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Flow of information in the pharmaceutical supply chain.

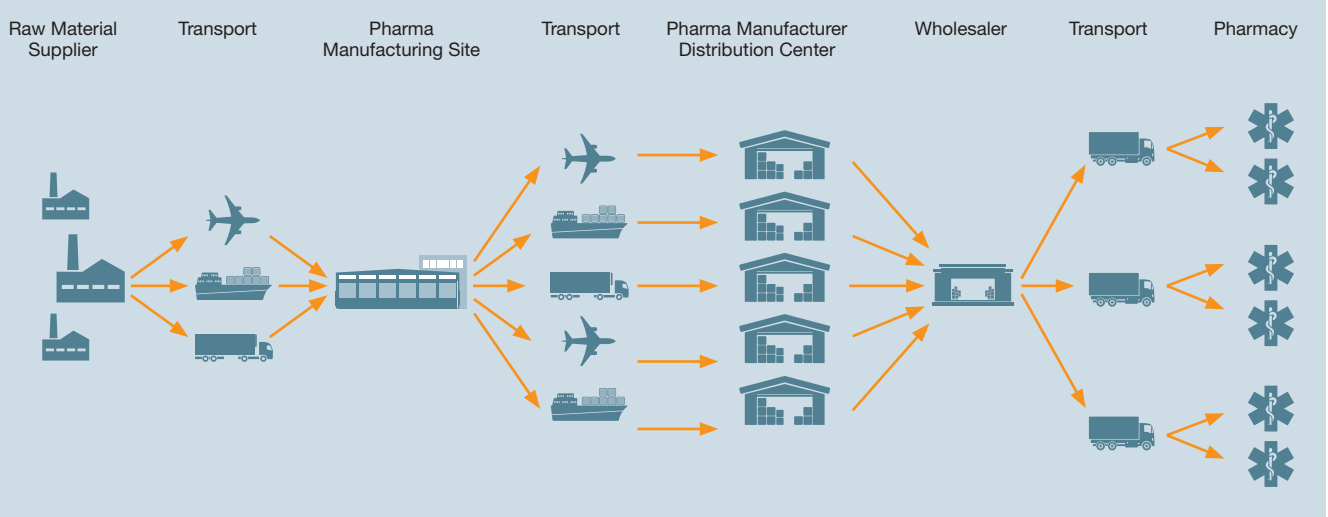
Executive summary

Distribution of pharmaceutical products from manufacturer to patient poses a big challenge for today's industry. In a globalised and complex supply chain, where drugs are being transported by air and changing ownership between various trading partners located in different parts of the globe, many questions arise:
How can safety and efficacy of the product be guaranteed? How can the risk of counterfeiting be minimised? How can products be protected during the last mile?

Since data reconciliation is usually needed, this paper discusses how electronic records of environmental parameters can be handled, as well as the data centralisation and decentralisation approaches to this topic.

Introduction

The traditional flow of goods along the pharmaceutical supply chain is illustrated in the picture below.



Pharmaceutical supply chain

Many entities and persons are involved in each of the steps above; for handling, storing and/or transporting goods. To name a few: API and excipients suppliers, CMOs (contract manufacturing organisations), regulatory bodies, third party logistics, freight forwarders, transport agents, air/ ocean freight carriers, custom agents, wholesalers, retail pharmacies, hospitals, etc. A lot of time and effort is spent in reprocessing (reimbursing, reconciliation, reordering, etc). Independent of the INCOTERMS of the commercial agreements between the parties, manufacturers need to make sure drugs arrive safely to end patient, since their image could be highly impacted if any health issues occur.

