LifeSciencesPath Shows the Way to Life Sciences Industry SAP

The Life Sciences Industry is Facing Rapid Change

Life sciences companies are facing an ever more complex business landscape with new risks and opportunities – and **a need for better digital end-to-end solutions** to manage the risks and take advantage of the opportunities.

These risks and opportunities arise from factors such as:

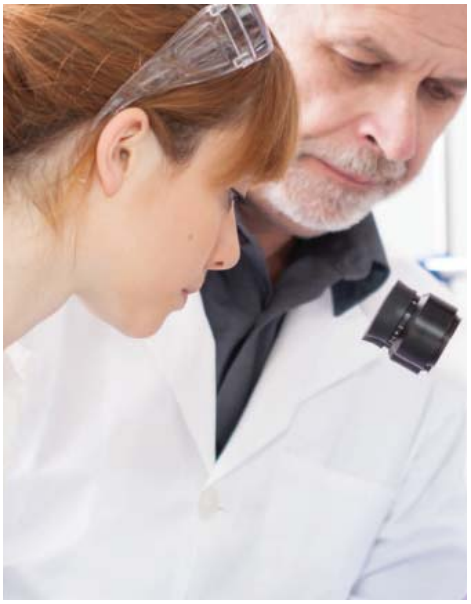
- The **shift to consumer-facing** sales and increasing patient demand for product information means a great customer experience a business requirement.
- The **lack of visibility and transparency** during clinical trials and throughout commercial operations creates inefficiencies and risks in the drug commercialization, business planning and sales processes.
- **Market pressures** from generics and non-traditional emerging competitors create business uncertainty and puts pressure on investments in innovation.
- A dynamically evolving **regulatory environment** requires increased knowledge and insights-based decision making to improve tracking of activity through the value chain.

Companies that want to address these issues n**eed reliable end-to-end digital solutions** to help them do so.

What is LifeSciencesPath?

LifeSciencesPath is Capgemini's SAP-certified S/4HANA package solution that is pre-configured with validation artifacts for accelerated implementation. LifeSciencesPath **enables life sciences companies to streamline operations,** providing greater visibility and control of core business processes.

Capgemini



It is the best choice for companies that want to **adopt industry-leading practices** and promote the standardization, simplification and scalability of business operations. LifeSciencesPath helps companies embarking on a green-field SAP journey as it can serve as the foundational system upon which the extended value chain can be built. It can also be used for companies with existing SAP implementations (brown field) who are looking to expand their business process footprint or to enhance existing processes by focusing on the latest leading practices and industry benchmarks. Capgemini's LifeSciencesPath is the leading practices reference system.

LifeSciencesPath provides a vast collection of tools, templates, resources and guides that have demonstrated acceleration with past implementations. Examples are:

- A master list of pre-configured reference business process solutions
- Process documentation and process flows
- Tested example data and integration test scripts
- Business process procedures: transaction-level work instructions (training material)
- GAMP® Validation deliverables templates (e.g. Master Validation Plan template, User and Functional Requirements Specification templates, Design Specification templates, Test Script template, Traceability Matrix templates)

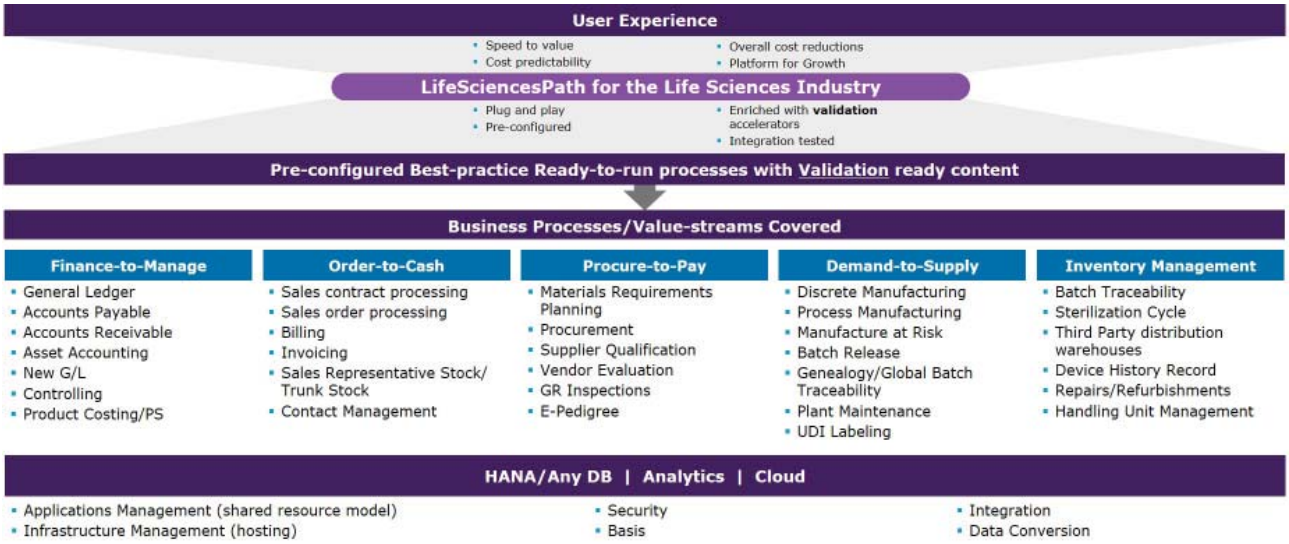
The LifeSciencesPath solution also provides extensive integration capabilities with other solutions (social, mobility, analytical, IoT, blockchain, cloud) that are driven by business needs. It can be quickly provisioned and deployed both on premise and in the cloud to provide flexibility, speed and a path to further business innovation. Various cloud-hosted options are available – including SAP's HANA Enterprise Cloud, SAP's Single Tenant Edition on HEC, Capgemini Cloud (AWS, Azure), or a partner-managed cloud. LifeSciencesPath for the Digital Enterprise includes S/4HANA's embedded machine learning and electronic data exchange (EDI).

