New GDP guidelines: looking beyond

Regulatory changes from country specific implementation of GDP guidelines will increase complexity. Arthur D. Little proposes to look beyond compliance to grasp opportunities

Changes

Overdue, long awaited and heavily discussed while in draft status, the final version of the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use have been published in the Official Journal of the EU on March 7 2013. Three changes require special attention in the view of Arthur D. Little for today's pharmaceutical distribution:

- **Temperature and Transportation (9.1, 9.2 & 9.4):** The required storage conditions are to be maintained during transportation. A risk-based approach may be utilized to fulfill the requirements of transportation temperature. A risk assessment of delivery routes should be used to determine where temperature controls are required. Data and systems should show that temperature limits were kept. Upon request, information is to be provided to demonstrate that products have complied with temperature conditions.
- **Unloading and reloading for transit and at hubs (9.2):** In cases where products are unloaded, reloaded or stored in transit, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facility.
- **Responsible Person (2.2):** Involved parties are required to employ a Responsible Person. Usually, the Responsible Person is a pharmacist with the equivalent degree. The GDP Guidelines however are not that specific but point out to competence, experience, knowledge and training with regards to GDP.

Complexity

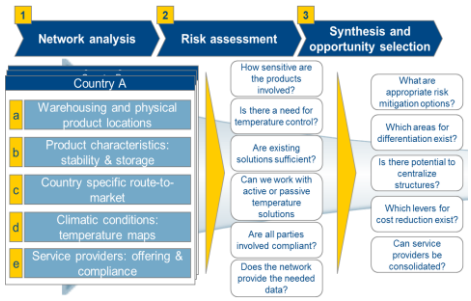
Against the background of stricter requirements as set forth by the new GDP Guidelines and the country individual interpretation and implementation that is about to follow, Arthur D. Little sees the complexity to increase:

- **Virtual supply chains** are characterized by a heterogeneous mix of Local Operating Companies (Affiliates), Marketing Authorization Holders and distribution partners, and product storage and warehousing across countries. Compliance with Good Distribution Practice throughout the entire distribution chain is all but straight forward**.**
- **Centralized warehousing structures** tend to send products over longer journeys and often across countries using several transportation companies. Frequently, monitoring systems are not integrated. Pharmaceuticals spend unplanned and undesired time in transit due to country specific holidays.
- **Country specific routes-to-market** are factored in and provide space for competitive differentiation. These routes vary widely across the EU member countries. Service levels, technology in use and capabilities of the parties involved in distribution are likewise disparate.

Resulting opportunities

The change in the regulatory environment and the emerging complexities both spark the need for action as well as they create space for opportunities. Arthur D. Little recommends mitigating the risk of non-compliance across EU operations. Beyond mere risk mitigation companies should actively search for opportunities in the following areas:

- **Differentiation:** Quality, improved route-to-market and related services offer the potential for competitive differentiation.
- **Profitability**: Overall, the new GDP Guidelines will increase cost of distribution. Companies which are best at implementing the requirements will benefit from a cost advantage over competition.
- **Value-addition:** Service providers along the distribution chain should pro-actively develop solutions that ease the sore for manufacturers. To this effect it will be crucial to think beyond GDP about topics such as supply chain visibility and end-to-end traceability.
- **Consolidation:** Changes in the regulatory environment often crowd out non-specialized businesses or companies of subcritical size. Formation and expansion of networks are likely effects, too.



Source:Arthur D. Little

What Arthur D. Little offers

Arthur D. Little supports companies to identify and realize opportunities to improve performance in pharmaceutical distribution. Based on insights from client work and discussions with decision makers, we propose a three phased approach. Our approach is targeted and combines risk assessment along the distribution chain with the ambition to make an impact by looking beyond GDP requirements.

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