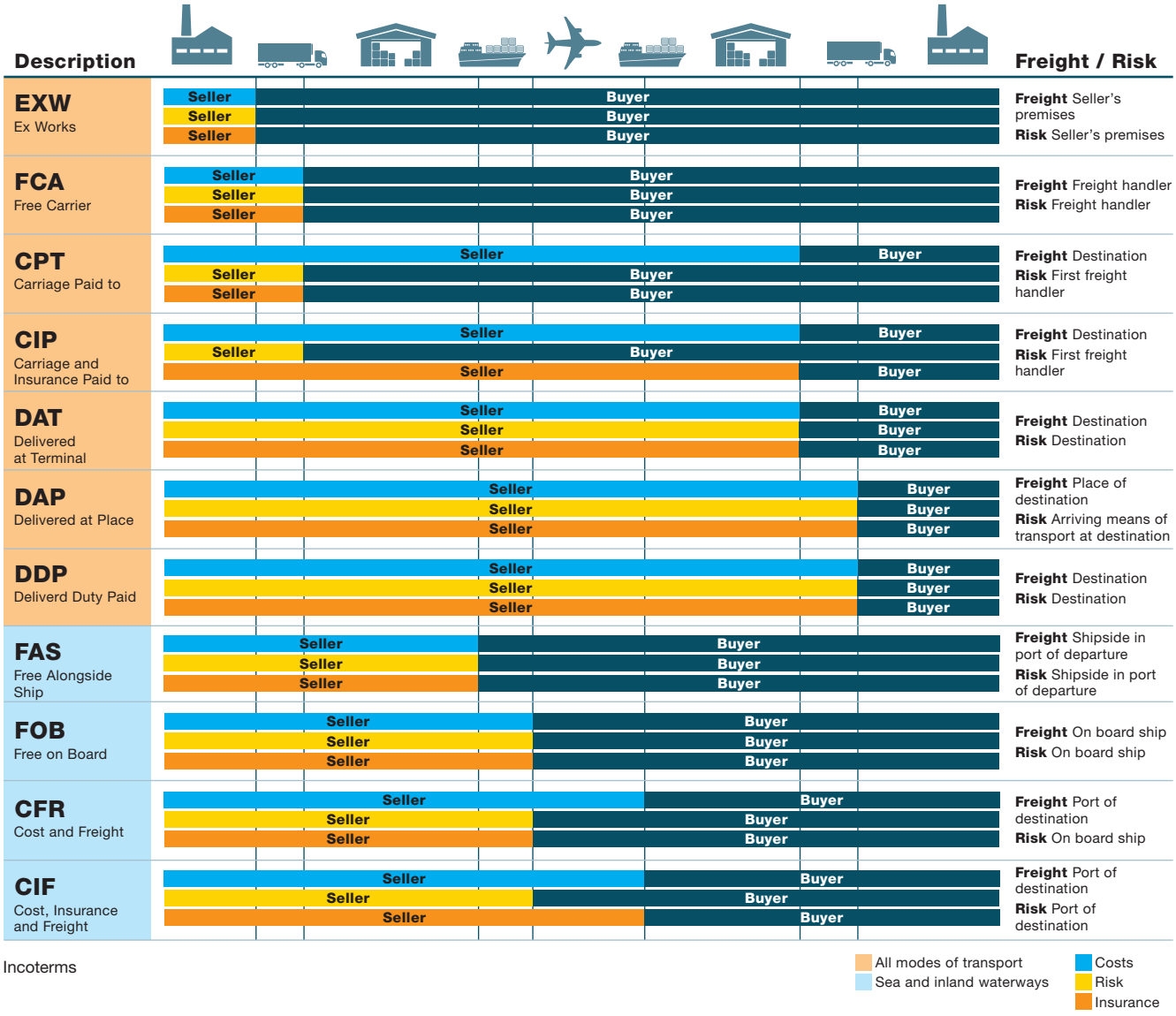
According to research conducted by Deloitte, the major pain points that arise for supply chain professionals are:

Compliance: Standards and controls requiring that all regulatory conditions are met

Flexibility: Adaptation to new business models and scenarios whilst keeping operational costs under control

Stakeholder management: Governance in place to enable communication, risk reduction and trust among involved parties

Traceability: Ability to monitor events associated with a product and all metadata related to it



The pharmaceutical industry is one of the most regulated among all industries and needs to prove compliance in every aspect from manufacturing, storing and distributing its products. To be compliant with all regulations and still be flexible enough for the market today is an art that all industry players desire, but only a few can master. In the industry value chain this flexibility leads to good stakeholder management and reduction of the trust barrier; former commercial partners are to be seen be more and more as real partners. Not only traceability, but also serialisation is a demanding topic for the industry, only with this can an end-to-end approach really be met.

Knowing and having transparency on the journey that one specific drug has taken before it arrives at the patient's house is helpful in the case of incidents and product recalls. Tracking these is important not only in a logistical approach, but also in the inherent quality parameters such as temperature and other environmental parameters which may have faced temperature excursions along the chain.

