

Benefits of SAP Business ByDesign for Life Sciences companies.

October 2023

As the biotech industry continues to evolve rapidly, Biotechnology Organizations must implement solutions to overcome limitations and disconnected business systems that impede their growth potential.

Companies require a system that can be utilized across the entire organization, from daily operations to management, enabling informed decision-making based on real-time data.

SAP Business ByDesign ERP is a flexible and scalable solution that allows companies to implement industry best practices at a competitive cost. It provides clear dashboards that can be shared, printed, or imported into presentations in real-time. It eliminates the need for management to spend days assembling data for presentations that is outdated in minutes.

In the life sciences industry, SAP ByDesign offers capabilities and benefits for companies such as efficient and integrated molecules project management with clear and real-time dashboards that track progress and identify areas at risk.

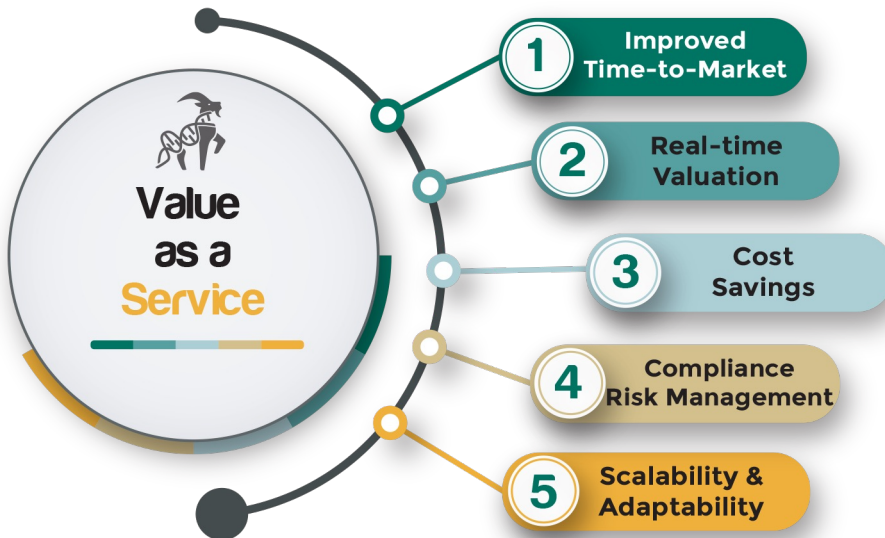
Additionally, R&D costs can be captured using multiple GAAP requirements for management reporting, statutory filings, and tax books. Each asset can be configured separately and indefinitely without affecting financial packages. The Valuation is clear, auditable, and in real-time.

Leading SaaS companies in the life sciences industry, particularly in lab management and validation, have developed specific applications that can be easily integrated thanks to the "click not code" concept.

Lastly, ByDesign ERP is highly valued by investors and plays a decisive role in acquisitions and mergers. It is not only because of compliance and risk management but also because it is designed to seamlessly integrate with SAP S4, making it a must-have for best practices.

In the following pages you will find a detailed use case, using simple concepts and examples, of the capabilities and benefits of SAP ByDesign for Life Sciences companies.

More than services, Value!



Improved Time-to-Market

- 🔧 Plan and manage the life cycle of therapies and drugs, real-time.
- 🔧 Pro-active & strategic planning.

Real-time Valuation

- 🔧 Informed decision making.
- 🔧 Different approaches for valuation: Cost, Income, etc.

Cost Savings

- 🔧 Implementation ROI < 12 months.
- 🔧 Decrease in Audit Fees.
- 🔧 Elimination of redundancies.

Compliance & Risk Mgmt

- 🔧 Digitization of Regulatory requirements.
- 🔧 Industry best practices.

Scalability and Adaptability

- 🔧 3rd party apps easy integration.
- 🔧 Built-in connectors for S4 Hana.
- 🔧 Click not code methodology.

Benefits of SAP ByDesign for Life Sciences companies.

