

Project Overview

The main objective of this project was the implementation of the SAP S/4 system at the SUANFARMA production plant located in Italy, after changing ownership from Novartis.

The second main objective of this project was the implementation of SAP **FIORI** technology so that users do not access SAP GUI under any circumstances.

Using Fiori Library apps, made possible to add alternative apps to perform the business processes.

Thanks to SAP FIORI technology implementation, users have adapted faster to the new system, feeling comfortable using it in their daily routine, increasing their productivity in business processes and reporting tasks.

In all company's areas

Finance





Purchasing



Warehouse Management



Production Planning



Quality Management



Plant Maintenance



Sales



Distribution

Under SAP Pharmaceutical Best Practices





Business Needs

When planning the digitalization and modernization of our current systems, we thought of implementing SAP S/4 following SAP Pharmaceutical Best Practices. Using these guidelines helped us incorporate all applications needed to meet most of the business requirements right from the start.

We implemented SAP S/4 after considering its own powerful database with improved performance cross searches.

SAP FIORI integration enables a company like ours several important benefits:



agility in operations and management processes

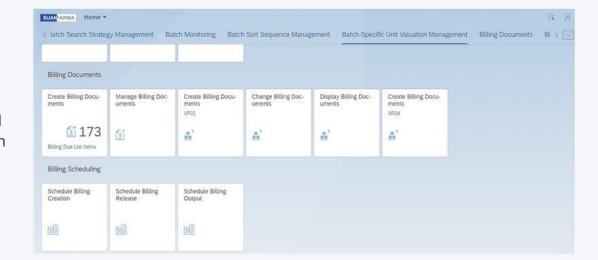


quick data retrieval from database which is critical to us because we need real-time data and



forecasting and effectiveness across different departments in the company

s/4 HANA based on FIORI and Embedded Analytics have provided the technological innovation initially required, enabling all intermediate controls in each area, user-customizable dashboards that have replaced and improved the previous functionality provided by SAP BW.



Key Success Criteria



Due to COVID-19 restrictions and Novartis setting January 1st, 2021, as the cut-off date for accessing its systems, all originally planned activities had to be **managed entirely remotely**



The system was validated in accordance with the GAMP and 21 CFR Part 11 compliance



100 users were affected by the transformation project, **different communication tools and methodologies** for remote project management were established in an agile way ensuring a right development of the project



Microsoft Teams application was established by both teams for meetings, consultations, training, etc.



Stratesys introduced **Sentient for Project Insights**, an innovative tool to facilitate project follow-up with which to analyze data almost in real time, favoring better decision-making



Business Requirements

During the meetings at the initial phase of the Project, every single requirement was detailed and classified by functional area and stored in the BBP document, which were developed in collaboration with both teams for each business area. A responsible person was identified in each area to help Stratesys consultants to develop, deploy and test the processes that were being implemented in the new system.

Using BBPs documents as a reference, the GAPs of the new system that needed to be developed for the accomplishment of the daily tasks of the users began to be identified. These GAPs were stored in an Excel file shared between the two teams, in which the control and monitoring of their development was carried out.

Our company was actively involved in the development of the system, collaborating as much as possible with the Stratesys team despite the difficulties caused by COVID restrictions. Suanfarma's IT director was also involved in the project on an ongoing basis, attending project management committees, refocusing the project path if needed, or helping solve technical problems, among other activities.

Stratesys executed a three phase SAP Methodological framework, which covers the full project life cycle:







Test







Implementation

Maintenance

Support of the SAP information systems

Project Methodology

The Project Management and the Delivery Model (Strate-MTH) methodologies are structured as a top-down format, where each phase of the project is detailed, and each phase is broken down into the tasks to perform. For every activity there is a detailed breakdown, describing the relevant tasks and marking key parameters as 'must-do' or recommended (attending to project dimension), functions, role matrix or key delivery products to perform on each task. Stratesys Methodological Model Strate-MTH is divided into 6 phases (3 for Delivery and 3 for Management), which are broken down into different activity flow charts.

Each activity is described through a detailed card, that includes all the tasks to be performed and supervised.

