



Business Transformation Case Study

"One-Stop Solution for Drug Development Platform in Life Sciences"

About The Client

Organization: CDDP

Industry: Life Science

About: The client operates in the highly regulated life sciences sector, requiring advanced solutions to manage compliance, data integrity, and mission-critical applications for their customers worldwide.

Technologies Used

- Cloud Services: Microsoft Azure, Cosmos DB, Azure Blob Storage.
- Collaboration Tools: Power Platform (Power BI, Power Apps, Power Automate), O365.
- Data and Validation: SharePoint, manual and automated validation workflows.
- Customer Support: Zendesk for ticketing and inquiry management.

Business Need

The client faced significant challenges in building a compliant, secure, and scalable drug development platform:

- Navigating stringent compliance standards, including FDA 21 CFR PART 11, HIPAA, and GDPR.
- Managing complex validation and testing workflows across multiple teams.
- Providing seamless integration with enterprise systems to improve collaboration and efficiency.
- Addressing the need for a robust customer support solution to manage user inquiries effectively.
- The client required a solution that met compliance and quality standards while streamlining operations and ensuring scalability for future needs.

The Approach

AlgebraIT employed a strategic and collaborative approach, focusing on:

- Conducted stakeholder discovery sessions to align platform goals with compliance and business needs.
- Established documented compliance frameworks to meet regulatory standards.
- Developed a scalable architecture utilizing Azure services, SharePoint, Dataverse, and Cosmos DB.
- Implemented low-code/no-code solutions using Microsoft Power Platform and O365 tools.
- Designed manual, automated, and CSV validation workflows to ensure accuracy and reliability.
- Deployed Zendesk to create a seamless customer support system.
- This approach ensured a balance between innovation, compliance, and operational efficiency.

The Solution

AlgebraIT delivered a tailored drug development platform with the following features:

- A compliant End-to-End Platform built using Azure, SharePoint, and Dataverse, with Cosmos DB for scalability.
- Integration with Microsoft Power Platform for process automation, data visualization, and workflow optimization.
- Robust validation workflows adhering to CSA guidelines to eliminate inefficiencies.
- A secure customer support system powered by Zendesk to improve user interaction and query resolution.
- Reusable, scalable components to facilitate future module expansion with minimal rework.

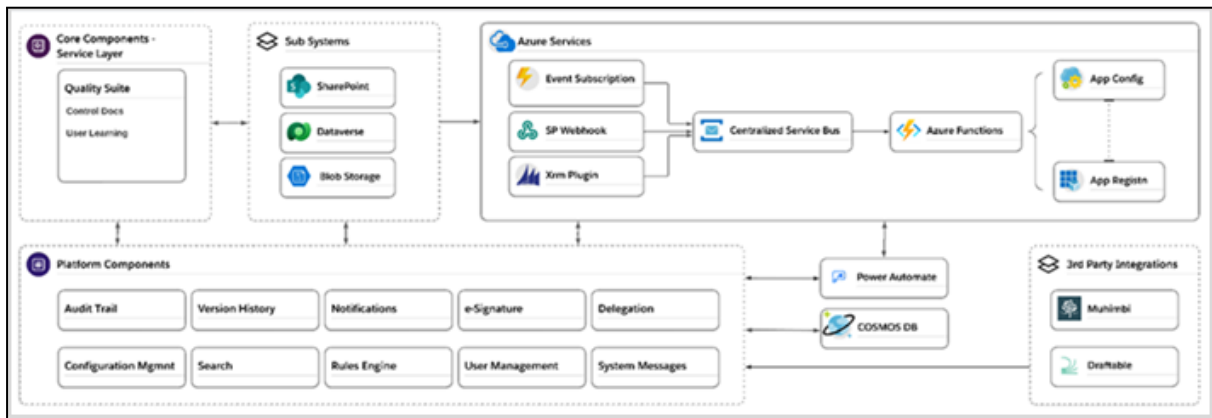
Benefits

The project delivered meaningful results:

