

NTT DATA

# THE ADAPTABLE SOLUTION FOR SERIALIZATION COMPLIANCE



## WHAT IS IT?

NTT DATA's **ATTP-EWM integration** accelerator simplifies and shortens the time required to implement complex integrated serialization into warehouses processes used by life sciences manufacturers or wholesalers and in other industries. It can adapt to different regional and national regulatory requirements and has been designed to adapt to evolving needs.



## THE BACKGROUND

The EU Falsified Medicines Directive and similar legislation seeks to standardize the identification of pharmaceutical products and ensure only legitimate products can be dispensed.

Manufacturers are obliged to print unique serial numbers on each product pack and communicate the numbers to a regulatory database. The dispensing pharmacy must then verify that the serial number for each product dispensed exists in the database and, once dispensed, the number is marked as “dispensed” preventing the product from being resold.

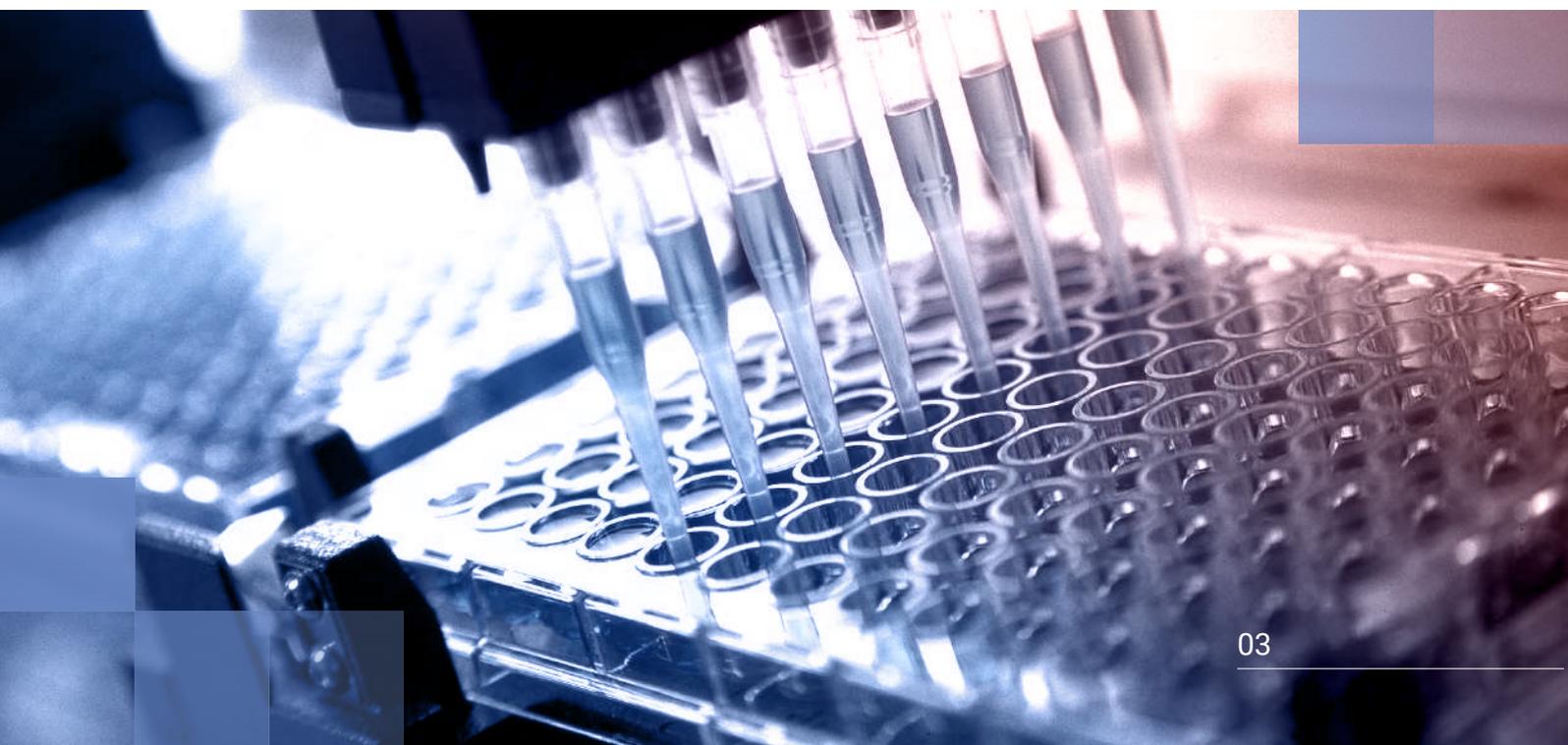
Some markets have gone further and demand a fully traceable supply chain at the level of saleable item, which requires the ability to scan logistical units in the warehouse operations of all supply chain participants.