- General Phase Description
- Activities Flow-Charts + Activities Definition (1 Card per Activity)
- Inventory of Activities/Deliveries
- Description of Key Deliveries
- Roles and Activities Matrix

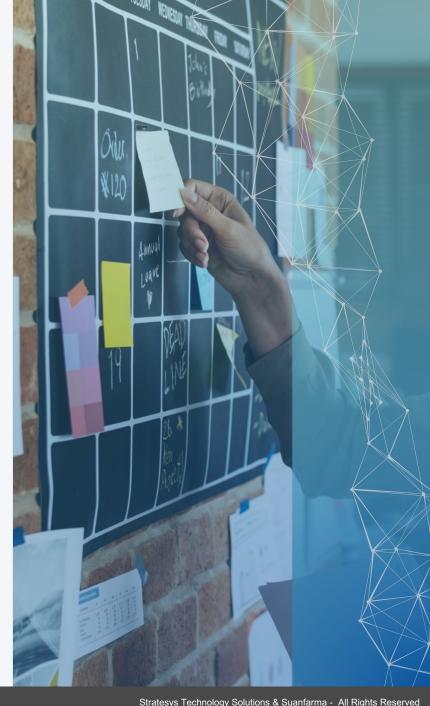
The most innovative feature we want to highlight was the activation by Stratesys' expert consultants of the Embedded Analytics solution integrated into SAP S/4 HANA as standard. Following the delivery of detailed manuals and the completion and recording of training sessions to key users, users were able to use this tool efficiently, verifying the benefits achieved compared to the solution available in the previous system. The most significant improvements achieved are as follows:



Availability of system information in real time, allowing to improve the decision-making process such as breakdowns in stock management caused by product quality problems that affect delivery times to the customer.



Increased number of users with access to high-value information. Since in the previous system they did not have access, nowadays the access to the current information of the company's processes has been increased and made easier, improving the operational situation.



Governance Model

Every internal work team designated a SPOC to act as the point of contact with Stratesys. These resources participated in the follow-up meetings, data requirement analysis, BBP validation and other activities together with external consultants from Stratesys.

During the first phase of the project, Stratesys consultants explained every SAP module and the corresponding standard functionalities to key users of each area to meet the company business processes and identify the GAPs to be covered by the SAP S/4 solution. Their extensive knowledge facilitated the understanding of the different processes to implement and develop the process flows in SAP to meet business requirements.

The internal areas of the company that have participated in the project are the following:



SUANFARMA Management team

IT Department





Key-users from each business area



PROJECT COMMITEEs

- Proper progress project management according to the agreed scope and milestones
- Closely monitoring the work performed by the assigned teams
- Approval of final deliverables
- Analyzing key decisions
- Identifying potential risks and other project needs
- Open issues monitoring solution proposal
- Report about the contingencies and project progress.

GOVERNANCE MODEL

- Detailed Planning -Project Launching
- Time Management -Resources Management
- Scope Management
- Supervision and Status Report

Thanks to the mechanisms proposed by Stratesys to monitor and control the progress of the project, we were able to reduce the negative impact of inconveniences that often arise in projects of this type and complexity.



STATUS REPORTS

- Global progress (project status and progress)
- Time and product advance rate (incurred / planned / estimated to complete)
- Budget status
- Taken actions
- Generated and delivered products Deliverable approval
- Next steps (next period activities)
- Potential Risks, open issues and decision-making

Scheduled deliverables for each phase of the project

This proposal was aligned with the designed project planning and kept full consistency with the proposed methodological approach.



PROJECT MANAGEMENT

- Project Planning
- Kickoff Meeting
- Monitoring and Control
- Change of Scope Document
- Follow-up Report
- Project Closure Report





- Requirements Analysis
- GAP Analysis
- Functional Specification
- Roles and Authorizations
- Components to Develop Inventory
- Interfaces and Integration Points Inventory



PROTOTYPE



DEVELOPMENT & TESTING

- Detailed Design and Development
- Test Planning
- Test Execution
- Master Data loading plan
- Functional Specifications
- Testing Plan



CHANGE MANAGEMENT

- Planning & Strategy -**Training Actions**
- End-User Material (User **Guides and Training** Video Recordings)



Time Delivery Methodology

We decided to follow Strate-MTH methodology because it is specially designed to support the management and delivery phases in SAP implementation projects and Stratesys has shown that this methodology has helped to ensure that a large number of projects are carried out efficiently.

