The Intelligent Enterprise for the Life Sciences Industry

Improve people's lives with delivery of personalized patient solutions, at scale and as a service



Paving the Way for Sustainable Business Model Innovation

Traditional blockbuster drug sales models will be supplanted with personalized therapy treatments, driving life sciences companies to evolve business models in a more patient-lifecycle service-based context. The nature of biopharmaceutical R&D and medical device design and engineering processes will increasingly become patient-centric research opportunities across collaborative networks. Traditional back-office functions such as finance, IT, HR, data management, and customer contact have matured into a single global business services organization that owns the value chain relationship. Supply and logistics networks are flexible and agile. Successful business model innovation, process optimization, and workforce productivity are directly linked as part of the goal to deliver great customer and employee experiences. Embracing the opportunities presented by new technologies and implementing the right business initiatives will form the foundation for a successful digital transformation and staying ahead of the innovation curve.

The life sciences industry is being reshaped by four major trends:

- Sustainability: Increasing numbers of regulations focused on sustainability will force life sciences
 organizations to expand their sustainability efforts, where they will need to show how they
 contribute to overall sustainability efforts to demonstrate their value outside of the medications
 they develop.
- Empowered patients and personalization: Patients are increasingly taking control of their health
 approaches and are demanding therapies that provide promised outcomes. Personalized
 medicines are emerging at faster rates, with higher price points and improved patient results.
 Being able to provide outcome-based patient engagements and connect with patients directly
 becomes paramount.
- Big Data driving health networks: The need to provide therapeutic outcomes at lower costs is transitioning traditional, fragmented value chains to new ecosystems that integrate suppliers, contractors, and regulatory agencies.
- Regulatory pressures and rising healthcare costs: As public health issues continue to arise such as the COVID 19 pandemic and the opioid crisis, with their associated impact on healthcare costs regulatory pressures will continue. Unsustainable healthcare costs are driven by complex channel models and R&D investments. Costs that outpace GDP are constantly scrutinized. Energy, health, and sustainability compliance laws steadily increase and vary from country to country.

Business Model Innovation

Successful business model innovation, process optimization, and workforce productivity are directly linked to delivering great patient, customer, and employee experiences.

In the future, patients will be more accountable for their own care and have greater access to their personal health information. Technology will allow patients to use smart devices to monitor their health in real time while collaborating with their physicians from home. Patients and payers will demand personalized treatments with superior but also cost-effective outcomes. These personally targeted therapy treatments will enable the supply chain to adopt more agile modes.

Life sciences companies must use digital technologies to drive revenue through greater insights and collaborative partnerships, leveraging employee experiences.



Strategies for a Life Sciences Company to Run as an Intelligent Enterprise

Proven success strategies show a range of approaches to creating new business outcomes based on existing products and processes, as well as developing disruptive new business models.

Improving Customer Outcomes

Identify customer segments and service them directly for more holistic approaches that improve quality of life. Radical transformation of the supply chain and manufacturing processes will enable greater agility in supporting targeted therapy treatments, personalized patient approaches, and smaller product segments, as well as provide real-time views of patients and their interactions. This means the customer, or patient, can be served seamlessly by hospitals and clinics for high-cost therapy, even when there is some disruption to the ways distribution models work through wholesale and retail chains.

Competing as an Ecosystem

Drive down costs and improve efficiencies through collaboration with partners from across the life sciences network. Life sciences companies will start toward this goal by collaborating more closely with manufacturers and suppliers to help ensure quality standards on ingredients, packaging, and finished products, using customer feedback to enrich the customer experience. Collaborating on product design across the extended network of research institutes, hospitals, and innovative startups will enrich products to meet patient needs and shorten time to market.

Enabling the Digital Supply Chain and Smart Factory

Digital technology on the shop floor and in the supply chain is not new. What is new is the way production and logistics are sustainable and intelligently connected to the rest of the business and able to deal with external impulses such as short-term demand and supply fluctuations or changes in volatile demand patterns. Supply chains and manufacturing network processes must stay compliant while protecting business margins. This requires increased digitalization across the business, including continuous process verification; regulatory checkpoints; artificial intelligence to check the status of chemical and biological reactions; warehouse functions; and error reduction through automated processes such as e-labeling.

Focus on Customer and Automation

<u>Carestream Health</u> provides diagnostic medical imaging equipment to approximately 90% of the world's hospitals. As demand for its products increased, so did its need for digital transformation. Manual order-processing procedures impeded rapid order fulfillment, so Carestream decided to automate back-end processes and data management while integrating the front-end commerce site to improve the overall customer experience.



