Achieving Agile and Rapid EQMS Deployment by Leveraging the Cloud

Quality Management is a pervasive and strategic set of business processes and technology that touches all aspects of business and culture. However, for a number of reasons, sometimes companies need to rapidly deploy a new system, specifically one targeted at immediate improvement for a specific quality process.

There are many possible reasons for needing a rapid deployment driven both internally and externally. These include factors such as:

- Elevated customer expectations
- Pressures from regulatory agencies
- Disparate and additional quality processes (in the case of an acquisition)
- The need to demonstrate rapid return on investment (ROI)
- Changes in management team or new strategic initiatives

In this Research Spotlight, LNS Research will examine effective strategies for rapid EQMS deployment. This includes considering the cloud delivery model, as well as the trends and governance seen and required, respectively. It will explore the demand for concise, disciplined scoping and the increased importance of selection and configuration best practices. The report is concluded by ensuring adequate emphasis is placed on output (reporting) and that training and support provisioned to deliver a successful outcome.

Cloud Delivery Model Trends and Considerations

A cloud-based delivery model is well suited to rapid implementation. It eradicates most technical barriers to deployment such as access to infrastructure, IT resources, and technical expertise. LNS Research data confirms that, in planned EQMS projects, a significant shift from the legacy bias for on-premise towards an increased share for cloud-based deployments is occurring.

“I don’t understand why people are scared about moving to the cloud. I’ll be honest, it’s been heaven on earth for us.”
- VP at a leading medical device company
For those in regulated industries like life sciences, there are specific efficiencies like vendor-performed software validation. Pre-executed Installation Qualification (IQ) and Operational Qualification (OQ) are tangible and allow for significant cost, resource, and time savings in a complicated process.

Manufacturers implementing EQMS today realize there must be no compromise in governance, and knowing this, the best EQMS vendors rely on top-tier providers like Amazon Web Services (AWS), Rackspace, and Iron Mountain, among others to provide the very best in documented security, availability, and disaster recovery solutions. Top-tier providers ensure that cybersecurity provisions are comprehensive, and these include Intrusion Detection Solutions (IDS), biometrics, background checks for staff, training, and certifications (ISO/IEC 27001 Information Security Management Systems). These measures are supported by formal third-party audits that provide assurance of appropriate levels of security, availability, processing integrity, confidentiality, and/or privacy (SAS 70/SSAE 16).

Often, a private cloud deployment is the preferred approach to add an additional security measure. A private cloud is essentially an individual cloud deployment of a single-tenant EQMS instance, and while not as efficient from a vendor administration perspective, does offer assurances that multi-tenant, public cloud offerings cannot. From an application perspective sensitive data in the EQMS should be encrypted and vendor personnel trained in and gov-
erned by security policies and procedures. This may also include assurances of governance to safe harbor and HIPAA-HITECH requirements for personal data and privacy.

Beyond immediate IT resource efficiency, the cloud supports short-term tactics and long-term strategy. For many companies this long-term strategy includes harmonizing and delivering an EQMS hub for multiple processes. This hub integrates with other enterprise platforms like ERP or CRM, and enables seamless interoperability between additional modules as desired in the future. It also includes reporting and analytics that deliver insight and intelligence for a more proactive approach to quality.

**Rapid EQMS Deployment Scoping: Building Block for the EQMS Hub**

Scoping is pivotal for success in a rapid deployment. To achieve this the project team must document and ratify scope at the outset of the project and stick to it. Scope considerations also may include decisions to improve a specific weak process. As the organization implements the new platform, its work provides a foundation for future expansion. As priorities dictate, the organization can then expand in a way that subsumes and replaces other functioning, yet inefficient and disparate tools over time, but does so rapidly per individual weak process. This effectively repeats the approach while building on the first module.

The EQMS must provide enablers for changes to configure and improve the quality system over time. But rather than a ground-up initial configuration and merely replicating ineffective, institutionalized processes, improvements should be based on out-of-the-box configurations that leverage best practices and allow for further improvement as feedback is gained.