The WHO Annex 5 addresses definitions for Good Practices at Distribution of Pharmaceutical products with the aim of assisting in ensuring quality and identity of the pharmaceutical products during all steps of the distribution process. It is clearly stated that each part in the chain has the responsibility to ensure that the quality of the pharmaceuticals and the integrity of the distribution chain is maintained. It also states that all the personnel involved should be trained and qualified in requirements of GDP as applied.

From a therapeutic point of view, since the beginning of the year 2000 there has been an important change from small molecules fixed dose and combinations to therapeutic monoclonal antibodies optimised specifically for a group or an individual with specific characteristics (environmental and biological like its genomics, proteomics and metabolomic patterns).

Producing, transporting and administering those biopharmaceuticals poses an even bigger challenge for the industry, since they tend to be much more sensitive to degradation and undesired modification when exposed to temperatures and humidity beyond limits. The cold chain must be completely under control in this aspect, taking into consideration that even the commercialisation of those components is done between continents with completely different environmental conditions. Some of those biopharmaceutical and cell therapies would require to be kept at -20 °C.

Challenge:
How to deal and manage quality related parameters at all parts of the supply chain of pharmaceutical products?

Discussion
Data decentralisation for the complete chain can be a potential solution for the market in a blockchain structure, where data are exchangeable and encrypted, distributed throughout the parties with each one accessing the required blocks. This approach is in its preliminary steps in the sector. Many questions like those included below need to be aligned between all parties involved:

- How to establish an electronic connection between non-adjacent trading partners?
- Can trust be established between parties so information can be shared without the risk of exposing proprietary information?
- Some trading partners would have their scope drastically reduced
- The architecture is not yet present and should be agreed upon by all parties
- Acceptance and auditing procedures for this decentralised approach by regulatory bodies
- Will product quality parameters like temperature and humidity be disclosed at this blockchain?

For the bulk of information (point of origin, point of destination, packing list, commercial invoice, etc.) on supply chain, the decentralised approach could be interesting.

However, for quality parameters at the manufacturing level, having more control in a centralised way through the information of all environmental parameters during production, storage and transport in a single and secured platform leads to better data integrity and end-to-end temperature reports.

testo Saveris Pharma Solutions combines, in a single platform, data from transport and storage into a secure and validated software database (in compliance with 21 CFR Part 11), and can be scaled up according to business needs.

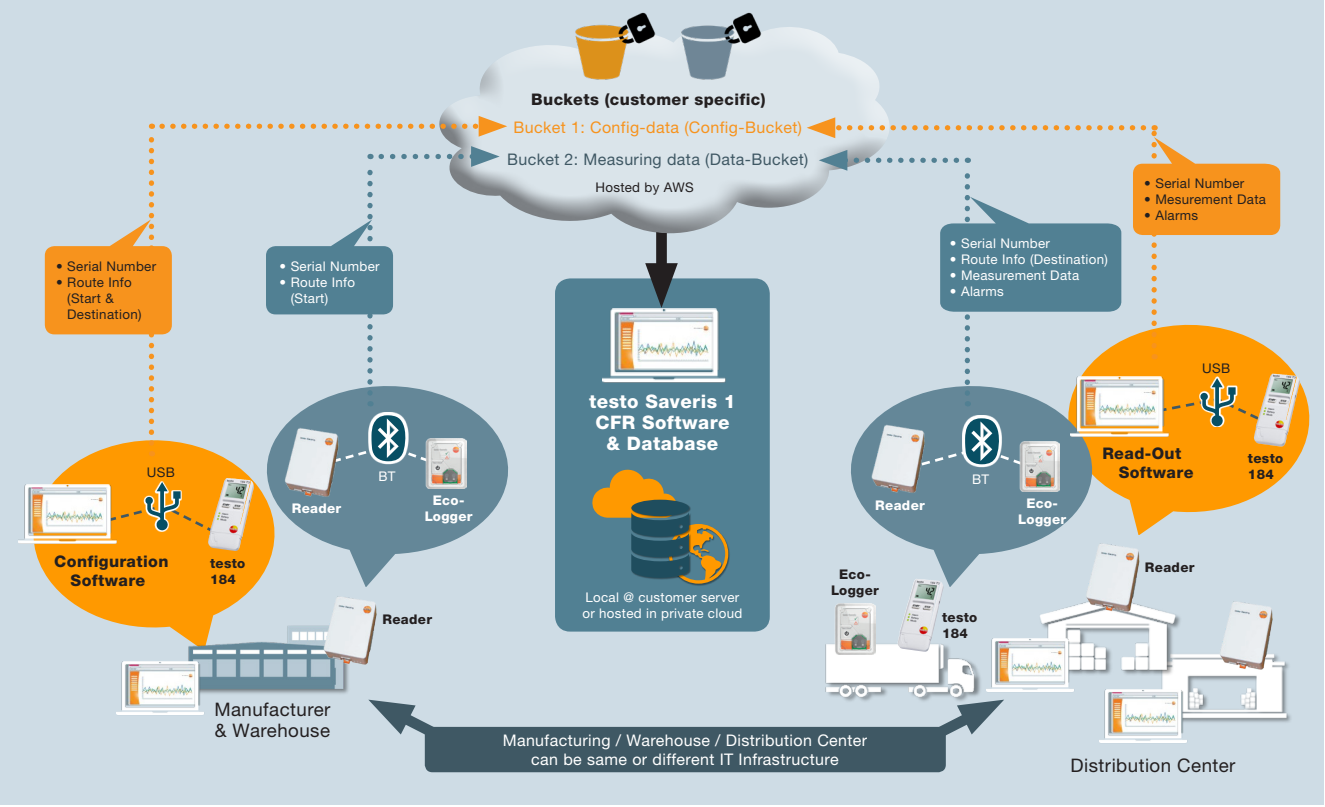
This data integrity is guaranteed, since no data conciliation will be needed and there is no need for manual data transcription from one system to another.

