



## A STRONGER SUPPLY CHAIN: Stryker Tying Process Vendors To MedAccred; Others May Follow Suit As FDA Takes Notice

► By Shawn M. Schmitt

**SUPPLIERS OF EIGHT SPECIAL MANUFACTURING PROCESSES** – including sterilization, welding and heat treating – will have to be accredited to industry-managed supply-chain oversight program MedAccred if they want to do future business with device giant Stryker. "Awarding business based on accreditation [to MedAccred] is the end goal," the company's manager of supplier controls told *Medtech Insight*. The program's aim is to ensure high-quality finished devices and offer clearer supply-chain visibility, giving manufacturers greater confidence in the vendors they choose. Industry heavy-hitters Medtronic, Johnson & Johnson, GE Healthcare, Philips Healthcare and Becton Dickinson are also strong supporters and users of MedAccred, giving it even more industry street cred. Meanwhile, resource-strapped US FDA is mulling over how it can best benefit from the burgeoning program.

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Vendors of eight critical manufacturing processes will have to be accredited to a new industry-managed supply-chain oversight program if they want to do future business with **Stryker Corp.** – and other big medical device firms will likely follow suit.

Scott Goolsbey, manager of supplier controls for the device giant's endoscopy division, told *Medtech Insight* that Stryker will eventually grant business based on whether suppliers are certified to MedAccred.

"We're currently engaging several of our suppliers with MedAccred, and we're socializing the program within our suppliers," Goolsbey said. "Eventually, the direction is to be making business decisions based on MedAccred. Awarding business based on accreditation [to MedAccred] is the end goal."

Developed by industry a few years ago and administered by the Performance Review Institute, MedAccred is a consensus-driven approach to ensuring special-process quality throughout the supply chain.

**"First, we have to assess the impact to our business, but at this point, what we are able to say with high confidence is that MedAccred will be a factor in the awarding of new business," Stryker's Scott Goolsbey says.**

The program's aim is to ensure high-quality finished devices and offer clearer supply-chain visibility, giving manufacturers greater confidence in the vendors they choose. It focuses on these process-specific activities: cable and wire harness, heat treating, plastics extrusion, plastics injection molding, printed boards, printed circuit board assembly, sterilization, and welding.



MedAccred audits suppliers of special processes using collaboratively created audit criteria, and accreditation is granted and accepted by the program's subscribing members. The process-focused audits are performed by industry-approved and -trained subject-matter experts.

At Stryker, several of its suppliers are in the process of scheduling audit time with PRI to become certified, while a few have already been accredited to the program.

"The accreditation audit is a very, very specialized audit in each of those special process areas. And so, when a company – one of our suppliers – passes this audit [and] becomes accredited, we can be very confident that they're operating at a very high level and their process is going to be in control, and ultimately, they're going to be able to meet our specification for that product," Goolsbey said.

"So, quality is a result of that," he said. "We believe that the consistency in the overall quality with regards to being able to meet our specifications will be improved because of MedAccred. And ultimately, that reduces risk, and that improves the product's performance in the hands of our customers."

Goolsbey stressed, though, that Stryker's current vendor relationships will not change. Rather, supplier accreditation to MedAccred "is mainly going to be a consideration when awarding new business. It's not likely to affect existing business," he said.

Stryker is conducting an impact analysis to determine exactly how MedAccred will affect its quality systems and business systems.

"It certainly will impact our quality system, and that's part of our ongoing impact assessment at the moment," Goolsbey said. "So first, we have to assess the impact to our business, but at this point, what we are able to say with high confidence is that MedAccred will be a factor in the awarding of new business."

The device-maker is involved with MedAccred beyond using its services to select vendors. Stryker has also lent technical experts to the program as it develops audit criteria, and the firm also has seats on MedAccred's management council.