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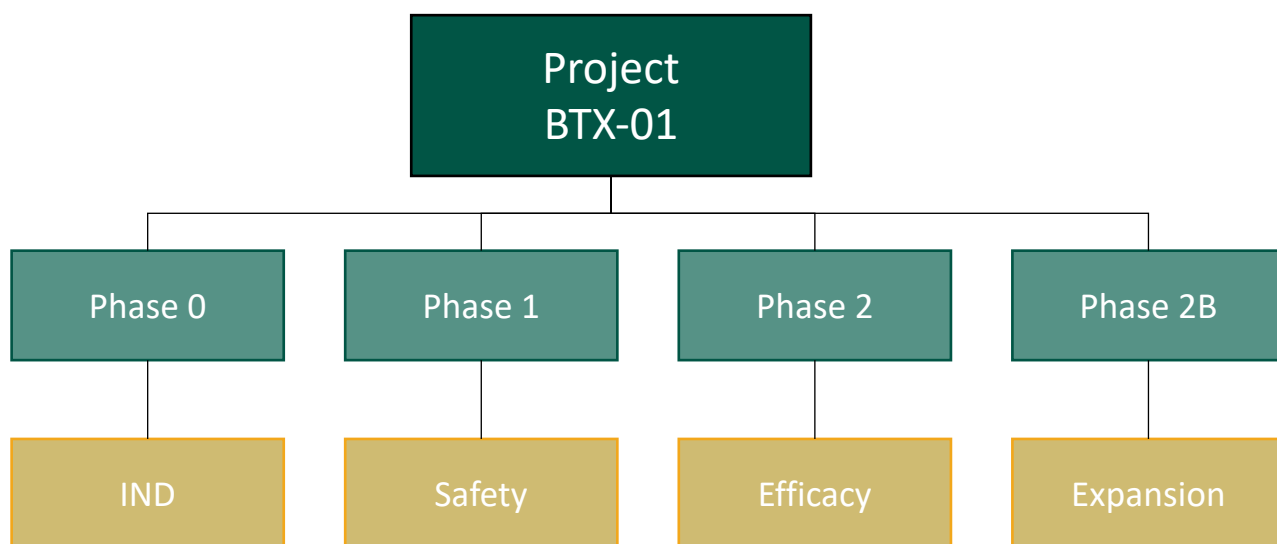
Use Case of SAP Business ByDesign

Capabilities and benefits of SAP ByDesign for Life Sciences companies.

Scenario Overview

We will observe the life cycle of molecule BTX-01 and the several phases of development (Discovery and IND in Phase 0) as per the below. We will look at the works of the Phase 2.

