SAP S/4HANA Implementation Success Brings Penicillin Production Back to the United States

CASE STUDY

EXECUTIVE SUMMARY

In light of recent current events, the United States has begun to see the critical need for pharmaceutical companies to reshore production for essential medicines, including drugs. To date, the United States has remained heavily dependent on China for critical antibiotics, as little to no pharmaceutical companies have manufactured these drugs within the country for many years.

Now, a recently acquired amoxicillin manufacturing plant is ready to reopen and begin arming the U.S. with domestically produced antibiotics but were struggling to align their business and technology processes in a quick and cohesive manner. After surveying a variety of potential vendors, USAntibiotics made the decision to engage with ITRadiant and Court Square Group on this streamlined project.

Together, ITRadiant and Court Square Group partnered to help USAntibiotics migrate and implement a robust SAP S/4HANA 1709 solution in just 16 weeks, as well as provide ongoing support for the preparation of validation documentation, training, and testing beyond the initial launch of the new system.

ABOUT THE CLIENT

USAntibiotics is a global leader in pharmaceutical manufacturing, with more than ten manufacturing facilities spread across three continents. USAntibiotics' extensive portfolio consists of more than a hundred high-quality molecules which cover a vast array of therapeutic segments and caters to more than fifty international markets around the world. As a proven leader in innovative medicine, USAntibiotics believes that research and development of products and processes that will fundamentally change lives should always be at the forefront of everything the company does.

THE CHALLENGE

It was recently announced that USAntibiotics' Tennessee-based antibiotic manufacturing facility and related assets will reopen and once again begin manufacturing and packaging amoxicillin-based products. In order to start production, the drug manufacturer needed to migrate and rebrand an existing, off-shore SAP system to fit their new business model within six months.
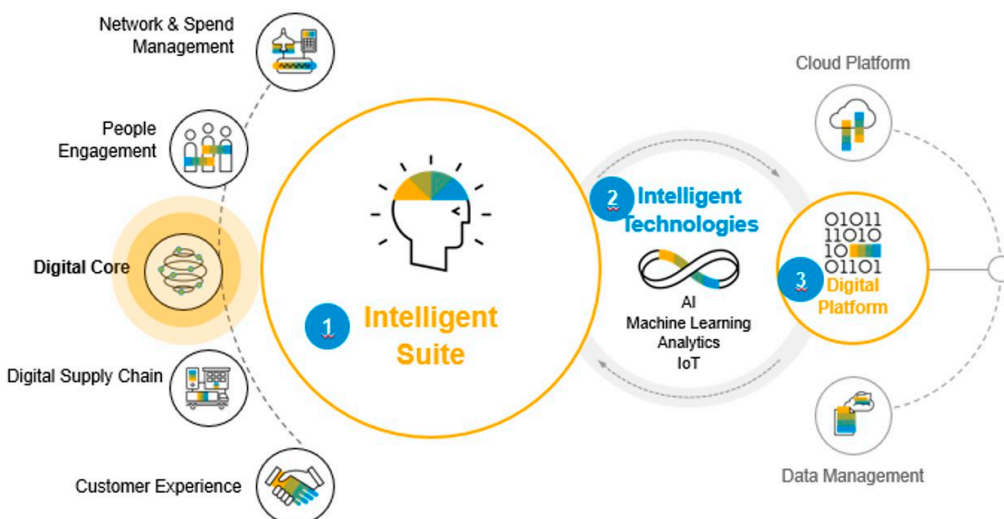
Since the parent company's SAP model did not fit their exact needs, including a lack of finance, sales, and distribution business processes, the newly created solution required these sections to be seamlessly integrated. Additionally, there were gaps in some areas of the previous SAP that needed to be addressed, as well as key considerations concerning the manufacturer infrastructure to determine if cloud hosting or physical servers would offer a better solution.

While migrating an existing system is more challenging than fresh implementation, the process was broken down into incremental steps over the span of six months: project preparation, solution mapping and realization, user acceptance testing, cut-over and final preparation, and go-live and hyper-care support stages.

