Helping a Global Medical Device and Pharmaceutical Company Comply with EU Regulations

Trusted partner for your **Digital Journey**

Atos | Syntel

Business goals

The client is a top 5 medical device, pharmaceutical and consumer packaged goods manufacturer with approximately $70 billion in annual revenue. In order to comply with new regulations, they needed to assess the business impact and understand if any changes were required to the way the organization does business.

Technical challenges

As part of their parent company's compliance program for new European Union Medical Device Regulations (EU MDR) , the client engaged Atos Syntel to execute a gap assessment and change management program for their products, to ensure they comply with new EU MDR rules. The client also needed to gauge the impact of the regulations on their business. The new guidelines required the client to change the way product information was presented on labels, so their large product portfolio and multiple labeling systems made the task challenging. The client also faced difficulty in performing a gap assessment for all product labels and IFUs across a vast portfolio of products.

Our solution

Atos Syntel had a decade-long working relationship with the client and was familiar with the processes and systems encompassing more than ten franchises/subsidiaries in North America and the EU.

Through a robust knowledge capture process, we gathered inputs in order to align the label changes with collaboration partners, assess EU language gaps, and ensure the labels were compliant with artwork, restriction of hazardous substances (RoHS), intended use, intended user, product lifetime, indications, contraindications, undesirable side effects, adverse reactions, sterilization, reprocessing, storage and other requirements.

We also conducted a risk and translation assessment, analyzed various components, specifications and templates, and implemented a scalable regulatory compliance mechanism. Then, Atos Syntel performed a language and symbol assessment for 40,000+ labels and IFUs, plus nearly 2,000 labeling components within the first 12 months, to ensure they were fully compliant with EU MDR.

Additionally, we were able to meet stringent compliance timelines through our familiarity with the client's processes and by implementing automation for critical processes like quality checks.

Results delivered

- **32% increase in productivity** by using Atos Syntel's tools and accelerators
- **Improved product quality by 15%** by automating quality checks
- Generated a **42% cost savings** and **25% higher business efficiency** by leveraging Atos Syntel's accelerated global delivery model

Atos Syntel is a leading provider of integrated IT and knowledge process services and a member of the Atos Group, a global leader in digital transformation with 110,000 employees in 73 countries and annual revenue of over €11 billion. We help enterprises accelerate their digital journeys, increase agility and business performance, evolve to "Digital native" standards, and deliver scale and flexibility for the Digital Age.

Atos Syntel unites Atos's scale and world-class technology capabilities with Syntel's industry focus, global delivery model, and services powered by intelligent automation.

Learn more at: www.atos-syntel.net