Proper Bearing Installation

Certified Bearing Specialist (CBS) Takes on Expensive Fan Application

Gregory (Keith) Boutwell, CBS and executive account manager at B&D Technologies (a division of B&D Industrial), explains how he used his bearings expertise to save a customer thousands of dollars through correct bearing installation.

"A customer had a zone fan application with $2,000 worth of bearings being replaced every 4–6 weeks. I went to their location and looked at the application with a manufacturer's representative. The manufacturer representatives' solution was to change the grease as the bearing was running too hot. The customer had four of these fans and the investment in failures was adding up. The customer was pretty adamant that something was not being done right as he was sure that they were not getting that many bearing failures from the manufacturer.

I got the customer a price on grease and asked that when he replaced the next bearing to let me know so I could watch the installation. As I observed the maintenance man change out the bearing, I noticed that he took the stab ring and tossed it into his toolbox. I asked him about not using the stab ring and his answer was that it serves no purpose. He told me the stab ring was included just to take up space in the housing. I told him it indeed was for taking up space but it also would limit the expansion on his bearing, therefore giving him a fixed and floating bearing.

I asked him to install this one with the ring and we'd document the installation. We documented the installation and reported it to the maintenance manager. The maintenance man was insistent that adding the spacer ring would not make any difference in the operation of the bearing nor would it be the reason that the bearing was heating up. We took the old bearings to the shop and he broke it open and showed me a bearing housing full of sludge and dry matter that at one time was grease before being cooked out with the heat that was being produced. I also suggested that he install covers on the side of the bearing that was open to the elements. Fine particles of carbon black were present in all parts of the bearing.

I kept close tabs on the bearings that had been changed and asked about them about every other trip to the customer's plant. I was always told by the maintenance manager that they had not had any problems since I had gone over with them about how to correctly install the bearings. I was also given the chance to solve other bearing problems that they have been having. This cut into the sale of the bearings to this customer and I increased my sales of grease. But in end I developed the reputation of being a problem solver. And this brought many more opportunities.

As a result of the success I had in solving this customers problem I was able to gain his confidence and he allowed me and my supplier partners to perform training on lubrication, proper installation and preventative maintenance tips. The end result that I was hoping for has been achieved. I have gained confidence in the work I have done not only by the maintenance management but by the maintenance personnel. The maintenance man that was so adamant that I was incorrect has become a long time friend and he will call on me and present me with other problems that he has in the plant.

Even though I have been in the bearing and power transmission market for a long time, I have found out that training and refresher courses on everything from type of bearings to lubrication to causes of failures will always be beneficial. The Certified Bearing Specialist certification was an eye opener in that it encourages you to use catalogs and to find the answers to problems. Sometimes if you do not look at a problem head on and try to widen your base of knowledge you become complacent in what you are doing. The CBS program keeps you on your toes and helps to broaden your horizons by giving you an additional resource. **PTE**

Certified Bearing Specialist

BSA's Certified Bearing Specialist (CBS) program is the only bearing industry-specific program that identifies and quantifies the specific skill sets to certify an industry professional as a bearing specialist. The CBS program is all about developing the expertise to help customers and end users make the best bearing decisions. Take advantage of this complimentary access to a Certified Bearing Specialist. Please email your question to *info@bsahome.org*. An expert CBS will respond to your inquiry and it may appear in this article.

For more information:
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Gregory (Keith) Boutwell has been in the bearing and power transmission business for 41 years. He has spent his entire career in the Columbus Georgia location of B&D Technologies. "No matter how long I am in this business I will always learn something new every day."