"Overall, we see [MedAccred] as driving aligned expectations in these special process areas through all tiers of the supply chain," Goolsbey said. "That means that all of us – meaning all OEMs [original equipment manufacturers] – will be sending the same signals to our supply chain. So, all of the suppliers that are performing these functions – heat treating, welding, cable and wire harness, and so on – they're all going to be hearing the same expectations from their customers. That's going to help out everybody's quality."

Goolsbey conceded that some of Stryker's vendors might not want to participate in MedAccred. If that happens, "the idea will be initially to understand why [they don't want to join], and then eventually, we'll be making sure that everyone understands that we see [MedAccred] as a way to differentiate suppliers," he said.

"And so we'll just have to see long term what our supplier strategies are. But in the short term, if there's a supplier that indicates that they're not interested, we'll just try to understand why that is," Goolsbey added.

Stryker's plan to keep MedAccred in mind when awarding new business gives a huge push to the burgeoning program, given that the firm ranked No. 10 in the 2016 edition of the MTI 100 – *Medtech Insight's* rollcall of the top 100 companies ranked according to sales.

Further, heavy-hitters **Medtronic PLC, Johnson & Johnson, GE Healthcare, Philips Healthcare** and **Becton Dickinson & Co.** – Nos. 1, 2, 3, 6 and 9, respectively, on the MTI 100 chart – are also strong supporters and users of MedAccred, giving the program even more industry street cred.

And, given that those companies ring up billions of dollars in combined device sales each year, even the most uncooperative of suppliers might be eventually persuaded to become accredited to MedAccred to make sure they keep a seat at the table.

### Should Firms Mandate MedAccred?

MedAccred is modeled after Nadcap, a popular supplier quality initiative for the aerospace industry that is also administered by PRI. The institute says 93% of respon-



dents to its 2015 survey of Nadcap participants said the 27-year-old program adds value, while another 88% said it improves the quality of their product.

Some attribute Nadcap's success to aerospace OEMs that mandated suppliers to become accredited to the program. (PRI conducts more than 5,500 audits each year for the aerospace industry.) But Julia Markardt, a PRI electronics staff engineer, envisions the device industry taking a path that's more akin to Stryker's approach.

**A mandate for all suppliers – old or new – to conform to MedAccred would be a “very powerful tool” to make the program more widely used by industry, device industry expert Ravi Nabar says.**

“At this point, I don't believe that it's even a plan to follow the way the aerospace industry [mandated supplier certification to Nadcap]. I think the medical device industry is going to be different, and I think it should be different,” Markardt said at FDAnews' 14th Annual Medical Device Quality Congress in Bethesda, Md.

“My expectation is that this really will be something companies are going to use to grow in terms of awarding new business – that will probably be the direction that things will take, as opposed to removing suppliers that already have existing business,” she said.

And Stryker's Goolsbey pointed out that a device firm is “playing with fire” if it scraps its current vendors for new ones, because switching suppliers introduces risk.

“Trying to reduce risk by doing a manufacturing transfer is sometimes also increasing risk,” Goolsbey said.

Yet device industry expert Ravi Nabar says a mandate for all suppliers – old or new – to conform to MedAccred would be a “very powerful tool” to make the program more widely used by industry.

Nabar has worked with industry and PRI since 2012 to

help establish the foundational framework for MedAccred, first as head of supplier quality assurance at Philips, and more recently as head of supplier quality at Baxter Healthcare.

Requiring certification to MedAccred “has been discussed at length, but somehow in the medical device industry it's not happened yet. I hope it will go in that direction at some point,” Nabar said at the Quality Congress.

However, “one of the limiting factors is the small number of commodities that are currently covered [by MedAccred] that apply to the medical device industry,” he said. “As MedAccred becomes broader in that sense, then there may be a better opportunity to mandate.

“But as of today, the percentage of suppliers covered by the mandate would actually be a fairly small number because the total number of suppliers is quite large, but the number of suppliers that are covered by the existing [MedAccred process-specific activities] are actually a very small fraction. But mandating it would be a great way to go.”

