LEANspiration CONSULTING GmbH
JUST THE MOST IMPORTANT THINGS FOR YOU

ARXUM

Blockchain for Pharmaceutical Industry

With **Blockchain Technology** the pharmaceutical and medical device industries are provided with a unique chance of improving overall compliance and regulators are getting the complete and immutable traceability of products and processes. The pharmaceutical and now as well the medical device industry are heavily regulated, because first of all it is a question of trust in the protection of patients. Where no trust is, one has to proof that everything is cGMP conform. With the new Blockchain technology the status quo can be changed to a point, where regulators can trust and rely upon always available lifecycle data from pharmaceutical and medical device products, production, distribution and logistics. All generated data is accurate, verifiable, secured through encryption, automatically written into the blockchain layer, so all information is always recorded. Blockchain is providing all these abilities regarding compliance and business aspects.

This can be illustrated in use case examples:

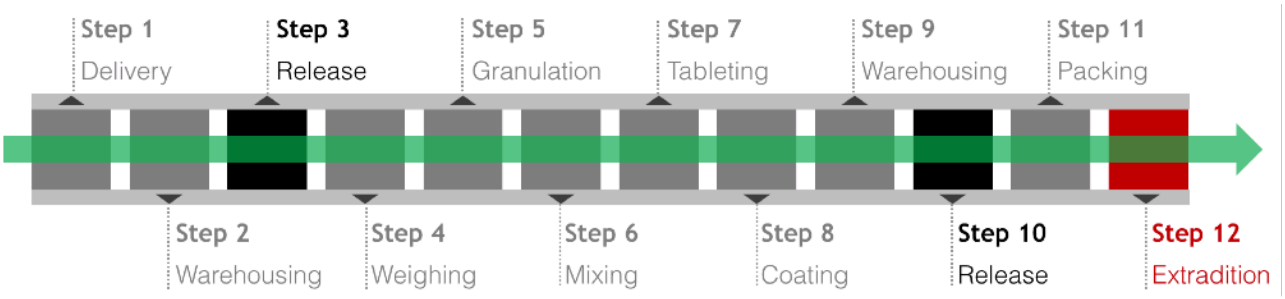
Use case I: Pharmaceutical Supply Chain and the Counterfeit Drug Problem

Due to the U.S. Drug Supply Chain Security Act (DSCSA) supply chain security has recently gained attention in order to battle the counterfeit drug problem. Counterfeit drugs are drugs that do not contain the active ingredients they are supposed to and consequently can harm patients. The supply chain in the pharmaceutical industry is complex, with drugs changing ownership from manufacturers to distributors, repackagers, and wholesalers before reaching the customer.

Using the immutable Blockchain technology can increase trust and transparency, with customers, doctors or patients being able to track pharmaceutical products throughout the complete supply chain.

Use case II: Process Documentation for Film Coated Tablets

The pharmaceutical production process of a film coated tablet can be verified using blockchain token for proving each operational step with the necessary process parameters, including calibration verification and engineering or qualification/validation of documents, if needed. With Blockchain technology it is possible to collect all process data live within production for all different steps in order to prove the cGMP compliance of the overall production, storage, packaging and distribution at each point in time.



Use case III: Linking cGMP Requirements and Fulfilment with a Unified Data Access

Today, most documentation is still paper-based or based on electronic files. But there is not yet an electronic link between the cGMP requirement and its proof. By linking requirement documents, process execution documentation and personal signatures with digital fingerprints on a Blockchain, everything is tied together under one single point of entry. Blockchain technology provides on common data access interface for inserting and extracting data, applicable in all corporate areas and divisions, regulating authorities and auditors, making all data access easier and all processes holistically traceable.

Auditors can directly see a complete chain between requirements and their implementation in the production process to be correctly verified. This will build a deeper trust into the overall qualification and validation activities.

Use case IV: Drug Development and Clinical Phases Verified by Blockchain

The very same strict and secure documentation mechanisms can be used for drug development activities, from technical trial, clinical studies as well as pharmacovigilance, providing a deep transparency inside the drug development system.

ARXUM Business GmbH, located in Zug, crypto valley Switzerland, provides the blockchain based system solution to set the scattered businesses in the pharmaceutical industry on a blockchain basis, down to the granular level of linking production machines to smart contracts on the Blockchain.

ARXUM uses Blockchain technology to integrate data from diversified sources in the pharmaceutical & medical device industry. A prescription or a manufacturing order is created as Ricardian smart contract on the Blockchain. All manufacturing peers, such as clients, manufacturers, suppliers, transport agents and providers of digital services, gain fine-controlled access to relevant production data.

Blockchain technology provides for immutable traceability on several levels:

- Manufacturing and batch release data, indications, etc.
- Access control on who is getting which product
- Full traceability and full track and trace of orders and products
- Accessible in any case for regulators and controllers

The global **ARXUM Production Protocol** is one single standard to connect all manufacturing players to a protected Blockchain infrastructure, providing end to end visibility on all relevant production events. Practitioners, manufacturers, material providers, transport agents, payers and insurances, as well as internal stakeholders such as engineering, maintenance and operations have discriminated access to the same data on the blockchain. All data is securely stored with digital fingerprints and protected against manipulation. This provides secure product identification, immutable traceability and a complete audit trail for internal or external regulators.

Doctors can create prescriptions as smart contracts on the Blockchain

Insurances have access to approve payments.

Further service integration is enabled through data access.

