

PharmaLex corrects serious non-compliance issue and protects millions of £s of annual sales for product range

Situation

PharmaLex were given the responsibility of providing regulatory services to a pharmaceutical company who had acquired two licensed medicines in a range of formulations and strengths from big pharma. These originator products had EU sales in the millions and PharmaLex were engaged to provide regulatory support to all the client's local EU affiliate offices.

Challenge



PharmaLex soon discovered that there was a significant level of non-compliance between the registered manufacturing and quality documentation and the procedures and specifications applied by the manufacturers. Since there is a legal requirement to manufacture in accordance with the registered information and the manufacturer could not change how they made the products, the company faced the possibility of having their licenses suspended and having to stop selling product until such time as the marketing authorizations had been updated. This corrective action would take 6 –12 months.

Solution

Using our quality and manufacturing knowledge and deep technical regulatory expertise, PharmaLex designed and implemented a plan to manage the situation.

1. PharmaLex performed a risk assessment for the quality of the medicines and concluded that patient safety was not adversely affected

2. PharmaLex defined the changes required and a plan for bringing the licenses into compliance. Using our quality and manufacturing knowledge and deep technical regulatory expertise, PharmaLex designed and implemented a plan to manage the situation. Full manufacturing and registration documentation compliance

3. PharmaLex proactively initiated communication with scientific staff at the competent authority to gain their agreement that the products could remain on the market

4. PharmaLex executed the plan, corrected the licenses and delivered a compliant situation.

Benefits



Full manufacturing and registration documentation compliance



The protection of the existing sales of millions of £s



Protection of the client's reputation in the eyes of regulatory authorities in the EU



Continued product sales