

PTA PLASTICS

Greg Fish, Corporate Director of Quality, explains the motivation behind the decision to achieve MedAccred® accreditation, the challenges involved and the benefits the company has seen as a result of accreditation.

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After we first heard about MedAccred, we conducted an in-depth review of the injection molding audit criteria internally and met with PRI to review the audit and accreditation process, in order to get a full understanding of what was required. At this stage, plastics assembly was being phased into the MedAccred program and there was an opportunity to participate in the pilot of the audit criteria.

'An aggressive timeline'

As we already did business, including plastics assembly work, with most of the MedAccred Subscribers it made sense to participate in the plastics assembly pilot to begin to learn about the audit process and then once through the accreditation for plastics assembly, we would pursue injection molding accreditation. This put us on an aggressive timeline with only a couple of months to learn the plastics assembly audit criteria and put all the requirements in place.

Since the MedAccred audit, PTA Plastics has...

- **Reduced finishing defects from an average of just under 1,000 parts per month to 134 parts per month**
- **Improved total internal scrap (including molding and finishing) from 2.78% to 1.81% of parts produced**

Prior to our MedAccred journey, we had created processes based on our plastic assembly equipment supplier's recommendations and captured these in part specific instructions. Over the years we have had literally hundreds of customer audits and took any and all input

and observations as opportunities to learn and get better. Many of the current subscribers have been customers for PTA Plastics for many years and through launching numerous programs with them we have learned many best practices and adopted them whenever practical. Even with all of this experience we found that we had a lot of work to do based on a MedAccred gap analysis and got to work.

After performing a gap analysis, we set up a cross-functional team and held weekly meetings to address areas that did not meet the requirements. These were allocated among the team members and each topic was assigned a champion to get the concern addressed quickly and completely.

'Our status is one widely recognized by many in the industry globally'

This allowed us to record many processes that were not fully documented in the past as they were not required to be for ISO are now documented which eliminates problems with tribal knowledge. Significant improvements were and are being made to part specific work instructions to make them clearer, more complete and easier to follow.

As well as the quantifiable benefits of gaining MedAccred accreditation, our status is one widely recognized by many in the industry globally. Internally, PTA employees are proud to work for a company who seeks to be on the leading edge as we were by being the very first company globally to be accredited for plastics assembly. This accomplishment is visible in our facility through our MedAccred Certificate being framed and posted in a prominent location along with the MedAccred flag.

PTA Plastics

PTA Plastics is an employee-owned plastic injection molding company founded in 1953 with the vision to bridge the gap between product design and production. Offering services such as design and engineering, in-house moldmaking, injection molding, value-added services, process validation and specialty molding, the company focuses on the medical industry, defense/security industries and emerging technologies.

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.