Patients can have access to specific medication data

Manufacturing facilities are connected and document production events and process parameters

Material supplies and intermediate storage conditions are documented

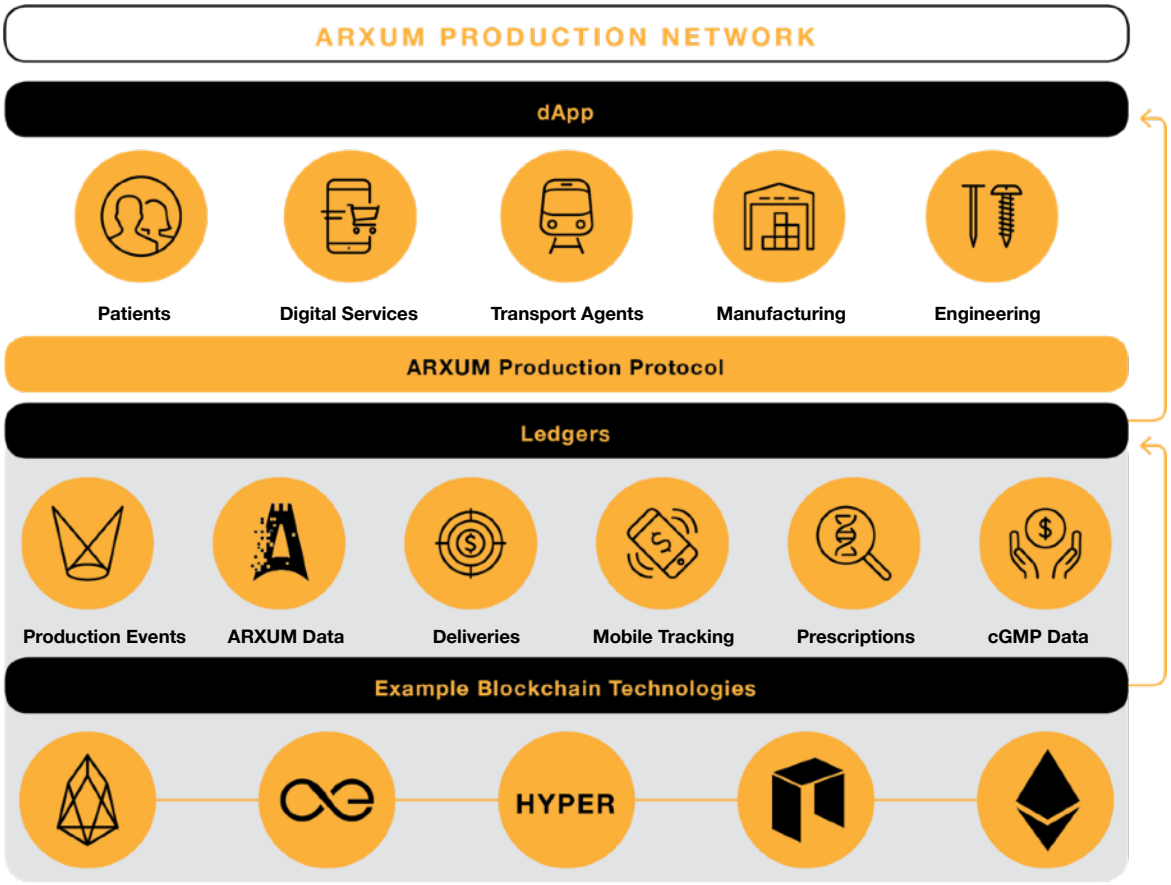
Transport orders can be generated automatically. Transport agents are integrated and delivery tracking is integrated

ARXUM provides the ARXUM Connection Box (ACB), a cyber-secure IoT gateway for production machines which directly communicates with the Blockchain, thereby eliminating potential manual manipulation. Further, existing IT infrastructure is connected to the ARXUM Production Protocol through a programming interface (API) towards ERP systems or manufacturing execution systems.

Based on the ARXUM Production Protocol, the ARXUM Production Network provides several, distributed applications to the different stakeholders to access the production and product data. Data is stored in different distributed ledgers, such as for prescriptions, production events and processing data, transport & end deliveries, product data or regulatory requirements.

The distributed ledgers are accessible for various purposes, such as post processing analysis, predictive engineering & maintenance. Various digital services can be integrated:

- Perform stock adjustments worldwide (manufacturer, pharmacies, doctors, patients, etc)
- Running various analysis algorithms on material distribution, delivery timings, geo-location data, ingredients, patient reports, etc.
- Artificial intelligence could track everything and pinpoint automatically in case issues needs deeper investigation
- Big Data analysis gives the possibility for better forecasts on regional product needs, e.g. in case of an emergency



LEANspiration Consulting GmbH, located in Stein, Switzerland, provides the regulatory background and experience in CSV to bring true value through regulatory preparation, systems validation and system performance qualification. In the pharmaceutical and medical device industry every tool needs to be controlled and verified. Due to years of experience in the introduction of new technologies LEANspiration cares for the regulatory fit of the ARXUM solution. This generates true value through regulatory preparation, systems validation and system performance qualification, including supplier qualification documentation for the hard- and software of ARXUM.

LEANspiration & **ARXUM** together provide the future oriented, secure and effective solution for the pharmaceutical and medical device industry. A new standard based on Blockchain technology, enabling a fully digitalized connection between end practitioners, patients, manufacturers and their suppliers down to machine level.

Contact Marc Gerspach: +41 (0) 79 393 30 05, marc.gerspach@leanspiration-consulting.ch

LEANspiration CONSULTING GmbH
JUST THE MOST IMPORTANT THINGS FOR YOU

ARXUM

LEANspiration Consulting GmbH
Münchwilerstrasse 3 • CH-4332 Stein
info@leanspiration-consulting.ch
www.leanspiration-consulting.ch

ARXUM Business GmbH
Gartenstrasse 6 • CH-6300 Zug
info@arxum.com
www.arxum.com