7th March 2013, is a landmark date in the evolution of Good Distribution Practice. As the date of publication of the New Guidelines (2013/C 68/01), it has brought in a new era of cohesive structure to the practice of Good Distribution of Medicinal Products for Human and Veterinary Use. The Guidelines will be made effective six months from the date of publishing. As anticipated, the published guidance is very similar to the draft consultation paper circulated for review during the latter part of 2011. The draft paper brought up four points of contention surrounding hubs, temperature controls and Returns. From the published document it is clear that calls for a risk-based approach were heard, and incorporated, within the final document.
The 10 chapters of the draft paper remain:

Quality Management
Personnel
Premises and Equipment
Documentation
Operations
Complaints, Returns, Suspected Falsified Medicinal Products and Recalls
Outsourced activities
Self-inspections
Transportation
Specific Provisions For Brokers

The published guidelines are much clearer. There is less scope for misinterpretation. During the consultation period a number of distributors, manufacturers and regulatory agencies provided their comments on the draft guidance. The four main areas of concern, and their outcome in the published document, are discussed here:

1 Hubs – Wholesale Distribution Authorisation required?

Draft document: Section 9.12 – “where medicinal products are held on the premises of a hub for longer than 24 hours these will be deemed to be acting as a storage site and required to obtain a wholesale distribution authorisation”

In contrast, the published guidelines Section 9.2, now state:

“Provisions should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.”

Chapter 9 further advises risk assessing delivery routes where temperature controls are required.

2 Hubs: should these be audited?

Draft document: Section 9.13 – “Where hubs are utilised these should be audited and approved prior to their use.”

The published guidelines do not mention the audit of hubs.

However in section 7.2 the guidelines mention that the frequency of audit should be determined and justified using a risk based approach that considers the nature of the activity contracted out:

Guideline (2013/C 68/01), Section 7.2 “The frequency of audit should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.”

In addition, Section 9.2 “Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.”

This would indicate that, as a minimum, hubs will need to be assessed using a justified, appropriate method on temperature monitoring, cleanliness and security. The method of assessment would depend on the outcome of the risk assessment.

An example of a risk based approach would be to know your product, understand the storage requirements, its tertiary packaging and assess the distribution route used, to name a few. This will give pharmaceutical companies and distributors a clear indication as to how they can effectively monitor their own product and ensure its Quality during transportation.

3 Temperature controls for ambient products

Draft document, Section 9.19 – “Validated temperature control systems should be used during transportation of cold chain and ambient storage products”.

The published guidelines now advocate a justified, risk-based approach. Validation vs. monitoring!

Guideline (2013/C 68/01) Section 9: “it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.”
Other areas of interest

The draft paper mentioned that the RP should be permanently on site. However, the published guidelines state that the RP should “fulfil their responsibilities personally and should be continuously contactable. The Responsible Person may delegate duties but not responsibilities.”

As part of the anti-counterfeiting measures, and a hot topic with many regulatory authorities, is Vendor/Supplier/Customer qualifications. In order to secure the supply chain, it is expected that Qualifications are performed of suppliers/manufacturers (upstream) and customers (downstream).

It is expected that all parties in the supply chain, subjected to these guidelines, should perform these qualifications initially and on an on-going basis. This also applies to brokers.

The publication of the Guidelines (2013/C 68/01) should be congratulated as a feat of accomplishment. Creating a singular document to cover the whole of the European Union is no simple task, given the differing local regulatory requirements, language and cultural differences. Rather than creating a draconian document that is cumbersome for the industry, the final published document promotes a unified culture of Good Distribution Practice. It points out areas for consideration. It is left for the professionals to apply the principles of the Guidelines using their knowledge, judgement and experience within a risk based framework.