From Best Practices to the Vertical Edge

In a digital world, innovation is no longer just the domain of the R&D teams who build the next generation of drugs and devices. Innovation must become an integral part of each department and discipline, so they all contribute to the evolution from best practices to industry next practices, right to the "vertical edge." This enables cross-functional teams to experiment with new ways to create unique value for customers, thus generating top-line, bottom-line, and green-line improvements.



Business Process Innovation

The journey to become an intelligent enterprise is a collaborative effort among our customers in the life sciences, our partners, and SAP. The world is changing quickly, and there are many untapped innovation opportunities.

Industry 4.0

Industry 4.0 is also about digital transformation, using new technology that makes it possible to gather and analyze data across machines and business systems – the intelligent enterprise . This enables faster, more-flexible, and more-efficient processes to produce high-quality personalized medicines at reduced cycle time. SAP believes that to truly achieve the benefits and impact of Industry 4.0 and become an intelligent enterprise, a company needs to embrace Industry 4.0 holistically across its entire organization.



Moving Toward the Vertical Edge

We have identified several initial innovation spaces where we see the potential to move to next practices and the vertical edge jointly with our customers. Life sciences core processes offer a significant potential to move from current best practices to next practices using digital technologies and a digital mindset.

Next Practices Vertical Edge Order-to-cash process Business-to-business (B2B) order B2B-to-consumer (B2B2C) commerce collaboration · Chargebacks, rebates · Life sciences customer collaboration Bids and tenders Project and portfolio management network Intelligent products Customer service Cell gene therapy, targeted treatment therapy management · Compliant field service Customer 360-degree view Outcome and value-based · Customer experience management reimbursements Launch strategy and IP management Management of regulatory submissions Healthcare practitioner (HCP) spend transparency · Forecast-to-stock process · Procure-to-pay process Source-to-pay process Collaboration with contract Supply network optimization Sourcing and supplier development manufacturing management · Harmonized sourcing and supplier organization management · Core HR and payroll Learning management and training · Talent management Contingent labor Total workforce management Manufacturing networks, part Accounting, financial continuous Tolling, subcontract manufacturing Intelligent clinical trial supply ENABLING THE DIGITAL SUPPLY CHAIN AND SMART FACTORY · Transfer pricing, profitability Product costing Cold chain in manufacturing and logistics Make-to-order process Make-to-stock process Batch size of one targeted treatment · Recipe development and formulation therapy management Supply chain visibility Product segmentation Batch release compliance Batch characteristics Smart factory Sustainability reporting Lot traceability Predictive maintenance · Laboratory planning information system · Plant maintenance Manufacturing execution Technology transfer Manufacturing insights Development batch record and Item-level traceability electronic batch record; design history file and device history record Calibration and asset intelligence Elimination of waste through solutions with embedded insights into business processes

We see opportunity in innovation spaces that are sparsely populated or even empty today. We know that many innovative ideas are out there in search of a platform that can turn imagination into reality.

Industry-leading business applications and SAP's business networks are a solid foundation for next practices and innovation at the vertical edge.

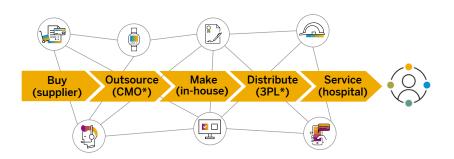


Improving Customer Outcomes

Efficient targeted therapy treatment management – Large pharmaceutical enterprises are acquiring biologics and therapy companies to grow their businesses and diversify their portfolios. The supply-chain time period for cell gene therapy is less than a month from blood sample collection to drug infusion. The digital supply chain covers planning, sourcing, process manufacturing, and distribution along with analytics and can provide transparency and visibility across the life sciences value chain.

BEST PRACTICE

Support make-to-stock scenarios with cold-chain temperature monitoring during logistics, distribution, and patient service at the end of the linear value chain.



NEXT PRACTICE

Enable make-to-order scenarios with batch size of one for cold chain time in and out of refrigeration during manufacturing, with the patient at the center of the supply chain. Chain of identity, chain of custody, and agile billing scenarios must be supported.

Service (hospital)

Store (DC*)

Distribute (3PL)

*CMO = Contract manufacturing organization 3PL = third-party logistics DC = distribution center

Innovations at the Vertical Edge

Develop real-time data-driven decision-making and orchestration of the patient process with financial implications at each stage of the supply chain with a batch size of one.