## J&J: ACCREDITED SUPPLIERS CAN ‘SOURCE PRODUCT’

PRI's Markardt says there are companies other than Stryker that plan to favor vendors that are certified to MedAccred when conducting new business.

Johnson & Johnson is one of them, according to Scott Dauphinee, the device firm's director of supplier quality.

“One of the things my company is doing and really focusing on is, we're giving suppliers that have accreditation [to MedAccred] a benefit: They get to source product with it,” Dauphinee said at the Quality Congress.

“Now, it's not our only selection criteria, but it's one of the selection criteria,” he said. “And the other OEMs are looking at doing the same thing because ... it's a known good. So, we need to make sure [accredited suppliers] get credit for doing this.”



## A Global Reach – And A Hefty Price Tag

Forty suppliers, contract manufacturers and OEMs participate in the program, says Connie Conboy, MedAccred's director.

The program reaches outside the US; PRI has accredited suppliers in China, Mexico and Europe, among other manufacturing hotspots. "We didn't want MedAccred to be US-centric and not include manufacturing that's being done globally," said Conboy, who is also director of strategy and business development at PRI.

"Wherever the manufacturing is around the globe, that's where we're accrediting companies and doing audits," she said. "And that's a very important element, because every company today has lots of operations around the globe typically, especially the big companies, where they have a global supply chain. So, they need to ensure that those facilities are meeting their requirements."

**Manufacturer subscribers to MedAccred pay a one-time fee of \$30,000 to support the program's development, and an annual fee of \$60,000.**

For example, heat-treatment specialist Bodycote has three facilities – in the US, UK and France – certified to MedAccred.

And electronics manufacturer Flex (formerly Flextronics) also "has three different facilities accredited – one in Mexico, one in China and one in Romania. Now, they're adding to that list," Conboy said. "Flex is telling us that they're going to have three or four more additional facilities become accredited this year."

Manufacturer subscribers to MedAccred pay a one-time fee of \$30,000 to support the program's development, and an annual fee of \$60,000 to have access to PRI's eAuditNet "Qualified Manufacturers List" of accredited suppliers. Subscribers can also vote on accreditations and provide program oversight, if they so choose.

Such hefty price tags could mean that smaller firms might be priced out of the program altogether. But in an interview with *Medtech Insight*, Conboy said the cost is "actually pretty affordable if you look at the ability for [firms] to provide oversight across their supply chain using this process."

She added that producing a high-quality product with the aid of MedAccred means companies can nip potential troubles in the bud, potentially saving them millions of dollars that they might've spent on, say, sorting out a device recall due to poor sterilization.

**"The top three reasons for [Stryker using MedAccred] are the same: quality. So, quality, quality and quality. We're going to drive quality in our supply chain," Stryker's Goolsbey says.**

"That goes right to the core of what would be real liability costs for organizations," Conboy said. "We target the critical process areas that really create those issues for companies and for patient safety. We're zeroing in on the key processes that could result in patient safety problems."

"Because of that, it should be a very affordable approach, overall," she noted, pointing out that PRI will periodically review MedAccred's fee structure as the program grows.

To help offset costs, paying customers of MedAccred – both manufacturers and suppliers – could save money on liability insurance if they're insured through Medmarc.

Device industry insurer Medmarc "is willing to issue a significant reduction to companies that use the MedAccred accreditation process and are accredited," Conboy said. "That is extremely valuable for companies because they can drive down their insurance premiums. Medmarc is convinced that this program is going to reduce liability for companies, and for them as the insurer for these companies."



Striker's Goolsbey says MedAccred also has the potential to be a money-saver because "it will change the way we audit our suppliers." By having more confident control of vendors, knowing that they're being audited regularly by PRI, device firms might consider dialing back their own supplier audits, saving time and cash.

"We have the potential to eventually spend less time at our suppliers as a result" of the program, Goolsbey said. Not spending money conducting its own audits will be an "expected indirect benefit" for the firm. But, he quickly added: "It's certainly not a reason why we're pursuing MedAccred for our suppliers."

