Stamp of Approval

The transportation of pharmaceutical products has many regulations that differ by country. Companies must ensure they are qualified and compliant with Good Distribution Practices for a successful supply chain

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Over the past 10 years, Good Distribution Practice (GDP) has become something of a buzzword when discussing best practice within the pharmaceutical logistics industry. However, a vast amount of confusion remains over its meaning, especially when it comes to which guidelines and licenses apply to each part of the supply chain.

Part of the problem lies in the fact that there is no single global standard. While the WHO provides global guidance, levels of GDP compliance vary significantly across the world. Each country has its own interpretation of exactly what GDP entails, and these are usually influenced by one of three regions: the EU, US, and the rest of the world. Generally speaking, the more advanced the country, the more comprehensive the GDP guidelines will be.

However, it is interesting to note that, within the *US Pharmacopeia* (USP), which provides guidance to the US pharma industry, there has been a significant focus on supply chain security, with less emphasis on GDP as a whole. This is currently being reviewed, with the revision of Chapter 1079, in line with the introduction of the Drug Quality and Security Act (DQSA), sometimes referred to as 'track-and-trace'. The DQSA means that supply chain integrity and GDP compliance within the US are now being addressed by the FDA, and it is the USP's goal to provide supplementary clarification and guidance on the requirements set out in the DQSA (1).

GDP in the UK

Similar developments related to GDP have also been taking place within the UK, specifically in relation to the requirement for a wholesale dealer license – or wholesale distribution authorisation (WDA) – when providing short-term storage for refrigerated items. In August 2014, the Medicine and Healthcare Products Regulatory Agency (MHRA) published the document *Short-Term Storage of Ambient and Refrigerated Medicinal Product – Requirements for a WDA*, which stated the following:

- Sites holding ambient products in excess of 36 hours must be licensed
- Sites where refrigerated products are held, even when this is for less than 36 hours, must be licensed (2)

This changed things quite significantly, as it meant that organisations throughout the entire supply chain were now required to obtain a WDA under the aforementioned circumstances. The new guidelines affected manufacturers, logistics companies, airlines, shipping lines, and trucking companies. However, while some of these embraced the change and applied for the license, many found ways to delay the process due to the expense of implementing the necessary changes, as well as confusion over what was actually required.

To understand this confusion, it is helpful to look at why a WDA is required for companies that are storing or shipping temperature-controlled medicinal products and the impact that temperature excursions can have on the safety and efficacy of the product by the time it reaches the end-user (the patient). Many pharmaceutical products are highly sensitive to changes in temperature and need to be kept within

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a very specific range. The smallest shift out of that range can damage the quality of the product, making it less efficient or dangerous to the consumer.

A report by CargoSense in 2014 noted a loss of approximately $35 billion caused by temperature excursions in healthcare, with 30% of scrapped pharmaceuticals being attributed to logistics issues alone. The report also highlighted that 25% of vaccines reach their destination degraded by incorrect shipping and 20% of temperature-sensitive products are damaged by a broken cold chain (3). These figures show exactly why this is such a crucial area to focus on.

Such changes in temperature are more likely to happen in some areas of the supply chain than others due to naturally greater risks involved in storing products for lengthy periods or transferring them between environments and stakeholders. As a result of this, there are a few areas where a WDA is not required and many more where it still is.

When Is a WDA Not Required?

There are a few examples of when a WDA would not be required:

Example One
A trucking company collects a product that needs to be stored between 2-8ºC and transfers it from the shipper directly to the consignee. The product never leaves the vehicle between the start and end point and the temperature control system runs continuously.

Example Two
A third-party logistics (3PL) company collects a product from the customer and transfers it back to their warehouse, again with the temperature-control system running continuously.

Example Three
A control room temperature product is stored in a warehouse for no more than 36 hours.

In each of these examples, the risk of temperature excursions is minimal as the product is being stored in a highly regulated environment. Because of this, a WDA would not be required. However, each of these scenarios would still require strict compliance to GDP guidelines.

For instance, a company that operates a fleet of temperature-controlled vehicles throughout Europe to support the pharma and life sciences sector is not required to have a WDA, but they do maintain strict standards to ensure they remain GDP compliant. Such measures include fully training their drivers, temperature-mapping their vehicles, and providing evidence of a robust quality management system.

Another company may hold a WDA for a number of operations across the EU, but does not require one for their work outside of the EU. However, they are continuing to work towards GDP compliance across their entire network to provide a global standard to their clients around the world.