Project Planning

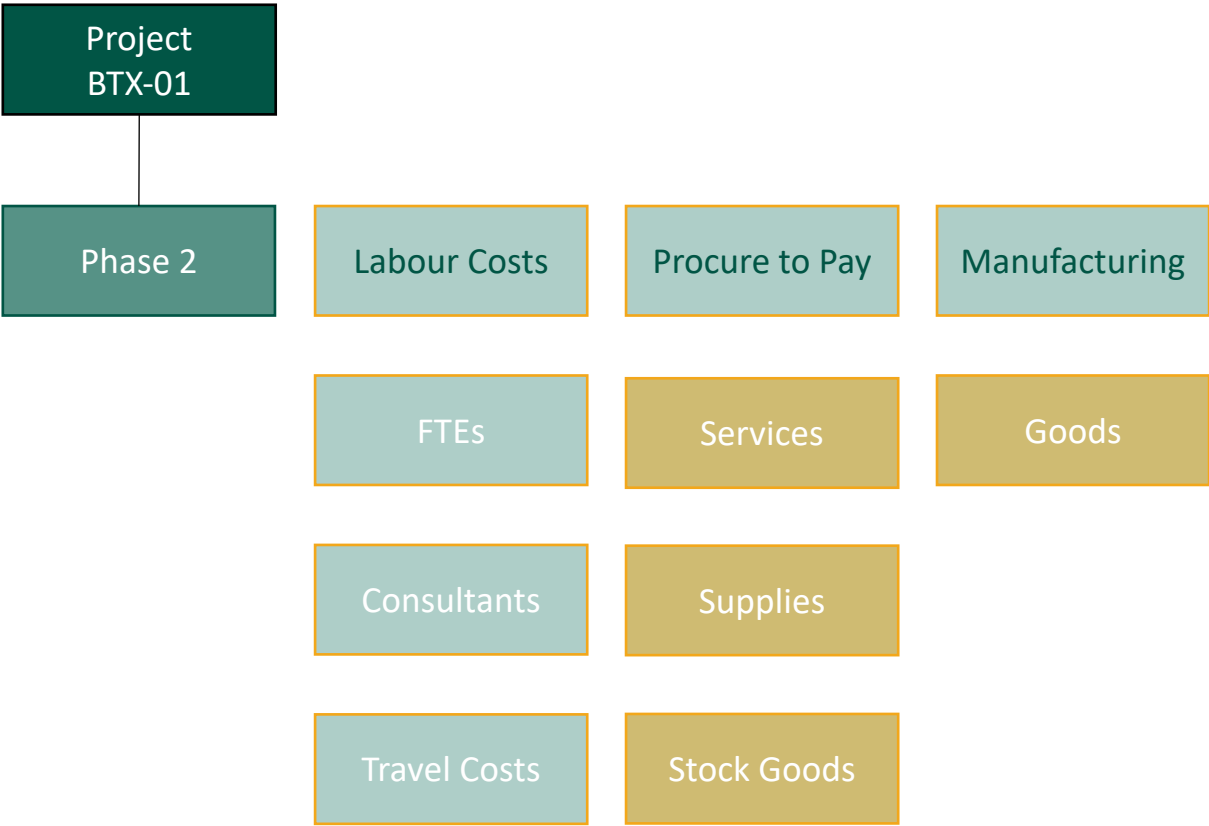


In the Phase 2 costs monitored will be labour costs, internal and external, travel costs, materials used for production, manufacturing and billing (sales).



Use Case of SAP Business ByDesign

The Project Management business scenario enables you to plan and execute the entire lifecycle of projects of any scope. It provides the core processes required to manage projects, including scheduling, resource staffing, and cost estimation and management.



Use Case of SAP Business ByDesign

Labour allocation.

During the month, the Clin Ops cost center reported in their time sheets that 25% of their time was spent on the molecule. Allocation of time sheets can be done by individual.

QA reported 12% and T&E costs for site audit. Travel were approved thru the **T&E budget approval request**.

Also, the CRO appointed one consultant who will work on the project and billed for his time.

Labour Costs	FTEs	Consultants	Travel Costs
Clin Ops	25%		
QA	12%		Site Audit
Medical	35%		Congress
MFG	55%		
CRO		15K€	



