Getting More Value from Logistics Quality

Optimising logistics quality management for efficient compliance, competitive advantage and customer value

With its raison d'etre of saving lives and improving the health of people around the world, the assurance of quality lies at the very heart of the pharmaceutical production and distribution process.

Cost of Quality (COQ) is a measure of all the costs relating to the quality of a product and its adherence to regulatory and in-house standards, guidelines and expectations. *"Any cost that would not be incurred if quality were perfect"*[1] is a simple way of describing COQ.

The costs concerned can be of several types:

- preventative costs e.g. training costs
- measurement/appraisal e.g. audit costs
- remedial and failure costs i.e. the costs associated with fixing defects/deviations and all associated consequential costs such as diverse business impacts

These latter 'external' costs, although difficult to predict, can have huge bottom-line consequences.

PHARMACOS NEED TO...

- **MINIMISE their exposure to risk. Undue risk relates not only to direct financial consequences, but also to the potential impact on productivity, patient safety, and corporate reputation.**
- **IMPROVE their compliance with regulations. Every batch of medicinal product must be certified by a Qualified Person (QP) of the Marketing Authorisation Holder (manufacturer or importer) before being released for sale.**
- **SIMPLIFY their QA processes while improving their effectiveness.**
- **REDUCE their costs of compliance. There is an increasing recognition of the costs of both compliance and distribution and the scope for containing the associated overheads.**

WHAT ARE THE COSTS?

In practice, the COQ can be a very nebulous sum to pin down since different pharmacos tend to follow very different costing procedures and cost-allocation policies.

According to APQC[2] business quality measures have:

- no standard definition
- no standard components
- no common calculation

With quality being a rather abstract concept invariably involving fragmented, multi-departmental processes, it is usually very difficult to put firm dollar figures against it.

Furthermore, it is a moving feast. Keeping tabs on the costs of quality is not made any easier by ever-changing regulatory requirements, increased outsourcing and accelerating M&A activity. The net result of all these confounding factors is often a hugely complex and disjointed quality management system.

Estimates of the COPQ in the pharmaceutical sector range from 25-40% of turnover[3] and up to 40% of operating expenses[4]. This compares to other quality-driven industries such as semiconductors which demonstrate only 4-8%[4].

Others have estimated that pharma quality costs can be 3 - 6 times larger than profit levels illustrating that *"this is a huge opportunity that has been largely untouched thus far."*[1]

Indeed, analysts have stated that less than 50 percent of companies In the life sciences industry, really know what the COQ is for their organization[6]. And when you drill down past GMP to GDP, the awareness is likely to be much, much less.

Certainly GMP compliance costs are measured in the multi-million pounds per annum for a typical medium or large pharma company[7]. GDP costs are often seen as a sub-set of overall GMP costs making them even harder to identify and uncouple.

"Logistics networks are becoming increasingly complex as ever more environmentally astute technology is developed and demand for biologics and pharmaceuticals from emerging markets such as Asia and Africa continues to rise and next generation cell and gene therapies are brought to the market"[8]

WHERE ARE THE GDP COSTS?

But GDP costs are substantial. According to some sources[9] the pharma industry loses as as much as USD 35Bn annually just on account of temperature failures alone. This extraordinary figure relates to lost product, clinical trial loss, replacement costs, wasted logistics costs, the costs of root-cause analysis, and process remediation.

Indeed the cost of investigation and reporting is believed to substantially exceed the cost of wasted product. For example, IATA cites the average cost of investigating a ***single*** pharma temperature excursion at USD 6,500[10].

"It is impossible to determine the total cost of compliance accurately due to the fragmentation and complexity of the compliance universe"[7]

Regulatory investigations and excursion assessments are an expensive and resource-consuming activity. And the same can be said for insurance claims for losses and damages. These can be equally time and labour consuming and come with highly unpredictable outcomes.

However, as we have seen, many, perhaps most, pharma companies don't, or are unable to, measure the waste attributable to GDP deficiencies.

Some of the quality-related logistics costs include:

- **Dedicated compliance staff - skilled quality team is expensive**
- **Cost of external consultants - specialised knowledge and independent expertise is expensive**
- **Cost of specialised external facilities - testing houses, cold chambers etc.**
- **Management time - not easily quantified**
- **Validation exercises - including seasonal and recurrent shipping lane validations**
- **Shipping field trials - expensive and time-consuming**
- **Qualification exercises - equipment and packaging, calibrations etc.**
- **Cost of equipment - protective packaging, data loggers, reefers etc**
- **Cost of qualifying equipment and validating processes**
- **Shipment record keeping**
- **Shipment monitoring**
- **Training**
- **IT systems development**
- **Facility upgrades**
- **Opportunity cost from diverting scarce internal resources**
- **Establishing written procedures and SOPs**
- **Cost of deviations - reporting, RCA, CAPA, product waste, delays**
- **Lost customers, delayed market penetration, regulator fines, and other market impacts in the event of quality default.**

Abrogating GDP quality to the supply chain is asking for trouble. Risk itself, the ability to manage risk, and the concomitant costs of mitigation and compliance are distributed very unevenly throughout the logistics chain.

Pharmaceutical companies can outsource the work, and even the risk but, at the end of the day they cannot sub-contract the responsibility. Ultimately it is the legal obligation of the pharma client, as MAH, to ensure that its logistics partners are conducting their operations safely, competently and compliantly.

> ***"A typical excursion can take over 40 labour hours to investigate and involves input from multiple departments. Reducing that time by 10% per investigation through better collaboration efforts can save hundreds of thousands of pounds for a pharmaceutical organisation."[12]***
>
> **Saddam Huq, Global QA Senior Manager, Distribution & Cold Chain, GSK Vaccines**

So the answer does not simply rest in the drawing up of 'watertight' service contracts. Passing all risk down the supply chain does not lead to the lowest cost and certainly does not lead to best value for the client.

And, it is important to note that the highly competitive logistics industry, with its net-profit margins languishing in the lower single figures, rarely has the financial slack to throw money at unexpected problems when it comes to quality conformance.

The costs of poorly managed quality and lax regulatory compliance within the logistics chain will always end up at the door of the client in some shape or form. Usually with an enormous price-ticket attached.

In this environment, the only approach to logistics quality that is going to fly in the long-term is that of a 'right first time' doctrine driven by the shipper client.

THE BOTTOM LINE

The benefits of improved and more efficient quality control and better compliance are obvious, if somewhat difficult to ascertain in practice. One study[13] of pharma manufacturing, however, demonstrated a more than five-fold return on investment in quality improvements. The overall benefits in terms of assured compliance, enhanced risk attenuation, increased customer value and lower overall costs are manifold.

Because, the reality is that poor quality is one of the biggest 'cost icebergs' in business. The hidden costs of poor quality management was vividly conveyed in a 2018[14] study which showed that the median cost of a single protocol amendment for a Phase II clinical trial amounted to $141,000 rising to $535,000 for a Phase III amendment.

As the value of pharmaceutical continues to climb, as the latest bio-medicines become more sensitive, as regulatory oversight becomes more stringent, as drugs are packed in larger containers, and as the demand for medicines intensifies in the virus-age, the potential for risk and loss in the logistics chain is increasing sharply.

A more integrated approach to GDP compliance presents the only sustainable way of improving outcomes, reducing costs and extracting more value in these unprecedented circumstances.

> ***"We have thousands of excursions every year and it takes up to 25 man-hours to assess each event"[11]***
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> **Roman Mijnhart, Senior Director Quality Global Supply, Sanofi Genzyme**

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