Business Transformation Case Study

"Controlled Document Management System in Life Science"

About The Client

Organization: A Global Leader in the Life Sciences Industry

Industry: Life Sciences and Healthcare

About: The client operates in the life sciences industry and requires a secure, compliant, and customizable document management system to meet regulatory demands. They sought a solution to manage controlled documents efficiently while adhering to standards such as FDA 21 CFR PART 11 and GxP.

Technologies Used

- ➔ Microsoft 365
- ➔ SharePoint Online
- ➔ Power Automate
- ➔ DocuSign
- ➔ Muhimbi
- ➔ React JS
- ➔ TypeScript

Business Need

The client, operating in the highly regulated life sciences sector, required a robust and compliant Document Management System (DMS) to:

- ➔ Address the limitations of SharePoint Out-of-the-Box (OOB) features.
- ➔ Integrate seamless eSignature workflows for document approvals.
- ➔ Ensure compliance with FDA 21 CFR PART 11 and GxP standards.
- ➔ Automated document formatting, dynamic watermarking, and version control.
- ➔ Provide detailed audit logs for enhanced traceability.
- ➔ A customized and scalable solution was essential to meet regulatory demands and streamline document management processes.

The Approach

AlgebraIT employed a client-centric and compliance-focused approach to deliver a tailored solution. Key steps included:

- ➔ Customized SharePoint Framework (SPFx) with React JS for advanced functionality.
- ➔ Integrated DocuSign with Power Automate for secure electronic signatures.
- ➔ Automated watermarking and document conversion using Muhimbi API.
- ➔ Leveraged Power Automate for dynamic data population in Word Online.
- ➔ Developed a custom solution for version control and audit logging.
- ➔ Collaborated with regulatory Subject Matter Experts (SMEs) to ensure adherence to FDA and GxP compliance standards.

This approach ensured alignment with the client's regulatory and operational objectives.

The Solution

This project involved implementing a robust and regulatory-compliant Controlled Document Management System (DMS) for the life sciences sector using SharePoint Framework (SPFx). The solution was designed to enhance document management processes, ensure compliance with stringent regulatory standards, and streamline workflows through advanced automation and integration. The delivered solution included:

- ➔ A fully customizable Document Management System built on SharePoint Online.
- ➔ Seamless eSignature workflows with DocuSign integration.
- ➔ Automated document formatting and dynamic watermarking.
- ➔ Real-time version control and detailed audit logs.
- ➔ Compliance with FDA 21 CFR PART 11 and GxP standards through documented policies and procedures.

Benefits

The implementation delivered significant outcomes:

- ➔ Fully customizable document management system built on SharePoint Online.
- ➔ Achieved PART 11 compliance with secure and auditable processes.
- ➔ Streamlined document lifecycles with automated workflows.
- ➔ Real-time version control and detailed audit logs ensured data integrity.
- ➔ Designed to accommodate evolving business needs and regulatory changes.
