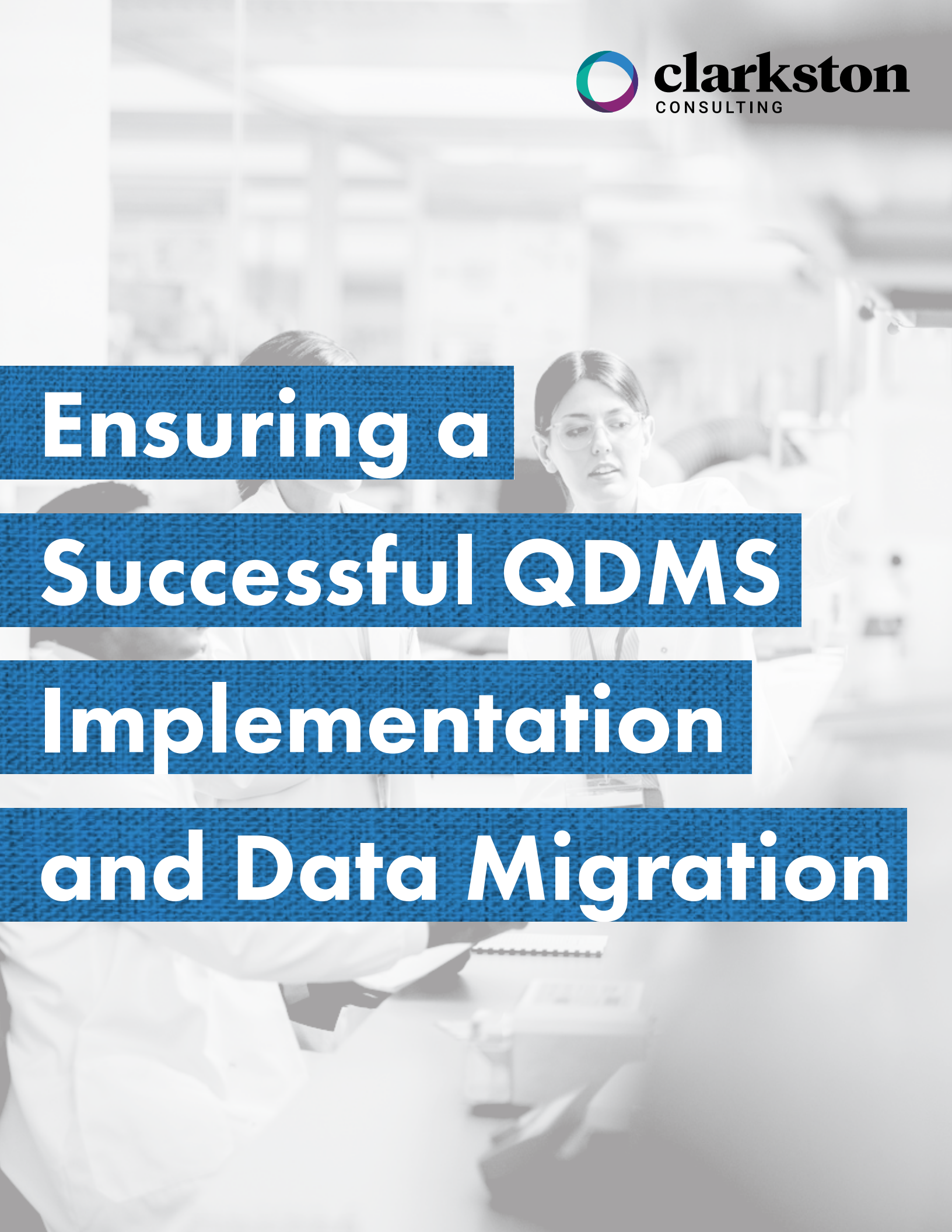




Ensuring a Successful QDMS Implementation and Data Migration

A Quality Document Management System (QDMS) is a software solution that facilitates the creation, storage, management, and tracking of [electronic quality documentation](#) in accordance with regulatory and [quality management system](#) (QMS) requirements. It helps organizations streamline their document-related processes, improve collaboration, and enhance security by establishing structured guidelines and tools for managing documents effectively.

In the comprehensive landscape of quality management across the [life sciences industry](#), many organizations are currently faced with replacing or upgrading their current QDMS. Key drivers for an upgrade include, but are not limited to:

- 1 Harmonization of processes, data, and user experience across a global enterprise-wide platform
- 2 [Organizational maturity](#) results in the current solution no longer meeting the needs of the business
- 3 Technology advances highlighting the current solution not being scalable, reliable, or user-friendly

In addition to the key aspects of upgrading or implementing a new quality documents system, we are going to focus heavily here on how to [manage data](#) migration for such projects. Migrating data from a legacy system to a new target solution can be one of the most complex areas; however, it can also be one of the most important areas for the organization.

