Case Study - **Product Compliance Project**

Global Product Compliance Project

CLIENT — Top 10 Pharma Company.

PROJECT — Since 2004, Pharmalink Consulting have been successfully performing a large-scale Global Quality Compliance program for a company, covering approximately 1400 Quality Dossiers worldwide.

OBJECTIVE

Short term – get product moving around Europe again.
Long term – bring all dossiers and licenses up to date providing sustainable compliance.

SOLUTION

The team that Pharmalink Consulting assembled has successfully driven all key stages of the compliance process including:

- Quality Dossier collection and collation into CTD format
- CMC Compliance Assessment
- Product Remediation

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Project Details

- **Dossiers Collected –** 270
- **Dossiers Collated –** 270
- **Compliance Assessments Performed -** 270 (10% TPM)
- **Remediation Packages Prepared –** 564
- **Markets -**

  AT, BE, BU, CH, CY, CZ, DE, DK, EE, EL,ES, FI, FR, HU, IE, IS, IT, LT, LV, MT, NL, NO, PL, PO, RO, SE, SK, UK

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Project Details

- Throughout the compliance project in Europe, the Company was forced to halt product shipment until gap analysis was completed. This put enormous pressure on the team, yet the impact on product shipments remained minimal.
- Various stages of the compliance process were performed remotely from the client, across the Pharmalink offices in North America, Europe and Asia. All objectives and milestones were successfully achieved ahead of target dates.
- The Pharmalink team reached 45 in number at the height of the activity but remained flexible dependent on the workload so were able to adjust accordingly. Pharmalink was able to offer office facilities for the purposes of the project.
- The resulting completion of the European section of the project meant a satisfied client who has continued to employ Pharmalink for regulatory activities across multiple sites in Europe and the United States.

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