IT Automation Retirement Plan for Manufacturing Closure at Merck & Co., Las Piedras

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Abstract

This project establishes a complete IT Automation Retirement Plan to support the manufacturing closure at Merck & Co., Las Piedras, by December 2025. It defines a regulatory-compliant framework for decommissioning IT systems, aligned with FDA/GMP, ISO, ITIL, and data protection standards. A structured methodology was applied to assess system inventory, validate data integrity, and securely archive records. During execution, systems were prioritized by criticality, validated, and decommissioned in phases to avoid disruptions. The project involved cross-functional teamwork, such as quality assurance, IT compliance, and manufacturing, to guarantee the project's alignment with the organization's goals and regulatory compliance. Lessons learned and documentation standards were harvested to advance knowledge transfer and reuse in future site closures or technology retirement activities. This framework scales verified operational models for regulated industries, reducing the risks associated with operations without compromising their compliance and integrity.

Introduction

Merck & Co. Inc. is a global company that produces medicinal chemicals, vaccines, and pharmaceutical products to enhance humanity's health standards worldwide. Las Piedras is one of the key manufacturing sites of the Merck Company in Puerto Rico, which manufactures and distributes superior-quality pharmaceutical products. Since establishing a new site, GMP compliance, and advanced automation practices, the MES and SAP systems have been used effectively and comply with the regulations. Due to the company's restructuring plan, the Las Piedras site will cease MFG operations in December 2025.

The operational retirement of IT automation systems within MFG Las Piedras proves challenging because a thorough strategic approach is necessary to fulfill regulatory standards, safeguard data security requirements, and ensure a smooth transition of production facilities. A poorly designed approach poses significant risks of data loss, operational disruptions, and security threats to the system, so industry best practices should be followed. The primary challenge is performing system-based asset retirements that comply with company policies and governmental standards across the manufacturing site. Poor retirement management of outdated IT materials leads to current security risks and increased maintenance expenses. The project creates a life cycle retirement structure that follows IT governance principles and industry standards. A retirement plan for IT equipment must always protect data security and operational stability, including regulatory compliance rules.

This project establishes a comprehensive framework for managing IT automation system retirements, ensuring alignment with MFG policies, FDA/GMP and ISO standards, the IT Infrastructure Library (ITIL), and Data Protection Authority regulations. The plan defines a structured approach to retiring IT automation assets while maintaining compliance standards and minimizing operational disruptions. It mainly aims to maintain data accuracy and effectively address management requirements during all stages of retirement. Moreover, the project identifies how records must be retained for the period required by regulatory authorities and organizational policies. The project adapts to industry best practices and international regulations to ensure continued data integrity and standards in future changes concerning operations or technological uptakes.

Literature Review

ITIL 4 is the latest framework that helps organizations better manage IT assets throughout their life cycle and ensure proper termination. Research indicates that asset decommissioning requires a straightforward process to ensure the maintenance of appropriate service operations during plant shutdowns or major change management work [1]. The GAMP5 handbook for pharmaceutical automation suggests using a risk-based technique to control system testing and shutdown processes. A retired system must maintain its validation status, and all data needs to be archived with complete documentation that follows GxP and FDA standards [2].

These rules require safe legal storage methods to maintain data accessibility for the targeted project, safeguard archived data, and prepare it for access after use [3]. Even though reshoring promotes resilience, it is not precisely known how closing this GMP-compliant automated plant affects data protection and follows manufacturing regulations. Organizing IT retirement activities by industry standards requires proper planning to ensure compliance [4].

Regulations require that electronic record systems be disposed of by standards that demonstrate secure data access and clear audit trails to meet government requirements. Good data archiving and record retrieval depend heavily on proper system decommissioning to satisfy regulatory standards [5].

Methodology

The project employed a structured approach with clear steps to achieve its objectives. IT automation assessment and inventory creation for all systems scheduled for retirement began. System dependencies were identified, and system interactions were analyzed. This phase also included reviewing data retention requirements. All essential data is received in a secure archival storage system, ensuring accessibility for the designated retention period.

