



Digital Twins in the pharmaceutical industry

Progress report

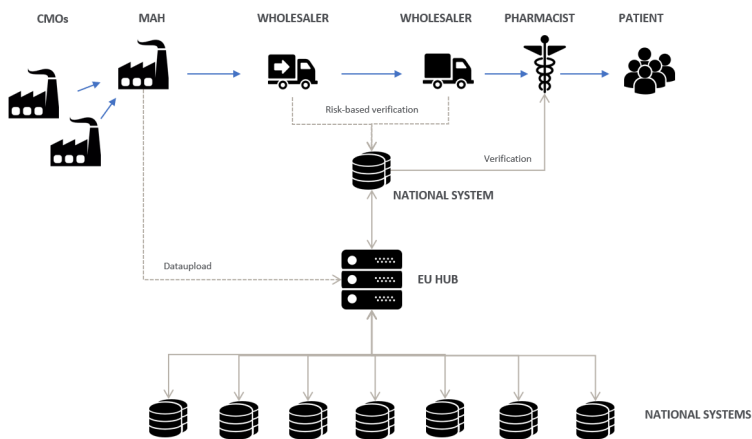
In the pharmaceutical industry, Digital Twins are being used to combat product counterfeiting. They not only offer added value for the industry, but also ensure greater patient safety. In this white paper, we answer the questions how exactly Digital Twins are used in the pharmaceutical industry and what we have learned from the implementation of Digital Twins.

As with all innovations, new scenarios or solutions and the associated terms must first be defined and shaped by the respective actors. Digitization already involves hundreds of terms – not all of them are clearly distinguishable from each other. Depending on the industry or application scenario, they may vary and yet all refer to the same thing – it is always a question of definition. Digital Supply Chain, Digital

Twin or traceability can be synonymous or at least overlap. For example, the term „Digital Twin“ is not used at all in the pharmaceutical industry. In most cases the terms Traceability, track&trace or Digital Supply Chain are used. And still the pharmaceutical industry works with the Digital Twins of its products every day.

Digital turn in pharma

At the beginning of the 2019, the introduction of the Falsified Medicines Directive (FMD) made pharmaceutical serialization a major issue. Here, serialization means that every single package can be tracked. Manufacturers and logistics specialists not only know where a batch is at any given time, but can also trace each individual sales unit via its unique serial number. This means that the authenticity of each individual medicine can be checked before it is dispensed to the patient in the pharmacy.



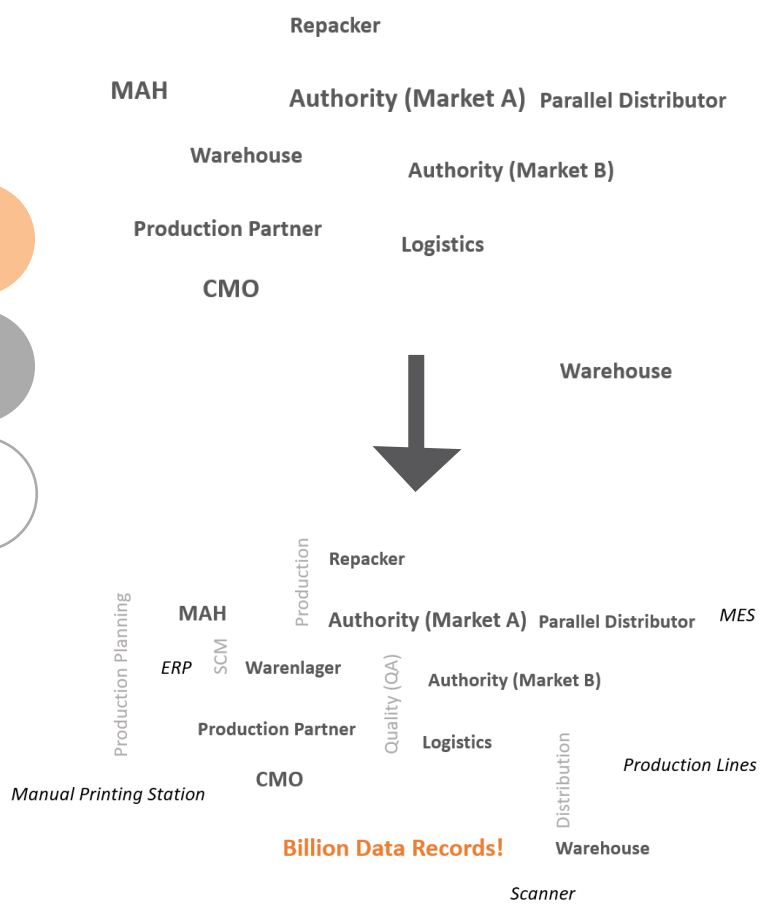
European Stakeholder Model

Pharma serialization – A challenge in practice

Tracking a product lifecycle sounds simple at first. But the implementation in practice requires above all: cooperation, networked players and, on an international level, a deep knowledge of the various regulations. Manufacturers, repackers and contract manufacturers must communicate with each other and with the authorities. This means that there is a widely ramified network of production planning, produc-

tion, supply chain management, quality management, distribution and, ultimately, pharmacies or hospitals, which operates with the Digital Twins of medicines. Billions of data records are created along the network, which must be stored and made available on a long-term basis. However, the serialization regulations in the EU are only the beginning. In Saudi Arabia, Brazil or China, similar or even stricter and more complicated guidelines will be introduced in the medium term. Internationally operating pharmaceutical companies will face even greater challenges as they have to expand these networks, at least in part, and find ways to communicate with authorities and service providers beyond European borders.