As it relates to quality management, companies collect significant volumes of documents and associated metadata over time. These documents and metadata often reside in [outdated, on-premises systems](#) that were implemented several years prior and have seldomly been updated. Over time, an organization might start to feel they are too embedded with their legacy system to make any changes. The thought of having to embark on a document management upgrade, with associated data migrations, can be overwhelming.



Pre-Planning

Strategic planning for a project like this should include a very [thorough assessment phase](#) before embarking on the design and execution journey. This will assist with reducing some of the frustration and stress that can come with upgrading your quality documents system. The assessment can also ensure that the full scope is agreed upon and key stakeholders are aligned before building the project plan, timeline, and budget. As part of the assessment phase, the data migration plan should also be drafted and reviewed by key project team members.

From the start, it is important to identify the proper roles and responsibilities needed to perform the QDMS implementation or upgrade. This involves [assembling the right team](#) that will be required to perform essential duties. When we focus on the data migration element, you will want to have a clear owner for the following duties:

- 1 Defining and agreeing on the scope of the data migration, within the full project scope
- 2 Documenting business requirements for data and related risks and mitigations
- 3 Preparing, reviewing, and approving the data migration plan and required deliverables
- 4 Performing document and/or data enrichment for the migration
- 5 Executing the data migration and ensuring that the approach, deliverables, verifications, and results are correct, accurate, and complete
- 6 Providing oversight and responsibility for ensuring data migration [compliance with regulatory authorities](#) (e.g., FDA, EMA) regulations, internal policies, and procedures
- 7 Communicating regularly with the project team and key stakeholders
- 8 Ensuring [end-user training](#) once the data migration is complete

With such essential and critical tasks, it is increasingly important to ensure that the right people with the right skills are a part of the project team and provided with the proper tools and resources necessary to meet the timeline and budget of the project.

Data Migration Planning

Developing a [data migration plan](#) involves several key steps to ensure a smooth transition of documents and associated metadata from one system to another. One of the first steps in developing a healthy data migration plan is to assess the legacy system design & architecture. Another key step is to analyze the capabilities & limitations of the target system. A necessary assessment must be made to determine how fields, processes, tools, data, and users in the source system correspond to the target system. Any unaccounted-for findings should be documented as GAPS. All GAPS should be evaluated by the team before beginning any data migration efforts.

Next, you will want to plan for and define what data to migrate and when. A couple of questions that quickly come to mind are:

-  What will be the use of the data in the target system? Do you really need to migrate all data elements from the legacy system?
-  Will the new system or upgrade be implemented in a phased approach, or will the data have to be migrated all at once?

Along with the implementation plan, it is also important to develop a timeline of data migration milestones that can help break the project into manageable phases, identify risks and mitigations, establish how data will be validated, and create a fallback plan. A solid plan is essential to any project, however, one that includes significant data migration needs to be solidly defined and understood by all project members.

Finally, you will need to determine the tools that will be utilized for migration, considering when internal personnel are available and whether to acquire any third-party resources. During the [assessment phase](#), and before execution, you will need to understand if data is to be checked for any errors, inconsistencies, or missing information and how it will be transformed and formatted for the new target system. After the data migration is performed, you will need to develop a testing strategy to confirm connectivity, location, and accuracy of the data transferred.



Training, Close Out, and Final Review

It is good practice to formally close out and review the data migration effort. After the data migration has been executed and tested to ensure it meets the needs of the end-users, the project team should then [ensure training is provided for end users](#) on the new system and create necessary user manuals for ongoing use.

As a key part of the close out, the migration process, challenges, and resolutions should be clearly documented and reviewed with key stakeholders. Evaluate the migration process and gather feedback from users about the migration and system performance. There should also be a clear model for providing ongoing support to address any issues that arise after migration. Identify areas for improvement for future migrations and optimize processes or data structures as needed.

Getting Started with Your QDMS Implementation and Data Migration

New QDMS implementations or upgrades can be significant projects for any organization. A clear assessment phase can help ensure a [successful implementation](#), along with strong project governance and roles and responsibilities. Similarly, data migration can be time-consuming and intimidating, but very necessary and provides significant benefits if executed correctly. It takes careful examination of the organization's existing legacy system, strategic plotting of how to manage data in the target system, and strong leadership and project planning to ensure the right resources and timeline.



A well-structured data migration plan is essential for a successful QDMS implementation and data migration. Ensure that you communicate regularly with project stakeholders throughout the migration process and be prepared for unexpected challenges. Following best practices, organizations can more easily upgrade their QDMS from an obsolete legacy system to a modern, more efficient, and reliable solution.

ABOUT CLARKSTON CONSULTING

Businesses across the life sciences industry partner with Clarkston Consulting to enhance strategic decision-making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

For more information about how we can help your company, [please contact us](#).

