

IT'S A RISKY BUSINESS

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“Adopting a culture of quality risk management will provide a platform for continuous improvement.”

It is evident when reviewing the Good Distribution Practice guidelines that there has been a shift in emphasis towards Risk Management in the distribution of temperature-sensitive pharmaceuticals. Whether it's the publication of the recent EU guidance, the revisions from USP or the PDA's technical report 58, there can be no mistaking one thing - shippers and manufacturers are ultimately responsible for examining their supply chains using a 'risk-based' approach.

Let's be clear what risk is by using the definition from the International Conference on Harmonization (ICH) and its Q9 document:

Risk is defined as 'The combination of the probability of occurrence of harm and the severity of that harm'.

Harm is defined as 'Damage to health, including the damage that can occur from loss of product quality or availability'.

Hazard is defined as 'The potential source of harm'.

This might sound straightforward but a 'risk-based' approach warrants an in-depth analysis including an evaluation of the elapsed time since the validation of the current temperature-sensitive shipping and packaging solutions. Some suppliers have utilized the same solutions for decades although technology, regulations and guidelines have continued to evolve. The production process also has challenges related to contract manufacturing, multiple vendors and locations that are distant from the point of sale. Identifying the potential sources of harm to a product being transported through several temperature zones, multiple transit points and a variety of modes can be an exacting task.

During all of these stages, patient safety is of course paramount, but we also recognize that the pressures for more cost-effective supply chains can be immense. It is not surprising therefore, that managing risk has attracted a more aggressive regulatory stance both at GMP and GDP levels. It is also a good explanation for the additional call from regulators for written agreements between manufacturers and their logistics supply chain partners.

Risk Management is designed to assist organizations in safeguarding the quality and supply of product to customers and ultimately the end user. It is about anticipating hazards and controlling risk through an ongoing process of risk awareness, reduction and / or acceptance, and review. This approach can help justify needed improvements and investments, and prevent both potential problems for customers (e.g. product recalls or even patient harm) and loss of business.

Moreover, though implementing risk management might well be initially linked to a single product or supply chain process, it should not be considered as a one time action. Adopting a 'culture' of quality risk management that is embedded in the processes and procedures used by manufacturers and their supply chain partners will have long-term benefits. The level of awareness to risk will inevitably improve and provide a platform for continuous improvement.



In their recently revised GDP guidelines (2013/C 343/01) the European Commission has a relatively simple statement regarding the distribution of temperature-sensitive products:

“Risk assessment of delivery routes should be used to determine where temperature controls are required’.”

The first part of any ‘route qualification’ process should start with the creation of a Qualification Master Plan that sets out stages, processes and responsibilities. And sometimes, simplest is best - use the power of your internal team and your external logistics suppliers to initially map out every distribution and handling stage for your product. Additional detail should be added considering both the physical and documentary processes and conditions.

Through the various transport modes, identify those steps and handover points that are most at risk. Look at this from a seasonally adjusted temperature environment and quality control processes, and consider how to mitigate the risk to your product. Is the route and transport supplier capable of managing that risk? Is there a contingency plan in place? Are there written agreements and SOP’s in place? What importance is placed on process control and process measurements versus measuring end results when it is too late to prevent an unsuccessful shipment?

Identifying the physical steps and risk points is important to maintain the efficacy of any drug. But what about qualifying your supplier of thermal protection and having more than one validated solution to further mitigate the risk of failure? Just like good cold chain management starts with the manufacturer, having a range of validated solutions ‘ready-to-use’ will provide you with the means to maintain that correct thermal protection, regardless of the distribution challenges.

The market for both passive and active solutions has expanded over recent years and there is now a comprehensive array of suppliers. Shippers should validate their choice of solution providers by predetermined criteria:

- Availability – is the solution always available at seasonal peaks and internationally?
- Solution range – does the supplier provide both active and passive solutions?
- Performance – have their solutions been validated to your needs?
- Re-usability – does the supplier have a program for packaging re-use?
- Custom-built solutions – new/different products may need new solutions and thus, can the supplier respond to new requirements?

All of these considerations will provide you with a far more comprehensive risk assessment of your supply chain and provide a built-in confidence that a product will not be compromised regardless of whether it has been transported 5 miles or 5000 miles. It also creates contingency plans that can really make a difference to successful transportation.

Risk management should not be centered only upon the choice of which route, which logistic provider and which type of packaging solution to use. Key to minimizing risk is to qualify more than one thermal shipping solution and preferably utilizing a provider that can offer both active and passive solutions to meet the specific needs of your product.