When Is a WDA Required?

A WDA is required by such a wide range of stakeholders across the entire supply chain. It will be easier to look at each area in turn.

3PL Companies
Approximately half of the world's top 10 air freight forwarders currently hold a WDA license in the UK, and many more are working towards obtaining one (4). Such a high percentage can be explained by the fact that 3PL businesses typically store and transport pharmaceutical products, automatically requiring them to maintain the strict standards set out by the MHRA.

Having a WDA license gives 3PL companies an advantage in the market, as pharma shippers are looking to outsource in this area. If a 3PL firm does not hold a WDA or is not working towards one, they are highly unlikely to be considered for work.

It is slightly different within the rest of the EU where WDA licenses are used more for wholesalers than 3PLs. Once you move outside of the EU, WDAs become non-existent. However, in the UK, they are incredibly important for 3PLs and should not be overlooked.

Airlines
Over the past few years, awareness of the need for greater compliance within the airline industry has increased. A report by IATA (based on data from Pharmaceutical Commerce) found that, while the global pharma industry was booming, air cargo's share had declined significantly between 2010 and 2013 (5).

One of the main reasons suggested for this decline was that over 50% of all temperature excursions occur while products are being handled by airlines and airports, leading to an unacceptably high level of loss.

As a result, the IATA set up the Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma), with the aim of creating a global standard across the air freight sector. Several airlines have obtained or are working towards CEIV certification, but only a few have gained full health authority approval in the UK. This is because CEIV certification is not recognised by the MHRA, so UK-based

airlines are focusing more on obtaining a WDA license.

For example, an airline that was working towards WDA approval chose to outsource ground handling to another company. In that instance, both the airline and the Ground Handling Agent (GHA) needed to have a WDA to comply with the MHRA's guidelines.

GHAs

GHAs have an incredibly important role to play in maintaining GDP compliance. GHAs work with both UK and non-UK airlines. Not only do they need a WDA for the UK, but also the CEIV Pharma certification when working within the EU.

Creating Pharma Corridors

Because of the increasingly complicated requirements put in place to ensure product integrity is maintained throughout the entire supply chain, the logistics industry has shifted towards collaborative partnerships between all key stakeholders. This has led to the development of strategic hubs and 'pharma corridors', in which groups of GDP-compliant companies work together to offer customers assurance that their product will be handled in a completely compliant way from start to finish.

The benefit of this is clear considering the lack of a global standard. If shipments are being made internationally, having a chain of companies that understand and are compliant to the highest standards within their region provides added reassurance to the customer.

An example of this is the Pharma Aero initiative formed in 2016 between Brussels Airport and Miami Airport. The collaborative approach taken by these two airports really highlights the focus on improving pharmaceutical handling within the air freight industry. The initiative now has 18 members, including shippers, airlines, freight forwarders, and GHAs (6).

What about Sea Freight?

The movement of pharmaceutical products via ocean has only begun to gain momentum in the past few years.

As health authorities have increased pressure to reduce prices, manufacturers have been forced to lower their own costs and turn to the relatively affordable option that sea freight offers. Some shipping lines have embraced this new opportunity and are slowly working towards GDP compliance.

However, due to the sheer number of service providers in the chain, along with a lack of standardised protocols, each port has its own way of operating. This complicates the process significantly.

It will be interesting to see how things develop over the next few years. For now, though, it is helpful to note that, as sea freight is considered to be in-transit, rather than storing pharmaceutical products, they are not required to work towards a WDA.

Ensuring GDP Compliance

The best way to ensure that a company is ticking all the right boxes and providing a GDP-compliant service is to work with an independent expert that understands the requirements inside out and can guide companies through the process. They will be able to complete a thorough audit and gap analysis and support a business in making any changes necessary to reach compliance and gain a WDA or CEIV Pharma certification, if required.

GDP accreditation can also be obtained from independent organisations that will assess a company against local and regional guidelines. Though such accreditation may not equate to health authority approval, it does provide a certain recognisable standard.

The bottom line is that, regardless of the part of the pharma supply chain, compliance is crucial. The EU GDP guidelines are the nearest the industry has to a global standard, but even they are not universal. Therefore, knowing exactly which regulations affect an

area of operations and working towards compliance for those is important.

References

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5. Visit: www.iata.org/whatwedo/cargo/pharma/documents/ceiv-pharma-infographic.pdf
6. Visit: pharma.aero

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