Serialisation & Traceability

Software Best Practises: Implementation & Data Integration

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Industry stakeholders have insisted that it could be a costly mistake to view serialisation as a project which only concerns engineering matters. As serialisation data is unique to the pack it requires not only the deployment of new treatment but also expanded staff investment and stakeholder engagement. Therefore, "To characterize it as an engineering issue is therefore to grossly underestimate its consequences, which touch virtually every business function in pharmaceutical manufacturing."[2]

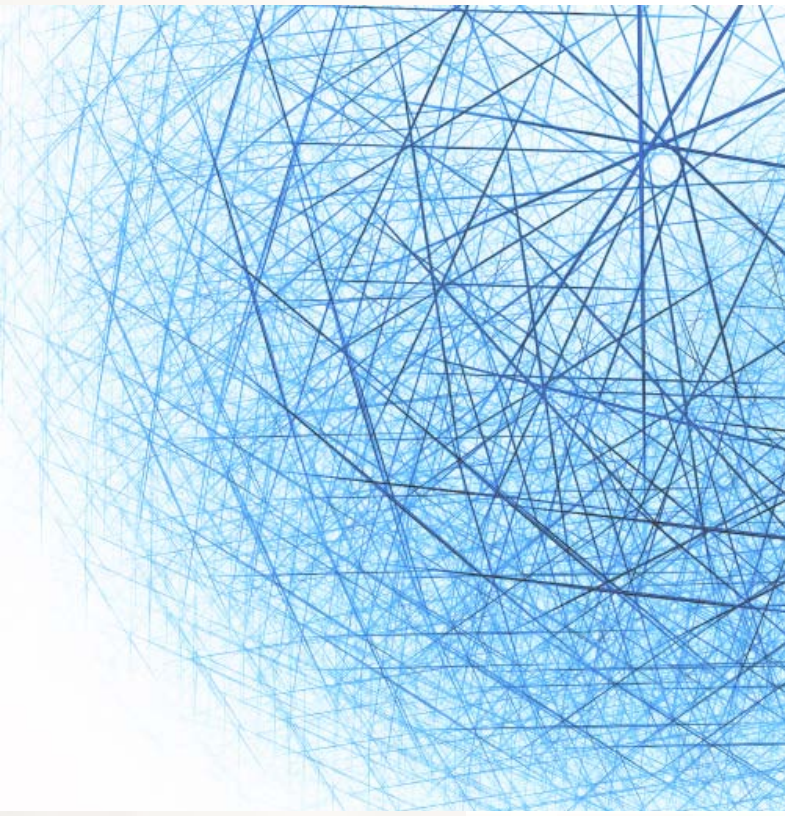
The updating of hardware for packaging lines may on first appearances seem to be a usual project comprising of routine timescales and considerations. However, some cases in the market have conveyed that installing and commissioning integrated serialisation ready hardware ends up being considerably more complex than first assumed.[2] New equipment capabilities have to be met in response to data requirements– including multi-substrate inks for TIJ printers and printer abilities to perform to aggregation and verification.

Effective data management is imperative to achieve regulatory compliance with a serialisation programme. Non-standard data exchange and integration methods are seen as one of the biggest hurdles in serialisation compliance.[4] These projects will also incur a surge in the amount of data shared between trading partners, with the volume of data units being determined by the length of the supply chain in question.

In light of the data responsibilities expected within serialisation projects, Pharma IQ consults with a selection of experts on software best practices - data integration and implementation.

Clear map of architecture:

Pharma firms should have a clear map of their current and their target architecture, due to the evolving ecosystem that operates in many pharma companies. Michael Kinsella, Program Director, Serialisation & Traceability at Servier notes that the pharma firm is currently rolling out a SAP implementation at their main sites simultaneously alongside other rationalisation projects concerning historical IT systems. So, here, a clear roadmap is imperative to ensure Servier is synchronized with their master data requirements to fulfill the needs in a timely fashion.



Partnership interaction

In response to partnership interaction with CMOs, Michael Kinsella from Servier noted: "The CMO area is quite tricky and it's often left until the last step because there is a lot of hesitancy about specifying

responsibilities. Who's going to pay for the interfaces? You may even have equipment that needs to be put into the CMOs to perform some of the data exchanges, you may need scanners, you may need re-labeling, you may need reprinting or re-aggregation capabilities in order to be able to send data back to a mother system and to maintain the integrity. So it's really quite complex." He adds that assessing CMO interaction is often underestimated. CMOs usually wait for the client to explain their needs, as it is the pharma companies who hold the marketing authorizations that are under the obligation to ensure boxes leave the factories in a conforming manner.

