

Case Study: Kaysun Corporation Inc.

Engaging in the MedAccred® audit process led to a series of positive changes for Kaysun Corporation Inc., including a 14% increase in its medical business

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Quality has always been a critical focus area for Kaysun Corporation Inc. The custom plastic injection molding company, based in Manitowoc, Wisconsin, was already certified under ISO 13485 prior to engaging in the MedAccred audit process, to produce injection-molded components for medical devices. Up to that point, Kaysun was principally guided by Six Sigma/COPQ and ISO 13485.

However, the company had a desire to further enhance its processes and systems to better align with the rigors, demands, and strategies of the medical industry and prospective medical device customers. Several of Kaysun's target customers in the medical device sector advised that to be considered for a partnership, injection molders must have MedAccred accreditation. This was, in effect, the catalyst for Kaysun to pursue MedAccred accreditation for plastics injection molding.

'Internal adjustments to the allocation of resources'

In 2018, Kaysun created an internal task force to facilitate all aspects of the MedAccred accreditation process and sought assistance from the Michigan Manufacturing Tech Center, and the Performance Review Institute (PRI), which manages the MedAccred program. Kaysun gathered related documentation and data, and conducted pre-assessment analyses, which provided structured feedback and actionable steps for the company to address gaps in process and validation systems.

During the auditing process, Kaysun navigated various challenges. The MedAccred approach necessitated some internal adjustments to the allocation of resources, to more up-front medical device product design and development, issue detection and correction, and risk mitigation.

'Customers gained confidence'

Its hard work paid off, with the changes implemented in product development and process validation resulting in a more methodical, stable, and repeatable production process. Very soon, Kaysun became better at proactively planning, managing scrap, and increased the overall efficiency of its medical device manufacturing programs. In addition, customers gained confidence that any injection-molded part would meet dimensional requirements and quality expectations due to the improvements.

Kaysun's success in passing the rigorous audit criteria earned it MedAccred accreditation in plastics injection molding in January 2019. The company has been re-accredited several times since the initial audit, and currently maintains a dedicated team and a relationship with PRI to ensure it can satisfy all accreditation requirements.

Outcomes of MedAccred process for Kaysun

- 10% revenue growth in medical business one year after MedAccred accreditation
- 14% revenue growth in medical business by second year
- More structured, stable, and repeatable production process
- Better proactive planning
- Enhanced scrap management
- Increased overall efficiency of medical device manufacturing programs
- Customers gained confidence that any injection-molded meets dimensional requirements and quality expectations



‘Increases of 10% and 14% in medical business’

Following the accreditation, a number of major medical device manufacturers contacted Kaysun for products and services. Kaysun’s new business development team also targeted the large manufacturers to grow new business.

Two years after accreditation, revenue within its medical business increased by 10%, and the year after, further increased by 14%.

In addition to the tangible changes, MedAccred accreditation also shifted the cultural mindset about quality processes and products within the company. Ray Dorow, Quality Manager at Kaysun, says the complexities of medical devices require detailed documentation and handling which, prior to engaging with the MedAccred program, were often seen as “necessary functions.” He explains: “With MedAccred, all levels of team members understand the ‘why’ behind our approach to a particular medical device and the need for proper validation, documentation, and quality control. The greater awareness has cultivated a culture of continuous improvement, collaboration, engagement, and pride in owning all aspects of each project.”

‘Quality-first mindset’

Ray says it allowed Kaysun to strengthen its infrastructure in terms of quality assurance, metrics, and documentation of engineering approach and process development; as a result, people were empowered with a quality-first mindset. “This led to a holistic review of the molding process, inclusion of more aspects in validation, and

a more impactful system for identifying issues and correcting them prior to formal production,” says Ray.

He adds: “As more major medical device manufacturers require suppliers to hold MedAccred accreditation, it’s clear they acknowledge the qualitative difference it makes in their supply chains, operational efficiencies, and devices. MedAccred has compelled Kaysun to further embrace excellence.”

Kaysun Corporation

For more than 70 years, Kaysun Corporation has offered custom injection molding and engineering solutions to OEMs for the design, manufacture and assembly of complex, tight-tolerance plastic parts.

The MedAccred Program

The MedAccred program is an industry-managed, consensus-driven approach to ensuring critical manufacturing process quality through the medical device supply chain. Audits are conducted on behalf of subscribing members using collaboratively-created audit criteria. Accreditation is granted and accepted by the MedAccred subscribing OEM members. Audit criteria incorporates industry-accepted performance standards and manufacturer specifications that meet regulatory requirements.

