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

BUSINESS CHALLENGE

The regulations companies have to comply with are increasing and could pose temporary challenges for businesses. Assessing the impact of the regulations on business is therefore important as altered policies may require the organizations to change in the way they do business. Our client is amongst the top 5 US-headquartered multinational medical devices, pharmaceutical and consumer packaged goods manufacturer with an annual turnover of approximately USD 70 billion.

As part of the global European Union (EU), medical device regulation (MDR) compliance program driven by their parent company, the client engaged Atos Syntel to initiate a gap assessment followed by change management program for all their products to ensure they comply with the new EU MDR legislation. The client also wanted to gauge the impact of the regulations on their business. The new guidelines required the client to change the way product information was mentioned on the labels. Having a large bouquet of products spread across franchises coupled with multiple labeling systems made the task challenging. The client also faced a difficulty of performing a gap assessment for all product labels across a vast portfolio of products.

BUSINESS BENEFITS

Using **Atos** Syntel's tools and accelerators helped the client in **increasing productivity by 32 percent**

Automating the quality check function **improved product quality by 15 percent**

By leveraging **Atos** Syntel's onshore and offshore accelerated delivery model, the client **achieved 42 percent savings** in costs, and **increased business efficiencies by 25 percent**

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. The familiarity with the process helped us deliver the project sooner. Atos Syntel assessed more than 40,000 labels and IFUs in the last one year. We performed gap assessment on missing EU languages, artworks, restriction of hazardous substances (RoHS), and other similar internal and regulatory requirements. We also conducted risk and translation assessment, analyzed various components, specifications, and templates and implemented a robust and scalable, regulatory compliant mechanism. Additionally, we automated critical processes like quality checks to meet the stringent timelines.

For more information about our services, **click here**

About Atos Syntel

Atos Syntel is a leading global provider of integrated information technology and knowledge process services. Atos Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Our digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Our "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

To learn more, visit us at: www.atos-syntel.net