



CASE STUDY

Takeda Serialization Success Story

Executive Summary

International pharmaceutical manufacturer Takeda faced the task of implementing serialization and aggregation on over sixty globally distributed packaging lines. They were looking for a global vendor that would be able to create a standardized and repeatable process for Takeda's unique product identifier (UPI)—or track and trace—project. Configurable software, zero custom code and deep domain expertise were required to get the job done properly and to reduce down-time of packaging lines.

The Takeda and Systech partnership started with a pilot in Brazil, to deploy serialization and aggregation across all lines there. The project was successful, and Takeda made its broader corporate selection based on the experience in that region. There were also joint projects following in Taiwan, managed out of Japan, which led to the decision for Systech.

Systech met Takeda's expectation with an easy configurable software and a fully standardized packaging line set-up including all hardware components. In addition, they offered a robust set of implementation configuration documentation, based on thousands of line implementations Systech has been involved with. Takeda and Systech finally developed a standardized, repeatable team process for all line projects.

About Takeda

Takeda is a patient-focused, innovation-driven, global pharmaceutical company that builds on a distinguished 230-year history, aspiring to bring better health and a brighter future to people worldwide. The network of Takeda spans over 70 countries and regions worldwide including Japan, the United States, Europe, Latin America, Africa, the Middle East and the Asia Pacific Region. Takeda's pharmaceutical products are marketed in about 100 countries worldwide, including partnerships (marketing alliance partners).

Takeda has manufacturing facilities across the globe as well, including Japan, Russia, Poland, Germany, Austria, Brazil, Ireland, USA and Denmark.

Takeda's leading brands include:

ACTOS
ACTOplus met
ACTOplus met XR
Duetact
AMITIZA
COLCRYS

DEXILANT
ENTYVIO
KAZANO
NESINA
OSENI
PREVACID

PREVACID SOLUTAB
PREVPAC
ROZEREM
TRINTELLIX
ULORIC

“ This project created a best in class approach to deploying serialized packaging lines. ”

– **Josef Trapl**
Head of Technology



The Challenges

Takeda was looking for serialization solutions to address current and future needs that would also efficiently address new regulatory requirements as they emerge in all their markets. As data management is critical for all serialization initiatives, Takeda needed to implement a track-and-trace platform to enable bi-directional communication to and from the packaging line and enterprise systems. SAP is Takeda's standardized enterprise software platform, and the serialization solution needed to work seamlessly with it.

Manufacturers who invest in productized, configurable and expandable serialization solutions that leverage a standardized platform are well positioned to deploy serialization. They can also take advantage of future opportunities and are able to respond more quickly and cost-effectively to new demands. These solutions prepare manufacturers for the future while also keeping total cost of ownership (TCO) under control. Takeda also took this into account when looking at possible solutions.

The Solution

Systech's serialization platform was selected as Takeda's standard global serialization deployment.

In the end the projects were successful, and the Takeda/Systech approach worked well. Key to success was the overall standardization and modularization—of product, software, line equipment and processes.

Systech has developed a library of prepackaged modules to meet a wide array of packaging scenarios and serialization requirements. These Packaging Integration Modules (PIMs) can then be added to Systech's core solution to meet the requirements of each unique packaging line. Each module can be standalone or added with other modules allowing clients to design and build a solution for now that is expandable over time. Modules can be reused across multiple deployments to minimize risks, costs and downtime.

Given over sixty lines at Takeda, standardization, configurability and reusability were critical to minimizing implementation time and reducing project risks.

Configurable serialization software is designed with elements that can be assembled and realigned to quickly accommodate changing demands without requiring code rewrites. This eases handling multiple code schemas to comply with various regulations, enables in-house personnel to maintain the solution, and speeds implementation. In contrast, customized

solutions are rigid, making them difficult to implement and modify. By simply making configuration changes rather than rewriting code, configurable solutions minimize the need to perform line re-validations. As a result, manufacturers like Takeda see less line downtime, increased productivity and reduced costs.

Adding serialization technology goes along with new packaging processes at individual sites which must be accommodated by the enterprise information technology (IT) infrastructure. Serialization creates the need for the packaging environment and the IT environment to communicate back and forth to each other in new ways. Takeda needed to make sure that data integrity is protected as it goes to its SAP enterprise environment. Also the flow of data coming down to the packaging level and through the packaging and serialization software should not slow down product throughput.

It was decided early on in the project to use Takeda's SAP Enterprise platform to provide master data and production work orders. So the solution fully utilizes that as a 100% automated SAP process. The combined system will process those available work orders automatically. The solution is highly integrated as every line at every site is using the SAP master data production work order, which is sent down for execution by the Systech solution. It also interfaces and leverages Takeda's SAP infrastructure for overall serial number management.

Standardization and Repeatability in Action

The Takeda serialization solution with Systech is for over sixty lines. These complex manufacturing lines and packaging facilities are based in seven different countries. To manage a project of this scope, standardization of processes, software and equipment is essential to meet a timely rollout. It was key to Takeda to facilitate and enable high-performing teams on the project.

