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PTC Therapeutics increased efficiency and reduced risk



Transition to SAP
S/4 HANA Cloud,
Private edition

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PTC Therapeutics is a fast-paced US biotechnology company operating in the rare disease space, where change is the only constant. The company embarked on a transformative digital journey to improve operational efficiency and support growing commercial production. This case study provides an in-depth review of the effort, including:

- The decision to adopt SAP S/4HANA Cloud, Private Edition
- Project accelerators and planning best practices
- Maintaining regulatory compliance for IT system validation
- Operational and business impacts

Background

Challenges and limitations of existing ERP system

PTC Therapeutics, headquartered in Warren, NJ, is at the forefront of developing treatments for rare diseases. As the company grew, it required a more robust and scalable enterprise resource planning (ERP) system to manage increasingly complex operations. For example, PTC's external supply chain model crosses over 35 countries, involving many legal entities and complex transactions.

PTC's existing ERP solution proved inadequate for handling the intricate requirements of internal manufacturing, supply chain management, and financial management for pharmaceutical production. The limitations of their existing ERP solution were especially apparent as the company transitioned from preclinical and clinical stages to full-scale commercial operations. In addition, their existing solution was deployed in a public cloud, which meant expensive testing and validation of software upgrades every quarter to maintain GxP guidelines and regulations for the pharmaceutical industry.

The decision to transition to SAP S/4 HANA Cloud, Private Edition, was driven by the need for a more robust system capable of supporting these complexities, especially in a highly regulated environment. In addition, a private cloud solution meant they could manage the timing and frequency of upgrades, ensuring the ERP system remained in GxP compliance.

Chris Famula, Head of Enterprise Applications and Data at PTC Therapeutics, led the initiative, leveraging his extensive experience in IT and SAP implementations to drive this mission critical project.

Key project goals

Simplify transactions with a multi-tiered supply chain

SAP's well-established business network means PTC could easily interface with their Contract Manufacturing Organizations (CMOs), providing the opportunity to automatically communicate manufacturing quality information such as expiration and batch genealogy.

PTC felt the network would solve the complexity of financial interactions with their multi-tiered subcontractor matrix. When PTC partners are also on the SAP business network, the two-way integration creates a standard across all subcontractors, thus avoiding a bespoke integration with each supplier.

Create a common supply chain and finance ERP system

Connecting PTC's supply chain and finance models was also a major requirement for the project. In the past, PTC manufacturing and finance teams operated on two completely different ERP systems. In addition, multiple offline manual processes were documented and managed via spreadsheets. Given the upcoming transition to commercial operations, PTC needed to modernize, streamline, and automate workflows.

Adopt a private cloud solution

PTC's existing ERP solution ran in a public cloud, which meant software upgrades were continually pushed to them without control over timing. Adhering to GxP guidelines for IT software requires costly Computer Systems Validation to maintain compliance with their ERP system. The choice to move to a private cloud implementation gives PTC control over upgrade schedules, ensuring their IT systems always remain compliant.

PTC liked that SAP's private cloud has a time-tested GxP package, including all the SAP Computer Systems Validation documents for implementation, operational, and performance qualification. Process stages, pre- and post-approval for test scripts, User Acceptance Testing (UAT) workflows, defect handling guidelines, and GxP compliance requirements were readily available to the project team.

Integrate clinical trial supply chain management

Integrating PTC’s clinical trial supply chain management into the ERP system was a major requirement for the project. In their experience, clinical trial supply chain management systems completely differ from conventional supply chain systems. They are typically managed by different personnel, and study protocols and timings must be meticulously tracked. If any timings are broken within a multi-year trial, the entire clinical trial is undermined. From an IT perspective, that means ensuring the ERP systems are designed to incorporate information on the trial protocols, studies, patients, etc.

SAP has a long investment history in process industries such as drugs, chemicals, and food. PTC was eager to access additional functionality provided by SAP to meet their unique needs. SAP’s solution also has the intelligence to connect the clinical trial systems data with those used in the underlying supply chain planning systems.

