CUSTOMER STORY

Amman Pharmaceutical Industries
شركة عمّان للصناعات الدوائية

Amman Pharma Drives Efficiency Through Document and Quality Management

Scigeniq™

Amman Pharma wanted to begin digitizing its operational processes to improve efficiency by moving from manual, paper-based processes to more flexible, digital processes, but it wasn't sure how to start. To understand the best path forward, it worked with Scigeniq to understand its user requirements and define specifications for implementing a document management system (DMS), a regulatory management system (RMS), and a quality management system (QMS).

This case study covers the implementation of Scigeniq's DMS to support Amman Pharma's digital transformation goals and identifies the benefits achieved from the implementation.

Problem Statement

Amman Pharma wanted to improve its document management and quality processes. Existing processes were manual and prone to errors. Documents such as standard Operating Procedures (SOPs), product development documentation, regulatory filings, and more were stored across the company with varying degrees of access control. Review and approval processes were manual, with little to no ability to track what changes were made to a document and by whom.

In addition, it was time-consuming and challenging to support audit reviews.

By implementing an electronic document management system, Amman Pharma could centralize its documentation and improve how it manages and shares those documents within the company and through audits.

Technology Overview

This project included the implementation of Scigeniq DMS (Document Management System), a key solution in the Scigeniq Suite of Solutions for Life Sciences and pharmaceutical companies.

Scigeniq DMS is a robust document management solution tailored for life sciences organizations to help streamline the document-handling process, including control, tracking, and management of quality documents. A highly flexible and user-friendly application, the DMS provides a secure, centralized repository for various document types, ensuring compliance with regulatory standards, complete with workflows for document creation, review, and approval in a CSV-compliant, validated environment.

Use Case Implementation

Implementing Document Management

The Scigeniq team worked with Amman Pharma to configure the DMS to support all of its documents. The team assembled the first set of documents and created a corresponding metadata spreadsheet. They also developed a detailed and complex taxonomy structure in the DMS to support documents for different products and countries. Over the project period, two groups of documents were migrated, resulting in over 7,000 documents in the DMS.

Amman Pharma can now provide real-time visibility into document changes, including viewing previous versions. A robust review and approval workflow was implemented to ensure the proper review process was implemented, and automated notifications were configured to ensure all reviews and edits were completed in a timely manner.

Benefits and Outcomes

With the DMS in place, Amman Pharma can realize many essential benefits.

From an overall digitization perspective, three key benefits are noted:

1. Amman Pharma serves multiple countries in the Middle East and Africa, and is planning to expand to other countries globally. As a result, it must comply with each country's regulations. Scigeniq DMS is configured out of the box to comply with regional and international authorities' legislation and regulations.
2. Scigeniq's cloud-based solutions provide Amman Pharma with the flexibility to quickly scale as its documents and data grow. In addition, these cloud-based solutions ensure that all employees can access the systems, regardless of location, using desktop and mobile devices (including tablets and other touch interfaces).
3. Onboarding new employees is now easier because processes are electronic and automated.

More specifically, many benefits come with implementing a document management system. For Amman Pharma, these include:

- A centralized repository for all documents supporting all products and countries. With a centralized system, the team can easily upload, review, refine, and approve documents.
- Electronic planning and resource management: The team can efficiently perform periodic document and quality event reviews and streamline the effort required to locate documents or records for audit.
- Automated workflows help speed up document and action review and approval processes, including e-signature support. Automatic notifications at each workflow stage, from document or record creation to expiration, enhance tracking and ensure timely action.
- A robust search capability speeds up the search and retrieval of documents, including the ability to search on title and content within the document.
- Improved access control: The team can assign permissions to users to control who can view, update, and print documents and records. Printed documents feature full version history, watermarks, and customized headers and footers.
- A complete audit trail tracks all actions taken on a document or record. Audit trails ensure accuracy during reviews or audits conducted by regulators or industry bodies.

With an electronic DMS, Amman Pharma can now improve quality processes. As they work with the system, they will be able to track and measure against industry benchmarks, shown in Table 1.

KPI/Benefit
Data Integrity
Reduced Errors (Documentation Clarity and transcription)
Improved data integrity (completeness, traceability, accuracy and data loss)
Efficiency and Growth
Process execution: Reduced reconciliation, Data entry time and. Increased productivity, process efficiency
Improved data management: reduced Document Record Retrieval Time, more efficient data tracking and storage, more Analytics Capability
Reduced Preparation and Distribution Time
Reduced Document Review/Approval Reduced reconciliation, Time
Logbooks Issuance
Regulatory Compliance
Improved Regulatory Compliance: Increased Regulatory Compliance Rate. Reduced risk of regulatory fines and penalties
Cost Savings
Archive and Storage Cost.
Improved cost saving: Stationary (Paper, ink, ... etc.)

In addition, Amman Pharma will be able to track a number of intangible KPIs, including:

- Increased adaptability
- Improved competitive advantage
- Improved knowledge sharing and communication
- Boosting production metrics
- Decreased environmental impact (moving from paper-based to digital)
- Improved brand reputation
- Increased employee morale
- Increased customer loyalty

Note: The expected payback of implementing Scigeniq DMS is typically between two and five years, although it could be earlier or longer in some circumstances.

Challenges and Solutions

As this was Amman Pharma's initial move towards digitally transforming its operational processes, the company needed support with mapping requirements and establishing baseline documents. Scigeniq was able to support them by providing baselines for SOP documents and defining baseline validation of the system. This validation was completed in under two weeks due to Scigeniq's DMS cloud-based architecture.

Also, Scigeniq's local presence and industry and regional knowledge enabled them to support Amman Pharma throughout the project by providing insights, guidance, training, and technical support when needed.

Conclusion and Call to Action

Amman Pharma wanted to enhance operational efficiency through digitization. Collaborating with Scigeniq, they implemented a new Document Management (DMS). The DMS has enabled centralized document management of all documents, improving accuracy, accessibility, and audit timelines. In addition, by implementing a cloud-based solution, Amman Pharma can adapt and scale its processes as it continues to drive future growth.

Delivering Technology-Based Advantages to Our Customers

Scigeniq is a leading provider of innovative regulatory compliance solutions for the pharmaceutical industry. With a focus on advancing regulatory affairs, Scigeniq empowers pharmaceutical companies to meet their compliance goals, streamline operations, and drive efficiency. Our cutting-edge solutions are designed to enhance collaboration, centralize data, and provide actionable insights, ensuring our clients maintain the highest standards of regulatory compliance.

For more information about Scigeniq, please visit www.scigeniq.com.