

PharmaLex ensures regulatory compliance for successful pharmaceutical product acquisition with sales growth of 22% in the first year

Situation

A pharmaceutical company had an opportunity to buy their first medicine and needed to understand their pharmaceutical regulatory compliance obligations prior to acquisition. This was a product that had been sold for a number of years in many countries across the world, so there was a huge amount of complex technical and scientific data. The medicine was used to treat potentially life-threatening infections and therefore played a vital role in critical care.

Challenge



The company was concerned that it was unable to evaluate the regulatory and safety benefit-ratio in order to make a fully informed decision on whether or not to acquire the product and what price to pay.



Consequently, there was a risk that they may have inherited some problems that could be costly to rectify. In another similar situation, a company bought a product without such an evaluation. Within a year of acquiring the product, it was taken off the market for good by the regulatory authorities, rendering the asset worthless.



If the acquisition proceeded, the company would be responsible for ensuring it complied with all the maze of applicable rules, regulations and legalities whilst maintaining supply to hospitals during the transition.

Solution

Using our due diligence methodology and deep technical and scientific expertise, PharmaLex was able to ensure the decision to acquire the product was correct from a regulatory perspective.

1. PharmaLex interacted with the scientific staff in the selling company to uncover all potential regulatory and drug safety risks.
2. PharmaLex used a structured interrogation of the regulatory data, coupled with strong commercial thinking, to identify the potential use of a quiescent license.
3. PharmaLex used its intimate knowledge of regulatory requirements to ensure the transfer of licenses complied with the rules and regulations in every country.

Benefits

The PharmaLex engagement delivered:



The opportunity for the company to negotiate the best price for the product.



The acquisition of a US license at no extra cost that provided access to the American market, contributed to sales growth of 22% in the first year.



Continued product supply preserving the market and customer loyalty, whilst ensuring regulatory compliance.