Upgrading the Ophthalmic Product Manufacturer's Quality Management Systems for EU MDR and ISO 13485:2016 Compliance

BUSINESS CHALLENGE

The global regulatory environment is going through a continuous change with regulations governing significant businesses are regularly altered. Companies are at risk of losing the majority of their business if they do not comply with the changed regulations. Our client is one of the leading global manufacturers of ophthalmic products, including contact lenses, lens care products, medicines and implants for eye diseases headquartered in the USA.

As part of the regulatory compliance program, the client wanted to upgrade their Quality Management Systems (QMS) in North America, which includes finalizing the QMS structure, development of new procedures and altering existing processes to comply with the EU MDR 2017/745 regulation, MDSAP and EN ISO 13485:2016 standards. The client had limited knowledge about the new EU MDR regulations and QMS updates and insufficient internal resources to initiate the due diligence and change management program. Besides, they had decentralized QMS systems across all divisions and manufacturing units and a large volume of SOP, WIs, manuals and other documents needing an upgrade. The client engaged **Atos** Syntel to help them upgrade their Quality management system and comply with EU MDR regulations.

BUSINESS BENEFITS

Process standardization helped in increasing the productivity of the workforce by **28%.**

Atos Syntel introduced a process of performing continuous quality checks of the products which led to **17% increase in product quality.**

By leveraging a combination of our onshore-offshore delivery model helped the client **achieve 45% cost savings.**

SOLUTION

Atos Syntel supported client's QMS change management program leveraging its expertise in QMS and technical writing capabilities, covering **more than eight** manufacturing units in USA and Canada with an estimated volume of **2000** documents. We initiated a detailed mapping of the EU MDR 2017/745 and MDSAP to quality manual, directives, standard operating procedures and work instruction manuals. This was followed by identifying new requirements and changes to all the documents within the QMS domain and updating of the quality manuals, SOPs/ WIs using a combination of the onsite-offshore delivery model. We also digitized physical documents and uploaded them on the D2 Document Management System. Finally, we performed a final quality check of the documents with the submission of gap closure report.

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.

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