

How to Keep All Your Licenses in Compliance

220 Marketing Authorization dossiers audited and 430 variation submissions updated – all in a matter of months.

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. In 2007, management made a commitment to get everything in order as quickly as possible.

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.

Resources, Resources and More Resources

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.

We have successfully filed so many variations that we can almost always predict what's required for a successful approval; in this project, 80% of all variations submitted have already been approved without further questions. ➤

The Importance of Feeling Secure

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.

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.

Let Quintiles Take Care of the (Endless) Details

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.

At Quintiles, *it's all about results.*TM

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