

MedAccred Rising to Ubiquity

MedAccred is emulating the Nadcap standard that came before it, and much like its predecessor, is on a sure rise to prominence.

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If you want to do business in the aerospace industry, you pretty much need to be Nadcap accredited. It's the ubiquitous gold standard that everyone looks for when they want to buy parts from a supplier, and if you haven't at least heard of it, I can guarantee you're not working in aerospace. What you may not have heard, however, is that PRI, the group that administers Nadcap, was approached by the medical device industry to develop a similar program over the past few years: MedAccred.

The quick and easy way to describe MedAccred is "Nadcap for the medical device industry." For those who aren't familiar with PRI's style of accreditation, however, programs like Nadcap and MedAccred differentiate themselves from other industry certifications by taking a microscope to individual critical manufacturing processes. As the mantra at PRI goes, other certifications are a mile wide and an inch deep, while MedAccred is an inch wide and a mile deep. Instead of looking at your entire facility, a MedAccred audit will focus on a single critical manufacturing process, which could be anything from laser welding to injection molding to brazing, and review that critical process from end to end in painstaking detail.

From the start, the focus has been to make MedAccred the same universally recognized badge of excellence that Nadcap is. PRI's goal with the program is to improve patient safety by addressing final product quality through oversight of the most critical manufacturing processes. And every year that ticks by has been a positive year for the program that has made that goal look like more of a reality. In every metric, MedAccred has been expanding.

The program itself is growing rapidly, expanding the number of critical processes they accredit for. Currently, MedAccred's processes can be broadly separated into six categories: cables and wire harnesses, heat treating, plastics, printed circuit board assembly, sterilization and welding. Within each category, however, are sub-categories, such as with plastics, which PRI currently has divided into critical processes surrounding extrusions such as blow film, tubing and over-jacketing and injection molding processes such as compression molding or micro molding. In all, MedAccred

has expanded to cover over 20 different critical processes and sub-processes.

And the industry shows no signs of stopping. Most recently, they added electron beam and fusion welding to that list, and they're currently in the middle of developing accreditations for new critical processes related to the mechanical assembly of plastics, including three sub-processes, the production of printed boards (bare boards), both flexible and rigid, and sterile device packaging, covering three sub-processes. And after that, there's no end to the number of other processes being requested by participating companies that haven't yet received a task group.

"The industry is really excited about the program to improve their final product quality and, most importantly,



MedAccred is an audit program that takes an in-depth look at individual, specific critical processes instead of looking at your entire facility.

patient safety. Each year, we're probably going to be adding two or three new critical manufacturing processes to what we accredit," Connie Conboy, director of MedAccred, said.

They're also busier than ever. Last year, MedAccred accredited approximately 30 companies. And according to Conboy, they're currently expecting to perform over 60 audits in 2018, a number that is only growing as more companies apply for an audit in these early months of the year. They've also gotten more global. In 2015, MedAccred performed their first audit off of U.S. soil. Fast forward to today, and they're regularly auditing companies across a dozen countries ranging from Mexico to China to a number of European countries, and pretty soon, India and Israel will be added to that list.

One potential explanation for MedAccred's sudden explosion of audits is that large manufacturers are starting to

accredit multiple facilities. Early adopters have been accredited for a few years now, so some of the bigger players in the industry have had a chance to get used to the program in one or two test facilities and are starting to prepare a significant number of their production operations for accreditation. Flex, for example, had three facilities accredited two years ago, then in 2017 doubled that number to six. But that number is expected to jump significantly by the end of this year.

While that might make MedAccred's growing numbers a little less impressive, it's not enough to explain away its

If you're worried about passing your audit, there are multiple resources, both within PRI and from other organizations, that you can take advantage of to improve your readiness.



expansion entirely. The program is also attracting a larger following, with more companies actively getting involved in MedAccred's taskgroups and requesting new accreditation categories.

Most notably, the number of subscribers, companies that provide the program's oversight and funding, has doubled to six, with Baxter Healthcare, Medtronic and Boston Scientific Corporation joining the established group of Johnson & Johnson, Stryker and Philips. Stryker in particular has doubled down on MedAccred, beginning to require that future suppliers be accredited for their new product business.

"They are an exceptional group of industry leaders helping to assure that MedAccred has a positive impact on patient safety while expanding the global reach of this vital program," Conboy said.

PRI, of course, hasn't been idle in creating real enthusiasm across the medical device industry. According to Conboy, the organization has been "actively educating and communicating with all companies that might have an interest in the program." They've been doing a significant amount of individual outreach, both at conferences such as FDAnews Medical Device Quality Congress and Medical Device Supplier Quality Conference and by getting in touch with suppliers and OEMs directly.

Most of these direct efforts have been focused on education, both educating outsiders about MedAccred's message and advising accreditation hopefuls on how to best prepare

for the audit process.

"We're very open to working with any of the companies that are interested," Conboy said. "If they want us to do a presentation and provide information about the audit criteria, we're very willing to do that, or if they want to learn more, we will even provide specific training."