Partner with experienced consultants

Choosing the right implementation partner was crucial for project success. PTC selected UST, renowned for its deep understanding of the life sciences sector and its consistently successful track record in GxP-validated SAP implementations. UST’s platinum service represented decades of experience and investment in their SAP practice. In addition, the UST team has an extensive background in designing and implementing ERP systems that solve the unique challenges of a life sciences supply chain. UST expertise and tailored approach were instrumental in ensuring a seamless and effective deployment of the new SAP solution.

“ UST provided platinum-level consultants with decades of SAP experience. **Chris Famula.**

Public vs private cloud ERP solutions

Full-scale on-premises GxP ERP solutions

Pros	Cons
<ul style="list-style-type: none"> • Strong platform for strategic enterprise requirements in Life Sciences manufacturing • GxP-compliant (validation testing control) • No auto-pushed upgrades 	<ul style="list-style-type: none"> • Can be costly, especially for companies who want to start with a small footprint • Hardware and infrastructure must be maintained

Light-weight public cloud ERP solutions

Pros	Cons
<ul style="list-style-type: none"> • Only pay for what you use • Easier to scale in the future • No hardware or infrastructure to maintain 	<ul style="list-style-type: none"> • Public system has a quarterly ‘push’ model for upgrades not suitable for GxP CSV • Limited presence in Life Science internal manufacturing • Weak Life Science processes and functionality

Only implement and pay for the design you need initially...



but choose a platform that will support tomorrow’s requirements

SAP Single tenant private cloud for GxP

Project accelerators

UST leveraged internally and externally developed project management techniques and frameworks to guide and accelerate the transformation.

Best practices planning template

Having worked with many highly regulated manufacturing companies, UST has developed a best practices template to improve the quality of the planning process. Projects are kicked off not with a typical whiteboarding session but with an actual system design that precisely defines target business process flows and system configurations. UST customers have experienced as much as a 70% acceleration in deploying SAP solutions with this templated planning approach.

PTC conducts business in 50 countries, has a multi-tiered CMO structure, and has highly regulated internal manufacturing processes. Given the complexities of PTC's business, establishing a realistic strategy for project implementation was essential. UST also wanted to ensure the platform design had a long-term vision for key business objectives, so a multi-year roadmap was also defined.

During the end-to-end mapping workshops, pain points and risks were documented to ensure PTC's needs were comprehensively addressed. For example, many of the issues outlined by the project team resulted from inefficient manual processes that often led to human error. Without automated workflows, reporting was weak, resulting in a lack of visibility to internal manufacturing metrics, which would be particularly problematic as they ramped up manufacturing. Detailed impact of these problem areas identified by the team included:

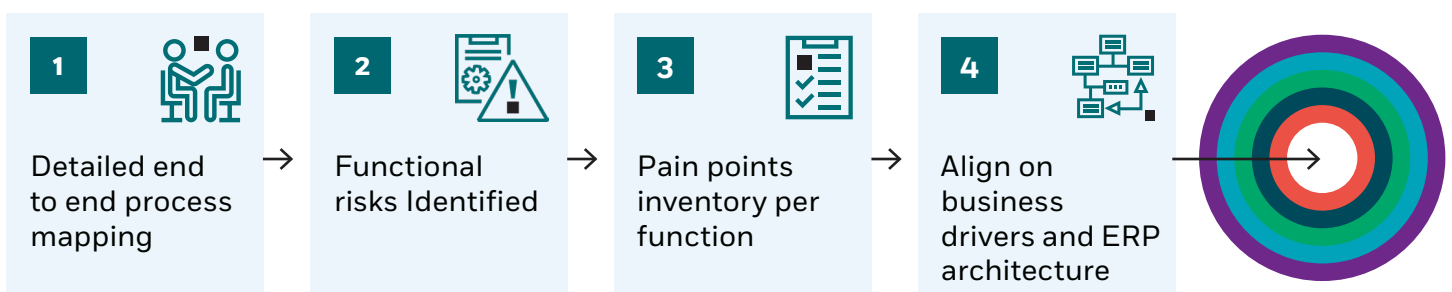
Manual processes:

