Building Better Logistics

Gathering real-time data on the happenings in a clinical trial logistics chain offers improved options for preventing temperature excursion and other environmental harm from affecting samples or medication

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Adopting real-time environmental conditions monitoring in the clinical trial supply chain is becoming increasingly straightforward, with technological development offering smaller, more affordable solutions with better connection options. However, merely discussing features or pricing does not in itself help with answering why this kind of technology would be important to fulfil specific operational needs. Looking beyond technology features and considering instead the drivers and benefits of digitalising monitoring activities in the logistics chain is imperative.

Let's begin by looking at some of the drivers behind why real-time monitoring should be implemented to logistics operations, so a shared understanding on why the matter is being discussed in the first place can be gained. These drivers can be divided roughly into three categories of operational efficiency, regulatory demands, and technological developments, which all affect each other in myriad ways.

Need to Exceed

Arguably, beginning with operational efficiency is easiest because organisations have the most intimate experience with this. Multiple stakeholders, even within a single company, are constantly looking to develop improved processes for quality management, more efficient operations, cost savings, or other such purposes.

Now, it is known that, within cold chain industries (and particularly in the pharmaceutical industry), logistics costs are relatively high when compared to non-cold chain operations. Room has also been seen in these operations to improve efficiencies and quality management processes by introducing real-time monitoring. Furthermore, these possible improvements are naturally intensified in clinical trial operations where high-cost, low-volume products are typically being dealt with.

Secondly, regulatory demands affect all pharma industry sectors from manufacturing to eventual patient treatment and even beyond in the form of pharmacovigilance. Naturally, regulation is the slowest moving of the three drivers, but with the EU Falsified Medicines Directive recently going into force and the continuing revision work done by the Pharmaceutical Inspection Co-operation Scheme, the EMA, the WHO, and others, there is constant progress being made in regulatory affairs. This often results in stricter requirements for pharmaceutical quality and safety throughout lifecycles (1-2). For pharma logistics, both quality

and safety can be improved with the introduction of real-time monitoring capabilities.

Thirdly, as an answer to the previous drivers, there are various new technology developments like artificial intelligence (AI), blockchain, and Internet of Things (IoT). These not only answer the needs of process development and regulatory demands, but also have an effect on what the two others must consider when developing their own processes further. The most relevant to this article is IoT, which is the technology that enables the kind of real-time monitoring that will be discussed throughout the article.

Now, this kind of multipoint influence web means that, while all these drivers work based on their own agenda in setting expectations for organisational actions, they are fairly transparent in their needs. Therefore, educated guesses on how to answer those needs can be made. As the situation stands, real-time capability in pharma logistics is one of the answers that can help fulfil the demands of all these drivers.

> “Real-time-based digitalisation can help the trial supply chain to better support the efforts of the investigators”