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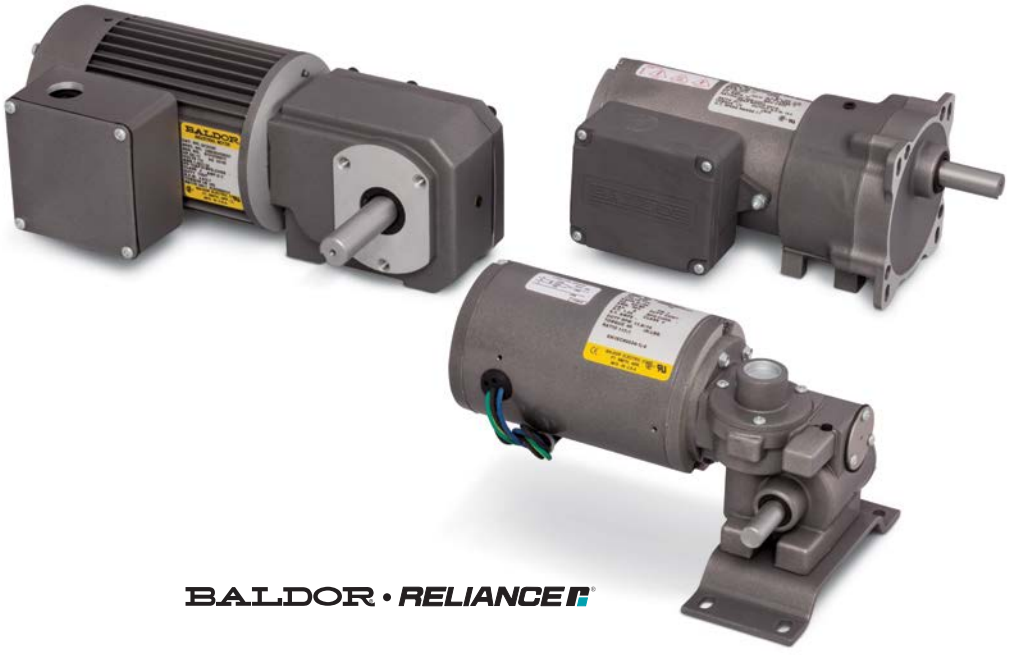

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Bringing Nadcap to the Medical Industry

MedAccred stands to plug a longstanding hole in medical industry standards, and it's growing in popularity.

Alex Cannella, News Editor

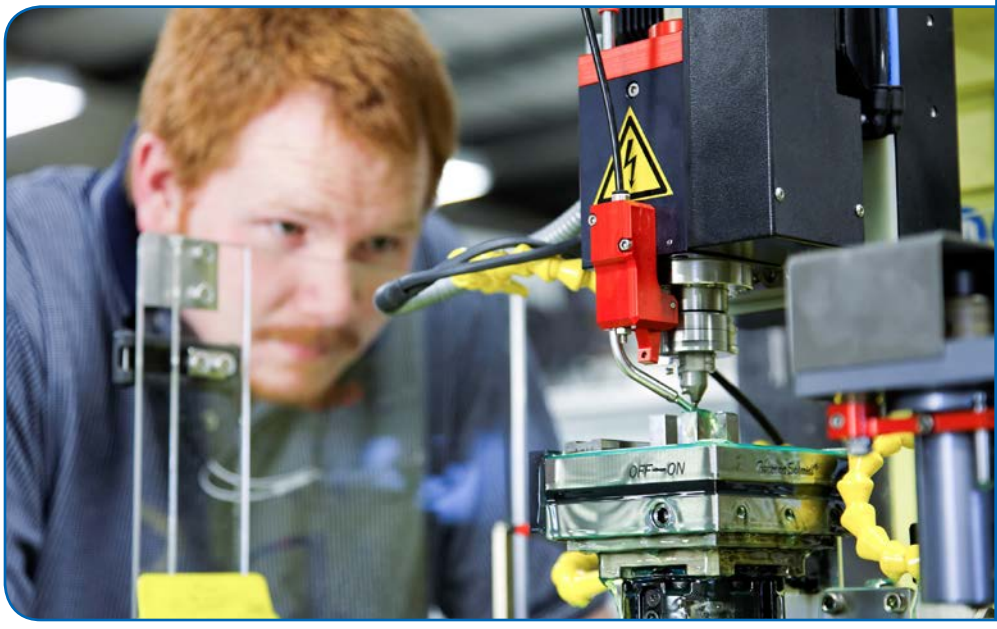
The medical device industry today has numerous standards and regulations to follow, most notable amongst them being ISO 9001 and ISO 13485. However, these requirements have a shared blind spot: critical processes (heat treating, sterilization, etc.). In the medical industry, all of the standards and audits suppliers need to adhere to focus on general system quality. If the critical processes aren't being looked at equipment can still fail because of poor craftsmanship.