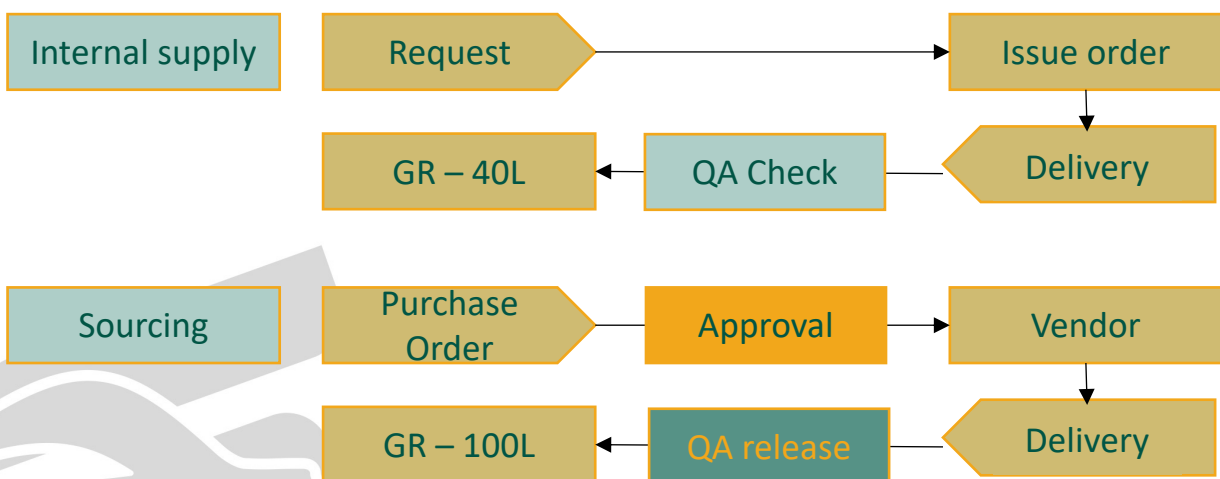
Use Case of SAP Business ByDesign

Manufacturing of a new batch – Sourcing.

The Manufacturing team is planning for a new batch and is looking at the planning for materials, i.e. “Glucose” in the project template. The quantity needed is 100L, and expiry must not be less than 6 months at time of production.

Labour Costs	Project Stock	Whouse 1	Whouse 2 3rd party
Inv. on Hand	17L	20L	40L
Ordered	0L	0L	100L
Replenishment	0L	20L	100L

Material in Warehouse 1 expires too early, thus a new order must be done for materials. An electronic Internal Order is sent to the 3PL.



QA checks and releases are setup in the Warehouse master data, per specific flow.

Use Case of SAP Business ByDesign

Manufacturing of a new batch – Manufacturing.

The Manufacturing team is looking at the latest Manufacturing Bill of Materials to produce a 250L Batch.

The Manufacturing Team compares that the formula attached in ByDesign is still the version approved in the QMS system.

Manufacturing BOM:

Batch 250L		Serial nb. BTX01-143
Glucose	100L	17L – PC/AGS025
		40L – PC/AGS177
		43L – PC/ROC17B
API Z	80L	50L – ZZS25A
		30L – ZZ48C
API Y	70L	70L – YYYY4587C

After assembly, the product requires 3 months to stabilize.

Thanks to Serial Number generation at Goods Receipt, purchased products can be easily be identified and traced down to the supplier lot, invoice, receipt date, QA approval, purchase order, etc.

Similarly, all manufactured products have a serial number which is mandatory for regulatory purposes.

Serial numbers are unique and can't be duplicated.

This applies even if products are received and manufactured outside of the company, as the 3rd party set up is part of the standard package.

Use Case of SAP Business ByDesign

Management Reporting

These are some examples of management reporting for the month. No accounting adjustments are needed. It's custom views.

Cost Center view:

Cost Center	Type	Actual	Committed	Budget	Total
Clin Ops	Staff	-100.00	0.00	112.00	12.00
	Travel	-2.0	-4.0	5.00	-1.00
	Prof. Serv.	-85.00	-75.00	160.00	0.00
MFG	Staff	-150.00	0.00	150.00	0.00
	Travel	-2.0	-4.0	5.00	-1.00
	Prof. Serv.	-25.00	0.00	-26.00	1.00
	COGS	-550.00	0.00	550.00	0.00

Project view by team:

Project	Dept.	Actual	Committed	Budget	Total
BTX-01	Clin Ops	-25.00	0.00	20.00	-5.00
	QA	-18.00	-5.00	22.00	-1.00
	Medical	-50.00	-15.00	70.00	5.00
	MFG	-305.00	40.00	340.00	-5.00

Any figure in the table can be expanded to obtain details, i.e. invoice, goods & services receipt, time sheets, manufacturing BOMs, etc.

Use Case of SAP Business ByDesign

CMC Dashboard

Specific dashboards are used by the dedicated teams to follow at any time the status of the project.