Reduced

Cycle time and overall logistics costs



Improved

Visibility of patient's drugs



Improved

Transparency throughout the supply chain

Competing as an Ecosystem

Effective integrated regulatory operations network – Provide increased assurance of product market compliance consistent with requirements of regulatory approval across multiple countries. As pharmaceutical and medical technology products are approved for sale by national regulators, life sciences companies face significant challenges in aligning supply chain processes with those characteristics that have been approved in regulatory chemistry, manufacturing, and control (CMC) documents.

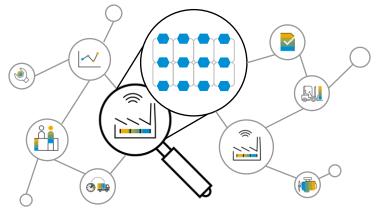
BEST PRACTICE

Life sciences companies are defining jurisdiction control processes within the supply chain that require market-specific definitions to ensure the right vendor of raw materials specific for a market is used, or that the correct process and plant is the supply node. This extends all the way to ensuring that sales orders are fulfilled only with stock that has already been approved for that market by material master maintenance.



NEXT PRACTICE

Segmentation is deployed to manage the growing number of characteristics required to demonstrate that biologics and medical device processes operate in the right design space. This represents a new paradigm for controlling supply chain planning, batch release and execution, change management, and version control.



Innovations at the Vertical Edge

The new approach will capture characteristics from the CMC data in a separate "segmentation" field, linking to and then cross-referencing both demand and supply, all under the control of the qualified person (compliance officer).



Lowered

Cost of master data management



<mark>Improved</mark> Regulatory compliance

Enabling the Digital Supply Chain and Smart Factory

Protect margins by keeping production processes compliant. Transferring product knowledge from drug development to commercial operations is notoriously slow and complex. Embarking on a systematic approach, integrated with business operations and regulatory compliance, is sure to dramatically change the game. However, capturing and moving product knowledge from one plant to another remains challenging. And inefficiencies in a process can add many months, leading to high costs and margin shortfalls due to delays in a new product launch.

BEST PRACTICE

Replacing the paper-based approach, key master data such as materials, equipment, and process parameters is entered directly into the system, with ranges defined, all during technology transfer.



R&D





Commercial manufacturing

NEXT PRACTICE

Life sciences companies will codify the knowledge learned by the various disciplines in product development, including engineering, chemistry, testing, and regulatory compliance. They can apply these insights to commercial production to reduce time spent transferring information from one site to another, or from in-house to outsourced production.



Innovations at the Vertical Edge

Enable the capture of product knowledge as it is developed, in a consistent and portable way to support automated handover to commercial operations. Put sustainable efficiencies in place to achieve sustainability goals.



Faster

Transfer of product knowledge from development to commercial operations



Improved

Regulatory compliance through batch record processes that align systematically with regulatory CMC filings

SAP® Solutions Enable Strategic Outcomes

To move forward with speed and agility, it helps to focus on live digital data and combine solution know-how and industry-specific process expertise with data analytics so that the right digital reference architecture is defined to deliver on strategic outcomes. This requires new, sustainable business capabilities throughout the value chain – provided by our life sciences solutions through our Intelligent Enterprise approach.

Required Capabilities

Research, Development, and Engineering

- Development batch record and design history file
- Recipe development and formulation
- Intelligent product process structure
- Change management
- Product lifecycle costing
- Intelligent clinical supply management
- Project and portfolio management

Competing As an Ecosystem

- Collaboration with contract development manufacturing organizations
- Harmonized sourcing, supplier management
- Predictive procurement planning
- Multilevel supplier collaboration
- Procure to pay
- Source to pay

Improving Customer Outcomes

- Segmentation and cell gene therapy
- Global supply chain control tower, sales and operations planning
- Integrated demand and capacity management
- Predictive quality management
- Demand-driven business planning

Enabling the Digital Supply Chain and Smart Factory

- Electronic batch record and device history record, LIMS*
- Toll, subcontract manufacturing
- Next-generation supply chain sequencing
- Connected shop floor Intralogistics
- Batch release hubSustainability reporting
- Minimizing energy cost
- Tracking carbon from raw materials used in manufacturing plant sites
- Forecast to stock and make-to-order manufacturing