"When you look at what the general auditing profile requirements have been in the industry, they have mostly focused on doing quality management system audits," Ravi Nabar, head of supplier quality assurance at Philips, said. "What those audits don't necessarily do, is actually probe deeply into the technical aspects of critical manufacturing processes that affect the quality of the product that's coming off of those manufacturing lines."

Matters are compounded by the fact that every OEM is responsible for auditing their suppliers, and there are so many different companies running audits that the regulation process can start getting in the way of production. Some suppliers do audits on such a regular basis that they have a team of staff whose sole job is to handle them.

"Right now, we can have several quality system audits from different medical facilities in any given month," Ed Engelhard, vice president of corporate quality at Solar Atmospheres, said. "They all cover the same exact ground. It's usually ISO 13485 or 9001 based. We're already registered to 9001, although we're not 13485. But the focus seems to be whatever the pet concern for that organization is, and we have to devote valuable resources to proving over and over again that we are essentially in compliance with requirements. And that's on top of already having a 9001 registration."

The situation is complicated and less than ideal for OEMs, as well. The medical device industry has seen a shift towards globalization and has numerous small suppliers applying their trade in the market. While OEMs can vet their first tier suppliers, it's much harder, if not impossible, for them to ensure the same level of quality is being maintained all the way down the supply line to third or fourth tier suppliers.



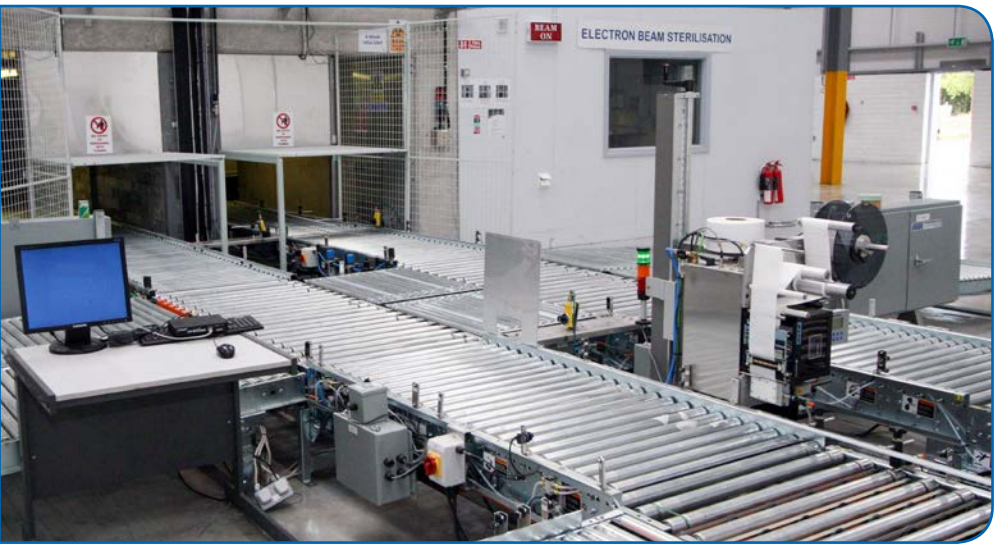
"We're in a place where there's a lot of outsourcing going on," Nabar said. "There's a lot of globalization, and yet the quality of what we actually put in the hands of our patients and customers is critical to the health of the public."

So the medical device industry's quality control infrastructure starts to look a bit like the wild west, with a hundred different sheriffs running around making sure their particular OEM's rules are upheld and their concerns handled, while some facets of the industry aren't scrutinized quite as closely as they should be. It's clear that some form of unifying requirements could go a long way towards minimizing these problems.

The answer that the industry is slowly starting to coalesce around is MedAccred, an accreditation for the medical industry designed to deal with this exact dilemma. Where other industry standards look at general quality across the entire facility, MedAccred zeroes in on very specific processes (e.g. heat treatment, sterilization, welding) and brings in experts in those fields to make sure suppliers know exactly what they're doing. The people behind MedAccred aren't looking to replace cur-

rent standards such as ISO 9001, but instead, the program will exist alongside and further strengthn them, filling in the blind spots they don't reach. In fact, the regular quality systems requirements are a pre-requisite for accreditation from MedAccred. The comparison most used was that quality management systems audits are a mile wide, but only an inch deep on individual critical processes. MedAccred, on the other hand, is an inch wide, covering only one critical process per audit, but goes a mile deep into every nuance of trying to do in the medical device industry. Trying to find process-specific experts from the industry, from the OEMs, as well as suppliers, who come together to write the audit criteria."

