A QUESTION OF CHOICE AND SUITABILITY

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The pharma and biotech industries are continuously seeking reliable ways of ascertaining the location, payload condition and the ambient environment surrounding their temperature-sensitive products during transit. It's rapidly becoming a regulatory, safety, security and commercial issue.

We are surrounded by data collection, data storage and data relaying technologies from Bluetooth, Wi-Fi, RFID, GPRS, satellite, cloud, data sticks, smart phones, among others. A bewildering array of different monitoring and capturing technologies makes for a big headache when it comes to selecting the best hardware device for a particular need. And, when you factor in the pace of technology change and advancement in this field, and the fact that there are no 'one size fits all' solutions, the adoption of a specific monitoring technology may not be an approach that makes sense. With this in mind, there are three basic parameters that should be evaluated when considering the use of data collection and transmission systems and services.

Shippers, forwarders and airlines need to be looking at systems that are, as far as possible, 'future-proof'. Data monitoring and transmission technologies are advancing rapidly and as we edge closer and closer to the prospect of real-time in-flight monitoring, users need to be sure they are not committing themselves to a technology that will be obsolete in a short period of time.

Secondly, while they may be bound by common regulatory parameters, every shipper has their own ideas about the best way of monitoring its particular products for quality. And rightly so, because all products are different, sometimes very subtly different. This need for flexibility and choice is further accentuated by the sheer number of different shipping environments, distribution conditions and mode choices that are available.

Thirdly, we are faced with the problem of conflicting regulatory requirements in Europe, the USA and many other air regulatory bodies. As far as the use of short-range devices are concerned, individual carriers must review the manufacturer's data and submit it to the FAA as part of their operational procedures and put in place the necessary training and infrastructure to ensure correct usage. In Europe on the other hand, the airlines have more responsibility for all types of devices and it is the responsibility of a carrier's engineering and quality groups to assess, select and implement any T-PED (transmitting portable electronic devices) systems that are adopted or approved. We are unlikely to see a harmonisation of the different national and regional approaches any time soon. Utilising an unapproved device can have serious consequences.

In addition, there can be issues surrounding the compatibility between different monitoring and tracking systems. If all cold-chain packaging manufacturers started embedding their own monitoring hardware and software into shipping containers, then shippers, forwarders and airlines would quickly find themselves having to deal with numerous different data sources, data formats, data devices and data locations. Far better for individual shippers is to define their own monitoring and tracking needs and request the resulting solution(s) from their supply partners.

Shippers also need to be considering the impact that mandatory track and trace security systems are going to have on the whole product monitoring process. For example, how sensible will it be in future to be running track and trace and environmental monitoring systems in parallel? Increased costs are just one of the obvious considerations and cross analysis and validation will be complex and time consuming.

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In practice, shippers often want different things. Some shippers want device-independent data recording, some want to use bespoke hardware or software and others just want ongoing flexibility. The need for flexibility in data capture can be readily appreciated by taking into account the 'human factor.' Far better in these particular cases is for a shipper to use a single data gathering and transmission solution for all their shipment methods that is deemed fool proof or one that does not rely on particular receiving-end infrastructure, training or additional cost.

Vendor-Fitted/Integral Container Monitoring Solutions

There are potential downsides to a reliance on vendor-fitted tracking and monitoring solutions. Ready-fitted monitoring equipment not only presents the buyer with 'a no choice solution' but also creates the not-insignificant burden of ensuring that all distribution partners in the supply chain carry the necessary approvals for its use. By example, unauthorized use of a device not approved for flight could result in a hefty fine for the airline.

There are a number of existing opportunities to procure an off-the-shelf packaging solution that is already fitted with a compatible monitoring equipment. However, the cheapest product monitoring solutions today are not necessarily going to be the cheapest solutions tomorrow. The cost of electronic apparatus has fallen dramatically. This rapidly reduced cost of monitoring is a good reason why it makes sense to be careful about getting locked in to a proprietary system too early. For example, there is currently significant development in Low Energy (LE) and new Bluetooth 5 smart devices that piggyback off smart phones or Wi-Fi networks. These devices will be capable of utilizing communication and location functions for real time data streaming to the cloud. This will avoid the data costs associated with many devices utilizing cellular or satellite systems.

The future holds for in-flight pharma monitoring/tracking will probably include hybrid systems which use a combination of technologies to provide real-time connectivity, global geographical coverage, additional monitoring features, dynamic control of container environments, a high degree of reliability and all with minimal power draw. What we see now is just the tip of a big iceberg, with hybrid systems using Bluetooth and Wi-Fi looking to be the next phase.

The emphasis will continue to shift from monitoring to control with the cost of the equipment, rather than the associated support systems, likely to continue to fall. There will also be further global harmonization of technical standards and regulation but this will be much slower than technical developments. The biggest challenge of all will be whether organizations, regulators and other stakeholders will be able to cope with the sheer volume and complexity of data generated and be astute enough to take advantage of the insights it brings.

At the end of the day, when we are talking about the safety of drugs for human consumption, it is vital that the quality controls put in place during physical transportation are driven by need and necessity rather than being subject to the limitations imposed by a manufacturer's stock solution.

All of these are reasons why it is sensible not to be jumping into the deep-end and implement a life limited technology during this period of rapid change. Cargo safety and security will remain the paramount concern for airlines and aviation regulators and one that will continue to be impacted by unpredictable events such as terrorist activity. The almost certain consequence is that we will see no let-up in the technical scrutiny of vendor-fitted container monitoring equipment.

While we believe strongly in the importance of great packaging solutions like our CSafe RKN and AcuTemp packaging, we understand the need. And while all these technologies currently being used have their adherents and all have their pros and cons, the good news is that CSafe containers are able to support GPS tracking and data logging systems from a multitude of service providers. CSafe Global has performed independent assessment of many of the currently available solutions and technologies. CSafe currently favours a number of solutions that we've tested for compatibility and broadcasting operation from within the containers cargo compartment in a warehouse environment and receives no compensation or benefit from any specific provider.

Therefore, feel free to contact CSafe Technical Support for independent advice, guidance and suggested solutions. At CSafe, we understand the issues at stake, we are conversant with the available technologies and we are very happy to talk to individual shippers about their specific data-capture and transmission requirements.

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