Depending on the responsibility or the contract held between various partners or the pharmaceutical company, it is not always completely clear what kind of investments the CMOs need to make and the interfaces they are responsible for.

"I think the first steps are not the specification of the interface itself – but more mapping out the relationship and the responsibility the business needs."- Michael Kinsella

This will involve categorizing the partners the pharma firm has, the type of CMOs and their responsibilities and requirements. Different arrangements may occur according to the authorisation of a product or the delegation of responsibility in the production, packaging and distribution of a product. Michael notes that in some cases pharma firms may decide not to integrate their systems into, or to interface with the CMO's systems or exchange data. They may simply connect to the national database to which the data is transmitted to. In other cases, there may be a business need to exchange data to facilitate certain business activities, especially where the product is still in the possession of the pharma firm. "If the product has left their possession or has been sold, the responsibilities for the data integrity or data exchanges change somewhat."

Test your CMO's readiness

Pharma firms need to evaluate the readiness of their CMOs – regarding expertise, system, status and if they are already connected to some of the established cloud vendors. Honesty and evidential proof is needed, as pharma firms need to confirm the foundations are in place and that relevant stakeholders are informed and synchronised. Although, this can be time consuming and resource demanding as this task should not be confined to email exchanges but physical meetings and site visits. Even so, this step is a necessity in a risk identification strategy, it's important to be aware of what level of risk exists to know if a system can respond to that risk.

Visibility of a CMO's status will be key for decision making and future proofing a data strategy according to Dhermita Desai, Serialisation Programme Manager, Concordia. This is especially in regards to software alignment. If there is no intention from the CMO to invest in the chosen software then a decision could be made to move these products to another CMO which has and is ready to function.

Alignment with software selection : Dhermita Desai noted in her own serialisation project on receiving feedback on the URS her strategy was refined slightly to simplify the integration process. After being informed that the time needed for on-boarding from the pharma firm's site to the manufacturers could take from three weeks to three months - it was decided that the vendor selection would be determined by choosing providers who were already connected to the most of Concordia's CMOs . Dhermita Desai explained: "Because we're a virtual company, it was quite critical for us to minimise time taken [and look for the most cost-effective route]".

If a CMO deploys a different vendor to a partner pharma firm functionality and compatibility complications can occur in regards to connectivity as well as artwork and printing. A failure in

connectivity could result in the entire validation process needing to be repeated by each party.

Interface adaptability :In finalizing the detailed specification of the technical interface - (the standards used, the format of data – is it XML, is it EPCIS, serialisation, aggregation or both?) - functionality and connectivity decisions are landmark differentiators.

Michael Kinsella notes that there are a range of connectivity approaches that can be taken. For instance, pharma firms could have a cloud-based solution at a corporate level so CMOs would connect at that level but may not connect at a factory to CMO level. Alternatively, there could be a system which the CMO reports events to so the pharmaceutical company can view the activity: has the product and the data been sent to the market, have they guaranteed the uniqueness of the numbers? The reverse angle is also a possibility, the numbers are sent from a central corporate system (to ensure every company uses a unique number) down to the CMO.

In regards to reporting to the markets, which is typically not done through the CMO directly, a useful strategy could be to conduct this via the corporate cloud. If the CMO or local subsidiary has to pay for a data report towards the market, multiple reports would have to be purchased. Whereas, the cost of this interface could be controlled if the pharma firm pays for one report coming from its corporate cloud.

Data conduct is seen as a considerable concern by many in the market with many questions raised regarding responsibilities for who sends the data and how it will be treated– how is the treatment of the data controlled after it is transferred to wholesalers? Also what will the data be used for once it is sent to national systems, especially if the data is extensively complex?

Maintain and manage your open communication: Dhermita Desai notes that it is vital to obtain the maximum level of information from your partners at an early stage. In her case, when working with 130 CMOs across a portfolio, it is important to have a solid communication strategy to avoid losing control. Programmes can be implemented such as Supply Chain Wizard to support organising CMO communication, which can be a worthwhile investment. This program can obtain feedback from partners through automated e-surveys and has capabilities to transmit reminders.