MedAccred is, effectively, an attempt to take the best practices and processes of Nadcap and translate them over to a new industry, and as such, the two programs bear many similarities. Both programs utilize audits performed by subject matter experts who are rigorously selected by industry representatives. Both use management councils



that critical process.

MedAccred is being administered by the Performance Review Institute, the same not for profit trade association that administers Nadcap, the widely recognized accreditation that does for the aerospace industry what PRI wants to do with MedAccred, and does it well. The organization's almost three decades of experience with Nadcap has assisted in the process of developing MedAccred faster than its predecessor.

"The industry standards are not as developed for critical processes in the medical device industry as they are in the aerospace industry," Joe Pinto, executive vice president and COO of PRI, said. "So we learn from Nadcap that we need to focus on industry standards as well as look at the OEM-specific requirements, and that's what we're composed of OEMs and suppliers alike to guide requirements and major decisions, with PRI acting as the administrator. The checklists for achieving accreditation are also similar. In fact, Nadcap's checklist was used as the starting point for some of MedAccred's own requirements.

"Nadcap has a lot of audit criteria, what the aerospace industry terms checklists, already developed," Pinto said. "So there was a very good base, and those audit criteria are intellectual properties owned by PRI. We were able to use a lot of those as the starting point for the medical device industry. And what we've done is taken those, and we have adopted them and added process validation requirements based on FDA guidelines to develop the medical device audit criteria."

No matter which side of the OEM/supplier fence you fall on, there are multiple benefits to jumping onto the MedAccred bandwagon. For OEMs, the obvious benefit is an increase in the quality of parts they receive, but it also allows for improved supply chain oversight and compliance. MedAccred not only does an aligned set of requirements make it easier for OEMs to see the quality of their suppliers and their suppliers' suppliers, but is also a global program with audits scheduled across the world, meaning that an OEM wouldn't have to send an auditor halfway around the world to do business with a small supplier in China.

"Many times the OEMs do not always get to see and do not get to audit the critical process suppliers that are maybe in the third, fourth or fifth tier of the supply chain," Pinto said. "So, by having a program like MedAccred, they can mandate that 'anybody that is supplyig these critical processes for my products needs to be accredited,' so even if they don't know who's doing it because it's happening at the third, fourth tier level, they would have assurance that it is being done by an accredited supplier who has proven to have the capability to do the process."

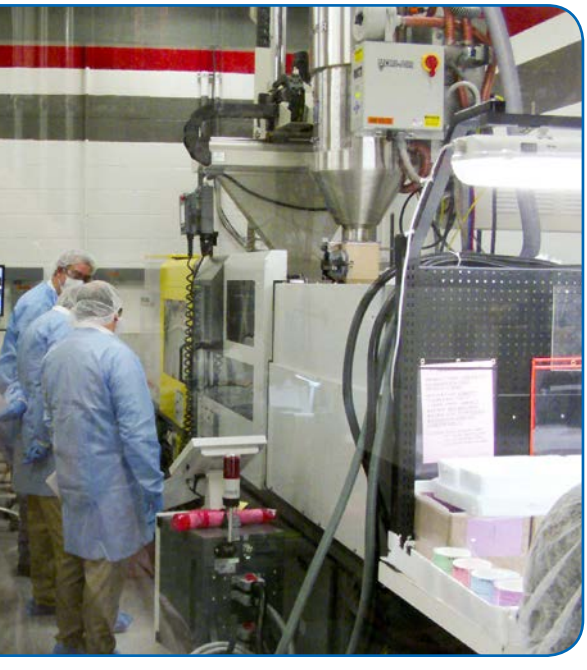
"For us as an OEM, to have all the visibility down to the different tiers, along with aligned requirements and expectations all the way down, that's a very difficult thing, and MedAccred is fantastic for that," Scott Goolsbey, supplier controls manager at Stryker, said.

Suppliers also have plenty to gain from aligning expectations with MedAccred. With a consistent set of expectations, suppliers know exactly which set of standards they need to meet, and less time will have to be spent on redundant audits from different customers. As the program grows and more OEMs continue to join, more people will be looking for suppliers accredited to MedAccred, and some businesses are adopting early in the hopes of taking advantage of OEMs' growing interest.