Rather, "the top three reasons for [Stryker] using the program are the same: quality. So, quality, quality and quality. We're going to drive quality in our supply chain," Goolsbey said.

### A Rigorous Audit For Suppliers

Meanwhile, to be added to MedAccred's list of accredited special-process suppliers, vendors pay \$8,200 for a four-day PRI audit or \$6,950 for a three-day audit, depending on the process they're being audited to.

Suppliers are audited annually; if they undergo three successful audits in a row, they earn what PRI calls "merit." Once merit is granted, a supplier won't see a PRI auditor for another 18 months instead of the usual one year. But if major problems are discovered during a subsequent audit, the vendor then loses its merit status and is audited yearly once again. (Because of the newness of the program, no supplier has achieved merit status yet.)

Conboy emphasized that the audits are not of suppliers' quality systems: "That's just a small portion of our audit – the quality system and how it impacts whatever critical process we're reviewing."

Rather, "we're looking at [vendors'] critical process capability. It's a deep dive into manufacturing processes to ensure that [OEMs] have that ultimate final product quality. We're conducting rigorous critical process audits with experienced technical experts," she said.

PRI expects to perform about 60 MedAccred accreditation audits in 2017.

## EXPANDING MEDACCRED'S FOCUS

PRI wants to expand the critical-process areas covered by MedAccred. To that end, the organization currently has its eye on developing audit criteria for sterile device packaging.

"All of the companies involved in the program are very interested in that particular area, and FDA believes that would be a very good area for us to pursue," PRI's Conboy said.

"Batteries is another area that seems to be very much of interest to industry. That's an area that perhaps we're going to be starting, as well," she added. "And software certainly is a very important area. It's just a question of how we want to allocate resources and which areas to pull into this process next."

Aside from batteries and software, these critical-process areas might eventually be added to MedAccred:

- Additive manufacturing
- Assembly
- Casting/forging
- Chemical processing
- Cleaning
- Coatings
- Counterfeit parts
- Electronic displays
- Fluidics
- Machining
- Material-testing laboratories
- Measurement/inspection
- Nondestructive testing
- Optics
- Packaging
- Power sources
- Raw materials
- Reagents



“The people who do these audits know these processes inside and out. They have a career path that has generally been in manufacturing in that particular critical process area for an extended period of time before they become an auditor for the program. So, they know that industry very well,” Conboy said.

Nevertheless, suppliers that want to take part in the program must have a quality system, preferably certified to The International Organization for Standardization’s ISO 13485 or ISO 9001 standards.

ISO 9001:2015 is the general quality systems standard applicable to all industries and is the base standard of ISO 13485:2016. Device-makers use ISO 13485 to ensure quality systems compliance with regulators in different countries, including Canada, Japan, Australia and the 28 member-states of the European Union.

MedAccred audits “are not easy to complete. And not all companies that get audited can achieve accreditation. It’s difficult to achieve, but the ones that do succeed are really setting themselves apart,” Conboy said.

“The suppliers that are getting these audits, they really start to see the value, even for their own oversight of their facilities. I think that’s been extremely helpful.”

### **‘This Accreditation Is Meaningful’**

If a vendor fails its audit, it must fix its problems and apply to be audited again.

“We did have a large supplier that was unable to achieve accreditation after a year-and-a-half of working at it,” Conboy said, noting that it was a “surprise within the industry” when that particular vendor failed to complete its audit.

That supplier “really didn’t meet the standards, so we stopped the process. What we said is, they can go through an entirely new audit and try to achieve accreditation when they’re ready,” she said.

“Especially during the first audit for suppliers, we try to work with them to enable them to understand what we’re looking for so they can address some of the areas, but we’re not going to give an accreditation to a com-

pany that hasn’t completed the work that they need to do, because this accreditation is meaningful and it really makes a difference in terms of their final product quality,” Conboy said.

