

SANMINA'S CULTURE A TEMPLATE FOR MEDTECH GROWTH



By Bob Marshall, Chief Editor

Published in: <https://www.meddeviceonline.com/doc/sanmina-s-culture-a-template-for-medtech-growth-0001>

With the increasing need for outsourced manufacturing of medical devices, where does a device company go to find the right manufacturing partner?

Perhaps we need an “eAssembly” matching website to help us evaluate the 29 dimensions of manufacturing compatibility. Or a “Manufacture.com”, where contract manufacturers post 26 pictures of their factory, write about their experiences, and tell companies what kind of devices make them happy. How about something simpler, like “It’s Just Labor”? Device companies could visit contract manufacturers’ cafeterias to talk with the workers during lunch, finding out what they really think about working there. Sound silly? Yes, it does, but what is the alternative?

I guess you could go with the old-school bar scene: Head to the nearest medtech trade show and look for the fanciest booth, with the most attractive sales people and the best giveaways. NO! There is too much at stake in finding the right manufacturing opportunity for both parties. Having worked for two different device contract manufacturers, and having made decisions to outsource manufacturing to other contract manufacturers, I’ve had both good and bad experiences.

Reflecting on one of my best experiences in outsourced medical device manufacturing, I reconnected with Tim McGinnis, VP of quality and regulatory affairs for Sanmina’s medical division, to gain insight from his success and challenges, and to talk about the company’s growth in medical device contract manufacturing.

McGinnis joined Sanmina in 1998, before the separate medical division existed. At that time, Sanmina did a lot of manufacturing for the medical device industry, but mostly made components and



sub-assemblies. The company did, however, manufacture a few finished medical devices, and they realized that doing so successfully required a deeper commitment.

“We started to see growth opportunities in the medical field, and right after the year 2000, we decided it would be best to form a medical division. Creating Sanmina Medical allowed us to build the medical quality management system we needed, and create the culture necessary to build medical devices,” McGinnis explained, precisely hitting the mark with his understanding of what Sanmina had to do. As leadership theorist and former MIT professor Edgar Schein wrote in *Organizational Culture and Leadership*, “The only thing of real importance that leaders do is create and manage culture.”

As one might expect, there were some hurdles to overcome while Sanmina took steps to fuel growth in its medical device contract manufacturing operation.

Early Challenges For Sanmina Medical

In the early 2000s, many medical device companies viewed contract manufacturers as vendors or suppliers. The relationships were transactional. “During that time, the OEMs were still a little reluctant to outsource higher risk products. Most of the finished devices we were making were lower-risk FDA class II products,” McGinnis said.

Sanmina persisted through the first decade of the 21st century and things began to change. Medical device OEMs were squeezed by the pressure to commercialize devices quicker, but at the same time, they faced constraints on capital expenditures (e.g., new buildings and assembly equipment). Medical device OEMs began to re-evaluate their relationships with contract manufacturers.

Could contract manufacturers add more value? Could they help optimize the design of the device? Could they take responsibility for procurement via the component supply chain? Could they validate the production processes? Could they hold finish goods inventory and distribute per the OEM's orders?

The answer to all of these questions is “yes,” and relationships between medical device OEMs and contract manufacturers began to evolve into partnerships. The dynamic transformed from “you assemble – I pay” to “we partner – we prosper.” McGinnis noted, “[medical device OEMs] were more willing to outsource higher-risk class II and class III devices; they began engaging us earlier in the product development process, and they were even wanting low-cost solutions. That was another challenge, because you don't just go overseas to set up a plant and say, ‘hey, we're going to build medical devices tomorrow.’”

The culture Sanmina had carefully created in the U.S. had to be replicated across 20 device-producing facilities around the globe.

Keys To Successful Partnering

When asked about the secrets to Sanmina's success in medical devices, McGinnis went back to the basics. He explained, “It's so important we have a good new product introduction process, where both parties are aligned on what's required to build

the products. We also need a good contract in place, with a quality agreement defining the roles and responsibilities for both parties — things like who does adverse event or medical device reporting?”

When McGinnis mentioned quality agreements, I couldn't help but ask him about FDA's final guidance document on Contract Manufacturing Arrangements for Drugs: Quality Agreements, issued in November. Though the guidance does not apply to medical devices, McGinnis said it's likely that FDA will issue a similar guidance for devices in the near future.

“ There was a reason why they [introduced the guidance] in the pharma industry, and the same reason exists in the medical device arena, as well. I would not be surprised, because the quality agreement is a very important part of compliance,” he said.

I asked McGinnis if Sanmina's culture and focus on compliance are differentiators for them, or if those tenets have become customer expectations. He replied, “I still think regulatory focus and discipline are differentiators. Yes, there are certain things expected when partnering with a medical device contract manufacturer. But OEMs understand the risks associated with these types of devices and appreciate the regulatory focus as a differentiator in the overall choice of a partner.”

Handling Visits From The FDA

Given the large number of medical device companies Sanmina serves, I was curious how they handle FDA inspections. McGinnis informs impacted customers when the FDA will perform an inspection at one of Sanmina's plants, but he does not need the customer to be present at the plant. However, he does ask the customer to have someone on standby in case there is a technical question about one of their devices.

“We have had situations where customers do ask to come, and if it's appropriate, we will let them attend, but they are essentially on call. Customers will not be interfacing with the FDA inspector directly,” McGinnis explained.

At the conclusion of an inspection, the FDA issues an establishment inspection report (EIR) and, if

there are any findings requiring remedial action, the FDA will document them on its form 483. McGinnis has had customers ask for both the EIR and the 483s, which Sanmina will provide to its customers after ensuring confidential client information is protected.

I ended my discussion with McGinnis by asking what he was most proud of in helping Sanmina grow its medical device manufacturing business over the last two decades. First, he is proud of being instrumental in developing and implementing the

medical quality management system (QMS) Sanmina still uses today. "We know, if our plants follow the QMS, it provides the necessary culture for producing safe and effective devices," he said.

Next, McGinnis is proud that Sanmina has been able to sustain a large medical footprint - 20 device-certified sites - while remaining compliant. "The bigger you get, the harder it is to manage, but we haven't fallen off as we've continued to grow," he concluded.