

Containment Control for the Pharmaceutical Industry

Simon McKeever, Chief Executive, Irish Exporters Association, July / August 2016

Exports

Containment Control for the Pharmaceutical Industry

Simon McKeever of the Irish Exporters Association profiles the challenges and solutions associated with containment control for the pharmaceutical sector



Simon McKeever, Chief Executive of the IEA

Ireland has become globally recognised as a centre of excellence in the Pharmaceutical and Medical Technology (MedTech) industry. Ireland is the seventh largest exporter of medicinal and pharmaceutical products in the world, second largest exporter of MedTech products in Europe and home to nine of the Global Top Ten pharmaceutical companies amongst the 75 such companies that actively manufacture and export from here. The US remains a dominant market for Ireland's pharma exports, growth markets including Asia-Pacific are showing increased growth over a smaller base. IDA have noted that the structure of the Pharmaceutical sector is changing. Ireland is winning a significant amount of capital intensive bio-pharma investment to support the commercialisation of a range of new drugs. Exports of Medical and pharmaceutical products accounted for €30,174 million (27%) of total exports in 2015, an increase of €7,945 million (+36%) over 2014. Given the scale of this industry in Ireland and the specific nature by which these goods must be shipped, the wholesale distribution of medicinal products is an important activity in integrated supply chain management.

"Collaboration between all parties, including manufacturers, logistics service providers, ports and airports, is crucial to ensure product integrity and patient safety"

Pharmaceutical products are exported by various modes of transport, predominantly road, sea and air, making the distribution network increasingly complex. The number of subcontracted companies involved in the supply chain for biopharmaceutical products with different modes of transport and temperature control requirements has increased significantly. Collaboration between all parties, including manufacturers, logistics service providers, ports and airports, is crucial to ensure product integrity and patient safety.

To this end, the European Commission published the Good Distribution Practice of Medicinal Products for Human Use Guidelines (GDP) in 2013. To ensure patient safety and compliance along the supply chain, medicinal products must comply with these requirements during storage and transportation.

A key aspect of GDP is to ensure that the temperature compliance of the products are monitored and recorded, within product specification, and that temperature excursions and deviations are minimised. The requirements for temperature control logistics that monitor the temperature in transit has been a game changer for the industry. The Irish Exporters Association (IEA) has been at the forefront of informing the Irish pharma supply chain of their GDP requirements through our IEA GDP Passport initiative. The IEA GDP Passport certification has become the gold standard for GDP in Ireland with all leading logistics service providers in the field now having obtained certification. As the pharma sector has grown in Ireland, the IEA has played a key role in ensuring that companies can reach and exceed the required compliance role in assuring quality of the supply chain and distribution of pharmaceutical and medical device products.

For further information on the IEA's GDP Passport Certification, contact Dr. Niall Stobie, IEA, Life Sciences Manager & GDP Programme Director.

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Given the scale of this industry in Ireland and the specific nature by which these goods must be shipped, the wholesale distribution of medicinal products is an important activity in integrated supply chain management. Pharmaceutical products are exported by various modes of transport, predominantly road, sea and air, making the distribution network increasingly complex. The number of subcontracted companies involved in the supply chain for biopharmaceutical products with different modes of transport and temperature control requirements has increased significantly. Collaboration between all parties, including manufacturers, logistics service providers, ports and airports, is crucial to ensure product integrity and patient safety.

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A high proportion of pharma and biopharma products are transported by airfreight to their market destination in temperature controlled containers. Due to the improvements in reefer technology (reefer is the generic name for a temperature controlled container) and remote temperature control sensing, there has been an observed modal shift from air to sea for certain pharma products. However, due to the clinical urgency of orphan drugs and certain biopharmaceuticals, such products are transported by air to their market destination.

The Falsified Medicines Directive, also introduced in the EU in 2013, introduces rules to improve the protection of public health with new harmonized, pan-European measures to ensure that medicines for human use are safe and that the trade in medicines is rigorously controlled. For legitimate products, it's essential that these be transported in a manner that ensures the patient or consumer receives products of the appropriate quality. These complex supply chains provide considerable opportunities for criminals to substitute or insert sub-standard and counterfeit materials and products. Therefore, vigilance by all concerned in the supply chain is vital and the IEA's initiatives are an important contribution in this regard.

Since 2007, the IEA has been liaising with Irish Life Sciences manufacturers, the Irish Medicines Board (HPRA) and logistics companies that service the market, to develop a voluntary Code of Good Distribution Practice for the sector.

The IEA GDP Passport Code of Practice, the outcome of this collaborative work, consists of a suite of classroom and online GDP training modules for freight forwarders, hauliers, as well as air and sea freight service providers, followed by a site audit and review process by a number of global pharma manufacturers.



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For further information on the IEA's GDP Passport Certification, contact Dr. Niall Stobie, IEA Life Sciences Manager & GDP Programme Director at niallstobie@irishexporters.ie