Getting involved in the program can

give further benefits as well, mainly ensuring that your company's voice gets heard and can shape MedAccred's requirements. This is doubly true now, in the program's formative years, when there are still details to be ironed out. Both OEMs and suppliers are being welcomed by PRI to come together in MedAccred's Management Council and technical Task Groups.

For suppliers, the other way to get involved is obviously through getting audited for accreditation. If you're interested in an audit, the process is fairly straightforward. Once in contact with MedAccred, a supplier details their products and figures out what categories they should be applying for. Right now, your options are cable and wire harness, heat treatment, plastics, printed circuit board assembly, sterilization and welding. Once a supplier knows what category they should apply for, an audit is scheduled, and the supplier is given a copy of the audit criteria. It's strongly stressed by both PRI and Engelhard, whose company was the first in the world to achieve accreditation with MedAccred, and thus has experience with the audit process, that you prepare with an internal audit to make sure you meet all requirements before the actual audit.



"If you think you can have an auditor walk in without preparation, it's going to be a very long, difficult week for you," Engelhard said.

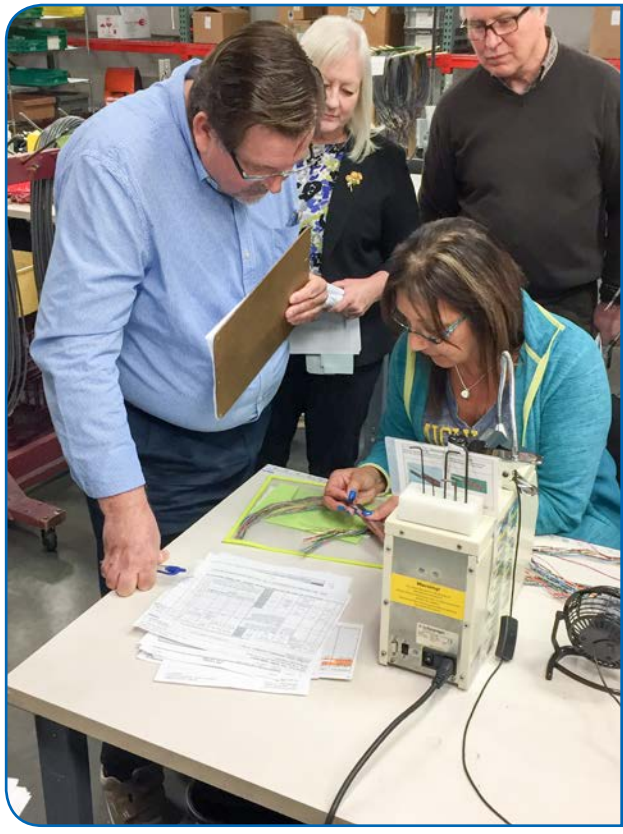
The audit process itself takes two to five days to complete, depending on the critical process and the scope of the facilities being audited. Once the auditor has inspected everything, they send their findings on to a PRI staff engineer, who approves the findings and analyzes if the supplier has completed the work to close them. The OEMs then review all the information and vote on the accreditation.

MedAccred is still a young program. The first roundtable meeting to develop it was held in December of 2012, and the first accreditation was awarded last spring to Solar Atmospheres. It'll be a long time before the program carries the same clout as Nadcap.

But despite its age and size, MedAccred's message is getting across and the program is gaining momentum. The program should complete more than 20 audits this year, and Pinto says they're aiming to do 200–300 audits a year as soon as 2019. PRI is also planning on expanding the accreditation to include more categories, such as one for batteries, as time goes on.

At the end of the day, however, the main reason MedAccred is speaking to some people is a purely humanitarian one: the betterment of patients through more reliable, potentially life-saving equipment.

"The medical field faces a lot of unique challenges that we can't necessarily address in MedAccred, but one of them should not be failures at the patient-doctor interface associated with the processes we do," Engelhard said. "That can't be allowed to happen. So to the degree that we can make a doctor's visit mundane and boring by controlling our processes, we should endeavor to do that. And that's why people should be involved in MedAccred." **PTE**



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