THE SOLUTION

USAntibiotics chose a cloud-first strategy for their new SAP S/4HANA environment and Court Square Group was able to provide SAP Certified hardware/software capabilities in a qualified manner within their ARCC (Audit Ready Compliant Cloud™). Since the ultimate solution needed to be validated for regulatory compliance needs, Court Square working in conjunction with ITRadiant was able to provide the entire Development/Test/Production environment to USAntibiotics within weeks of signing a contract. Court Square Group's cloud team worked hand in hand with the ITRadiant team to implement the underlying cloud environment that enabled ITRadiant to install the new version of SAP S/4HANA within a qualified and validated state. The combined team was able to provide secure external access to mission critical resources while maintaining regulatory compliance along the way.

SAP Life Sciences vision : Delivering personalized patient solutions at scale and as a service by leveraging digital supply chain in the intelligent enterprise

Image By SAP

The Intelligent enterprise framework

1. **Intelligent Suite**
   - Integrated business applications to run end to end solutions and business networks

2. **Intelligent technologies**
   - Advanced analytics
   - Internet of things
   - Machine learning /Artificial intelligence
   - Robotics process automation
   - Block chain

3. **Digital platform**
   - Data management to mange a consistent data foundation for digital processes
   - Experience data along with Operational data

This cohesive SAP S/4HANA 1709 solution completely replaced the ECC 6 EHP 7 previous version, allowing thirty-five users in two separate locations to utilize the new technology. This solution covered Financials, Sales and Distribution, Procurement, Plant Maintenance, Production Planning, Quality Management, Warehouse Management, Laboratory Information Management Systems (LIMS), Document Management System (DMS), and SAP Fiori.

THE RESULTS

The successful migration and implementation of this SAP S/4HANA 1709 system had a variety of far-reaching benefits, including:

- Migration from an on-premise environment to an Audit Ready Compliant Cloud™ environment

- Implementation according to a Fixed Cost, Fixed Time model

- Most of the work on this project was able to be done remotely, saving time and financial resources for all parties involved

- IQ, OQ, and PQ validation was conducted in parallel

- The system was established and stable from the beginning, never necessitating a single program termination

- User adaption process moved along smoothly and quickly upon launch

- Stable and secure ARCC hosting for entire solution without disruption to compliance processes

The 360,000-square foot facility will focus on producing penicillin-based Amoxicillin which accounts for 30% of all antibiotics prescribed within the U.S., as well as Amoxil Clavulanate. As the company ramps up to full production, they will be capable of producing 300 million capsules and two billion tablets yearly, both numbers essential to stockpiling enough amoxicillin in America to last up to five years, essentially freeing the U.S. from being dependent on Chinese manufacturers.

WHY COURT SQUARE GROUP AND ITRADIANT'S SOLUTION WORKED

With proven expertise in the life sciences industry as well as these vendors' ability to move quickly and flexibly, USAntibiotics was pleased with the end results produced by Court Square Group and ITRadiant. By working with Court Square Group, ITRadiant was able to implement their solution much faster in a highly regulated environment without worrying about encountering compliance complications down the road.

"These professional team[s] have proven to be a critical business partner providing exceptional service in the intake, setup, validation, go-live, and ongoing maintenance processes of our enhanced SAP HANA system for pharmaceutical operations," says USAntibiotics's plant head and general manager, Ronald Maye, "The team delivers on time and in full, and their customer service profile is surpassed by none."

ABOUT ITRADIANT

ITRadiant is a US-based information technology service firm dedicated to assisting life science organizations build, migrate, and implement new age SAP solutions while leveraging their team's vast experience in full-cycle, tailored project launches.

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ABOUT COURT SQUARE GROUP

Court Square Group is a qualified hosting, validation, and audit-ready compliant cloud (ARCC) provider for organizations of all sizes within the life sciences, biotech, pharmaceutical, and medical device industry. As a premier strategic technology advisor, Court Square Group's team of dedicated experts blend regulatory compliance needs of the organization with innovative technology solutions to offer streamlined results.

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