- TO-BE process model
- GAP Analysis
- GAP Inventory
- Functional specifications design
- Authorization model

- Scope & definition prototype
- Interfaces & integration points inventory
- Conversion data strategy
- Technical design
- Test plan

ISO 9001:2015

Strate-MTH methodology follows ISO 9001 & ISO 15504 compliance rules, and SAP (ASAP) Methodology to achieve the different objectives of any implementation project.



Arplus[⊕] ISO/IEC 27001







People Management



The internal project team were led by management team, IT area and for each SAP implementation business area one SUANFARMA key user. Thanks to the fact that the key users in each area are experts in their business processes and procedures, it was possible to implement the new system in the simplest way and to solve the deficiencies of the replaced system developing customized functionalities.



Stratesys is an SAP leader company and their work team included Senior Consultants that have a lot of experience and knowledge in their business area and using SAP Pharmaceutical Best Practices in the system (logistics and inventory management, sales and finances), SAP Basis work team and SAP FIORI, S/4 Senior Consultants and Technical consultants with extensive experience who helped in the creation of each specific development and the management team of the project.



Each consultant that participated in the project is certified in their corresponding business area or at least have worked in several implementations similar to this project in the past, providing a high level of expertise and knowledge in the Pharmaceutical industry.





Quality Assurance Methodology

Key areas in order to ensure the project's quality and minimize risks:



GOVERNANCE MODEL

- Detailed Planning -**Project Launching**
- Time Management -Resources Management
- Supervision and Status Report



QUALITY & RISK MANAGEMENT

- Project Quality Plan
- Quality Assurance
- Risk Management



DOCUMENT MANAGEMENT

- Deliverables -Review and Approval
- Document Management
- Document Tools

Quality management implies:

- Establishing the necessary mechanisms for the project management team to coordinate, process and certificate the scope changing application appeared along the project development.
- Reporting the status and effectiveness of changes to the project committee.
- Documentation, inventory, and evaluation of changes of scope.

Stratesys has implemented an internal procedure to audit projects effectively and ensuring projects according to certifications.

Another important issue in quality terms, is the mechanism for monitoring and validating deliverable documents, in terms of compliance with the scope and quality to be accredited.

A previous content verification by Stratesys and SUANFARMA team (ie. the project manager) is suggested as necessary in every deliverable, to continue with the following reception-validation-approval process.

Stratesys proposed to generate the following quality and management documentation, in order to meet the SUANFARMA expectations for this project:

- Status Report Model
- Detailed Planning
- Kick-Off Presentation
- Scope Change Document
- Quality Plan
- Transfer Plan
- Project Close Report

Risk Management

According to Strate-MTH methodology, risk management is an essential activity to properly manage our technologic projects.

At the beginning of the project (Preparation Phase) an initial Risk Matrix was designed to identify, classify, evaluate, and manage the different key success factors. A mitigation action was defined for every risk to prevent or correct it.

The Risk Matrix was continuously being updated according to the requirements of each phase of the project.

In addition, several committees were performed between both companies to mitigate the identified risks.

Risks management implies:

- Risk identification, classification, and evaluation.
- System and control definition to minimize risks.
- Allowing taking decisions that mitigate risks, as well as identifying contingency plans for non-controllable risks.
- Verifying deliverables meet the quality standards. It requires obtaining approval and sharing different visions.
- Planning the documentation of deliverables and ensuring that products are generated according to the methodological approach and nomenclature rules, coding, documentation, etc. established and approved.

Internal work team follow-up meetings were held every week to validate the project execution, adopt new decisions by the project team, director and client, planning, etc. to identify as soon as possible the risks that could arise and taking the needed decisions in the right moment.

The main risks of this project that were identified and mitigated are the following:

- Geographic dispersion and language
- Coronavirus restrictions
- Delayed data extraction from the older system







Best Practices



In this project we used the perspective of a **GLOBAL TEMPLATE** at starting point, we have created an extension methodology to guide the delivery and governance of SAP S/4 HANA Corporate implementation projects, that will provide support for the deployment of business processes in various locations.



