

Using a flexible resourcing model in a Marketing Authorization Transfer project to enable cost and resource efficiencies



A CLIENT SUCCESS STORY

Situation

A mid-sized biopharma company acquired an existing product portfolio from another company. There were eight products initially, spanning over 30 countries focused on cardiovascular and transdermal patches.

Challenge

Although the company had an established regulatory workforce, the team had little time to focus on the license transfer submissions and subsequent regulatory maintenance activities for the acquired portfolio. Additionally, the new portfolio of products was marketed in unfamiliar countries, so the existing team lacked expertise.

Solution

Parexel provided a flexible resourcing model to relieve valuable internal resources and pressure of peak and trough periods. We provided the client with nine full-time employees who were fully integrated into their organization. We supplemented this with additional local representation covering 32 markets as and when needed. In addition to the license transfer support, post-approval services for lifecycle maintenance included:

- Change control assessments
- CMC/labeling core/artwork changes
- Periodic reporting (ARs, Aggregate)
- Renewals / Market Expansion
- Publishing
- Local submissions and health authority interactions
- Translations

We provided activity-based unit pricing, which gave the company greater insight into the cost of regulatory affairs maintenance for both global and local levels.

Results

With our strong global footprint, we were able to support the company in local markets where they had no previous presence.

Our flexible resourcing model enabled the company's HQ and local employees to focus on new development projects and expansion strategies. They also saw an improvement with the quality and compliance of regulatory information management data and a reduction in dedicated full-time employees to support mature brands products – saving vital costs.

Find out more at:
www.parexel.com/regulatory-outsourcing