Integration with legacy tech systems:

Another, key best practice is to determine the level of autonomy had by the system specifically for serialisation and traceability. Whether – it needs to operate independent of the existing systems or it needs to interface into those systems and to what level.

In preserving integration levels with legacy tech systems, having a comprehensive overview of requirements in the URS will be vital so vendors can specify if they can meet criteria and are in line with the legacy systems and interfaces. The IT team and IT compliance team should be involved in shaping the URS requirements mentioned.

Michael agrees that the major decisions on software selections should involve a range of disciplines at

company level in the pharma firm. These teams, in regards to traceability, could include marketing supply chain, industry finance, counterfeiting department, trade department, legal department, etc. This communication is imperative to ensure that there are no choices make that are misaligned with the future company vision and software choices. A portfolio management tool could be instrumental with this. In some cases, older legacy software may have to be rationalized into fewer systems.

With decisions being made at this high level costs, risks for system maintenance and the number of interfaces needed can be controlled.

Michael noted that: "We have a lot of questions specifically about the label management software which is likely to be shared between our SAP system and our serialisation system. So this touches on a point where it's not really an IT project, but we want to standardise the labels that we put on our cartons and shipping units, and to do that, we need multiple systems to share the same master label template references

Long term vision strategies & concerns

With a view to protect and futureproof the serialisation and traceability software being implemented, open architecture and a vision for future modules are two key indicators of durable and robust data and software programmes. However, an accurate visibility of the stability of an interface's current and future specifications can be difficult to ascertain.

Systems need to be scalable and you need to have knowledge on how the changing and increasing demands will be followed in regards to volume.

Michael noted that: "Definitely the volume is increasing. For us, we made a rough estimate that 60% of our total volume will be serialised at least by 2020. So you need to be able to project into the future what kind of volume are you talking about for your product."

Cost management and future proofing running costs is also a major consideration – perhaps through sharing systems and platforms with other companies. Michael said that companies should look to: "clarify a roadmap which would take advantage of increasing functionality with a fair approach that could be reused by other clients and may be contractualised."

> **"I don't believe that the serialisation topic will end once the deadline is met in Europe. It's really only the beginning. The use of the data will continue and in 10, 20 years from now people will be doing different things with the data than we ever imagined. However, the first step is definitely to respond to the deadline [as] efficiently as possible, possibly by grouping platforms or by multiple clients sharing the costs." –** Michael Kinsella of Servier

Visibility & optimisation (higher level): Nitin Dahad reminds that the data gathered gives companies insight into a lot more than just serialisation information – it can provide complete logistics details through the whole journey of a particular product. This means that people running the logistics network can better understand their supply chain and this data might help them to make improvements and run more efficient supply chain networks. It can also help logistics managers use this data to manage shipping schedules and ultimately boost the bottom line. [1]

This same system is implemented in a pharmaceutical temperature-controlled supply chain, with temperature sensors added to the network or along with the shipment. It is possible to both pinpoint exactly where the shipment is at any time and overlay a temperature graph so that you get a complete picture of the shipment's journey and the temperature history.

If this is integrated into existing enterprise systems or workflows, the software technology solution can then provide insights into a complete transport fleet or network of warehouses. The data is available live, so alerts or warnings can also be sent by email or text to responsible persons that a digression or some other problem has occurred during the shipment's journey. [1]

Consolidation to reduce running costs:

Michael notes that companies which share a similar ethos could look to group and take advantage of national reports, project management costs or even the tender process. He explained: "Probably everybody will write the same tender document, ask the same questions of all of the suppliers and they will probably respond to everybody individually. There could be groupings, this kind of thing may seem radical, but running costs are quite significant and eventually they will pass investments made on the data interfaces."

Other innovative applications of the data could include targeted recalls and decommissioning shipments in bulk from the cloud system, as well as sending reports to the national system to deactivate sales of the product in question. Also, internal spot checks could be deployed so pharma firms can be more proactive in the combat against counterfeiting.

Instead of waiting for national authorities to respond to a suspicion of counterfeiting, there could be spot checks during the supply chain process or on the market, like market sampling and proactive verification of databases internally. Also, companies could optimise inventory management for example, with warehouses pharma firms could improve the management of product volume and stock quantities.

To gain further tips on data management strategies, software considerations and integration, join us at Serialisation and Traceability 2016 in Geneva.

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