The principal reason for serialization is to enforce systematic traceability, so ensuring patient safety, while also ensuring greater visibility from a logistics perspective.

According to a report by the European Federation of Pharmaceutical Industries and Associations (EFPIA), serialization also allows significant cost savings to be made by pharmacies due to better management of inventory and ordering patterns.

From the perspective of the user organizations, the EU directive has been a great success and regulatory bodies in other markets are now looking at implementing similar systems.

Serialization may also be extended to over-the-counter (OTC) market, and it is not unreasonable to predict that in forthcoming years, every pharmaceutical product, irrespective of the country of manufacture or intended market, will be serialized.



## THE CHALLENGE

Manufacturers of prescription drugs are obliged to implement serialization to comply with regional and country-specific reporting regimes that vary and are evolving.

To help automate these serialization processes in SAP environments, SAP offers Advanced Track & Trace for Pharmaceuticals (ATTP), which provides a corporate serialization repository, serial number management, and regulatory reporting capabilities.

Nevertheless, a common challenge facing companies that deploy ATTP is to make sure that the serialization-related processes are fully integrated in the different supply chain processes and can adapt to the specific needs of each manufacturer or wholesaler.

For example, when scrap activities are executed it is mandatory to decommission the serial numbers of the products to be scrapped. Integrating such a process usually requires large amounts of custom developments which costs a lot of money.

Even if the initial need is for a relatively simple vertical reporting solution, like that mandated by the EU's FMD, it is likely that reporting requirements will become complex and impact different stages of the supply chain.

For that reason some companies are already aggregating all products in their warehouse, even when this is not required. Aggregation refers to the application of codes to the outside of cases and pallets to enable the identification of all the individual packs inside.

If there is aggregation and ATTP knows which serial numbers are on the pallet, you cannot simply repack the pallet, because the physical situation will differ from that in ATTP.

In the case of aggregation, the object hierarchies in ATTP must be updated accordingly when pallets in the warehouse system are repacked.

NTT DATA developed its ATTP-EWM integration accelerator to handle complex processes like the one described and so significantly reduce the time required to integrate ATTP into an existing life sciences warehouse environment.

# NTT DATA EWM-ATTP INTEGRATION ACCELERATOR

The accelerator is a package that simplifies the implementation of complex integrated serialization processes in a warehouse, which can be based on SAP S/4HANA EWM or SAP WM. Out of the box RF transactions and an integrated picking solution support most of the warehouse processes typically employed by life sciences enterprises.

Processes that are customer-specific can be supported by using the building blocks that contain ATTP-related event logic. Because of the importance of validating any solution built using this accelerator to ensure GxP compliance, this package also includes a complete set of validation documentation.g

## Functional Areas Covered

### Pick Integration

These processes can be integrated in the pick process to confirm a Warehouse Task (S/4HANA EWM) or confirm a Transfer Order (SAP WM):

- **Loading (with repacking):** When serialized items are picked for markets requiring track & trace, the enhanced ATTP screen is triggered to capture serial numbers. When the pick activity is confirmed the loading and repacking (in case of partial picks) events are posted in ATTP.
- **Decommissioning:** When serialized items are picked for certain customers (export, Article 23, etc) or for scrapping/sampling activities the enhanced ATTP screen is triggered that allows capturing of serial numbers. When the pick activity is confirmed the decommissioning event is posted.

### Repacking

In the case of aggregation, the object hierarchies in ATTP must be updated accordingly when pallets in the warehouse system are repacked. An out of the box RF transaction is available to do this and building blocks are available to integrate this in warehouse repack transactions. Aggregated pallets can also be consolidated and by scanning the consolidated pallet numbers, an entire delivery can be decommissioned.

### Receiving

A PPF action is available that can be used to automatically trigger receiving events for STO processes. This is essential for serialized items requiring horizontal tracking as the outbound delivery from the issuing plant is linked to the inbound delivery from the receiving plant.

### Returns verification

In order to resell returned serialized items in the European market it is mandatory that the status of the returned objects is verified. An RF transaction is available that can be used to capture serialization objects that are returned and verify them against the EMVO database.

