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Serialisation Across Sites - From Product to Pallet

Roche implements a comprehensive serialisation program together with Laetus

Introduction

F. Hoffmann-La Roche Ltd, the globally active producer of pharmaceuticals, is the third largest pharmaceutical company worldwide. As early as 2009, Roche started a comprehensive definition of a strategy to introduce mass serialisation and traceability of its products throughout the entire supply chain.

The objective sought by Roche's long-term Supply Chain Control (SCC) program goes far beyond compliance with existing and future international legal requirements. In particular, Roche saw the challenge as a chance to create an adaptable and scalable global standard solution for the security of its own pharmaceutical supply chain. It ensures not only the long-term security of products on their way down the supply chain but is also the basis of future-oriented developments towards digitisation and patient safety.

Roche thus abandoned the philosophy of understanding serialisation merely as an add-on to existing processes and instead used the opportunity to reconsider processes and identify potentials for improvement to maximize the benefit for patients and the company. This visionary approach had far-reaching effects on the company's internal IT landscape. After completion of the one-year strategy development, Roche started the first phase of implementation, which comprises a total of six sites in six different countries on three continents, with about 50 quite different production lines.

Complex requirements call for a new way of thinking

Laetus, for more than 40 years a provider of quality and safety inspections, as well as of complete Track & Trace solutions for the pharmaceutical industry, has been selected as a partner by Roche. The decisive factor was not so much the pharmaceutical references that Laetus was able to produce but the compatibility of the Laetus approach with Roche's own global approach. Experience from the first project phase has shown that careful consideration has to be given to the complexity of the requirements and the scope of the project. Laetus convinced through the modularity and global scalability of its

Secure Track & Trace solutions, by its competence in project management and by its in-depth knowledge of the processes in the pharmaceutical industry.

Focus on integration into Roche's IT business structure

The focus was on implementing a comprehensive solution within the company's existing IT structure. This required the development of a standardised basic software/core solution to link the virtual world of the ERP/MES systems to the real world of production-level machinery through defined interfaces. The introduction of a basic software/core solution with interacting IT systems made a strict change management of all software components involved necessary. Moreover, the prerequisite for its use was a standardisation of the production equipment. This was a new approach that required significant modifications of Roche's IT business structure and machine park. The high effort required for this was offset by a decisive advantage: for future modifications, the software can be centrally administrated and validated – only the line functions close to the machines (cells) need to be tested locally.

Based on the experience from the first project phase, the Swiss company recognized the key role of IT for the entire course of the project. Therefore, intensive discussions were held at the beginning between Laetus staff and Roche's IT staff to develop a common understanding of the required functionalities. Roche provides a very detailed and well thought out IT specification for this purpose. This was the basis for the design and development phase of a solution tailored to Roche's needs. It was successfully implemented with the standardised S-TTS solution.

Secure Track & Trace solutions by Laetus

The Secure Track & Trace solutions by Laetus are modular in design and allow flexible scaling to adapt them to existing and future inspection requirements. A predefined cell is the lowest software level of the intelligent system architecture. The cell controls the equipment within a packaging line, such as printers and cameras. The number of cells depends on the required scope of marking. Each cell corresponds to one packaging step. The individual cells are independent of each other in configuration. Their tasks range from the inspection of pre-printed constant data to inline serialisation with additional batch-constant printing to multi-stage aggregation.

IMV-370 pack handling system for the inspection of bundles

If the line configuration has to be expanded due to a change of requirements, the advantages of the modular software architecture with predefined cells become apparent. The line configuration can be easily expanded by adding additional cells, and the predefined cells make the validation process easier.

Synchronisation of cells

The next higher software level of the Secure Track & Trace solutions is line management. This level synchronises all cells in the packaging line in accordance with the loaded recipe. In order to be independent of a permanent network connection to the next higher level of software architecture, line management receives the order data and the serial number from the next higher level and stores it. The line level also manages the different orders and controls their execution. Line management enables and disables the required cells and can start, hold and stop individual orders for a flexible response to production requirements. For this purpose, it communicates with each active cell and exchanges the serialisation-related data. This level of software architecture serves to implement fully automatic, semi-automatic and manual packaging steps.

Main database and interface with business IT

Plant management is the highest software level of the Track & Trace architecture. It consists of the central user management and the main database that manages the product data, equipment formats, all line configurations and the recipes. At this level, orders are either created manually or downloaded from the higher-level business IT. For this purpose, plant management is equipped with an interface (level 4) for the higher-level business IT. The S-TTS communication module that makes the bidirectional communications interface between the plant server and a higher-level (level 4) system (ERP/MES) possible is GAMP 5, class 5 compliant (programming).

