

Case Study: MRPC

MRPC is already seeing a positive impact on productivity, and “significant interest and excitement” from several large OEMs, in less than a year since achieving MedAccred Accreditation.

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MRPC, a contract manufacturer of medical devices, instruments, and disposables, wanted to improve management of its critical processes as a way to enhance quality, instead of relying on a reactive approach like product inspections. The MRPC team had already begun assessing its internal systems, with the intention of developing small pockets of excellence within the company.

Co-incidentally, a potential new OEM customer for MRPC also mentioned the MedAccred® program and how it uses an industry-managed critical process approach to evaluate system and operational controls, explaining that MedAccred Accreditation provides a “competitive advantage”.

Through the investigation process, MRPC learned that the Performance Review Institute (PRI) had partnered with the NIST Manufacturing Extension Partnership (MEP) National Network for a program called Medical Manufacturers MedAccred Accreditation Pathway (MedMMAP). This program allocates critical process experts to conduct on-site assessments and prepare manufacturers for a gap closure process. MRPC was already working with the local MEP for projects supporting the Manufacturing Excellence Journey.

Making preparations

MRPC completed a self-analysis, identified potential resources that could be applied to close gaps, then followed with a feasibility assessment to gain management commitment. The company

contacted a national MEP representative for the MedMMAP program to schedule a pre-assessment to baseline the current state. The MedMMAP assessment confirmed many key elements were already in place, but gaps in meeting MedAccred audit criteria were evident.

The key milestones and an estimate of resources required to achieve MedAccred Accreditation were presented to the MRPC executive team, where approval was given to proceed. The company, headquartered near Milwaukee, Wisconsin, U.S., established a steering team, while a Quality Assurance team led the initiative by developing a rolling action item list.

“Some of the actions were relatively simple, such as documenting what the team was already doing, while other actions required a team to design, document, and socialize new methods,” says Carl Lider, Chief Operating Officer at MRPC. “The process from the initial gap assessment to the Accreditation audit took about 14 months, but this included a delay from our original plan as we wanted to onboard a new Quality Manager at our Hudson, New Hampshire facility.”

Challenges along the way

An early consideration was whether to implement procedures across the company or at one plant. A decision was taken that all plants would implement procedures, but specific results would be captured at the Hudson location.

In addition, “Getting all plants to agree and allocate resources required was sometimes challenging, as was our (then) inability to conduct on-site assessments of compounds during a time when on-site visits were not yet fully welcomed by suppliers due to their pandemic control policies. However, we were able to work with PRI on a hybrid solution,” explains Mr. Lider.

Making internal changes

MRPC made broader use of the capabilities of its Enterprise Resource Planning (ERP) system. For example, using the asset management system for documenting the activities that were taking place, machine run-off and calibration, cataloging and maintaining ‘critical spares’, with established reorder points to support tooling and equipment.

“A certified operator program was already in place and maintained in the ERP training system where certification was required for



Operators to 'task in' to specific work orders, but we further employed the electronic training system to capture records of training for other activities such as safety and continual improvement," adds Mr. Lider. "The MedAccred audit criteria led us to review our Occupational Safety and Health Administration (OSHA) specific training which identified some differences across plants. This led to standardization across facilities such as powered industrial vehicle check-in process."

Other approaches were used, such as the '5S' methodology, 'Visual Management' techniques, and the '5 Second Take-Away' mindset, leading to, for example, the use of labeling for connections of process water.

Positive impact

Many of the improvements had a favorable impact on MRPC's Overall Equipment Effectiveness (OEE) and productivity measures. For example, on 'availability' which is expected to be directly and positively impacted as it relates to uptime.

At the time of writing, it is less than a year since the internal changes were completed and that MedAccred Accreditation was achieved. However, "We expect a favorable trend in the Cost of Poor Quality (CoPQ) to net sales and scrap metrics, and other evidence of improvement across the company," commented Mr. Lider.

New business opportunities and growth

"MedAccred Accreditation has enabled MRPC to build relationships with some of the world's leading medical device companies. We have seen significant interest and excitement with several large OEMs since our MedAccred Accreditation," comments Mr. Lider.

"This Accreditation, coupled with our capabilities in design for manufacturability, injection molding, finished medical device assembly, and global supply chain management, has enabled us to further conversations with key organizations," he said. "MedAccred is the next step in continuing our commitment to world class manufacturing and quality to the medical device industry. We continue to make investments in our team, systems and facilities to highlight our commitment to quality, for ourselves and for our clients."

Culture and mindset

Beyond processes and systems, achievement of MedAccred Accreditation has helped to permeate a positive and pro-active culture at MRPC.

"This MedAccred criteria promotes a culture of continual improvement and works well with MRPC's journey toward Manufacturing Excellence. Although it is up to MRPC to determine how we best meet and document the criteria, the organization has an understanding of 'what better looks like,'" says Mr. Lider.

The future

Mr. Lider concludes: "Our commitment to the medical device industry is unwavering, and receiving the MedAccred Accreditation for Plastics further demonstrates this to our customers, prospective customers, supply partners and our internal team. We've experienced multiple benefits across all our manufacturing locations since being accredited, and therefore we are pursuing accreditation for an additional MRPC manufacturing location."

About MRPC

MRPC is an ISO 13485 certified full contract manufacturer of medical devices, instruments, and disposables. With full range product lifecycle capabilities including design assistance, development, and manufacturing, MRPC is a turn-key manufacturing partner to some of the world's largest medical device companies, as well as cutting edge start-ups. Core competencies include: Design For Manufacturability; Silicone Molding, Plastic Molding and Extrusions; Multi-Material Molding; Finished Medical Device Assembly; and Global Supply Chain Development and Management. Learn more at: www.MRPCorp.com.

MedAccred

MedAccred 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.

Learn more at: www.p-r-i.org/medaccred

