can help drive priorities and further contribute to a successful implementation.

**Step 3 — Evaluation:** Evaluating the current system, process or programs, and identifying any gaps in the current state, requires a few steps but will help ensure all aspects of the implementation are considered.

- **Situational assessment** – A situation assessment requires critical thinking about the project goals and the current state and the identification of areas where the documented requirements are currently being met, how they are being met, and where there are shortcomings.
- **Business workflow** – The evaluation process also includes clarification of the business workflow or the tasks that have to happen to meet the timeline and milestones. Clarifying the tasks, and the order and process by which they must be performed, makes it easier to realize the project goals. The evaluation may reveal a lack of resources or technology needed to meet the timeline, and it is important that the responsible
parties know this is an expectation during the evaluation process.

- **Gap Analysis** – Once the situational assessment and business workflow portion of the evaluation is complete, a gap analysis should be completed before the implementation can continue. The gap analysis includes identifying any requirements that are not currently being met, anywhere requirements are currently being met but may be compromised, and what systems, programs or processes require changes in order to satisfy the project requirements and goals. Corrective and preventive actions should be considered at this point and timelines adjusted as needed to reflect the current state and appropriate changes.

**Step 4 — Definition:** Documentation is key to a successful implementation, so this part of the process is a critical step. While every step in the process should be documented, the definition of the system or program requirements and business rules for sustaining the program or process can now be finalized. There are several areas to be considered when finalizing documentation.

Business rules for sustaining the processes should consider not only the requirements, but also any internal legal interpretations that will affect daily tasks and work instructions supporting the requirements, as well as any industry guidance and best practices that will help define program or process considerations.

If the project includes a system implementation, such as a Customer Relationship Management (CRM) system, validation considerations and analysis would be included in the definition process and project timing. Project documentation for a system validation and implementation needs to include test cases for business scenarios and gaps identified during Step 3: Evaluation. Considerations for a system implementation should also include aligning system capabilities to the business requirements, and any integration and data specifications.

Appropriately documenting the process should also consider the real possibility of transitioning the project to new stakeholders or project leads. Clear documentation of the requirements and decisions allow for involved parties to understand the program and the variables considered in the decision making process. Identifying systems with pre-built connections, i.e., systems that are designed to work together, can help streamline this process.
Step 5 — Configuration: Configuration refers to the structure of a solution and during an implementation should not be confused by limiting the step to configuration during a system implementation only.

- **Define Solution Structure** – The process of defining the solution structure applies to any implementation, because it considers how business rules are applied in the solution, the process for managing policy and requirement changes, how changes are documented, and, if changes are required, whether any historical processes or applications need to be preserved. In a system structure, there is typically a requirement for an audit trail to be preserved both for historical applications and any ongoing system changes, but this needs to be contemplated for process and program implementations as well. Comprehensive policies, procedures, and work instructions are critical to finalizing the implementation and ensuring its ongoing sustainability.

- **Align Knowledge** – Again, aligning stakeholders to the program implementation requirements, processes, and technology helps to ensure there are not only no surprises during the implementation, but by contemplating the potential for regulatory changes that may occur during or after the implementation the change control process is well established before the need arises.

- **Integration for Final Configuration** – The final step in the configuration process is to conduct a final review of the solution structure and process, and ensure impacted stakeholders are aligned with the integration and solutions output. At this point, depending on the type and scope of the implementation, it may be prudent to consider a pilot program to ensure that the business, Quality Assurance, and any system needs will run smoothly and requirements are being met appropriately before full rollout.

Step 6 — Onboarding: The onboarding process is also referred to as the “Go Live” phase of the project, and a few final steps will help to support the successful completion of the implementation.

- **Train Teams** – A successful implementation cannot be realized without appropriately training the teams responsible for sustaining the system, program, or processes. Appropriate training both internal and any third party teams will rely on clearly documented expectations and well-defined work instructions. Training documentation also allows for smooth transitions when resource changes are made. Third-party support and training should also clearly reflect the corporate culture, legal interpretations, and requirements established by
the key stakeholders.

- **Establish Continuous Support Plan** — During an implementation of any kind, all involved parties look forward to its completion so they can get back to their primary responsibilities. While it would be nice if any program would be able to support itself, a continuous support plan is needed to ensure its success and sustainability. A continuous support plan takes several components into consideration, such as sustaining the program deliverables, ensuring ongoing compliance, and identifying ongoing third-party support liaisons.

**Provide Related Materials** — Relevant materials and retention requirements are required not only for documenting the implementation, but also for sustaining the program’s ongoing success. Considerations for communicating updates and changes, who is responsible for approving the changes, and the general workflow must be shared with the team responsible for ongoing support.

**Step 7 — Continuous Support**: After a successful implementation, the continued success of a program, process, or system relies on appropriate continuous support. Since various business areas are continually launching new initiatives, ensuring that compliance needs are appropriately considered can be established through regularly scheduled business reviews with key stakeholders. While everyone involved may want to move on to their daily tasks after the completion of an implementation, it is not uncommon for most key stakeholders to have some level of shared accountability and responsibilities in the continuous support of the program. Following a defined methodology for any implementation — regardless of size and complexity — will help effect a successful outcome. By appropriately contemplating compliance considerations, keeping impacted business areas included in the process, and keeping focused on your goals amid shifting expectations, you’ll be pleasantly surprised at how seamlessly the disparate elements of your implementation become harmonized.

*See next page for author contact details.*
Have questions? Need help? Contact this white paper’s authors:

Lori Peters — SVP, Commercial Operations
Judy Fox — Director, Compliance Services

About QPharma
Founded in 1994, QPharma is the industry leader in cloud-based software and sales for life sciences. The company provides solutions that include sample management and distribution, product launch management, online training, transparency reporting, field inventory services, and HCP/KOL targeting and engagement. QPharma is a National Association of Boards of Pharmacy Verified Accredited Wholesale Distributor, and an approved American Medical Association Database Licensee.

QPharma recently launched Ti CRM™, the first mobile life sciences CRM developed specifically to integrate with its market-shaping Titanium™ platform. Learn more at www.qpharmacorp.com.

22 South Street, Morristown, NJ 07960  |  (973) 656-0011  |  www.qpharmacorp.com