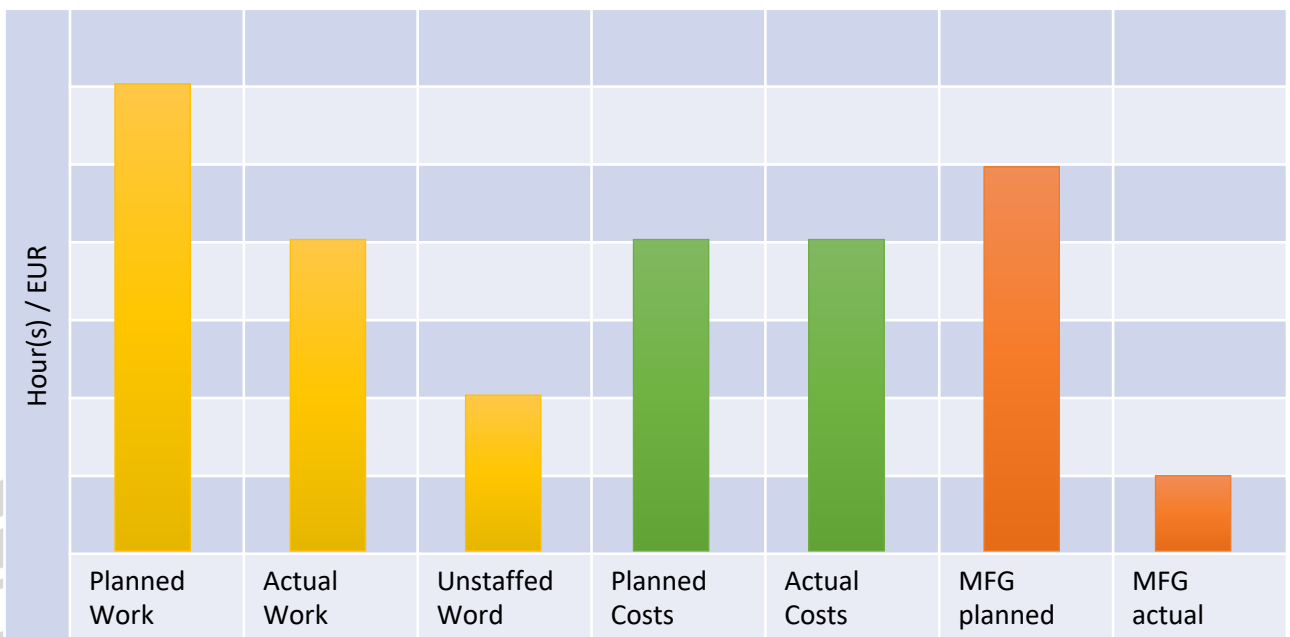
Reports available out-of-the-box are:

- Milestone Trend Analysis
- Project Cost and Revenue, Plan vs Actual
- Project Plan vs Actual Work
- Analysis per Team Member

In addition, the people in charge of all, or a part of, the project can approve time sheets.

At any time, people in charge can monitor if changes were made to the initial plan (deadlines, costs, etc.)

Review of project work report:



Any bar of the graphic can be expanded to obtain details, i.e. purchase orders, time sheets, manufacturing BOMs, etc.

Use Case of SAP Business ByDesign

Financial Reporting

Definition of multiple sets of books with different settings is possible. It enables to have sets of books with different accounting principles so that preparation of financial statements based on multiple accounting principles is easy. Accounting records are only processed once.

Let's look at the Assets Under Construction for BTX-01:

Project	Type	AUC Books	IFRS	USGAAP	US R&E Tax Credit
BTX-01	Research	75.00	0.00	0.00	25.00
	Development	323.00	323.00	0.00	50.00
	Depreciation	0.00	-3.00	0.00	-1.00

Revenue Recognition

The company has reached an out-licensing deal as per the following terms:

- 1) Non-Refundable down-payment of 20M
- 2) The company must deliver 5 batches in 24 months
- 3) If the batches fail to comply with Quality, a penalty of 2M per batch will be applied, 30 days after delivery.

