CASE STUDY

PharmaLex applies EU regulatory affairs expertise to rescue failing market application and delivers €3m revenue in first year sales

Situation

A pharmaceutical company had submitted a marketing application for a new product seeking approval in ten EU countries. The company required a partner with specialist EU regulatory affairs knowledge to avoid a costly failed application.

Challenge

The regulatory assessment had been ongoing for almost a year and the authority had informed the company that they should withdraw their application for all ten countries because there were a number of shortcomings in their data and in their responses to questions.

The authority recommended that the company start the whole process again; this would have resulted in a delay of at least 12-15 months in getting the product to market.

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Solution

1. Using our significant experience of interacting with regulatory authorities, PharmaLex was able to negotiate and secure one final opportunity to submit satisfactory responses to the agency.

2. PharmaLex built a constructive working relationship with the assessment team at the regulatory agency.

3. With our regulatory knowledge and scientific expertise to the fore, PharmaLex correctly interpreted the scientific product data and helped the company construct robust responses to the questions.

4. PharmaLex worked to the required deadlines to ensure the application succeeded.

Outcome

Licence approval in ten EU countries on schedule and avoided a 12-15 month delay

Product sales worth €3M in Year 1

A good reputation for the company in the eyes of the EU regulatory authorities

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