



## Introduction

Manufacturers and shippers of these products are under increasing pressure, as pharmaceutical and life science logistics becomes more complex and as the consideration towards better control of falsified medicines increases.

For most pharmaceutical companies (and perhaps those particularly operating under the regulatory guidance of the EU), a key challenge is the ability to create and maintain an innovative and competitive distribution channel strategy. This means looking beyond the traditional cost components of 'transportation' and taking a wider view of all the elements that go to make up the total cost of distribution. All of this is of course against a regulatory background that has placed much more GDP compliance in the hands of pharmaceutical manufacturers of finished products or API.

For many, this has involved an internal downstream change whereby the logistics/distribution/purchasing functions have clearly begun to play a greater role in the company's overall supply chain management. Whilst the Quality Assurance/Quality Control department retains a vital role in the product-to-market distribution strategy, there has clearly been a shift towards creating a more overall cost effective process.

No longer is it either practical or sensible to 'only' understand the basic shipping and distribution cost. In a recent survey for LogiPharma, 44% of respondents recognized that their bottom-line could gain further from supply chain improvements.

## Meeting the challenge of cost effective temperature control

In order to meet these new distribution challenges when deciding upon the right temperature controlled solution, it is important to look beyond the current traditional

decision criteria. Load size, value, route, journey length, customer requirements and destination challenges all go towards choosing a packaging and shipping solution, but there are some important other elements to consider.

Clearly passive solutions represent a potentially lower cost, but what about the storage of all that material whilst maintaining a stock sufficient to ensure an availability of material to satisfy customer demand? Additionally, if you are using any form of phase-change material, have you factored in the cost of providing suitable temperature conditions to accurately pre-condition those packs?

Any type of solution also requires adequate time for preparation and actual loading of product into the secondary packaging. Loading individual boxes by hand will clearly take longer than placing a euro pallet inside an active ULD or 'passive shipper'. Be sure you understand what's involved and don't forget the unloading process at destination.

Most significantly, choosing your solutions supplier should not just be based upon simple unit cost comparisons. True total cost of ownership calculations should take into account issues such as regional availability, any equipment positioning costs, the ability to provide a range of solution types & sizes and the increasing importance of reusability of passive boxes. This latter point is important since the box must retain its qualification status when being reused.

## Risk and Visibility Management

Having identified the need for improved knowledge of supply chain components, risk management through appropriate route qualification (both of which are key features of the EU GDP guidance EU343/01) must remain an important part of any changes in strategy. There is little to be gained in creating lower unit distribution costs



- **‘What gets measured gets fixed’.** If it can’t be measured its likely to remain a problem unsolved.
- **‘Share’.** Create KPI’s as part of a partnership for continuous improvement. Remember that performance measurement is a two-way process.

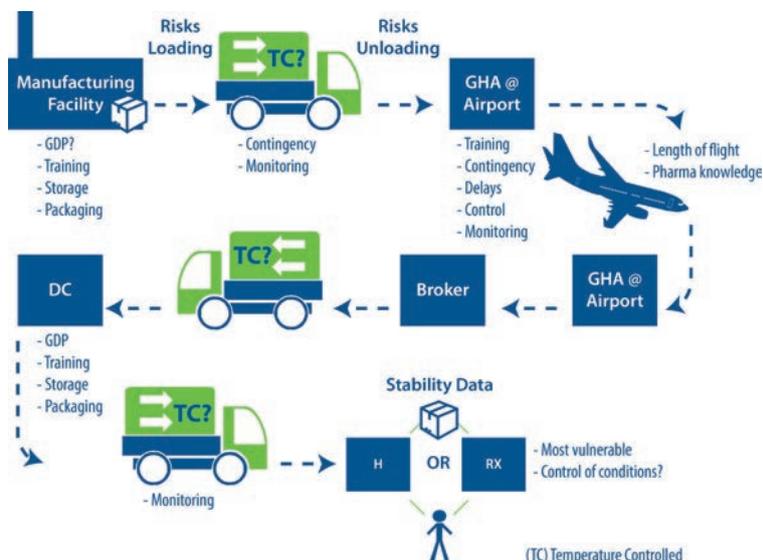
if this is eroded by a higher cost of compliance through, for example, increased temperature excursions.

That may well mean some additional up-front investment in creating new temperature profiles from test shipments (balanced against product stability profiles), but will provide beneficial gains in long-term supply chain strategy. Mapping the key GDP ‘risk points’ in your supply chain and having actions in place to mitigate those risks will undoubtedly contribute towards reduced failures and also aid the process of quicker recovery, should something go wrong.

Managing the changes from understanding the ‘Total Cost of Ownership’ also inevitably creates the need for increased visibility. This means not just that you can track a shipment from distribution through to customer, but the partners you have chosen (and qualified) are an integral part of your strategy and can provide the overall visibility you need to maintain that cost-effectiveness. Inevitably it comes down to choosing wisely and not just creating the right relationships but maintaining them.

Since there has been a shift in logistics process ‘ownership’, it is also essential to accurately and regularly measure and monitor the performance of any outsourced suppliers. Many companies will be familiar with the principles of developing Key Performance Indicators (KPI’s) and there are a few key aspects that need to be well established:

- **‘Measure the few, not the many’.** Don’t overcomplicate the process of measurement with unnecessary KPI’s and stick to what’s really important.



### Summary and Meeting the Challenge

The enforcement of GDP guidance will doubtless increase internationally and the evidence would seem to support an increased drive towards total supply chain integrity. Regulatory acts such as the Falsified Medicines Directive will continue to place greater emphasis on how pharmaceutical companies are really ‘managing’ their supply chains. With already up to 30% of the world’s pharmaceutical products being potentially counterfeited, the importance of secure as well as GDP compliant supply chains is of increasing significance to the sector.

The cost of distribution will naturally remain at the centre of any debate about supply chain effectiveness and clearly there is more that many companies can do to improve their bottom line by creating a better understanding of the true total cost of their supply chain. At the same time manufacturers must balance this by considering how any potential non-compliance of GDP principles and regulations might create increased risk of temperature excursions through an ill thought-out distribution chain.