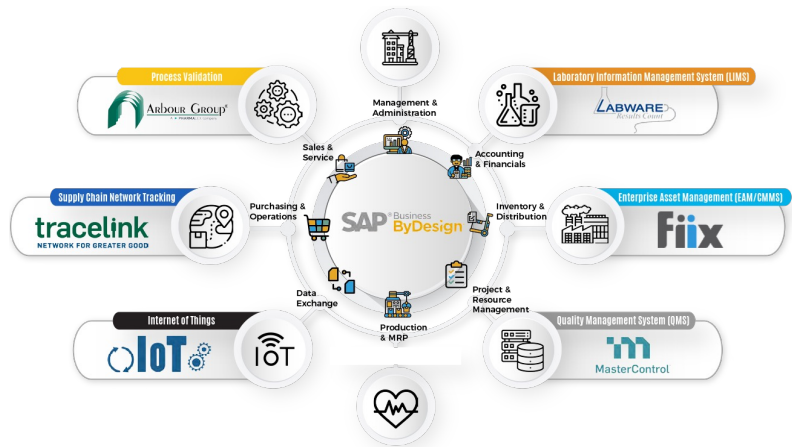
Financial statements would look like after the first batch delivery. Parameters are set at time of invoicing thus are customizable.

Account	IFRS	USGAAP
Cash	20,000,000.00	20,000,000.00
Revenue (PL)	20,000,000.00	4,000,000.00
Deferred Revenue (BS)	0.00	16,000,000.00
Deferred Costs (BS)	-10,000,000.00	-2,000,000.00

Additional Solutions for Scalability

ByDesign is a comprehensive and flexible solution for both local and global biotechnology organizations. It supports the unique needs of each company and provides excellent out-of-the-box business processes.

The best providers in the industry developed specific and ready to integrate applications in Business ByDesign.



Processes can be easily and quickly adapted to a company's specific requirements. Thanks to its built-in usability tools and open web services architecture, ByDesign can be seamlessly integrated with various service providers, world leaders in the industry, who have developed specific applications for this platform.

- ✓ The concept of "**click not code**" eliminates the need for expensive and challenging customizations that are difficult to maintain.

Furthermore, new applications are constantly being developed. You can check the current pipeline of upcoming applications here:

SAP Business ByDesign Road Map

SAP road maps illustrate the digital transformation journey. This product road map describes how the features and functional capabilities of SAP

<https://www.sap.com/documents/2017/06/b4e1765d-c37c-0010-82c7...>



SAP Business ByDesign Road Map

April 2017

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SAP Business ByDesign Benchmark

According to Gartner, SAP Business ByDesign ranks better compared to Microsoft and Oracle.

Compared to competitors reviewers reported the key strengths of SAP Business ByDesign:

- ✓ Easier to integrate and deploy
- ✓ Better service and support
- ✓ Better compliance and risk management

Reviewers from the Healthcare and Biotech Industry often quoted in the key strengths:

- ✓ Systematic workflow of organization
- ✓ Best industry practices business process agility
- ✓ The easy use of the application

You can read all the reviews below clicking the link below:

SAP Business ByDesign Reviews, Ratings & Features 2023 | Gartn...

Read the latest, in-depth SAP Business ByDesign reviews from real users verified by Gartner Peer Insights, and choose your business software with

 <https://www.gartner.com/reviews/market/cloud-erp-for-product-centric...>

Gartner
Peer Insights

Peer-driven insights, advice, and guidance
to drive technology and business decisions

SAP History w/Life Sciences Industry

- 97% of the life sciences companies in Forbes Global 2000 run SAP Apps.
- The top 20 pharmas use SAP Apps.
- All biotechs in the Forbes Global 2000 run SAP Apps.
- All medical devices companies in the Forbes Global 2000 are SAP customers.



CareFusion



Business Areas

Financial Management & Human Resources

Features and benefits

Business Package	Features and benefits
General Ledger	Recurring entries, automatic reversals, Excel uploads.
Fixed Assets	Fully automated w/various versions possible (IFRS, USGAAP, Tax Gaap)
Payables, Receivables, and Cash	Automatic scanning of invoices w/OCR and pre-matching to Purchase Orders.
Intercompany Consolidation	Fully automated.
Financial Closing Cockpit	Integrated closing tool that enable to follow individual tasks.
Budgets	Ability to release portions of budget, by cost center or project, budget check, multiple GAAPS
Payables and Receivables Processing	Almost 100% automated with MT940 uploads.
Expense and Reimbursement Management	Integrates the same engine as CONCUR. Possible to integrate with some Credit Card Companies.
Cash Flow Forecasting	Including budgets and POs if used.
Payment and Liquidity Management	Standard ISO files that fit the largest EU and Swiss banks. Some US are challenging though.
Workforce Administration	Simpler version of Success Factors. Does not integrate objectives and performance.
Time and Labor Management	Possibility to assign resources to projects, using different hourly/daily rates.
Resource Management	Possibility to contract & assign external resources to projects, using different hourly/daily rates.



