

A4L Solution Profile

Company: McKesson

Profile: Health care services
Repacker

The Situation

McKesson is one of the top healthcare services companies in the U.S. and currently ranks 15th in the Fortune 500. Over the past few years, McKesson has received numerous awards for the difference their pharmaceutical businesses are making for their customers.

Their distribution division supplies branded, generic, and over-the-counter pharmaceuticals to more than 40,000 customers in three primary segments: retail chains, independent retail pharmacies, and institutional providers such as hospitals, health systems, integrated delivery networks, and long-term care providers.

McKesson updates their product line on a quarterly basis, but conducts stability testing on new drug interests up to six months before a drug is released. Quality control support is aware of these additions, as it is part of their responsibility to schedule and participate in the launch of a new drug. SPL listings, which now total over 200 at McKesson, must be submitted for all of these new drugs.

In June of 2009, the FDA issued new drug listing regulations that required repackers and relabelers to list all of their products electronically, in the form of a Structured Product Label (SPL). And there was pressure from the FDA to have all listings submitted and validated in a very short timeframe.

Jatana McDermott, Quality Support Administrator at McKesson, knew that she would have to create SPLs using information that was provided direct from the manufacturer. As the single person responsible for SPL submissions, she knew that process would require a lot of attention. Jatana began to look at solutions offered by various software vendors.

In the meantime, the free tool offered by the FDA was available, so she tried it as a “getting started” exercise. Capturing manufacturer information from the daily med should have provided a bit of a head start, but the experience of taking the information and populating the tool from the FDA proved to be a challenge. The tool was difficult to use

and the resulting SPL submissions were full of errors. The time spent to redo and resubmit was getting increasingly frustrating. McKesson had to find an easier tool.

Jatana only had about a month to get her listings started and wanted to make sure that the tool was right for her. She was the only user and had no IT support.

The Solution

Jatana was clear about the characteristics of her ideal solution. It would provide McKesson with an easy-to-use, seamless product that would allow a single primary user to create, validate, and submit an ongoing list of drug changes—every calendar quarter.

Jatana identified two vendors' software solutions to review against her criteria. They each presented their solutions using McKesson labels as examples.

“It became very evident when I reviewed i4i’s A4L product that this tool was the one for me,” said Jatana. “The i4i product specialist knew exactly how our process worked and created a label exactly the way I would. I could relate immediately. The templates and Word interface allowed me to use the original material from the daily med. With a simple cut-and-paste exercise, my task was complete. With an easy-to-use, intuitive tool like this, I was able to get started very quickly.”



The Result

The McKesson regulatory group had always used another software product to confirm and proof the content from the manufacturer. Today this practice is used only as a backup. This confirms the success of A4L at McKesson. It lets even a single user create, maintain, update, submit, and validate.

McKesson actually trained three people on the use of the product but Jatana remains the primary user. Although her QA personnel do not have daily exposure to A4L, they can use it to create new listings when backup resources are needed.

There is no IT support in this McKesson location so Jatana has relied on i4i Support to help her with XML issues—and seems to rely more on i4i for FDA information than the FDA themselves. Jatana adds, “The product saves me from headaches on a daily basis.”

McKesson continues to change and expand its product line, with no worries from their labeling group.