The corporate template (or Global Template) was developed under the project and was based on how SUANFARMA implemented a global process in the SAP S/4 HANA Corporate, **ensuring the alignment of processes in all locations**, generating standards and definitions in the processes set and uniform support to the business requirements of the various Divisions / Countries according to a common definition. The definition phase of the Global Template covered all business requirements of all locations except the specific legal and fiscal issues 2021 SAP Quality Awards



The principal key aspect for a good global template was the design based on **SAP Pharmaceutical Best Practices and the SAP S/4 standard functionality**. We requested some specific developments because as a Pharmaceutical and international company we need to fulfill some industry-specific rules. Some of these developments were also requested to adapt the standard process offered by SAP to the processes defined in SUANFARMA previously in order to increase the efficiency and productivity of users.



All developments not covered by the standard functionality were stored in an inventory by Stratesys. In this file, the developments were coded to **facilitate their identification and different values** were indicated such as approval date, estimated effort, observations, status or delivery date.



The SUANFARMA team ranked these developments according to their priority and it was decided to divide their implementation into 2 phases to efficiently distribute the work of the Stratesys functional and technical team.

Production Readiness

Stratesys testing methodology framework (Strate-TEST) controls all the designed activities to assess the system 's functional and technical quality, as well as its performance before moving into a production environment. Stratesys testing services framework methodology covered the design and execution of all necessary testing scenarios to verify that all requirements have been adequately covered and the system was properly implemented.

Strate-TEST testing methodology framework:

- Component Test: This is the first validation in the system. It ensures that each application component is properly implemented and the configuration and that programming work units have implemented the appropriated technical design specifications.
- Assembly Test: Ensures that individual components which have been component tested work together in a logical group of functions. Assembly test was focused on implemented or modified processes
- **Product Test:** Designed to test the system and associated systems (also the interfaces) taking the requirements into account.
- Three cycles: cycles 2 and 3 to solve possible cycle 1 errors.
- User Acceptance Test: As a proof that the application runs as expected and meets all customer requirements.
- Performance Test: Identifies and fixes system performance issues before the system go live.

After **Test Phase** was completed, we passed to **Training phase** that included an initial training to key users based on these parameters:

- Preliminary design of the strategy (training approach) and training plan in accordance with the identified training requirements.
- Development of material to support training session (including user manual).
- Initial Training of a group of key users of each module or system (project team training to users' trainees)
- Deployment of training sessions program.
- Monitoring of the training actions and assessment of the quality of training.
- Focusing on planning, training materials and manuals, deployment and assessment of the actions and training sessions are being delivered.

To ensure the proper skill set for the technical staff and support team, the Stratesys project team carried out a knowledge transfer with the support team to provide the project documentation and project-specific information to enable a transition with minimum user impact and maximum maintenance efficiency.



Change Management

The implementation of a new IT solution or a business model usually implies a bigger impact and complexity than the one expected by an organization.

IT Implementation projects cannot be usually reduced to a "simple" installation of a new IT tool, in terms of impact to end-users. In fact, they may represent a deep cultural change. According to our experience, some human capital aspects that might appear in projects like this one, and can imply risks, are the following:

- geographic dispersion,
- cultural and / or language diversity,
- need to develop new and complex skills in employees,
- adoption of new ways of working,
- resistance to change

Change Management Program



Communication to inform, motivate and commit all parties

involved



Trainingin the new systems, applications, and processes



Post Go-Live Support to solve and follow-up on questions, issues or requests demanded by end- users

Based on our experience in similar projects, we understand that the design and implementation of a communication plan or set of actions to promote the launch of the new system can bring great value to the project, especially through activities aimed at informing, motivating and involving the end-user's community and other stakeholders.

The Communication Plan was designed in the early stages of the project and will be run along it, synchronizing communication actions with milestones and project phases.

The principal issue here was that we worked with a simple system and a lot of processes were based in Excel files, and now we can work with all processes unified into a robust and modern system using the latest technology, we can do all our daily processes with a mobile or a tablet if we want.

Change Management



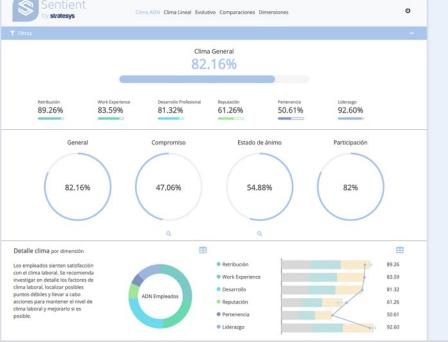
Sentient for Project Insights provided the data needed to visualize dashboards to measure the team's perception of project status and risks. This data could be consulted by all Suanfarma and Stratesys staff, or any other stakeholder who had access to it. Sentient helped us to interact between both teams in a much more efficient way. The goals achieved by this tool are the following:

- Provide sentiment insights on how the users are perceiving the activities made by the Stratesys Team (Meetings, Deliverables)
- Collect objective data to measure quality of the team performance

Thanks to Sentient, there was a continuous evaluation in the project management committees by both parties, allowing visibility of users' feelings, regarding the unavailability of the consultants in person and effectively managing the changes caused by the development of the project.