Business Areas

Supply Chain Management

Great features and benefits

Business Package	Features and benefits
Supply Chain Design	Offers a wide variety of scenarios as standard, including 3rd party management!
Supply Planning (MRP)	Standard functionality.
Supplier Management	Perfect for GxP compliance as sites can be monitored by QA w/ expiry dates.
Supplier Contracts (RFQs)	Manage and store RFQ and contracts in all the same place. Also linked to Purchase Orders.
Source of Supply Determination	For GMP and controlled products. Assigns a specific source of supply to a given product.
Self-Service Procurement	Standard functionality.
Purchase Requests	You can customize that once a PR is approved, that the PO is sent automatically. Only certain changes (price, vendor) will require re-approval.
Purchase Orders	You can customize that once a PO is approved, that the invoice is approved if no deviations are noted. No Invoice gets paid if goods/services aren't received. (other procedure).
Purchase Orders Approvals	Can define multiple levels of approvals, specific to vendors, cost centers, projects, etc.
Intercompany Purchasing	Pilot IC transactions from inventory. Generate Sales Orders and that's it!
Supplier invoicing	Possibility to scan automatically 100% of invoices with pre-matching. CONCUR's OCR engine.
Inbound Logistics	Receive goods by lot, batch and generate internal serial numbers for tracking.
Outbound Logistics	Send goods by lot, batch and generate internal serial numbers for tracking. Generates sales invoices automatically.
Internal Logistics	Send/receive goods by lot, batch and generate internal serial numbers for tracking. Generates IC documents automatically.
Inventory Management	Standard.
Inventory Valuation (Avg, std)	Standard.
Task Management	Possibility to assign tasks to users.

Business Areas

Projects Management

Great features and benefits

Business Package	Features and benefits
Project Management	From discovery to commercialization, all the molecule life cycle is reflected. Pilot all the sourcing of materials, inventory, time (internal and external), CRO costs.
Billable Projects to Customers	Within a click of a button, you can generate customers invoices by period or project phases / milestones.
Asset Under Construction	Perfect for valuation. You decide, in multiple scenarios and GAAPs the full depreciation or valuation of the project.
Intercompany Projects	Across several sites.
Sub-Contract to Projects	Assign contracts to projects.
Issue Materials to Projects	Materials from stock are assigned to the project.
Project Material Planning	Forecast and MRP for the materials to be used in the project.
Procure to Projects	Generate all the PRs/POs from the Project management.
Project Resource Search	Ability to copy, activate-deactivate projects.



Project Approach

Prepare Phase

Implementation starts with the Prepare phase which covers work streams and deliverables for: Project Management, Solution Design and Integration Preparation. This phase ensures that the project is planned accurately and the implementation scope is determined.

Project Management	Starts with handover to the services delivery team where the goals, objectives and success metrics are decided; project planning, kick-off and execution follow.
Solution Review	Review best practices and define the configuration to confirm project scope.
Integration Preparation	Validate the integration, making sure the security and infrastructure prerequisites have been met.
Verification	Is complete when all stakeholders agree on the scope to be delivered during the implementation.

MILESTONE: Solution Walkthrough and Demo of Main Processes

Realize Phase

The Realize phase helps to ensure that the agreed scope is manageable within the system and if needed, the adjustments are made.

Project Management	The project execution deliverable continues to control project status and risk management.
Project Team Enablement	With the project initiation, the project team is preparing for the project and working with the solution.
Solution Configuration	System configuration and testing with the sample customer data.
Solution Walkthrough	Demonstration to the customer how the end-to-end processes will look within the system.