The most basic tenet of standardization and repeatability is a solid foundation of requirements. In pharmaceutical packaging this is the User Requirements Specification (URS). The first part of the project was to create a "universal" set of requirements, which allowed the joint teams to deploy very rapidly around the globe. Standards were developed at every level, both for upgrades of existing lines or new installs. This involved a jointly developed and standardized global URS and qualification/validation package. Each

local team had one URS to work from, and there was a spreadsheet that had the line specifics and the product configurations for the standardized line. So again, this makes the job easier to work from a formalized URS, harmonized for all sites and lines, and documented and aligned with the relevant line hardware.

Josef Trapl, Head of Technology at Takeda, said that this project “created a best in class approach” to deploying serialized packaging lines.

Systech starts with pre-configured and documented line setups, known as Packaging Integration Modules (PIMs). Systech benefits from its experience with hundreds of customers and thousands of line implementations, leading to a repeatable methodology for the wide range of environments encountered. These packages, along with Takeda’s internal methodologies, are aligned with the Good Automated Manufacturing Practice (GAMP) V-Model.

There were five standard requirements specifications that Systech and Takeda developed, approved and utilized for all lines.

Due to their consistency these standardized documents were easy to review and approve for the global team. There was also a detailed spreadsheet created to highlight each line, each specification and linkages to the now standardized PIM documents. In some instances, Takeda decided to process some of their manual operations somewhat differently and there was no existing PIM that fit. So the project team created a new global PIM specification, and it became part of the standardized baseline moving forward.

Teamwork

One of the most consistent themes of the project being successful was teamwork. “Having dedicated project managers from Takeda and Systech enabled close collaboration, and ensured that the established standards were implemented and working as intended,” said Trapl. Starting from common, approved specification templates allowed for Takeda and Systech to have the same “way of working” on both sides of the customer/vendor equation.

Site Enterprise Serialization Detailed Design Specification

- Provisioning serial numbers
- Data flow sequence diagrams
- Notification events
- User accounts and access levels
- Email notification settings
- Provisioning and notification parameters (URL address, XML schema parameters)
- Lines and products (products, packaging lines, packaging levels, etc)

Line Enterprise Serialization Detailed Design Specification

- Line architecture
- MES/SCADA interface to line
- Line to device remote operator configuration
- Process descriptions (start lot, resume/suspend lot, power fail recovery, end lot)
- In-lot rework operations
- Manual palletizing operations

Line Enterprise Serialization Configuration Specification

- Class configuration
- Product configuration
- Process stream configurations for the core software platform

Packaging Integration Module Design and Interface Specification

- Process flows
- System station descriptions and functionalities
- I/O descriptions
- Timing diagrams
- Alarms and counters (if applicable)

Packaging Integration Module Configuration Specification

- Vision configuration
- IPS block configuration
- Printer driver configuration (if applicable)
- PLC tag configuration (if applicable)

The project team managed to enable individual line serialization and aggregation projects to be complete in two weeks.

Trapl said, “this harmonized how we were able to deliver line after line after line, consistently, with quality and to our standards, repeatedly. Without our internal project team and our Systech project management team exhibiting perfect teamwork, we never would have been able to meet the project targets in time”. The project team managed to enable individual line serialization and aggregation projects to be complete in two weeks.

Looking Beyond Serialization

Takeda distributes high-value medications across the globe. Many are distributed into geographies that do not have serialization requirements. These largely third-world countries have seen a consistent issue with product diversion out of the legitimate supply chain. Medicines intended for use in local hospitals for the treatment of difficult diseases end up being found in the gray market globally. The easy access of the Internet and e-pharmacies has exacerbated this issue.

Even though the point of serialized barcodes is to uniquely identify each and every package for product protection, it is truly a compliance solution—not a foolproof brand protection solution. In these markets, where serialization is not mandated, the presence (or not) of a serialized barcode doesn’t do much at all. Serialized barcodes, in general, can also be fabricated and duplicated to look legitimate.

The printing process introduces micro-variances in the printed image. Systech’s UniSecure product is able to use a camera on a packaging line to look microscopically at each barcode and establish a digital e-Fingerprint for each item. By using a smartphone application individuals can image the barcode and verify its authenticity with its e-Fingerprint that is stored in the cloud.

Takeda will serialize these high-value medicines and capture their e-Fingerprints before distributing globally. This leverages their serialization investment and provides cutting-edge brand protection and authentication capabilities for them. Across Takeda’s supply chain, parties will be equipped with the smartphone application to authenticate product along the way. This will ensure that these medicines arrive where intended, and that these critical, life-saving medicines help those who need it most.

Conclusions

Rolling out serialization on over sixty globally dispersed pharmaceutical packaging lines is a challenging task. Takeda’s success in working with Systech was driven by a firm commitment to standardizing all elements of the project—from equipment to software (as a product) to process. Establishing a consistent set of understood requirements and specifications was the foundation for each and every project. Having trusted project management from both Takeda and Systech created the environment for teamwork leading everyone to the same end goals.



Systech is revolutionizing brand protection. For over 30 years, global brands have relied on us to combat counterfeiters, prevent product diversion and meet regulatory compliance. Innovation is deeply engrained in our DNA—from our start-up roots in advanced machine vision to pioneering pharmaceutical serialization and transforming traceability and non-additive authentication. Our software solutions ensure products are authentic, safe and connected across the supply chain—from manufacturing to the consumer’s hands.

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