The rapid deployment mindset demands that where process automation, harmonization and efficiencies are required, the new tool (EQMS) is treated as a vehicle to accelerate arrival.

It is important to consider every requirement (functional and non-functional) with a future-state mindset to ensure weaknesses in existing processes are addressed and still provide the flexibility to add additional processes later. A good example is complaints management, where corrective and preventive
actions (CAPA) are a required process for interoperation. Another example is the subsequent expansion into an audit module that impacts the complaints process or uses for the basis of some audit. Without consideration for additional processes, the implementation potentially constitutes a point solution or process automation island rather than a foundation for the future. Therefore, a rapid or tactical deployment of a single EQMS module requires due consideration to obtain the ultimate goal of an EQMS hub.

Deploying to the cloud does not signify that integration points will not need to be established, either for master data from existing personnel, product, or other data from ERP, PLM, MOM, CRM, EHS, or other sources. Vendors with cloud offering maturity have strong capabilities that leverage Web services, APIs, and well-defined integration layers.

**Selection and Configuration Best Practices**

The four most common areas of quality management automated by manufacturers have remained consistent since LNS Research began its industry survey activities three years ago, and include Document Control (48% of respondents), NC/CAPA (46%), Employee Training (37%), and Complaint Handling (35%). It is not surprising, therefore, that these modules are most often targeted for rapid deployment scenarios.
The selection process in a rapid deployment does not necessarily occur more quickly than a standard deployment approach, though unnecessary delays can be avoided by planning appropriately and using the correct tools for evaluation.

Preparation for EQMS selection and implementation starts with forming a cross-functional selection team and creating a framework for objective analysis. Organizations should use standard demonstration agendas for vendors and scripts to ensure features are demonstrated in context, and likewise, standard evaluation checklists should be provided to the cross-functional team.

The cross-functional team should also outline pricing submissions to avoid becoming obfuscated by different vendor models. While solution selection best practices are always important, the stakes are elevated when dealing with a focused, rapid deployment, as any further expansion will rely on the new platform.
A detailed, well-planned, and swiftly executed configuration is of significant importance. In order to deliver on the goals of a rapid deployment the core elements should not have to be built from the ground up, but adjusted for some specific customer nuance. These core elements include:

- Access privileges
- Organizational structure
- Conventions
- Document formats/Templates
- Workflows
- Standardized forms

By thoroughly evaluating pre-configured content and leveraging core elements, it is possible to limit configuration discussion across multiple, non-co-located stakeholders. Without this evaluation, a “bare system” scenario has the potential to inject unacceptable delay and disruption in this phase with an inordinate and unplanned amount of time in coming to an agreement and executing upon configuration activities.

**Reporting and Dashboards: Standard Libraries and Capability for Advanced Analytics**

Early success for a rapid deployment can depend on the EQMS’ standard reports library. Having a deep core set of reports and the capabilities therein can be used as indicators of the maturity and capability of a vendor’s solution.
Organizations should also probe to decipher whether a vendor has truly considered the rapid deployment model. The ability to derive high risk and prioritized complaints both across organizational entities, and from training and competence matrices reports are two indications that is has done so. Additionally, a focus on output is critical for the success of a time-sensitive implementation and organizations must guard against a narrow, data-in mentality. Tangible value is unlocked by excellent reporting and the sooner this is realized in a deployment the better.

Using the core set of reports and building on it over time means value can be derived very quickly and intelligence and insight extended as the organization grows into the fully functional deployment. As even the fastest of deployments matures, end users should look for better insight and analysis capabilities, and every effort should be made to generate reliable and informative reports for each project. These reports have immediate shop-floor relevance and will ultimately demonstrate value to the executive, so the ROI is reinforced and communicated sooner rather than later.

Reports and dashboards are a critical component to receiving immediate value and evolving over time and it is important that vendors have this built in ahead of time.

