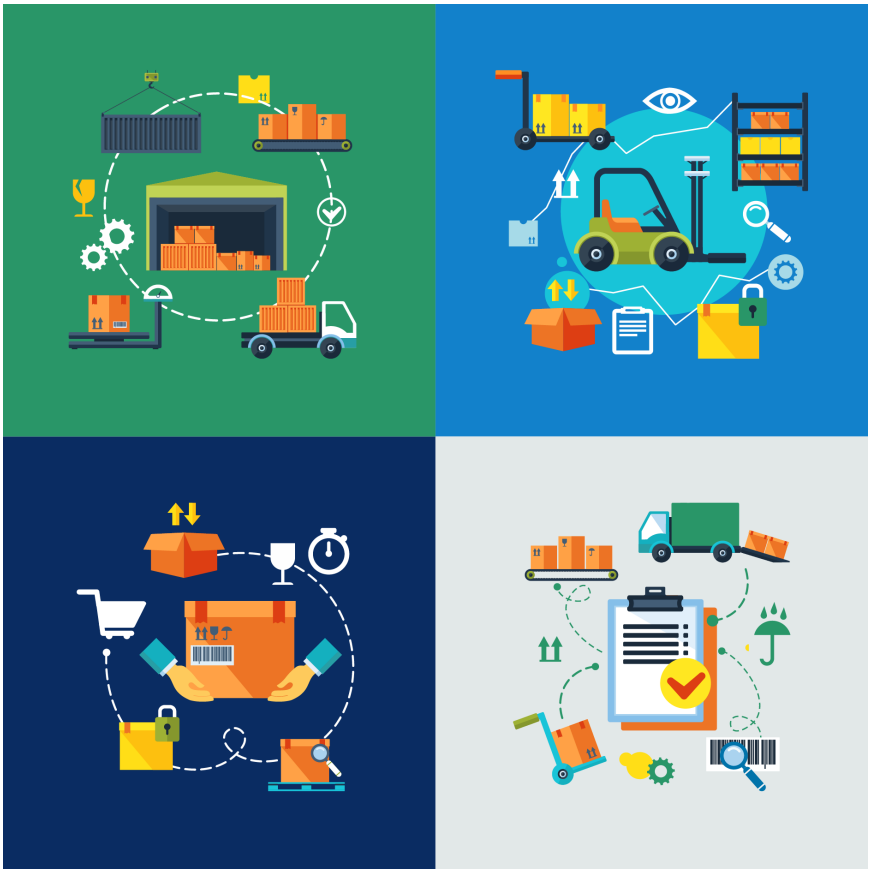
Stericycle®
GxP SOLUTIONS™

WAREHOUSE REMEDIATION PROJECT CASE STUDY



THE REGULATORY COMPLIANCE EXPERTS

ABOUT US

Stericycle GxP Solutions provides world-class compliance and validation services to multinational clients in regulated industries. Leading businesses in the biotech, medical device and pharmaceutical industries choose us to achieve regulatory compliance.

We have earned a reputation for excellence and reliability by maintaining a team of the top engineering and project management experts in the regulated industry. When combined with our innovation and targeted technology, this expertise enables us to create strategic solutions and deliver results in competitiveness and compliance.

We have a deep understanding of product lifecycles, regulatory issues and technology in the Life Science Industry, our expertise comes from years of serving the needs of regulated industries. This unique fusion of expertise allows us to provide Compliance Consulting Services that create strategic value, reduce ownership costs and ensure compliance.

"Thank you for displaying the very highest levels of professionalism and flexibility."

- Site Director, US Based Medical Device Manufacturer

"Your in-depth knowledge of validation within this corporation was vital to the success of this project."

- Director of Engineering, Multi National Medical Device Manufacturer

"We are extremely impressed with the quick delivery of this software validation project."

- Quality IT Director, Irish Based Pharma Manufacturer

"Your team have consistently delivered each project on time and within our set budget"

- Validation Manager, Irish Pharma Manufacturer

ISSUE

The Warehouse Management System (WMS) used by our customer, involved in the distribution of pharmaceuticals and medicinal products, facilitates the handling of goods inwards/outwards, the tracking of all materials and customer information.