Multichannel Fir Sales, Marketing, and Service

Learning

management

and training

marketplace

Total workforce

Task-based virtual

management

reality training

software and

Core HR, talent

management

engineering

Skill database for

- HCP spend transparency, compliant field service
- B2B2C commerce, order collaboration
- Marketing intelligenceCalibration,
- predictive maintenance
- Order to cash, chargebacks, rebates, repairs,

Finance Human Resources

- Outcome- and value-based reimbursements
 - Transfer pricing, profitability
- Real-time product costing
- Accounting and central finance

 $\hbox{*Laboratory information management system}\\$

The architecture of the Intelligent Enterprise in the life sciences industry starts with SAP Business Technology Platform and business applications from SAP, including industry cloud solutions that support organizations with their industry-specific end-to-end processes.

SAP Information Collaboration Hub – for a secure serialization data network

SAP Intelligent Clinical Supply Management solution— for reimagining clinical supplies operations and defining an industry standard

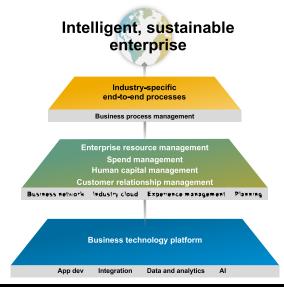
SAP S/4HANA®

- for order fulfillment

SAP Ariba* solutions – for efficient source-to-pay processes

SAP Service Cloud solutions – for omnichannel service

SAP Manufacturing solution – for automated, integrated, and flexible manufacturing



SAP Enterprise Product Development solution – to accelerate product and project delivery

SAP Product Lifecycle Costing solution – for R&D

Variant Configuration service – for exposing configuration and pricing models to the cloud

SAP Asset Strategy and Performance Management application – for efficient asset operations and performance

SAP Analytics Cloud solution – for providing insights for better decision-making

AmerisourceBergen Corporation

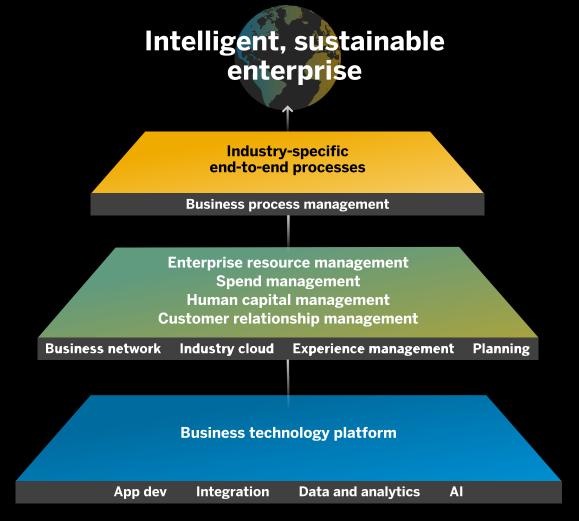
"We have had the unqualified and invaluable support of SAP experts from the beginning of our co-innovation effort. Together we produced a state-of-the-art solution that has succeeded beyond expectations from day one and simply left competitors in the dust."

Jeff Denton, VP, Global Secure Supply Chain, AmerisourceBergen Corporation

SAP's Industry Cloud: A Joint Innovation Space

We enable our customers to become intelligent, sustainable enterprises by bringing together our comprehensive portfolio of solutions and technology in service to customers' business process needs.

- It starts with our platform technology that provides the foundation of application integration, extension to a robust ecosystem of solutions, and data and Al.
- Then our industry-leading business applications work together spanning front-end and back-end systems that only SAP can provide.
- This all comes together to provide the customer with support for the end-to-end, industry-specific business processes they need to run as an intelligent, sustainable enterprise. Learn more.



Industry Innovation Spaces

Stand-alone applications struggle to deliver relevant business value. Enterprise applications always need access to essential business domains such as products, assets, factories, cost centers, employees, and customers. SAP's industry cloud provides direct access to business domains and processes in the intelligent suite through APIs. At the same time, our business and technology services provide the tools and infrastructure to create and run innovative industry cloud solutions.

Intelligent Technology at Your Fingertips

Business innovation needs digital technologies that are ready to use to solve a business problem.

SAP's industry cloud solutions, built on SAP Business Technology Platform, provide a full set of technologies ranging from user interfaces to robotic process automation to artificial intelligence and machine learning. All can be used readily in new solutions.