In the US, for example, the life cycle of a drug must be written along the entire supply chain in order to comply with the DSCSA guidelines. Russia, in turn, has introduced a system of complex codes and aggregation. This means that packaging hierarchies must also be mapped via the supply chain, from individual packages to pallets. In the EU, on the other hand, only end-to-end verification is used. The serial number is assigned to the individual packages and each package is only checked for authenticity again in the pharmacy. Unlike in the US, not every single station in the supply chain is recorded in the EU.



How does the pharma industry work with the Digital Twin?

The Digital Twin in the pharmaceutical industry can be understood as the digital image of a single sales unit, which reproduces the (complete) life cycle of the real product in digital form along the supply chain. To map and implement this complex process, tracekey solutions works with a Software as a Service solution (SaaS) in the Cloud. With our solution, we have made it to the top of serialization providers for SMEs within the past years. However, the highly regulated environment of the pharmaceutical industry also requires some special features on the software side. New versions are first made available on a test system, which are then tested by us and our customers

and only validated after successful testing and transferred to the production system afterwards. The infrastructure also includes disaster recovery, a backup system and all this on a multi-tenant platform.

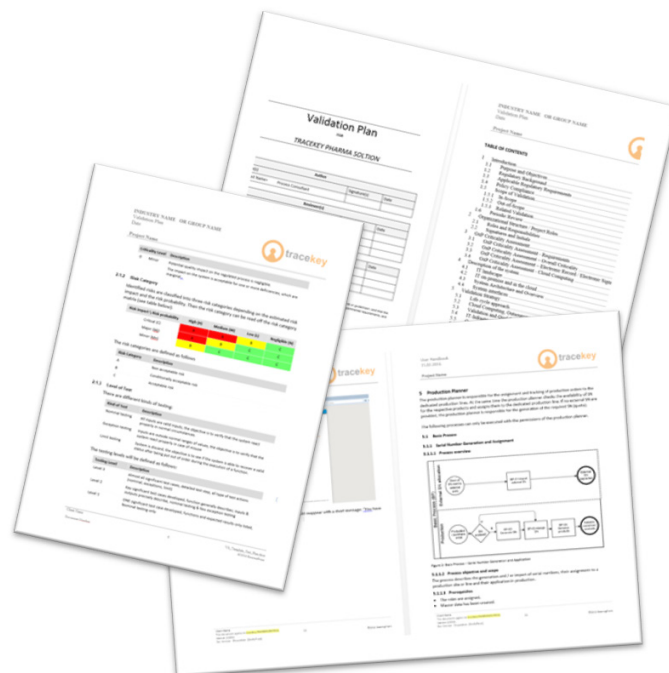
Standards are needed to implement digitalization for many different players simultaneously. Business Standard Connectors include, for example, Business Partners or the production systems. Besides, there are the Authority Connectors, including the EU hub, DSCSA, or RUS (MDLP/SUZ). All these players must be connected via software. This also means that a serialization software solution must process very different data formats and translate them into the form required by the EU.

Is the pharmaceutical industry a role model for other branches?

The entire pharmaceutical industry has undergone an immense upheaval within a few years and has been digitalized, so to speak, by force, i.e. by an EU regulation. What can other industries, whether strictly regulated or not, learn from this? We see the digitalization of the pharmaceutical industry as a model for others. A positive example is the EU stakeholder model. It did not specify how the regulations should be implemented in the individual countries. A Stakeholder Model has emerged from this scope for design, with securPharm representing the German organisation. Within Germany, it is the first official authority to check the authenticity of drugs. In this way, the simultaneous digitalization of the pharmaceutical industry throughout Europe could be broken down to the individual countries and implementation was made possible in a short period of time.

Our learnings

1. **Standards** help to define processes. But: Over-standardization is an inconvenience when it comes to establishing new processes.
2. **Continuous validation** is essential. In addition, documents must be standardized, because the legal requirements are not static. E.g. shortly after the first implementation phase in the EU already significant changes were implemented. The quality requirements for products and documentation are high and are subject to constant control. The software must therefore also be continuously adapted. To be able to meet these requirements nevertheless, it was necessary to move from individual projects to standardized products with likewise standardized documentation.
3. **Requirements** define the tool set. An early definition of a technology can be an obstacle here, since the requirements are decisive for which tool makes sense at all. Special technologies, such as the block chain, are currently being experimented within suitable application areas. Cloud systems focus on establishing a digital supply chain, while production-related systems are operated on-premise.
4. Clear differentiation between **IT systems** is achieved by classifying them into levels, from device level (L1) to the external network (L5). In practice, problems always arise when a system is overloaded with tasks from other levels, e.g. when the ERP system has to handle mass data from production.



About the authors

Daniel Althoff M.Sc. is product manager at tracekey and has experienced and shaped the digital transformation in the pharmaceutical industry at first hand over the past years. As a project manager he is responsible for innovative projects in the fields of Healthcare, cosmetics and automotive.

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About tracekey solutions

tracekey solutions is a RegTech partner of the life science industry and the leading provider for SMEs in Europe. Based on our many years of experience in the field of pharmaceutical serialization, we are constantly expanding our product portfolio with cloud solutions that meet the current challenges of the market.



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