According to Conboy, MedAccred has regularly trained companies when requested on what the program looks for during an audit and what to expect. Training often takes the form of a webinar, but MedAccred can also arrange to teach suppliers in person.

PRI's training program has very recently started being supplemented by government efforts from the U.S. Department of Commerce, as well. The Department recently set aside money for the MEP (Manufacturing Extension Partnership) program, and as part of that, awarded \$1 million for 2018-2019 for a program that's been dubbed "Growth through MedAccred." The program is designed specifically to help accreditation hopefuls get educated on the program and get their U.S.-based production facilities to pass muster during an audit. The program's new funding will allow government specialists to come to suppliers' facilities and help conduct internal audits, as well as assist suppliers with fixing any issues the audit might find.

"There's a wonderful opportunity for U.S. companies that are manufacturing in any of these critical process areas," Conboy said, "...There's quite a bit of opportunity for any company now to gain that support. And this is just the start. We expect that the Department of Commerce through NIST will continue to support programs to help U.S. companies with MedAccred. They're very interested in helping companies in the medical device industry. They want to see U.S. manufacturers be more competitive globally and be able to retain that business. They know that MedAccred is going to be a key to helping them grow their business in the medical device industry."

In general, PRI is seeing a lot of support from the government for MedAccred. In addition to the most recent award of funding, MedAccred also received a show of support from the FDA. After two years of working with PRI, the FDA has recognized the AMS 2750 pyrometry standard for heat treating used in the MedAccred heat treating accreditation requirements. This recognition makes it easier for medical device companies during the pre-market approval phase, since meeting a recognized standard "can support a reasonable assurance of safety and/or effectiveness" in devices, according to the FDA 2007 guidance "Recognition and Use of Consensus Standards." In other words, if you have achieved MedAccred accreditation, you have satisfied the FDA recognized standard for AMS 2750 for heat treating. This is a real benefit for the program, and one of the past few years' developments Conboy personally was most excited about.

"We worked with the FDA for two years on that pyrometry standard," Conboy said. "It's imbedded in our heat treating accreditation, so that standard really helps companies if they have a new product they're introducing and want to use a company that's MedAccred accredited for heat treating, it means they are meeting the AMS 2750 standard...it's

a very critical factor to assure the final product quality from that furnace, so the fact that FDA has granted complete recognition of that standard is a huge step forward for the medical device industry...This is a first for the medical industry in heat treating for the FDA to recognize anything.”

PRI’s first program, Nadcap, has become a ubiquitous presence in the aerospace industry. The mission with MedAccred has always been to focus on improving product quality and patient safety for the medical device industry, just like Nadcap is successfully addressing quality and safety for the aerospace industry. This focus on quality and safety is vital to both industries and as a result the medical device industry believes they should see a similar growth trajectory for the MedAccred program. MedAccred still has a ways to go before it reaches Nadcap’s level of scope and acceptance, however. As large as MedAccred may sound already, Nadcap’s dictionary of aerospace critical processes dwarfs its successor’s, so you can expect that they’ll be introducing new accreditations for years to come.

But every year, it looks like more of a sure thing that that’s exactly what’s going to happen. MedAccred is big, and it’s still growing. They’re at most major conferences. The FDA has demonstrated strong support for the program. They have the attention of many industry leaders. And according to Conboy, those leaders are increasingly invested in MedAccred’s success. Stryker’s move to begin requiring



future suppliers be accredited for new product business is starting to be echoed by other OEMs in the medical industry, and the number of companies requiring accreditation is likely only going to grow. The question isn’t if MedAccred will ever fit in its predecessor’s shoes anymore; it’s when.

“We’re still at the early stages, but there’s no question in our minds with the support from leading companies in the medical device industry, their involvement in the program, and the real understanding they have in terms of value of the program, we will continue to show strong growth” Conboy said. “This is something that PRI sees in the years to come will be like Nadcap. And I think most of the leaders in the medical industry see it that way as well.”

And eventually, when that goal becomes a reality, it’s going to become imperative that you get accredited yourself. With that in mind, the sooner you jump on the bandwagon and start that audit process, the less painful and rushed it’s going to be when your OEMs start asking for it.

Or better yet, get involved. Help shape MedAccred yourself. If you’re likely going to have to adopt MedAccred in the future anyway, you might as well start having some say in what that program looks like. Whether you’re a supplier or an OEM, there are numerous benefits for any companies that want to participate, even if you don’t become a subscriber. Feedback from participating companies regularly gets incorporated into MedAccred, including on selecting what critical processes get selected next, and if you get involved with the task groups, there’s opportunity to have your voice heard when developing the audit criteria for those processes.

But regardless of if or how you decide to get involved with PRI’s program, be sure to keep an eye on them. They’re an increasingly relevant presence in the industry, and if they continue on their current trajectory, you’ll be forced to pay attention sooner or later. **PTE**

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