The maintenance of the master data is carried out in the ERP system. The basic software, consisting of cell, line and plant management, is compliant with GAMP 5, class 4 (configuration).
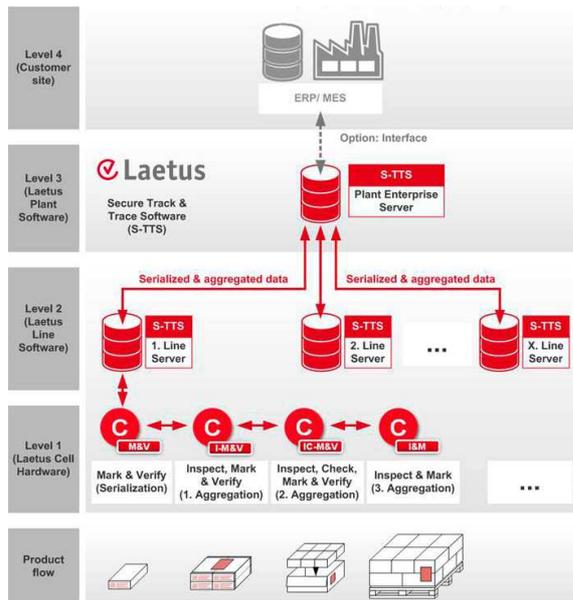
S-TTS software architecture

Networking standards of production IT system

Secure Track & Trace solutions are based on the four-level IT system defined in the standard ISA-95. Also, their architecture of levels communicating with each other and of the combination of tasks of individual cells into processes reflects a service-oriented architecture approach. The orchestration of services involved at the cell level, such as marking and camera control, automation control and communicator, facilitates internal data organisation and transfer between levels.
The S-TTS system architecture is mirrored in the areas of hierarchy levels and value stream based on the Industry 4.0 reference architecture model.

Roche project comprises around 50 product lines

In addition to the well-conceived software structure, the composition of the project team was also a decisive factor for the successful progress of the project. The Roche project team includes both IT and engineering staff and an international project management team from Laetus with different fields of expertise. Regular meetings and close consultation ensure a permanent actual/target comparison of the level of implementation, and enable constructive and flexible handling of technical problems that arise during the implementation phase.

Close cooperation is required not only between the two project partners but also with the OEM machine suppliers involved. In the so-called hot project phases, Laetus staff is permanently on site to ensure smooth implementation of the project.

Example of a multi-line solution across multiple sites

Each of the 6 sites worldwide produces, on the one hand, for its own local market, and on the other hand, for international markets. A typical line structure is composed at all sites of 1 to 3 machine cells so that the Secure Track & Trace solution had to integrate a total of approximately 100 machine cells. The first cell handles the serialisation of the folded box, whereas the second cell is in charge of the aggregation to shipping cartons and the third for the aggregation of the pallet. Laetus has the task, beside the supply of the Track & Trace software and its integration into the existing IT landscape, to supply the hardware components required for implementation of the Roche program to the six OEM machine suppliers involved. The Laetus application and system engineers cooperate closely with the OEMs concerned for the integration of the components into the machine cells.

The course of the project comprised a total of three large phases. The first phase was dedicated, as described, to the strategy definition and the preparation of the implementation. The second phase focused on the feasibility study and setting up the necessary project infrastructure and the first short-term serialisation requirements were implemented in it. Since 2013, the third project phase has focused on the full implementation and the fulfilment of medium-term serialisation requirements, and on aggregations up to the pallet level.

Center of Excellence enables tests with real data
By the end of 2016, the Roche project will be implemented on all originally planned lines and on additional lines that were not initially included in the program, and the validation will be successfully completed. According to the project planning, the implementation on the remaining lines is scheduled to be completed in the following year.

The validation phase could be significantly sped up by extensive preliminary validation in a test centre explicitly created for that purpose. The Center of Excellence in the IT headquarters at the Swiss Roche site of Kaiseraugst is equipped with a Laetus system with the full range of functions. This enables the testing and validation of new software versions prior to the roll-out in the real-life product line. The tests performed are no simulations with artificially created data material. The system uses real data for its modelling of data movements, such as the exchange of data between the plant level and SAP/MES at level 4! In this way, new software versions can be thoroughly checked and validated in advance, without the risk of a long downtime of the packaging line. Another decisive argument for the setup of this test environment was the desire to perform training courses under realistic conditions without interrupting the ongoing production process. The Center of Excellence offers ideal conditions for this, because it is equipped with machinery that is largely comparable with the actual equipment of the production lines.

In addition to the equipment, a manual aggregation station is provided: the CS-60 manual packing station can be used both for manual and for semi-automatic aggregation in the packaging line, depending on the configuration. The Laetus warehouse SW module (TTW) is provided for creating and processing shipping orders in the warehouse. TTW performs a re-aggregation of completed packaging orders and thus provides the interface between the production order and the shipping order.

Lessons learnt and outlook

Roche understood the necessary implementation of the various national serialisation regulations as an opportunity to set the long-term course towards security of the supply chain. To achieve this goal, the approach could not simply be retrofit to individual sites and lines successively to meet the specific requirements of a country. A vision of the long-term goals had to be developed to serve as a basis for the elaboration of a strategy for step-by-step implementation. The ultimate goal is the creation of a standardised, interoperable solution with a high level of integration. This can only be achieved through close cooperation of the global and local project teams on the company side with the Laetus staff responsible for the project. Because of the continuous and simultaneous mixture of prototype development, conceptual design and operation implementation, new findings and experience could be promptly integrated into the solution. The course of the project so far shows that such complex serialisation projects can only be successful if the precise requirements have been sufficiently clarified in advance, and all project partners and stakeholders involved work in close cooperation. Also, the software architecture on which the Track & Trace solution is based must be modular in structure so that it can be expanded in a scalable way on the basis of standardised modules. This prevents island solutions that are specifically developed for new requirements and are not compatible with the rest of the system.

Together with Laetus, Roche has created a solution that not only fulfils different national regulations but also provides the basis for a long-term increase of customer benefit and thus for Roche's own business value. In light of the cost and effort associated with such a serialisation project, such a strategy is more than justified.

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