

A4L Solution Profile

*Company Profile:
Pharmaceutical Repacker*

Company Profile: US repacker
Distribution, packaging, and labeling services

■ The Situation

The company in focus (referred to within as “Pharma-Serv”) is one of the world’s largest pharmaceutical services companies. Pharma-Serv specializes in repacking and distribution services to pharmacies, retail, and other distribution businesses. They also offer unique packaging and labeling services to other drug manufacturers.

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

Pharma-Serv had just one person assigned to complete all the SPL product submissions. Using the FDA’s free tool, the task became very cumbersome, and a backlog started to grow. And with each new type of packaging or labeling requirement, their listings became even more of a challenge for a single user.

In 2009, Pharma-Serv purchased A4L from i4i. The intuitive interface allowed the single user to become efficient in the creation and validation of their required drug listing SPLs.

However, turnaround in the department led to a lack of resources, resulting in a backlog, an out-of-compliance status, and the loss of their in-house A4L knowledge. To get back on track, it was critical that an experienced regulatory person be hired to take on the responsibility of fixing the SPL listing issues.

A new Regulatory Affairs Specialist (RAS) came on board, and one of his top priorities was to establish which SPLs required immediate attention in order to regain compliance for Pharma-Serv listings.

With over 200 drug listing SPLs, he was immediately presented with a daunting task. He had previous regulatory experience, including use of the free tool from the FDA. He knew the tool would not allow him to complete the amount of work required in a timely or accurate manner.

■ The Solution

Pharma-Serv needed to reinitiate its use of the A4L product immediately. It provided speed, ease-of-use, and accuracy, all critical features at a time of non-compliance.

To address the backlog and achieve compliance, the new RAS knew he would have to find some help in getting so many listings completed in a short period of time.

The solution was two-fold. He had to get the critical listings (98) done by someone else while he became familiar with A4L. The help he needed came in the form of the A4L supplier, i4i.

"i4i offers a very efficient and seamless conversion service which allowed me to obtain compliance while being trained on the product," he said.

■ The Result

Within a relatively short period of time, the conversion team at i4i had successfully created and validated all 98 listings for Pharma-Serv. Compliance was no longer an issue. The RAS was able to quickly master the A4L tool and started the process of completing the remaining SPL product listings, which numbered over 100.

"The use of i4i's conversion service allowed me to focus on getting the correct training and start the SPL creation process using A4L myself," he said. "The product was very intuitive and let me simply cut and paste most information. Through drop-down menus, using built-in terminology and FDA guidelines, I was able to get started quickly, resulting in all listings being created and validated."

"With A4L in house as part of my daily tool set, there is no longer the fear of becoming non-compliant. The preparation and validation of listings is a much simpler task."



Contacting i4i

For assistance using i4i products and tools, or for more information on technical support options, please contact:

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