- Cost data was entered manually because the procurement system was not directly linked to finances sub-ledger inventory data
- Inventory orders were manually entered
- Goods receipts required a 3-way matching process between disparate ERP systems and spreadsheets
- Manufacturing planning was done via spreadsheets
- Quality data was collected manually in spreadsheets and required a secondary check to verify accuracy

Lack of visibility:

- Difficult to locate materials needed to meet audit requirements
- Unable to trace orders after shipping
- Unable to trace CMO inspection lots
- Inspection data tracked manually
- No view of CMO inventory levels
- Manual accounting practices delay month-end processing

UST end-to-end mapping workshops



SAP Activate

The UST team also leveraged and enhanced SAP's Activate Methodology to solidify implementation plans for S/4 HANA Cloud, Private Edition installation. Activate is a project management framework that outlines project goals and implementation phases specific to the solution, ensuring an effective and efficient process. Built on the Agile continuous improvement methodology, the SAP Activate methodology takes an iterative approach to improve project quality.

UST worked with PTC stakeholders to document key activities and deliverables for Activate's six project phases: discover, prepare, explore, realize, deploy, and run:

1 Discover

This Discover phase improves system design quality by detailing the existing IT landscape and what will be impacted by the transition to SAP. As part of the Discovery process, the UST team conducted architectural reviews, created an inventory of assets, documented application dependencies, and outlined transformation risks.

2 Prepare

As the project team was onboarded, roles and responsibilities, project governance procedures, and an escalation matrix were documented. The project team then collaborated with business process owners to outline requirements using SAP's Business-Driven Configuration Assessment questionnaire. The initial project scope was finalized and ready for kick-off.

3 Explore

The project team conducted a fit-to-standard analysis, which validated the solution's functionality in the project scope and confirmed that the business requirements would be satisfied. The fit-to-standard exercise also matched PTC's business processes to the best practice processes documented by SAP.

The team captured optimizations and relevant standard configurations provided by SAP. Any gaps were added to the backlog for use in the next phase, along with requirements for workflows, reports, integrations, enhancements, and forms (WRICEF). Deliverables were signed off, and business users started working on data consolidation, cleansing, and formatting for the migration from the older systems.

4 Realize

In this phase, the project team incrementally built and configured an integrated business process and system environment based on the backlog document. Unit, string, integration, and user acceptance tests were also executed.

Master data is loaded into the system, and data migration testing verifies that data is in the correct format and ready to import into SAP. In addition, this is the project phase where end-user training is planned, and preparation for the cutover of configurations, master and transaction data, and WRICEF objects begins.

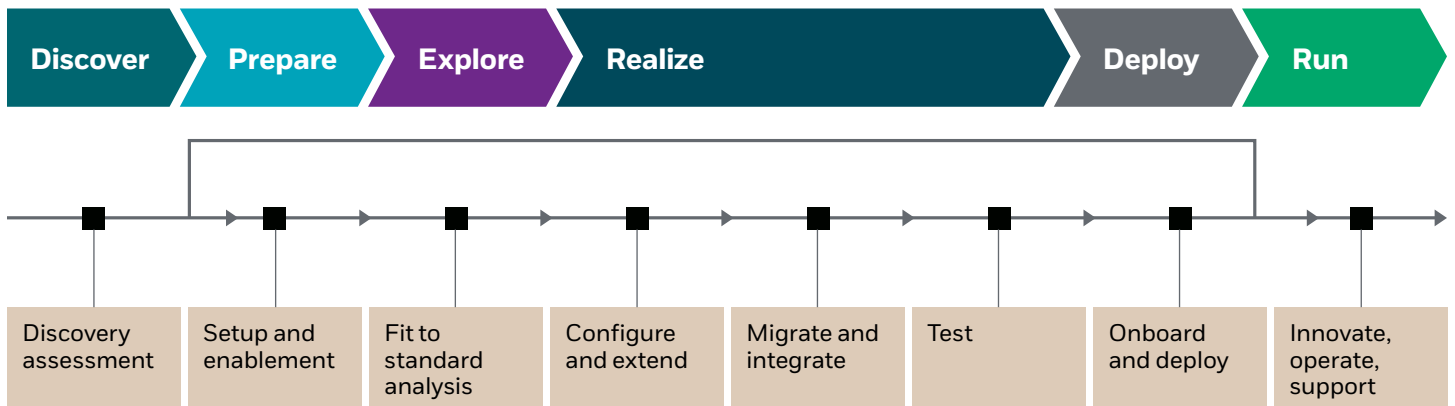
5 Deploy

In this phase, the team prepared the production system and confirmed organizational readiness. The cutover required downtime, so it was completed over a weekend to minimize user inconvenience.

