



Warehouse integration project

Client: Pharmaceutical Company

Location: UK

Value: confidential

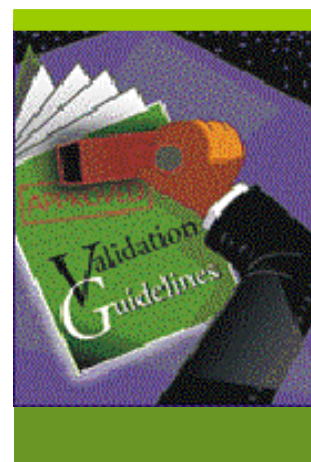
When the UK client was introducing a new integrated warehouse management system to a mature site with existing information management and MRP systems, they contacted ABB Process Solutions to assess the impact of the project and manage its implementation.

Ensuring the compliance of the whole system involved setting the validation strategy, leading the risk management process and managing the qualification activities surrounding the integration.

The purpose of the new Automated Warehouse and Distribution Centre was to provide storage for raw materials for both bulk and the dosage form manufacturing plants, in addition to providing storage and order fulfilment services for bulk exports and finished pack sales of Pharmaceutical and Animal Health Products to the UK and other markets.

The business processes in the 7440 pallet capacity high bay warehouse are realized using the new Warehouse Management System(WMS) which interfaces to several other Enterprise Computer Systems on site and other automated systems, for example five automated cranes. This complex structure required enhancements to the functionality of the site enterprise systems and the development of a bespoke interface. Careful management was required to ensure compliance with FDA and EU Good Manufacturing Practice regulations at all stages.

ABB consultants filled key roles in the project team with responsibilities for project management, compliance and business readiness of the integrated system. A validation strategy was adopted whereby this highly complex system was subdivided into smaller manageable subsystems. Using a GAMP 3.0 based life-cycle approach the majority of validation activities were conducted independently for each sub-system, with deliberate minimization of cross-subsystem activities. Strict change control and change planning were applied at all stages to manage the impact of changes between subsystems and across the integrated system.



In addition to the validation activities, ABB also monitored the Factory Acceptance Testing, audited the WMS supplier, and provided document review and administration services.

Project management and business readiness expertise ensured effective management of the Integration Project. SOPs and training were revised to reflect new business processes. The transition to the live production environment was also managed by ABB and a rapid cutover was achieved with minimal disruption to stakeholders.

On completion of the Warehouse Integration Project, a review of over 200 validation documents was carried out to ensure that any outstanding actions were appropriately closed off and that all documentation was complete prior to the preparation of the Validation Summary Report for the Warehouse Integration project.

The Benefits of this approach included:

- The successful delivery of the project, meeting all expectations of business management, QA and site operations
- A simplified project interface
- Opportunities were identified to simplify business processes and to reduce the scope of the validation activities



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