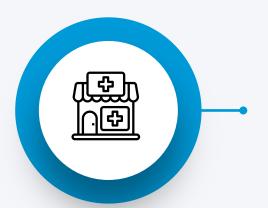
To increase visibility of the status of the project, the project manager assigned by Stratesys, set up a weekly communication every Friday, in which he informed project managers and key users of the tasks completed, those that were experiencing delays and the tasks to be completed the following week. In addition, follow-up meetings were held with project managers and leaders on a fortnightly basis.







Implementation time and costs Reduction

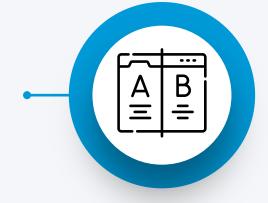


SAP Pharmaceutical Best Practices and standard functionality in as many business processes as possible.

This reduced the costs of implementing this project and of future system changes, as well as a simpler and more stable system.

This project was divided into two implementation phases that allowed us to reduce costs and time in the different phases of the project.

Workers had the least possible impact on their daily work and reduced considerably the risks and the efficiency of the internal work processes in the company.







Key challenges

COVID-19 and all regulatory constraints

Increased efforts, highlighting Stratesys' total availability and dedication



Lack of knowledge on SAP S/4 and FIORI technologies

No one in the organization had prior experience



Platform change management

Minimized impact and organized for the project success

With the help of Stratesys consultants, we started to work immediately without major problems after material master data was loaded in the system and we started creating purchase orders, sales processes, financial balances, etc.

Success Factors



Key **Contributors** to Success

Team involvement and dedication





Communication between both teams



Project development into 2 phases

Actual Business Benefits - KPIs









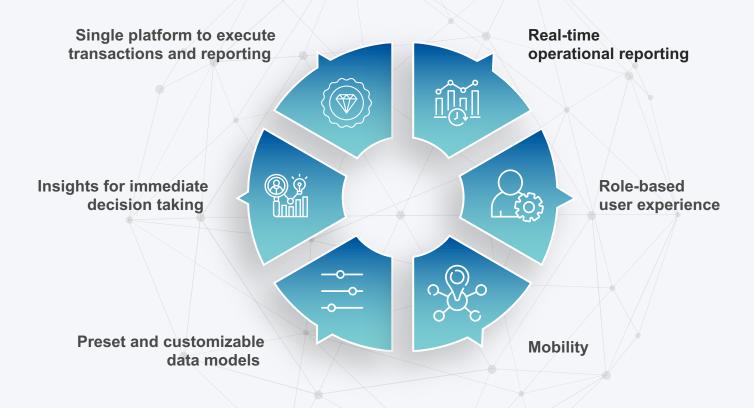




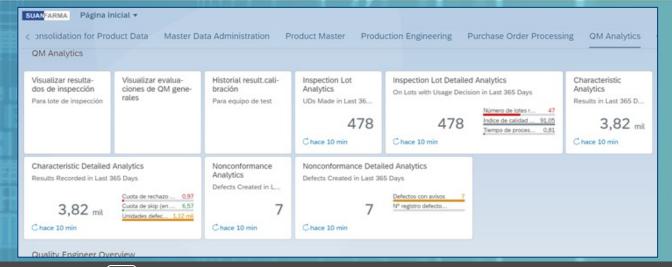
Project Innovation Technology Main Benefits

Embedded Analytics component included in the SAP S/4 HANA standard solution.

Its operational reporting on live transactional data to analyze real-time data using only SAP FIORI applications.



Embedded Analytics has contributed to improve the daily work of our employees in terms of productivity and convenience with the main work tool



Project improvement areas identified



Data migration and other data issues



Testing



Technical performance, integration, and interfaces