Open Innovation Platform and Ecosystem

SAP's industry cloud is the way for our partners and SAP to deliver solutions for customers that unlock new levels of efficiency, extend business processes at the edge, and enable innovative business models.

SAP partners find a unique environment in our industry cloud in which the data domains and business processes of the intelligent suite and our business networks are readily accessible through open APIs. This allows our partners to accelerate innovation by focusing on the differentiating business capabilities they want to build and deliver to our joint customers.

A spectrum of partnership and innovation models is possible, ranging from close co-innovation in identified white spaces to completely open innovation spaces with free competition to drive customer value.

The innovation models are complemented by a set of commercialization models that are strongly correlated to the value the solutions deliver to our customers' business.

Freedom of choice is a key value, so customers can choose any partner or hyperscaler to deploy their industry cloud solutions.

Open Ecosystems Deliver More Innovation

Open platforms, available to the wider ecosystem, have consistently delivered more innovation and choice for customers. Therefore, our industry cloud solutions can be run by the major infrastructure-as-a-service (laaS) providers, giving our customers the freedom to implement their own individual platform strategy.

RISE with SAP: Driving Business Innovation Together

Every enterprise needs to develop new business models to avoid being disrupted, gain efficiencies to fund innovation, and transform mission-critical systems without business risk. RISE with SAP is the solution.

RISE with SAP is a comprehensive solution with:

- · Cloud ERP for every business need
- Industry next practices and extensibility
- Analytics and business process intelligence
- Outcome-driven services from SAP and partners

Discover the value of RISE with SAP



Take the lead with industry innovation for top-line, bottom-line, and green-line growth

- ✓ Grow revenue by creating differentiating business models in your industry
- Increase margin with built-in industryspecific processes and best practices
- Unlock new efficiency with intelligent automation across mission-critical processes
- Manage sustainability with companywide transparency and controls



Never stop improving with continuous insight to optimize business processes

- Prioritize optimization opportunities with instant analysis of processes, activities, and tasks
- Sharpen process performance based on actual system usage, best practices, and industry benchmarking
- Accelerate your progress with tailored insight on where to automate business processes with Al



Secure your business with a trusted partner for your needs, every step of the way

- Run your mission-critical operations at their best around the globe
- Reach the cloud without compromise with solutions for every business and every regulatory requirement
- Take charge of change using a versatile platform to speed innovation
- Own your tomorrow with a guided journey and outcome-driven practices from SAP and our partners

RISE with SAP is built to fit your needs

RISE with SAP is designed to support your business needs – for your industry, in your geography, for your regulatory requirements – with SAP responsible for the holistic service-level agreement, cloud operations, and technical support. It includes:



Cloud ERP

SAP S/4HANA Cloud



Business process intelligence

Business process intelligence starter pack



Business platform and analytics

SAP Business Technology Platform (CPEA credits)



Business networks

SAP Business Network Starter Pack



Outcome-driven services and tools

From partners

RISE with SAP is the foundation for an intelligent, sustainable enterprise in the cloud. We look forward to joining our customers on their transformation journey into the future. Find out more about RISE with SAP.

SAP's Comprehensive Partner Innovation Ecosystem

SAP has been the proud solution provider for the life sciences industry for almost five decades – starting from humble beginnings and growing into a position of supporting the core business of our customers. Ninety-five percent of the most innovative life science companies in the world run SAP solutions.

SAP's industry cloud opens the door for a new level of co-innovation with our customers and partners, enabling next practices and new business models that help customers capture the new opportunities of servitization and outcome-based businesses and take the next step toward becoming become sustainable, intelligent enterprises.

Our open partner strategy gives our customers the choice of whom they work with to design the business models of the future; whom they partner with to define and implement business processes for efficiency and growth; and whom they trust with running their infrastructure.

There are many journeys life sciences companies can take into the digital economy to become sustainable, intelligent enterprises. No matter which they choose, our scalability, security, global reach, vibrant business networks, and business process knowledge across life sciences and adjacent industries are the success factors for our customers, our ecosystem, and SAP.

Our life sciences partner ecosystem includes, among others:



















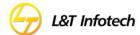








































Engagement Model

SAP is the partner for the life sciences industry in the long run. We have established a co-innovation and collaboration model with many of our customers that is based on mutual trust and long-standing value-based relationships.

This is the foundation to chart a company's journey into the new world of customer experience – to improve customer outcomes, compete as an ecosystem, and tackle the challenges posed by the digital supply chain and smart factory.

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