MILESTONE: System Readiness Acceptance for Testing

IProject Approach (Continued)

Verify Phase (Testing)

The Verify phase ensures the system and people are ready to switch from the previous systems and run their processes in SAP Business ByDesign.

Project Management

The project execution deliverable continues to control project status and risk management.

Data Migration

Deliverables go through all phases starting with the data preparation to its further cleansing and testing within the system.

Integration Setup

Initial testing within the test tenant and then uploading to the production tenant.

Solution Testing

Once the testing documentation is prepared, customer fully tests the system with the migrated data.

Cutover Planning

Identification and scheduling of all the tasks and resources. The Project Verification Quality Gate is complete when all stakeholders agree on the scope to be delivered during the implementation.

MILESTONE: UAT is conducted. All stakeholders agree that the solution meets the requirements. Cutover plan is validated..

Launch Phase

The Launch Phase is the final step that ensures successful solution adoption and usage of the solution.

Project Management

Customer handover to SAP Support and the project closure.

Solution Adoption

Adoption preparation and execution. Customer uses the change management plan to roll out the new solution within the organization.

Cutover Execution

Go-Live with a productive system.

MILESTONE: Go-Live

About LifeScience Services GmbH

LifeScience Services GmbH is a boutique management consulting firm that specializes in providing advisory and project management services to leading life sciences organizations.

Located in the heart of Switzerland, in the canton of Zug, LifeScience Services benefits from its proximity to several global players and a thriving community of small and medium-sized biotech companies.

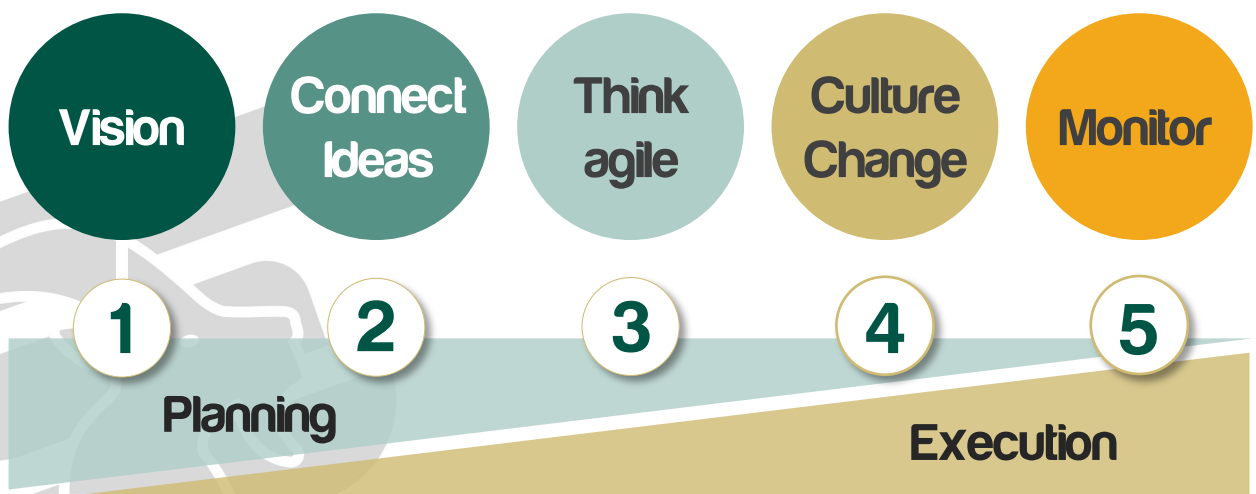
At LifeScience Services, we offer a comprehensive range of services, including strategy consulting, digital transformation, operations consulting, corporate development, and commercial launch readiness, among others.

Our team of expert partners brings extensive experience gained from senior positions in the life sciences industry. We work closely with our clients to develop customized solutions that drive measurable impact and create value.

Our mission at LifeScience Services is to provide high-quality and independent consulting services that have a positive impact on the patient's journey. We are committed to making a meaningful difference and helping our clients succeed in the dynamic and evolving field of life sciences.

As #GOATConsultants™, we are dedicated to delivering nothing but the best service.

Our Unique Project Methodology



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