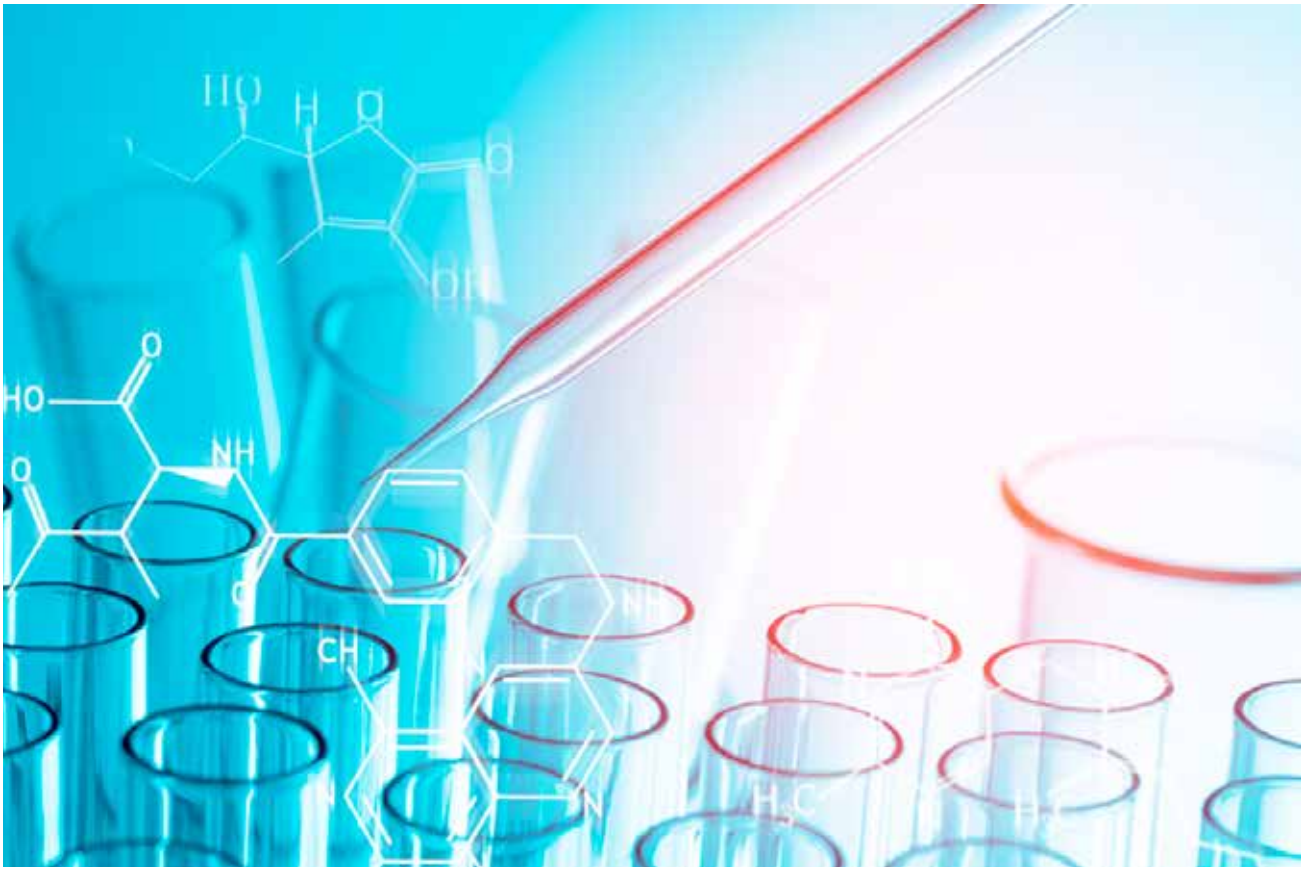
Correct Me If I'm Wrong

Let's now delve into how real-time monitoring benefits a clinical logistics operation in the short term.

As previously mentioned, in clinical trials, the operational efficiency of standard pharma logistics comes into an even more powerful focus due to stakeholders needing to handle fairly low volumes of high-cost products. In plain language, this means that any deviation from standard operating procedures (SOPs) will mean greater costs in quality inspections and possible waste per individual product.

Before the kind of real-time monitoring that can be applied to clinical trial logistics today was accessible, the opportunities to perform the corrective actions that would save a shipment of trial therapeutics would have been much rarer. In turn, this would lead to lengthy inspection periods, delays in the trial schedule, and, ultimately, affect the logistics environment by playing havoc with the on time, in full (OTIF) delivery model, which trial logistics teams aim to provide.

Comparatively, with real-time monitoring capabilities, utilising the



kind of corrective actions that would help ensure OTIF is not only possible, but practically mandatory from both the regulatory standpoint, as well as from the perspective of the logistics manager who endeavours to provide the best possible service (2). Using real-time data to automate the deviation detection process and to set off alerts when excursions have not yet happened can thus be used to amplify the effectiveness of corrective actions and to ensure safety and quality in the clinical trial logistics process.

Of course, this kind of deviation detection also makes it possible to validate pharmaceutical quality much faster and easier than with any manual means of measurement, not least because real-time technologies practically demand online data storage capabilities to deliver best efficiency. This, then, means that the consignee has full end-to-end visibility to the condition of the medicinal product immediately at the time of delivery, and can very quickly validate it as usable, or quarantine the shipment for inspection.

With these improved corrective capabilities, there is also, of course, much less risk of having to set a shipment aside in the first place, which, again, helps with eliminating delays and, consequently, with OTIF as well. Furthermore, as long as the data on excursions and any actions triggered is also recorded automatically along with the environmental conditions data, addressing the aforementioned driver of regulatory demands with a complete and compliant audit trail is much easier.

