

Case Study - Merger & Quality Compliance Project

Merger & Quality Compliance Project Large Pharmaceutical Company

CLIENT	Top 10 Pharma Company.
PROJECT	Since 2000, Pharmalink Consulting have been engaged in an operational role in a license integration, site rationalization, and a quality compliance project.
OBJECTIVE	Short term – Assist client company meeting legal and commercial obligations and targets as a result of merger. Long term – complete source transfers and related regulatory activity to enable seamless supply chain.
SOLUTION	The team that Pharmalink Consulting assembled successfully enabled license transfer and documentation incorporation all key stages of the compliance process including: — site transfers including internal and TPM sites, covering markets worldwide. — Performed quality & compliance reviews.

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Project Details

- Pharmalink was the operational regulatory partner in the UK and US for site rationalisation and product quality compliance resulting from a high profile merger between two large pharmaceutical companies. The key performance indicator was the need for cost saving and manufacturing rationalisation – central to these activities.
- Pharmalink was tasked with identifying requirements, timing, and delivering site transfers for worldwide markets. In parallel with this activity the team completed a quality compliance review on all products that enabled a full regulatory strategy to be available when sourcing decisions had to be made.
- The Pharmalink core team of 25 was adjusted as requirements varied and reached 60 at its peak. Following the merger activity in 2005 Pharmalink has maintained smaller team to continue routine source transfers.
- The volume and complexity of the project was managed successfully and key merger targets achieved. The client was satisfied and continues to employ Pharmalink for a variety of regulatory activities across its sites.

