

Industry Calls for Qualified Transport to Secure Supply Chain

A recent study conducted by Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. revealed that a staggering 43% of critical and major product deficiencies are directly related to ineffective temperature control and monitoring during transportation and storage. The World Health Organization (WHO) also recently suggested that 25% of all vaccine products arrive at their final destination in a degraded state.

Given the high cost of conducting global clinical trials and the even higher cost of failure, regulatory agencies and pharmaceutical companies alike now demand that every party involved in the pharmaceutical supply chain – transportation and logistics providers included – conform to GxP guidelines.

What is GxP?

“Pharmaceutical ‘Good Practice’ embraces a variety of different processes and oversight mechanisms that apply to each sequential stage within the supply chain,” says Dr. Rüdiger Lomb, Global Director, Quality & Technical Compliance for World Courier. GMP, for instance, pertains specifically to the *production* and *control* of marketed and investigational products during the manufacturing process while GSP and GDP deal with the appropriate *storage* and *distribution* of pharmaceutical products. All are guided by GCP, or ethical clinical trial conduct. “These conventions have been designed and are accepted by the industry as the international standards for ensuring public health and safety as it relates to product quality.”

In recent years international regulatory agencies have worked diligently to eliminate any inherent ‘weak links’ in the supply chain and now routinely extend their guidance documents to cover all individuals or companies involved in any aspect of pharmaceutical product distribution. Key international guidelines currently in effect as products move off the factory floor include:

- WHO’s “Good distribution practices for pharmaceutical products” and “Guide to good storage practices for pharmaceuticals”
- FDA’s “cGMP / 21 CFR 211”
- U.S. Pharmacopeia (USP) <1079> “Good Storage and Shipping Practices”
- Canada’s “Guidelines for Temperature Control of Drug Products during Storage and Transportation”
- Ireland’s “Guide to control and monitoring of storage and transportation temperature conditions for medicinal products and active substances”

- EU's "Guidelines on Good Distribution Practice of Medicinal Products for Human Use" (94/C 63/03)

Need for Professional Partners

Even with these guidelines in place, pharmaceutical practitioners can still face enormous uncertainty once clinical trial materials leave their control unless they are working with a proven GxP-compliant logistics provider.

"The application of regulations in the real world presents tremendous challenge," says Dr. Lomb, "particularly given the highly complex nature of today's temperature-sensitive pharmaceutical supply chain. Studies are now routinely outsourced to multiple and often difficult countries where fragile infrastructure cannot ensure efficient transit times. Researchers may also be dealing with multiple time zones, extreme climates, lengthy protocol approvals and import timelines, language barriers and local unfamiliarity with the clinical trial process, among other variables. Without experienced in-country partners, it can be extremely difficult to harmonize the goals of the regulated with those of the regulators – that is, to ensure the smooth flow of materials to and from the research sites (the goal of the pharmaceutical community) without compromising product integrity (the goal of the regulatory agencies). Ultimately it is the responsibility of the pharmaceutical company to ensure its suppliers comply with all applicable regulations."

According to Dr. Lomb, a qualified GxP-compliant service provider will have strong local representation in all site locations (as opposed to only in selected locations). Its operatives will ensure that all proper import and export permits are in order, facilitate clearance and assist with any customs issues, make packaging recommendations suitable for each shipment and provide the appropriate packaging solutions, monitor temperatures in transit and during warehousing to the degree necessary, facilitate drug returns and take corrective actions when required – all in accordance with documented SOPs and with a view to minimizing delays and safeguarding the integrity of materials during transit.

In Summary

"Before choosing a supplier, know that GxP guidelines are applicable to all parties involved in the supply chain including transportation providers, that compliance will be enforced by regulatory authorities, and that the pharmaceutical company is ultimately responsible for non-compliance anywhere within its supply chain," says Dr. Lomb. "Each study is different and must be approached methodically to ensure optimum results. While the shipper must set the priorities, he or she will need to rely on the off-site expertise of others. There is no 'cookie-cutter' approach to clinical research, so I recommend that pharmaceutical practitioners select their service providers with care."

According to MHRA, the top five GDP deficiencies are:

- lack of, or inadequate written procedures
- general storage – temperature control and monitoring
- cold chain transportation
- unauthorized activity
- cold storage – temperature control and monitoring

About World Courier

World Courier is the largest and most experienced specialty courier service with a network of over 140 wholly-owned ISO 9001-certified offices operating in 50 countries. It also operates the world's largest integrated company-owned network of GMP-compliant investigational drug storage facilities in 11 developing and strategic locations. With its fully GxP-compliant transport and supply chain system, World Courier meets the most demanding industry requirements for managing time- and temperature-sensitive clinical trial materials used in global studies.

About Dr. Lomb

Since joining World Courier in 2008, Dr. Rüdiger Lomb has brought his considerable technical expertise to bear on shaping and refining the company's Quality Assurance program. Dr. Lomb was formerly Group Head (Director) of the Global Logistics Clinical Supplies Division for Bayer Schering Pharma AG (Germany) where he was responsible for the auditing and qualification of depot and transportation service providers. He was also responsible for the set-up of study-specific distribution scenarios and service provider selection, for the set-up and maintenance of a global depot network comprised of internal and external service providers, for the set-up and assessment of KPI reports from selected service providers, and for storage/distribution-related trouble-shooting during ongoing clinical trials. Dr. Lomb is a licensed pharmacist and holds a Ph.D. in pharmaceutical bio-chemistry.