Suppliers must pay to be re-audited, but “it’s not a wasted amount of money,” she claims.

### **PRI doesn’t discuss its MedAccred audit findings with regulatory agencies.**

“We’re identifying areas where they’re having some real issues, and things that are happening in that factory that are causing final product quality defects for them. And so, it’s actually very valuable for them to identify the areas that they need to fix,” Conboy said. “It’s not expensive if you think of it as, they have somebody in their facility identifying the areas they need to fix to improve their quality.”

PRI doesn’t discuss its MedAccred audit findings with any regulatory agency – even US FDA.

“FDA can see who’s accredited, but it can’t see who’s gone through an audit and hasn’t passed it,” Conboy said. “That’s not something that we have shared or plan to share. This is something that remains confidential. And the actual findings themselves – that’s confidential.”

### **FDA Takes Notice; Invited To Observe Supplier Audit**

Although PRI pledges not to involve FDA in vendor audit findings, the organization has nonetheless invited the agency to witness a MedAccred supplier audit.

“We want FDA to understand the depth of the audit we do, and they’re very interested to see how rigorous and thorough the audit is,” PRI’s Conboy said, noting that the agency plans to take the organization up on its offer.

FDA “wouldn’t be doing the deep dive into the particular manufacturing operation that we’re looking at, nor would a typical OEM be doing an audit to the depth that we’d be doing with the process audit,” she said. “So,



FDA is going to be seeing something over and above what they normally would be looking at during a typical quality system inspection.”

The supplier that volunteers to have its audit observed by FDA would be held harmless by the agency if investigators happened to notice any problems.

## **FDA believes MedAccred helps ensure that so-called “critical-to-quality” specifications flow down to sub-tier supply chains.**

“We don’t want a company to be harmed by the fact that FDA has gone in and been able to observe an audit,” Conboy said. “Now, companies that agree to do this, to be honest, they’re pretty confident that they have good practices. They’re very proud of what they’re doing. So, I would be very surprised that there would be any issues that FDA would be uncomfortable with.”

Still, “I don’t think all companies are going to be comfortable doing this,” she said. “It’s just going to be a couple that will be willing to do it. It’s a bold move for a company.”

Conboy isn’t sure when the agency-observed audit will be scheduled, mostly due to “a number of internal changes” currently happening at FDA’s Office of Regulatory Affairs that are occupying investigators’ time, she said in a June 30 email to *Medtech Insight*.

ORA conducts all of the agency’s field activities.

One such internal change is likely “program alignment,” which began on May 15 and has fundamentally transformed the way ORA inspects makers of a variety of commodities, including devices. (Also see “*Program Alignment Falls Into Place: Everything You Need To Know About US FDA’s New Inspectional Approach*” - *Medtech Insight*, 8 May, 2017.)

“FDA really has a lot of confidence in [MedAccred]. They are very pleased with the approach that we’ve taken, so they seem extremely supportive, and they’re looking at how they can embed it in their oversight of companies

and how they can most effectively utilize a program like this,” Conboy said.

For example, FDA could use MedAccred to identify companies that are more mature in their approach to quality, freeing up investigators to look at other manufacturers whose quality systems might not be as healthy. In fact, the agency is currently wooing firms to take part in a pilot program that aims to determine the manufacturing maturity of device firms. (Also see “*Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot*” - *Medtech Insight*, 25 May, 2017.)

FDA, which rarely inspects device industry suppliers, declined to be interviewed for this article.

Conboy also said PRI has discussed with the agency synergies that exist between MedAccred and the joint FDA/Medical Device Innovation Consortium (MDIC) Case for Quality, which encourages companies to make quality assurance an organization-wide concern rather than the responsibility of a discrete quality assurance unit.

