



ARE YOU READY?

SAP S4HANA IMPLEMENTATION

CASE STUDY: COMPLIANCE &
REGULATORY ISSUES



SAP S4HANA Implementation

PROJECT OVERVIEW

The client, a large multinational pharmaceutical company, is implementing a new global ERP (Enterprise Resource Planning) system, SAP S4HANA, and needed an experienced professional to lead the Quality Workstream for the business. There are several consulting companies, each with specific technical skills in SAP implementation, hired to work with a core team of internal employees for the implementation. The scope is unprecedented in the Pharmaceutical Industry. All the SAP modules are being deployed in multiple global markets and manufacturing sites in record time - less than three years from project charter to full completion. This very aggressive goal necessitated SAP deployment in cut over waves and managing an interim state with two separate live ERP systems until all the markets fully transition.

The client selected CAI for this project for two reasons. CAI has been a trusted partner providing quality services for this Company at a competitive cost for many years, providing a variety of professional services. In addition, the agent that was selected to work on the project has unique Quality Management leadership skills required for success

CLIENT CHALLENGES

While the objective of the project is to use SAP without modification, the “out of the box” software solution does not meet all the business requirements for the Quality Unit. SAP modifications are required to tie together all the required Quality Systems to ensure that the product release process in SAP is comprehensive, compliant, and efficient. The solutioning is complicated by the need to incorporate the legacy systems and/or data that were outside of the original SAP system, which are all being replaced as well.

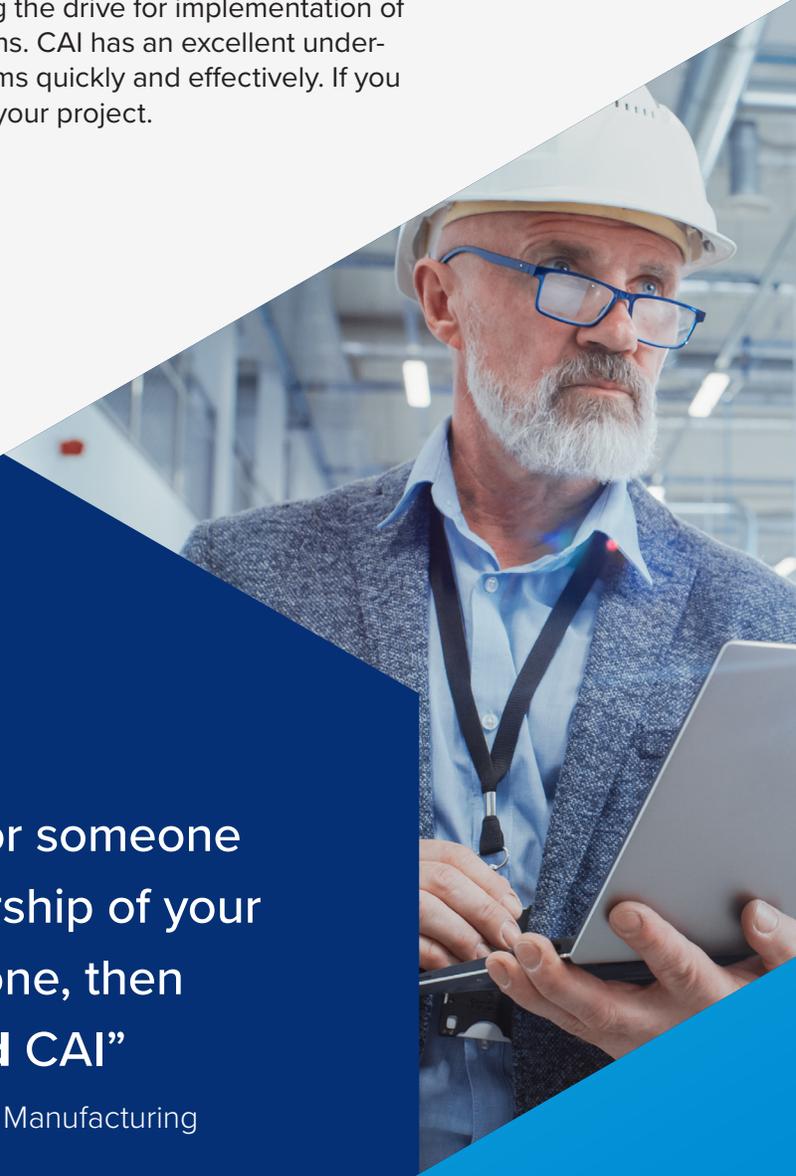
CAI SOLUTIONS

CAI provided a key resource to lead the Quality Workstream overseeing the scheduled activities necessary to meet business needs. Working side by side with the other consultants and with the internal client employees, new solutions are being developed, validated, and implemented. Interim manual solutions for inventory control and product release were identified and implemented as work groups transitioned from the legacy SAP system to the new S4HANA system in waves

PROJECT SUCCESS

The project is completing successfully and on time and to date. There have been no delays in product release and no compliance risks or gaps identified. The Senior Vice President Head of Manufacturing Quality and Compliance for the Company states “The S4HANA project has been a success for us to date, with about 30-40% activities to complete. We have managed to stay compliant with all regulations, while keeping the business moving forward. Excellent support from CAI to the project.”

In addition, feedback from another senior leader within the Company’s Quality organization is as follows: “I have worked with CAI consultants for over two years implementing SAP together in a complex global regulatory environment. CAI does work at a higher standard, communicates effectively and are very easy to work with. During the project, CAI has provided essential project management for our department to ensure we meet the aggressive timelines all while supporting the drive for implementation of industry best practices and efficiency in our operations. CAI has an excellent understanding of the industry, which helps us solve problems quickly and effectively. If you are looking for someone who can take ownership of your project.



“If you are looking for someone who can take ownership of your project and get it done, then **I highly recommend CAI**”

– Senior Vice President, Head of Manufacturing Quality and Compliance



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