

Adopt an Ecosystem That Scales With Your Business

NTT DATA's Process, Application & Automation, Infrastructure and Security (PAIS) Solution for Life Sciences

Benefits

PAIS Solution for Life Sciences is preconfigured to align with the current phase of your business and can be implemented quickly.

- Prebuilt, embedded automation
- Pricing as a percentage of revenue and users
- Contracted TSA entry / exit timelines
- Front- and back-office servicing, including:
 - » Regulated customer inquiries
 - » Clinical service desk
 - 3PL interaction and finance & accounting
- 3PL servicing and contracts management, including:
 - » Shop floor and plant
 - » Engineering
 - » Lab equipment

Within the pharmaceutical mid-market, as well as in the emerging biotech and medical device spaces, there are typically three phases of growth — discovery, development & clinical, and commercialization — each of which has specific technology needs.

In the discovery phase, scientific study and other research for new innovation requires certain technologies right from the start. For example, a medical device company may require computer-aided design and manufacturing systems, a shop floor for assembly and the relevant software running on a secure infrastructure. This phase requires an ecosystem of about six to 10 applications, and cost is paramount.

When shifting from discovery to the development & clinical phase, companies need a slightly different set of applications with a more expansive infrastructure. Security tends to remain the same, but additional business processes now run apps for ordering, invoicing and managing the supply chain. Add in a contract manufacturing organization (CMO) and production or contracting with a third-party logistics (3PL) supplier, and this stage leads to an increase in administrative and corporate activity. Also, staff has likely increased by about 40% to 50%, so efficiency is key.

The commercialization phase adds further complexity, with ongoing regulatory requirements, as sales, marketing and other functions focus on growth. Companies must prepare to scale globally, which may include looking at potential partnerships and possible acquisitions or divestments. It also requires a very large application portfolio for manufacturing and 3PL, in addition to a quality management system (QMS) and corporate applications, as staff may have quadrupled in number.

This is where the Process, Application & Automation, Infrastructure and Security (PAIS) Solution for Life Sciences can help. Our custom ecosystem solution can ease the transition as your operations grow. It scales with your organization by providing an application portfolio within a managed services infrastructure that includes security and robotic process automation (RPA). And we offer this breadth of services as a single provider, giving you the functionality you need for a monthly fee, with flexible licensing options based on preference.

Process, Application & Automation, Infrastructure and Security (PAIS) Solution for Life Sciences



A simple solution for a complex environment

Using multiple vendors and commercial off-the-shelf software packages can lead to a significant outlay of time and money on support, licensing and other IT overhead activities. This means less time for innovation, process optimization and continuous improvement. NTT DATA offers a scalable, single-vendor solution for one monthly fee — so you can get back to focusing on growth. Our Process, Application & Automation, Infrastructure and Security (PAIS) Solution for Life Sciences comes bundled with the following:

- · Managed business processes with built-in automation
- Preconfigured applications based on your unique needs
- Built-in best practices that follow good automated manufacturing practices, comply with Food and Drug Administration regulations and are auditable for compliance with 21 Code of Federal Regulations (CFR) part 11 guidelines
- Prebuilt, rapid integration framework for the surrounding ecosystem
- · Qualified infrastructure with managed security services

Solution features	Examples
Preconfigured functionality	 Plan to manufacture: supply chain planning, including bulk drug, API and packaged products Procure to pay cycle: direct/indirect materials purchase Schedule to produce: CMO, CPO integration for inventory tracking, lot traceability, and track and trace Quality control: checks and approvals, electronic records and signatures based on 21 CFR part 11 and GxP validations Order to shipment: sell to wholesalers and/or distributor channels, outsourced logistics and 3PL integration
Foundation and data setup requirements	 Finance reporting structure and supply chain operations structure Basic HR functions (employee/supervisor, approval hierarchies) Master data setup (products, customers, suppliers, pricing, general ledger accounts)
Engagement model	Choose your platform: enterprise resource planning (ERP); ecommerce; customer relationship management (CRM); configure, price and quote (CPQ); and internal ops (travel, payroll, HR information system) Identify your locations, user types, current contracts and transferability terms Decide languages and coverage for your omnichannel clinical and service desk options Introduce your business process automation team to NTT DATA functional partners Participate in process validation workshops Go live on your configurable system in approximately 45 days Go live with your secure, global solution in approximately 6 months
Prebuilt ecosystem	CRM (Salesforce, Veeva, IQVIA OCE) Ecommerce (SAP Hybris, Oracle Commercial Cloud, Magento, Sitecore) Logistics, manufacturing and research (3PL, CMO, contract research organization) Laboratory information management system (LIMS), quality and compliance (QMS), and labeling Internal operations (electronic data management system, collaboration, travel, F&A, CPQ, payroll)
Accelerated solution deployment	 Industry best practice template validated in 90-minute work sessions Model company low-code/no-code ERP (Oracle, SAP) Clone and clean approach to an isolated or new instance in 90 days
Business process services with pragmatic automation	 Suspect to cash, forecast to replenish, procure to pay and plan to make process-oriented functionality Product recall Compliance-ready with GxP support for installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) Repeatable process automation as an NTT DATA investment

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Why bundled services?

With our PAIS Solution your midsize IT organization will be able to focus critical resources and budget on new technology, not on the administration of multiple partners. You can shift from budgeting for capital expenditures (CapEx) to budgeting for operating expenses (OpEx) because NTT DATA commits to software versioning, such as two updates to your current version with no additional fees.

Process



Preconfigured pharmaceutical business process with audit-ready GxP support for IQ, OQ and PQ

Application & Automation



- Fit-for-purpose applications of your choice enhance the employee experience, made possible through NTT's buying power
- License-free automation platform focuses on business value

Infrastructure



- Managed qualified infrastructure, be it private or public cloud, encapsulates compute, storage and the network
- Built-in refresh cycles with full onsite audit support as needed

Security



Integrated and managed security services, including software, hardware and global threat detection, as well as best-in-class solutions

The goal of the PAIS Solution for Life Sciences is to meet your organization's need to modernize core applications and integrate with a broader fit-for-purpose application layer to create a new ecosystem that focuses on the employee experience. Our bundled service gives you the opportunity to reduce multi-vendor interactions, support time, licensing administration and upgrade costs, because NTT DATA becomes the single point of responsibility with predetermined costs, terms and services — and no surprises.

Visit **nttdataservices.com** to learn more.

NTT DATA Services, a global digital business and IT services leader, is the largest business unit outside Japan of NTT DATA Corporation and part of NTT Group. With our consultative approach, we leverage deep industry expertise and leading-edge technologies powered by AI, automation and cloud to create practical and scalable solutions that contribute to society and help clients worldwide accelerate their digital journeys.