The framework reviewed applicable FDA/GMP regulations, ISO standards, ITIL guidelines, and data protection law standards to verify compliance with all retirement operations. The framework also sets the minimum data storage duration for each data type and creates safe methods for record storage. The retirement process underwent risk analysis for data breaches, system failures, and operational disruptions to establish appropriate mitigation plans. All data storage processes benefited from backup protocols and security patches, as these retention period protection measures, combined with redundancy protocols, guarantee uninterrupted data accessibility and security.

The implementation established a communication strategy to inform essential stakeholders about the retirement process, including IT staff and compliance officers, manufacturing personnel, and external auditors. Following retirement, stakeholders received instructions through policies regarding their authorization to access data.

This established approach enabled the project to deliver safe operations, efficiency, and compliance for IT asset retirement procedures. The method will safeguard data integrity while minimizing operational interruptions.

Results

This phased IT automation retirement plan successfully contained operational disruption and fully complied with FDA, GMP, and ISO regulatory standards. Specific validation processes accompanied each decommissioning step to revoke access, validate data export, and ensure complete system disengagement from production and quality processes.

The retirement plan for each task includes the corresponding start and end dates. This outlines the key phases of the IT Automation Retirement Plan for the manufacturing closure project at Merck & Co., Las Piedras Site. It highlights the relative importance of each phase within the overall process.

Table 1 presents the retirement plan for each task, including the corresponding start and end dates. This outlines the key phases of the IT Automation Retirement Plan for the manufacturing closure project at Merck & Co., Las Piedras Site. It highlights the relative importance of each phase within the overall process.

Table 1: IT Automation Retirement Plan

Task	Start Date	End Date
Project Kick Off	2025-03-01	2025-03-08
Evaluation of IT Systems	2025-03-09	2025-03-22
Identify Dependencies & Data Storage Needs	2025-03-25	2025-03-28
Risk Assessment & Mitigation	2025-03-25	2025-04-05
Secure Data Storage Implementation	2025-04-06	2025-04-12
Retirement Process Execution	2025-04-14	2025-05-01
Post-Retirement Review	2025-05-05	2025-05-20

The distribution of efforts across various stages, including project initiation, execution, data storage implementation, risk management, and post-retirement review, with the corresponding percentages for each stage.

Figure 1 showcases the distribution of efforts across various stages, such as project initiation, execution, data storage implementation, risk management, the percentage for each stage, and post-retirement review. Each segment reflects the focus areas in the decommissioning process, ensuring that all critical components, such as IT system evaluations, data storage needs, and risk assessments, are adequately addressed.

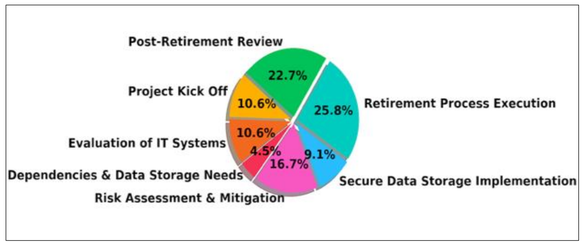

Figure 1: Retirement Plan Phase

The team updated its archival strategy by creating a joint system for managing user access control, plus recording system validation and archival history. Better teamwork and workload balance allowed the team to make up missed time, bringing the schedule completion to May 25, 2025. Team members have begun preparing the project for secure system deletion and data testing operations.

Conclusions

The IT Automation Retirement Plan for closing the manufacturing operation at Merck & Co., Las Piedras, implements an organized framework for decommissioning vital systems that complies with requirements by FDA, GMP, ISO, and IT governance standards. The project protects operational integrity and data security through implementation phases, including system inventory analysis, risk assessment and validation, secure data storage, and system deactivation. Validated archival procedures and early schedule recovery prove that the project team successfully achieved its planning goals through collaborative actions that followed regulatory frameworks. Through this project, pharmaceutical manufacturers can establish a protocol for future decommissioning activities within their industry. This can be extended to other regulated sites in Merck's worldwide network or other pharmaceutical businesses exploring decommissioning complications.

Future Work

Future work should focus on improving the scalability and sustainability of the framework. Future decommissioning projects can be further streamlined by automating archival tracking, standardizing validation templates across sites, and including additional global guidelines and tools for compliance validation. Formal post-project audits and ongoing training for the IT and QA teams will also help institutionalize the knowledge gained and ensure compliance with the IT Global Standards.

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