Regarding data integrity for the stationary monitoring loggers in manufacturing, many quality parameters can be integrated into the system architecture whether in digital or analog format, depending on the sensors being used.

Loggers communicate in different protocols (wired or non-wired) and their data converge in the testo Saveris Base, which may be configured for alarm handling into a secured database hosted on premise or in a customer's private Cloud.

For the transport loggers, at the point of origin their route and quality parameters (T, %RH, shock) are configured and the loggers travel with the package. When arriving at its final destination they are read out via USB or Bluetooth reader.

The data are conciliated with the route/ quality parameters and then all of the data is written and saved into the secure database where it can be accessed for further data analysis and reporting.



testo Saveris Pharma Solutions System Overview: Transport

With this approach, no data need to be manually reconciled and data integrity is maintained in the central and secured database. Access to the platform and database software is only possible to authorised users, while PDF reports for each trip can continue to be generated at the destination. This approach allows the track of the goods through the chain to be guaranteed, and in an aligned process, end-to-end reports per lot of product can be generated by the authorised users even at the manufacturer level, so it can be ready for inspection by regulatory bodies and quality assurance.

Conclusion

Because it deals with human lives, the pharmaceutical supply chain is a complex structure comprising many trading partners and regulatory bodies with a lot of information needing to be reconciled and ready for audit all the time. At the same time, the supply chain seeks cost reduction due to increase in process efficiency.

If, on the one hand, a decentralised approach of data handling such as distributed ledger (blockchain) has the potential of reducing reconciliation and re-processing of information for the overall data, there are still a lot of open questions for its wide adoption by the pharmaceutical industry.

On the other hand, manufacturers of pharmaceuticals and biopharmaceuticals could prefer to keep all the product quality data in a centralised database, so they can be easy accessed and ready for any kind of audit or inspection.

testo Saveris Pharma Solutions integrate transport and stationary monitoring in a single system within a secure 21 CFR Part 11 software, all without losing the flexibility of having received a report for transport printed at the delivery points.

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About Testo

For more then 60 years, Testo has been known for creating innovative measuring solutions made in Germany. As a world market leader in portable and stationary measuring technology, we support our customers in saving time and resources, in protecting the environment and human health and in increasing the quality of goods and services.

2,800 employees work in research, development, production and marketing for the high-tech company in 33 subsidiaries all around the world. Testo impresses more than 1 million customers all over the world with high-precision measuring instruments and innovative solutions for the measurement data management of tomorrow.

An average annual growth of over 10% since the company’s foundation in 1957 and a current turnover of just short of a quarter of a billion Euros impressively demonstrate that southern Germany and high- tech systems go perfectly together. The above-average investments in the future of the company are also a part of Testo’s recipe for success. Testo invests about a tenth of annual global turnover in research and development.

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