Specifically, she said FDA believes MedAccred could help ensure that so-called “critical-to-quality” specifications flow down to sub-tier supply chains. (Also see “*Are Your Suppliers Keeping A Sharp Eye On Critical-To-Quality Attributes? You Should Know, FDA Investigators Say*” - *Medtech Insight*, 27 Oct, 2015.)

Critical-to-quality practices result in higher quality outcomes, the agency says. (Also see “*FDA: Don’t Wait On ‘Case For Quality’; ‘Build Bridges’ To Better-Than-Baseline Practices Now*” - *Medtech Insight*, 1 Apr, 2015.) and (Also see “*New FDA Pilot Program To Finger ‘Critical-To-Quality’ Points; First Up: Implantables With Batteries*” - *Medtech Insight*, 13 Nov, 2013.)

## **Process Validation Checks Added To MedAccred Audits**

PRI’s Conboy says MedAccred is a “living program” that the organization will update and improve when necessary; for example, a review of process validation activities was recently added to its supplier audit criteria.

“That was something that the companies involved in the program felt would be very helpful,” Conboy



said. “And so, in addition to doing the deep dive in the manufacturing process and all of the key elements of the manufacturing area, we’re also now incorporating process validation and ensuring that that is being addressed effectively.”

She said “it’s very helpful for suppliers to have guidance in terms of what they need to be doing to most effectively address process validation because – especially if you’re down in the third tier in a supply chain, or the fourth tier – you’re not even sure what you’re supposed to be doing with regards to process validation. So, this provides for them how to approach it most effectively. And then there’s oversight provided to ensure that they are doing it effectively.”

**“If a supplier is accredited to MedAccred, that means they understand process validation, and that’s a big deal for the FDA,” Global Technologies’ Paul Hugo says.**

FDA is closely scrutinizing device manufacturers’ process validation activities more and more during facility inspections, and process validation has popped up in recent years as a top observation in agency warning letters. (Also see “Compliance 360° Part 9: US FDA Is Looking Closely At Process Validation – Are You Ready?” - *Medtech Insight*, 5 Jun, 2017.)

Therefore, knowing that a firm’s special-process vendors have a firm grasp on process validation is a bonus for FDA, says Paul Hugo, director of corporate quality for Global Technologies.

Hugo told *Medtech Insight* that “to complete the MedAccred audit checklist, [suppliers] have to have FDA’s interpretation of process validation implemented in their facilities. If a supplier is accredited to MedAccred, that means they understand process validation, and that’s a big deal for the FDA.”

Global Technologies, which provides assembly and

product development solutions to OEMs, was the first company to gain cable and wire harness accreditation to MedAccred in early 2016. The supplier was recently re-audited and recertified to the program.

MedAccred “forces us to apply the disciplines of good manufacturing practices on a more thorough and consistent basis,” Hugo said. “In fact, our training procedures have been markedly improved over the course of the three years we’ve been involved” in the program.

At Global Technologies, “our methods for doing ESD [electrostatic discharge] and solder and all of those things – we had them, and they were certainly functional and adequate for what we were doing – but I’d say we’re moving more toward a world-class solder discipline and a world-class ESD discipline than certainly we were three years ago,” he added.

Hugo noted that the company’s recordkeeping activities were strengthened as a result of MedAccred’s audits.

“There’s an element of the [audit] checklist that talks about device history and the device history record,” he said. “So, we had to draw parallels to how we kept our manufacturing records and how they would apply as a medical device record. That was really the big improvement that we made there: We now believe our records are compliant to [FDA’s] recordkeeping requirements.”

Further, the program “helps our discipline of making sure, as employees cycle through our facility, that they are at a higher training level when they are asked to perform certain functions,” Hugo said. “For example, if they are terminating [wire], they must go through some basic termination familiarity, and that’s even before they are allowed to address any machines.”

Wire termination is work performed on the end of a wire that allows it to connect to a piece of equipment.

“We are more thorough and more efficient today than we were three years ago,” Hugo said. “MedAccred definitely separates us from most of our competition.”

*Published on July 5, 2017*