

Securing Compliance

Resources to Keep All Your Licenses Current

Challenge

A customer needed help getting licenses up to date for some 220 Marketing Authorization dossiers, representing 32 products across 27 EU and four other countries — quickly. The company had made many manufacturing improvements for their various pharmaceutical and biological products over a period of 10 or more years, yet had not submitted all the necessary documentation to keep those licenses updated and in compliance.

Solution

Quintiles took on this massive, complex task and quickly deployed the right experts. Our experienced regulatory team conducted a comprehensive gap analysis and immediately began addressing needs. Quintiles integrated seamlessly with the customer's teams, gaining their trust and finding the most efficient ways to apply our regulatory expertise to meet the aggressive timeline.

Results

Quintiles quickly brought the company into an audit-ready state in less than 12 months. Quintiles prepared 430 CMC variations, 309 of which — 72% — were approved without further questions. This allowed the customer to achieve full compliance within the required timeframe.

Updating 430 Variation Submissions

Our customer had a series of pharmaceutical and biological products that had been on the market in various countries for 10 years or more. Over time, they had made a number of manufacturing improvements, and they needed to update their myriad licenses.

The task was enormous — auditing some 220 Marketing Authorization (MA) dossiers and ultimately preparing about 430 variation submissions. It was a substantial, and urgent, assignment for the customer's in-house regulatory staff, and it came on top of their significant ongoing new product responsibilities.

The company trusted Quintiles to handle the entire project and — equally important — to ensure timely delivery.

The Resources to Get It Done

First, the customer realized that a project like this is extremely labor-intensive. Quintiles had the resources to get right on it — a European regulatory team of almost 80 professionals who provide a thorough understanding of national requirements in all 27 EU countries, plus four others involved in the project: Australia, New Zealand, Turkey and Switzerland.

A Foundation of Trust

This was a priority project for the customer. They needed to know that their provider could get the job done right the first time, and Quintiles quickly established a high level of partnership and trust.

} We have successfully filed so many variations in most countries that we can almost
| always predict what is required for a successful approval.

Flawless Execution

The customer is organized product by product, and we structured teams that mirrored theirs from top to bottom: Senior reviewers at Quintiles each had specific customer counterparts. We also mirrored their project management structure and even their administrative support. In short, we quickly adapted to the most efficient way of working and closely integrated our teams with theirs to ensure a flawless workflow throughout.

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About Lifecycle License Management

Improving manufacturing processes is a more or less continuous activity, and the lifecycle management of multiple licenses takes a tremendous amount of work. Quintiles has the experience and resources in place to handle even the most complex projects, and to free up your in-house regulatory staff to focus on new product approvals.

Whether you need to bring old licenses into compliance or keep multiple licenses current, you can trust Quintiles to take care of it.

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