

M & A IT CARVE-OUT PHARMACEUTICAL MANUFACTURER PROJECT MANAGEMENT CASE STUDY

Client Profile	<p>Industry: Pharmaceutical Manufacturing</p> <p>Annual Revenue: \$125M</p> <p>Countries: 5</p> <p>Locations: 8</p> <p>Employees: 1,400+</p>
Challenge	<p>Having worked for the ownership previously on a similar project, Informatik Group (IG) was engaged to assist a newly formed Contract Pharmaceutical Manufacturer with an infrastructure and application carve-out along with the establishment of a new entity. Several sites were carved away from various well-known international pharmaceutical firms to form the new company. Location sites were in: Puerto Rico, USA (2), Ireland, and the United Kingdom.</p> <p>The challenge was to scope the carve-outs and lead the transformation activities, provide third-level steady state support, and to drive the transition and separation of applications, including SAP ERP, from Merck to Avara Pharmaceutical Services using the appropriate application and integration of project management processes identified for this project.</p> <p>Our client needed to disentangle from the Seller’s ERP system and establish a new SAP ERP system which added complexity to the implementation and project management approach and the timeline. Additionally, quality control is an essential operation of the pharmaceutical industry. Drugs must be marketed as safe and therapeutically active formulations must be consistent and predictable. Updates to existing systems and new system implementations posed unique validation requirements regarding computers and automated data processing systems and software changes before approval and issuance into production.</p>
Approach	<p>Working on sites that manufacture pharmaceuticals, IG’s team was required to adhere to Good Manufacturing Practice standards and provide a very high level of change control and documentation.</p> <p>Validation strategy included:</p> <ul style="list-style-type: none">• Standards for documentation such as version control, handwritten approvals, document naming and numbering convention, development of formats and templates.• Standards for testing such as pre-approval before execution, specific test instructions, expected results and actual results, reference to support documentation, test problem reports and resolution.

IG applied best practices by:

- Establishing only one project schedule
- Ensuring that validation as the responsibility of the business owner(s)
- Validating to satisfy business requirements, not the FDA
- Creating Quality Assurance and Validation at the beginning of project preparation and planning
- Communicating the validation requirements and expectations at the beginning of the project
- Maintaining one set of project standards and templates
- Applying rigorous change control and problem reporting
- Aggressively managing the feedback loop

Solution

IG developed a detailed project schedule which was approved prior to execution and established a detailed migration plan on how to transition from Current state to Future state.

Additionally, the team developed a business process scope definition, business blueprint and design documentation, gathered user requirements, drove unit, quality assurance, and user acceptance testing which included integration and UAT test scripts, and defect management.

Finally, IG applied ITIL compliant service and change management throughout the project life cycle.

Project Success Factors

The project scope was broad (warehouse, engineering, finance, procurement, purchasing, production planning, and execution, etc.) and it required a significant effort in data cleansing to convert legacy data into a format suitable for the new system. With project management, this dedicated effort was achieved prior to conversion.

For Project Integration and Project Quality Management:

- The overall level of preparation was deemed excellent with the number one objective of the project as process compliance which had an immediate impact on Avara's plant abilities to withstand an audit from the FDA.

For easy Change Management and Change Control:

- A less complicated infrastructure was established.

For Project Communications Management:

- Team members and stakeholders were extremely aware of the extent of the changes that were about to take place and for which they would have to take responsibility.



The application of an ERP-specific project management methodology put Avara Pharmaceutical Services at an advantage when implementing a highly integrated suite of applications where new control processes found acceptance more quickly than in a less regulated manufacturing environment.