Capgemini LifeSciencesPath Supports Life Sciences Business Processes

The LifeSciencesPath S/4HANA Digital Core has prebuilt, integrated end-to-end business processes that were designed specifically for life sciences companies, dramatically reducing the work needed to start getting real value from the SAP solution.

The business scenarios built into LifeSciencesPath provide a broad scope of leading practices to address common challenges within the life sciences industry and ultimately deliver business value through technology enablement of business process. LifeSciencesPath guides life sciences companies to focus design efforts on the 20% of business processes that drive 80% of value. LifeSciencesPath includes the following "value streams":

- Finance-to-Manage — Integrated finance across all operations
- Procure-to-Pay — Procurement and inventory management process with supplier quality and batch & serial number traceability
- Order-to-Cash — Frictionless customer processing to increase loyalty and profitability
- Demand-to-Supply — Multi-mode manufacturing, contract manufacturing and quality-management processes



How Capgemini's iCaptivate Methodology Makes a Difference

Capgemini has completely reinvented the methods that drive SAP-enabled business transformation initiatives with its iCaptivate Methodology. Customers do not start with a blank canvas; much of the groundwork is already done for them through pre-built LifeSciencesPath solution design and documentation content. The Capgemini iCaptivate repository:

- Contains pre-populated content for more than 400 leading practice, industry-specific business processes
- Provides market-tested implementation content and guides, including configuration documents, process flows, business process documentation, KPIs/metrics and key design decisions
- Includes built-in site and country-specific content to address localizations to the global template
- Has built-in business process integration aligned with SAP's Solution Manager
- Drives the lean concept of design error-proofing by tying each process to the individual configuration nodes and key decisions required to complete that piece
- Provides timely upstream visibility into areas of greater implementation risk, like project management and governance, organizational change management, data management, development and integration, security and compliance

The digital transformation journey is enabled by leveraging the LifeSciencesPath solution and iCaptivate Methodology seamlessly to accelerate implementation and deployment without sacrificing quality. Less wasteful haste, more efficient speed. To achieve this goal, LifeSciencesPath provides:

- Pre-configured end-to-end business process scenarios that address 80% of the typical business requirements of life sciences manufacturers
- A strong, experienced and knowledgeable implementation partner in the life sciences industry
- A clearly defined scope and time-frame for implementation
- Reliable, repeatable delivery
- Early visibility into areas that require additional attention

Capgemini's approach to Computer System Validation

Life sciences companies continue to face compliance challenges as the industry landscape evolves, which is further complicated by recent regulations such as GDPR and UDI. Through Capgemini's approach to IT compliance and validation projects, our clients have successfully addressed major events and market trends such as M&A, introduction of breakthrough technologies (e.g., cloud), adoption of Agile software development and poor audit outcomes. They have done this while reducing compliance costs through lean compliance and labor arbitrage by outsourcing specific IT compliance activities.

Now, with cloud, SaaS, complex infrastructure and middleware, and global access to data, companies find themselves with less control over the platforms and the applications that they have traditionally controlled within the four walls of their data centers. Furthermore, the systems and data management responsibility may be shared with partners (with regional or global responsibilities). Regulatory agencies and the industry are looking closely at data integrity and risk mitigation, and the focus of validation has transformed to a true risk-based approach. This translates to time invested in activities that identify and mitigate risks to data integrity and business objectives while being able to demonstrate that data integrity is assured throughout the life of the record (and with less time spent on overlapping testing and documentation activities).

Our holistic IT compliance service uses a pragmatic, risk-based approach to Computer System Validation and IT-related compliance, based upon a GAMP 5 framework. It ensures a compliant computing environment, system integrity, effective compliance processes, minimized cost and administrative complexity, and higher levels of quality and regulatory compliance. Our harmonized and integrated approach to IT compliance addresses the full regulatory landscape that impacts IT, including those set forth by local and international agencies (e.g., GxP, QSR, ISO, SOx, GDPR, HIPAA), in a consistent manner and without duplication of effort.

Capgemini has dedicated validation practitioners who bring experience and insights to support SAP implementations for navigating through Computer System Validation (CSV) requirements. These are the same resources recognized by the market as thought leaders for the many articles published, and are often invited to lead workshops, speak at conferences, and facilitate industry forums. We have qualified resources for strategic, tactical, and compliance maintenance projects. As an end-to-end service provider, Capgemini understands business and compliance, not just technology.

Why Capgemini?

LifeSciencesPath is a ready-made solution that allows life sciences companies to get a running start with SAP implementation. The solution has been configured for on-demand Computer System Validation. Capgemini has a rich history of highly successful collaboration with leading companies across the life sciences industry making it the best choice for implementing SAP within the life sciences industry, and we look forward to being part of our clients' success stories.

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About Capgemini

A global leader in consulting, technology services and digital transformation, Capgemini is at the forefront of innovation to address the entire breadth of clients' opportunities in the evolving world of cloud, digital and platforms. Building on its strong 50-year heritage and deep industry-specific expertise, Capgemini enables organizations to realize their business ambitions through an array of services from strategy to operations. Capgemini is driven by the conviction that the business value of technology comes from and through people. It is a multicultural company of over 200,000 team members in more than 40 countries. The Group reported 2018 global revenues of EUR 13.2 billion.

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