In this way, real-time-based digitalisation can help the trial supply chain to better

support the efforts of the investigators while simultaneously delivering complete audit trail data for regulatory, quality assurance and other trial-specific supply chain purposes.

Developing Success

Now, while in the short term, real-time monitoring in the logistics chain is an effective means of improving efficiencies in individual processes and gaining cost savings through triggering corrective actions, this does not mean that it is the main reason for digitising the supply chain. The true value in real-time monitoring not only comes from adopting it as a means of acting immediately, but as a way of strengthening sustained process improvement in trial logistics.

Now let's say, for argument's sake, that while we talk about corrective actions, alerts, and the like, we talk about planning to fail. This is natural because it is nigh impossible to take into consideration all the possible situations that may affect the logistics chain

during a particular shipping operation. Therefore, the best way to deal with this kind of uncertainty is to plan for how to deal with the most obvious deviations from SOPs.

However, by not only using real-time monitoring to log the environmental conditions during shipment, but also the actions the staff takes in case of excursion, data is accessed on where, when, and in which circumstances these possible excursions and corrective actions have taken place. Furthermore, how effective SOP-prescribed actions have been in containing the situation can easily be checked.

By introducing this kind of more holistic data about SOP functions to analyse, it is easier to drill down to root causes and develop better processes for both corrective and preventive actions (CAPAs). As these new and improved CAPAs are taken to SOPs to see how they perform compared to the earlier situation, they can be developed even further. When this kind of data-to-analysis-to-behaviour-change approach to improving logistics functions becomes permeating in an organisation, it will be of more overall benefit than any single short-term action, no matter how much it might create cost savings or prevent waste.

This also means that while organisations are still planning for failure, they are simultaneously developing for success. By repeating and re-repeating the process development to analysis cycle, it is possible to develop such SOPs that do not just prescribe the best action to take in case of a deviation, but actively aim to decrease the number of deviations and to take some or even most of the uncertainty out of the supply operation. This will also eventually mean less time spent on CAPA management because they become less frequently triggered when the overall logistics process improves over time.

In financial terms, this materialises in both cost and time savings due to less product waste and work required by corrective actions relating to deviations. It also means fewer inspections, easier regulatory compliance, and less paperwork, so in the long term, real-time-enabled analytics will address both the regulatory and process development drivers that digitalisation must answer.

Naturally, real-time also offers other opportunities besides affecting existing operations. These include processes such as lane assessment for new route openings, subcontractor due diligence management through improved visibility to shared/outsourced operations, and other such activities which ensure that you are not just reacting and correcting case by case, but are taking a proactive approach to delivering best possible logistics functions.

Technology Support

Lastly, and to circle back to the third driver mentioned earlier, a few technology developments, namely AI and blockchain, will be looked at.

Now, with AI capability, it would be much easier to automate the analysis part in the process development cycle described above, but also to then use the AI to prescribe those developed CAPA responses to make sure that the triggered actions would be the correct ones to answer each individual deviation.

With the rise of blockchain technology to offer secure communications among stakeholders, it also becomes possible to share logistics data and even best practices for handling encountered deviations. Of course, this kind of transparency between organisations is built on trust, so it may be some time before we will see a blockchain use case for full-scale logistics collaboration instead of just as a very basic track and trace method. However, there have been various attempts at sharing data to achieve sustainability and best practices in the logistics sphere, so we might even see something along these lines fairly soon.

However, to take best advantage of these two technology developments, real-time data that enables analysis and is worth sharing needs to be accessed. The third of these technologies mentioned earlier, namely IoT, is, at the moment, the best way to access this kind of data and deliver the digitalisation capabilities that would offer the benefits we have been discussing throughout this article.

Therefore, real-time data will undoubtedly be at the forefront of digitalisation efforts in many organisational strategies in both the immediate and the long term. However, it should be noted that even though the benefits that have been discussed arise from introducing real-time monitoring to logistics operations, the technology is not a silver bullet that would solve all logistics challenges immediately. Digitalisation as an enabler for success will also require organisation-wide buy-in and the capacity and mental inclination to review and develop processes in a sustained fashion.

References

1. Visit: www.picscheme.org
2. Visit: www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers#eu-gmp-guide-annexes:-supplementary-requirements:-annex-13-section

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