## Key Features

- Barcode decoding
- Object capturing / validating
- Event generation (e.g. decommissioning, loading (with repacking), (un)packing)
- Easily adjustable for different customer specific warehouse situations
- Ready-to-run solution for S/4HANA EWM RF pick integration
- Easily adaptable to WM pick integration
- Stand-alone transactionsg



## BENEFITS

- **Lower Costs**

Reduce compliance costs for existing and upcoming serialization requirements, such as country-specific reporting.

- **Complete Supply Chain Visibility**

Boost the efficiency of your supply chain with total visibility into material movements of pallets, cases or even down to item level.

- **Future proof**

Accommodates different regional and national regulatory environments and their future evolutions.

- **Shortens Time to Value**

Stand-alone transactions can be used out of the box while full integration to customer's environment is considerable simplified and accelerated.

- **Improves Customer Satisfaction**

Repacking functionality allows customers to order partial pallets instead of limiting them to full pallets, so boosting customer satisfaction.



# SYSTEM REQUIREMENTS

- SAP Advanced Track and Trace for Pharmaceuticals
- S/4HANA Extended Warehouse Management (Embedded or stand-alone) or SAP WM



# WHY CHOOSE NTT DATA FOR YOUR SAP LIFE SCIENCES PROJECT

## We are experts in life science

NTT DATA has worked with a diverse range of enterprises in the life sciences industry for 25 years. We have a 20-year track record specifically helping manufacturers in this sector and have a full understanding of the end-to-end manufacturing and quality business processes used in this sector, which is characterized by increasingly complex systems and disaggregated value chains.

NTT DATA has a team dedicated to S/4HANA transformation and an S4/HANA Center of Excellence that establishes the most appropriate evolution strategy for companies that want to evolve to S/4HANA and other SAP solutions, platforms and technologies.

As well as a range of sector-specific accelerators, we can help life science companies unlock the true potential of SAP S/4HANA with **it.lifesciences**, a collection of more than 300 industry best practice processes already available and ready to adapt for your organization. These include processes to optimize R&D, compliant manufacturing, quality control, supply chain management, and more.



## SAP Global Strategic Partner

NTT DATA is a formidable force in SAP services with more than 20,000 SAP professionals, 2,700 SAP clients worldwide, 21 delivery centers and operations in 41 countries. It is a truly global organization committed to seamlessly working together with its clients to deliver SAP-centric projects that can be delivered at scale and across multiple locations.

Our solutions leverage our business-specific expertise and skillsets in SAP technologies but also in other digital technologies, such as AI and IoT, for example. NTT DATA has achieved the highest accolade awarded by SAP, Global Strategic Partner, which recognizes its ability to offer a wide range of best-in-class business consulting and solution implementation services in support of SAP technology.

# THE NTT DATA DIFFERENCE

## NTT Data SAP Life Sciences Template

- Fully customized SAP S/4HANA system including all core areas such as finance, procurement, sales, logistics and production
- Includes new SAP modules such as EWM, IBP, TM, VMS, etc.
- SAP Business Technology Platform and Cloud Integration

## NTT Data SAP Life Sciences Accelerators

- **Internal Cold Chain** helps life sciences companies better manage their internal cold chain by ensuring the right freezing and thawing times for temperature-sensitive products are strictly enforced using scanners or RFID to identify and track batches.
- **CMO Cockpit & Integration Framework** has been developed to help pharmaceutical companies support the SAP processes for contract manufacturing in an integrated way. It includes a model CMO plant, data governance to simplify the onboarding of CMOs, and role-based apps to support manufacturing and supply chain processes.
- **Analytics Framework for Operational Excellence** allows pharmaceutical companies to easily monitor the KPIs necessary to achieve operational excellence. It includes a data model, a set of KPIs and extractors/views for data acquisition using S4/HANA.
- **EWM AP Integration** simplifies and shortens the time required to implement complex integrated serialization into warehouses processes used by life sciences, so ensuring compliance and improving supply chain visibility.



## ABOUT NTT DATA

NTT DATA – a part of NTT Group – is a trusted global innovator of IT and business services headquartered in Tokyo. We help clients transform through consulting, industry solutions, business process services, IT modernization and managed services. NTT DATA enables clients, as well as society, to move confidently into the digital future. We are committed to our clients' long-term success and combine global reach with local client attention to serve them in over 50 countries. Visit us at [nttdata.com](https://www.nttdata.com).



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