6 Run

After the system's go-live date, UST followed pre-determined hypercare protocols for post-implementation support. This involved closely monitoring performance and quickly responding to issues, concerns, and feedback. Knowledge transfer to PTC was completed, and defects in documentation were resolved.

SAP Activate Methodology



Change management rigor

Change management was a central focus throughout the life of the project. For example, the well-documented software delivery lifecycle, including demonstratable data integrity and version control, ensured a GxP-compliant process for S/4 HANA Computer System Validation.

PTC emphasized the importance of thorough preparations for deployment, including rehearsals and mock data loads into the new system. This proactive approach helped mitigate potential issues and prepared the staff for new workflows.

By investing in the core tenets of change management, UST pre-empted long-term problems. Communications around the project created awareness and excitement across the organization. UST developed training materials to empower employees directly working on the project. Training encompassed system transactions, process workflows (including some manual steps that still existed), exception handling, and run-time guides. With a solid training foundation, IT teams were well-equipped to manage the dynamic and organic evolution of the complex solution in production.



Results: Increased efficiency, reduced risk

One of the biggest benefits of the massive transition was that PTC could evaluate and automate business processes while also leveraging SAP's value-added capabilities.

For example, because PTC works with over 50 companies worldwide, bank statements reflect a variety of currencies. The finance team had to convert the statements to US dollars manually. Leveraging SAP's multi-bank connector, PTC automated these manual financial reconciliation tasks. They saw a significant improvement in workflow speed and reduced human error, and 'a happier finance department' says Chris Famula.

PTC adopted SAP Ariba as its procurement solution to improve collaboration with supply chain vendors. Ariba's cloud information gateway provides a large ecosystem of integrations and IT architecture mappings. Since many of PTC's vendors were already on the SAP Business Network, connecting and automating workflows is much easier. The project team discovered that implementing the Ariba gateway created complexity with the business logic of PTC's systems and backend data models. However, since SAP owns the solution, PTC felt there was one 'one throat to choke' if they ever ran into problems such as an upgrade causing an issue. PTC now manages its supply chain vendors more effectively and can respond faster to unforeseen changes and challenges.

The new SAP system also significantly enhanced supply chain planning. Time-consuming and error-prone offline manual processes were transformed into automated workflows, improving inventory accuracy and reducing the workload for the supply chain team.

The issues identified during the planning phase were eliminated by combining disparate supply chain and financial systems and siloed spreadsheets. For example, PTC now accurately reports on business metrics. The additional visibility has fostered a culture of continuous improvement by measuring and reporting on the efficiency and accuracy of business processes.

Since implementing SAP, the PTC team has received glowing reports from across the organization, including procurement, finance, and the user community. Ongoing support from the business helps ensure long-term success for this project and future IT initiatives.

References

The Beginner's Guide to SAP Activate, SAP Community

[The Beginner's Guide to SAP Activate – Best Practi... - SAP Community](#)

Preparing for Fit-to-Standard Workshops, SAP Learning

[Preparing for Fit-to-Standard Workshops \(sap.com\)](#)

SAP Activate Methodology: Improve Project Quality and Success

[SAP Activate Methodology: Improve Project Quality and Success | LeanIX](#)



For more than 24 years, UST has worked side by side with the world's best companies to make a real impact through transformation. Powered by technology, inspired by people and led by our purpose, we partner with our clients from design to operation. Through our nimble approach, we identify their core challenges, and craft disruptive solutions that bring their vision to life. With deep domain expertise and a future-proof philosophy, we embed innovation and agility into our client's organizations—delivering measurable value and lasting change across industries, and around the world. Together, with over 29,000+ employees in 30+ countries, we build for boundless impact—touching billions of lives in the process.

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