The remediation project involved completing the activities required to bring the computerized system within the Warehouse Management System into compliance with the Validation Master Plan.

SOLUTION

This remediation process covered the following:

- Documenting the system's identification, purpose, and operational outputs.
- Documenting the system's current status and proposed procedural and technical remediations.
- Documenting the system remediation requirements and summarize the remediation plan.
- Performance of remediation activities, which were documented in a qualification report.
- A final Validation Summary Report was generated to document the completion of the remediation project. This report summarized all the remediation activities performed.

The WMS computerized system had three components; the Caché system, the Oracle system and the Vocollect system. Each of these systems has their own individual server, and were identified as a legacy system with a GMP impact. A gap analysis was performed, and a detailed system remediation plan was developed for the computerized aspects of the WMS.

The following activities were completed for the system remediation plan.

- A Functional Specification for the WMS computerized system of the Movianto group was generated to capture the current system. This document contained system specifications such as functional and operational requirements (including software and hardware).

- A Risk Assessment was generated for the computer aspects of the WMS. A risk based approach was employed for all validation activities.

- A Requirements Traceability Matrix (RTM) wsas generated for the WMS computerized system based on the information detailed in the functional specification. This listed the system specifications and the qualification activities completed on the system.

• A Hardware and Software Specification was produced to accurately describe the computer aspects of the WMS.

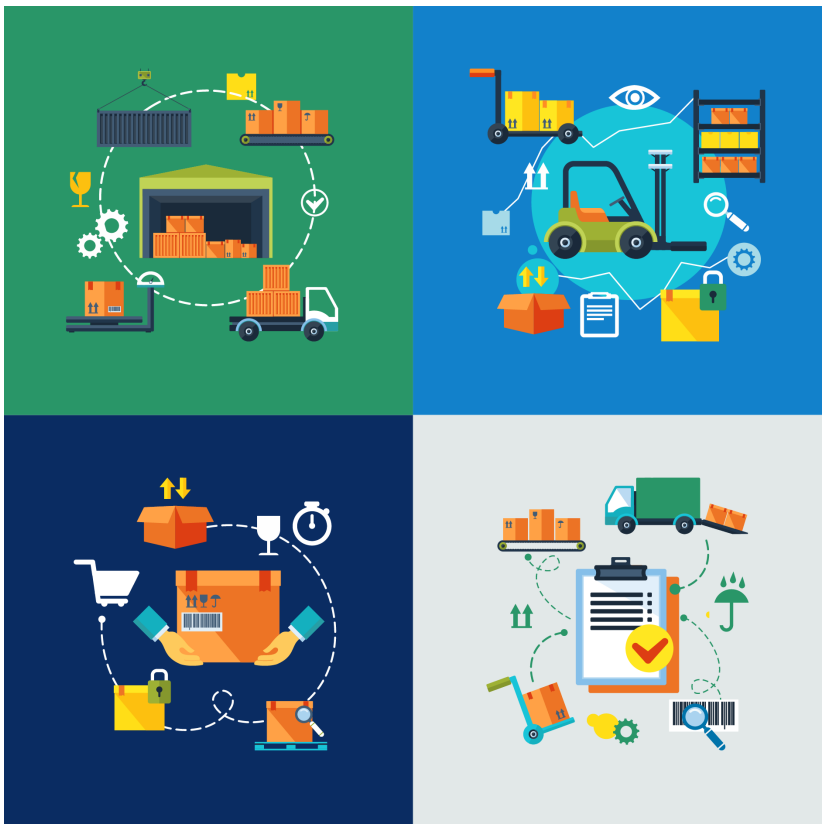
• Relevant SOP's for system use and administration were put in place.

• An OQ protocol was generated, approved, and executed in a Test environment. The OQ document directly related to the functional specification.

• A PQ protocol was generated, approved and executed to formally qualify the system in a live environment. The PQ provides documented evidence that the WMS computerized system performs as is required by our customer.

RESULT

The Validation Summary Report summarised all of the validation activities performed on the system. It verifed that the remediation activities were completed satisfactorily and that the customers WMS was in compliance with the Validation Master Plan.



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