**Training & Support**

Well-planned, detailed, and responsive support is a defining success factor in EQMS adoption and, where required, regulatory compliance. While training and support for rapid deployments are compressed and focused efforts, the plan for support must detail clear responsibilities and direct channels for quick response in order to maintain momentum in configuration decision making and for rapid adjustments. It is in the early stages post-configuration where specifics around validation must be dealt without delay and documented accordingly as any delay here will preclude go-live. Validation for the performance quality (PQ) element requires that no further changes are made and test scripts can be executed and verified.

The cross-functional selection and implementation team should take responsibility for ongoing organizational readiness for the specific EQMS module rollout. These are generally regional and plant level champions. These key roles
must be fast-tracked in their understanding of the limited scope functionality and the success criteria.

To avoid delay these trained champions become the level one support personnel internally with a simple escalation path available as a responsive back up. In direct support of this, vendors should (ideally) provide a single point of contact or named personnel familiar with the specific project. This is support that provides continuity and deployment-specific expertise in their application support both in the near-term, and through any subsequent expansion for additional quality processes.

Continuous Improvement

A rapid deployment does not mean lessons learned are not recorded and applied to the solution. Configuration decisions will be improved upon over time and maintaining clear channels of communication and a backlog or register of improvements for configuration should be a requirement and considered a responsibility of all team members. End users will be a consistent source of improvement suggestions and should be acknowledged and informed of improvements regularly.

As efficiencies and functionality offer alternatives to steps within a current workflow—adopt or add to the backlog as improvement suggestions for the EQMS. In order not to affect validation status (for those in a regulated environment), all changes should be made in a controlled way and impact on validation status assessed. An example of change is the consolidation of similar or the same document(s) that could be elevated to a group or enterprise-wide status, therefore delivering a reduction in duplicated document maintenance effort. Organizations should be aware, however, that changes should be put into effect on a prioritized basis and to avoid too-frequent adjustments. Updates should be considered every few months based on the backlog.

Some deployments will remain single-module implementations, but with success and the value of a harmonized, closed-loop process for one area of the multi-site QMS, expansion becomes easier to justify. With the core configuration completed quickly due to out-of-the-box best practices having been adjusted, these provide a good foundation for subsequent modules. When done correctly, organizations can be pulled into expansion, rather than by actively pushing.
Recommendations

- For many businesses multi-tenant is acceptable, but for more cautious and some more heavily regulated industries, the peace of mind of single tenant (segregated data) platforms is the appropriate choice.
- Select vendors that have documented evidence of their hosting environment’s security provision. This should range from physical security and personnel (including training) through top-tier firewalls and intrusion detection.
- Determine whether public or private cloud is right for your organization based on corporate policy.
- A rapid deployment requires discipline in scope. Broader, longer-term scope should be considered, mapped, or included in selection criteria, but should not be part of the rapid deployment schedule/project.
- Thoroughly evaluate interoperability (module to future module within the application) and integration (external data sources, ERP, CRM etc.) capabilities and the approach, including provision of APIs.
- Core elements must still be configured. Leverage as much pre-configured or template content as possible. This is not to say that some further configuration will not be required.
- Give reporting equal functional status as capturing and managing data. Identify a baseline set of reports to include as part of your initial roll-out.
- The value of well-planned training is a common casualty in the process. Consistent attention to training as part of organizational readiness for implementation and the appropriate structure to support the quick deployment are key.
- Track and communicate plans for continuous improvement. Keep end-users informed and ensure the selected solution allows for changes to be made without their intervention.

Distribution of this report made possible by:

LNS Research provides advisory and benchmarking services to help Line-of-Business, IT, and Industrial Automation executives make critical business and operational decisions. LNS research focuses on providing insights into the key business processes, metrics, and technologies adopted in industrial operations.

Author: Rob Harrison, Research Analyst, rob.harrison@lnresearch.com

www.pilgrimquality.com