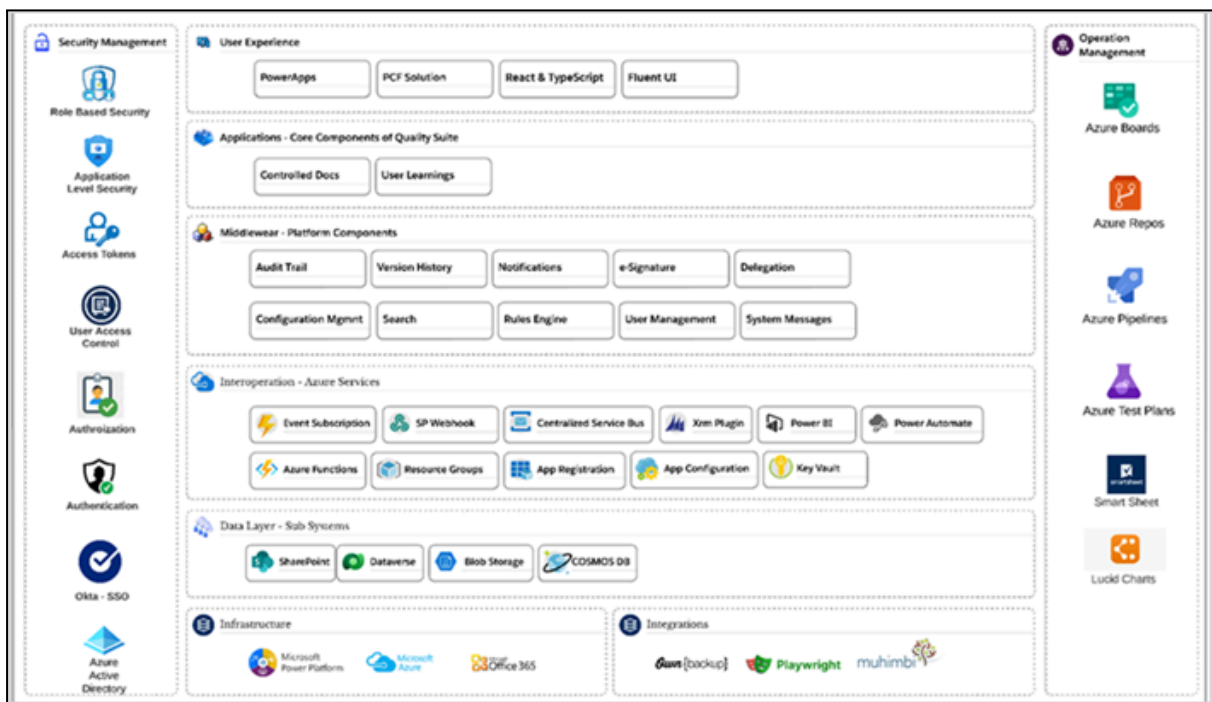
- Fully operational, PART 11-compliant software product meeting all specifications.
- 60% Improvement in compliance adherence due to robust frameworks and automated processes.
- 40% Increase in operational efficiency through streamlined workflows and cloud-based architecture.
- 30% Reduction in validation and testing timelines with automated workflows.
- Enhanced user satisfaction with a Zendesk-powered customer support system.
- Future-proofed architecture supporting scalable integrations and reusable components.

Visuals

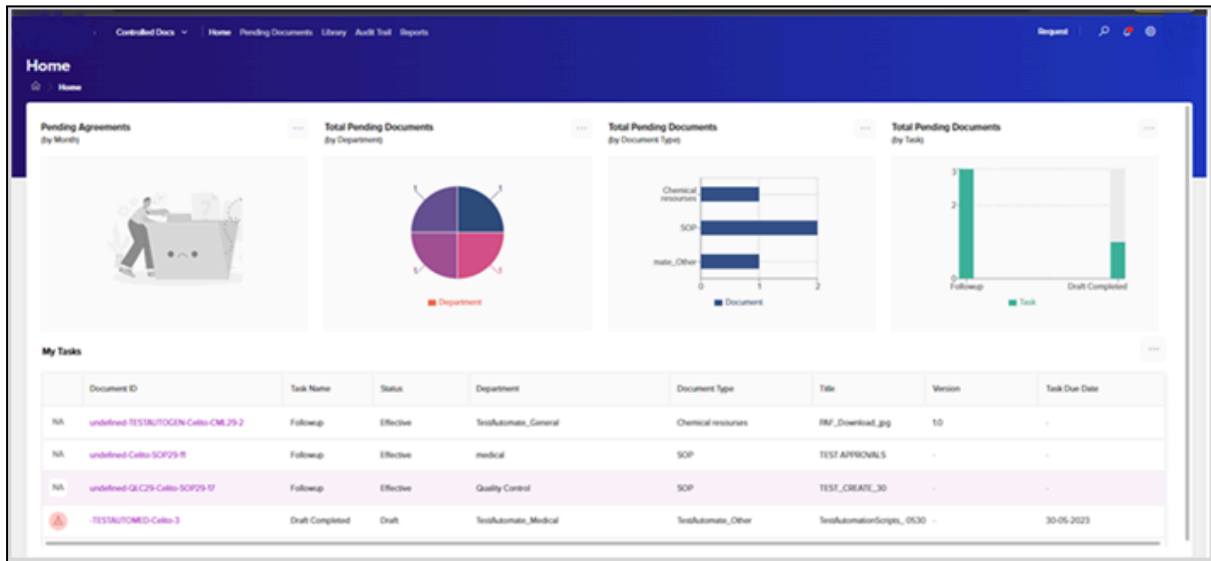
1) Functional Overview



2) Architectural View



3) Application View



Controlled Document Request

Details

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- 02 User Roles & Due Dates
- 03 Document
- 04 Preview

User Roles & Due Dates

Owner *

Subject Matter Expert (SME) Regulatory Evaluation Task Due Date

Collaborator

Collaboration Due Date Is Business Admin Review Needed?

Required Approver Quality Approval Due Date

Proposed Effective Date Follow-up Due Date

Save Next

