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As Device Firms Take Costa Rica By Storm, Quality Control Experts Champion 'Pura Vida'

by Shawn M. Schmitt

"Pura Vida" – a Spanish phrase meaning the "pure" or "simple life" – isn't just the unofficial motto of Costa Rica; rather, it's a state of mind, locals say. But as more and more medical device manufacturing facilities pop up in the tiny Central American nation, quality assurance professionals there have discovered that ensuring top-notch product quality doesn't necessarily make life simpler. To jump that hurdle, QA experts from a variety of firms – including Medtronic, Precision Concepts and Creganna Medical – have banded together to lean on each other as they search for solutions to quality systems issues, as well as knowledgeable input on hot quality and compliance topics.

When Costa Rican quality assurance experts Martin Camacho Grünwedl, María Celina Corrales and Vanessa Rivel need a helping hand to understand, say, a complex standard, or they're stumped by a burning compliance, quality or regulatory issue, they know exactly where to turn: to each other.

Despite being employed by three different medical device firms with facilities in the country – Grünwedl from Medtronic, Corrales from Creganna Medical, and Rivel from Precision Concepts – they periodically meet, along with other QA managers and professionals from an array of other firms, to find sought-after answers and much-needed support.

Costa Ricans "like to do things the right way," said Rivel, Precision Concepts' quality systems & regulatory compliance manager. "When we have quality problems, we really do try to solve them and not to hide them. When there are defects in the manufacturing lines, we try to address them,

to solve them, and not sweep them under the rug.

"That, of course, generates confidence in our businesses," she added. "We all win when we learn together."

Grünwedl, a Medtronic senior quality manager, chimed in: "For example, *all of us need to comply with the new 2016 version of ISO 13485*. We all know we need some training on that. Or there might be topics from [US] FDA we need to know about – we get together and talk about those new things, if there's some new approach from the FDA. So, we're all learning together about those types of things, and we support each other."

Companies use international quality standard *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. The standard's requirements for device manufacturers are similar – but not identical – to FDA's *Quality System Regulation*.

> ***"Sometimes companies have issues – they'll say, 'I don't know how to do this thing' – so we cooperate with each other and help," Medtronic's Martin Camacho Grünwedl says.***

During other intercompany powwows, "we talk about, for example, CAPAs [corrective and preventive actions] and CAPA investigations, or we'll discuss the importance of good writing and to be prepared for that," Grünwedl said.

When it came to learning better writing techniques, "there was one company that was looking for that training, so we all got together to have one training for all of us at the same time," he said. Grünwedl pointed out that the meetings – held every two or three months by an organization known as CINDE – "is also for people to improve their technical knowledge on quality and the different tools we need."

Founded in 1982, *CINDE* is the Costa Rican Investment and Trade Development Board. A nonprofit, private entity with no political ties, it serves to promote the country and attract foreign investment.

Medtech Insight spoke with Grünwedl, Rivel and Corrales on June 1 at an industry educational

conference on process validation and risk management in San Jose, Costa Rica, hosted by the Biomedical Division of the American Society for Quality. With strong support from local device-makers, CINDE lobbied to bring the ASQ meeting to Costa Rica, which took about two years to plan and take shape.

Several companies "had been talking for a long time that it was important to have this process validation meeting in Costa Rica," Grünwedl said. "Process validation is one potentially difficult topic that is common between the companies, and we talked about how we needed experts here in Costa Rica teaching us about these things.

"Sometimes companies have issues – they'll say, 'I don't know how to do this thing' – so we cooperate with each other and help," he noted.

> *Medical devices are Costa Rica's No. 1 export, and the country is the No. 2 exporter of devices in Latin America.*

That level of collaboration between companies may sound overly warm and fuzzy to American, Asian or European ears, where device firm employees are more cautious when engaging with their peers from different companies, even when in a cordial professional setting such as a medtech conference.

But in Costa Rica, "Pura Vida" rules. The Spanish phrase that means the "pure" or "simple life" isn't just the unofficial motto of the country; rather, it's a state of mind, locals say. Helping each other for the greater good is something that is woven into the fabric of the nation and its people.

Nevertheless, that doesn't mean QA experts become overly chummy with their counterparts at potentially competing firms.

"At our meetings, when we talk about issues firms are having, we're not necessarily talking about specific issues that a specific company is having. Rather, it's overarching training; for instance, how should you approach a CAPA?" said Corrales, Creganna Medical's senior quality manager. "Of course, we're not going to share confidential information."

Why Costa Rica?

Support amongst peers is needed now more than ever because the country is in the midst of a

device manufacturing boom. It may be surprising to some that medical devices are Costa Rica's No. 1 export, and the country is the No. 2 exporter of devices in Latin America.

According to CINDE, exports of devices grew at an average annual rate of 14.3% between 2005 and 2015 (from $580m in sales in '05 to $2.2bn in '15). This growth was likely one factor that led FDA to open a field office in San Jose in 2009. (Also see "*US FDA opens offices in Latin America and Europe*" - Medtech Insight, 5 Feb, 2009.)

Everything from high-risk class III devices to low-risk class I's are made in Costa Rica, including medication delivery systems, intravenous pumps, bovine heart valves, and surgical and diagnostic instruments. Baxter was the first international firm to settle in the country, opening its doors in 1988.

The number of companies that have opened manufacturing facilities there has more than doubled over the past decade or so. Data from CINDE shows that 68 firms – from giants such as Medtronic, Boston Scientific and Covidien, to smaller ones like Precision Concepts and Creganna Medical – crank out product here, mostly in San Jose's outlying areas of Alajuela and Heredia.

> ***"We don't have too many quality issues at the companies here. That's also something that is very attractive for the companies that are investing here," Grünwedl says.***

Moving facilities to Costa Rica makes sense for some firms, especially those based in the US, because it's cheaper to make product and pay wages, and because it's convenient for doing business – the country is roughly only a five-hour flight from most Gulf Coast states and Costa Rica shares the United States' Mountain Time Zone.

"We are very close to the States. It's the biggest market of medical devices in the world right now, and because we're in the [Mountain Time Zone], it's very easy to communicate with headquarters," said Creganna Medical's Corrales, whose firm makes medical balloons, and metal and braided shafts, among other products.

Medtronic's Grünwedl believes it's the Costa Rican people who make moving manufacturing sites to the country even more attractive.

"We have very good, educated people here. They know English. It's part of the education," he said. "We abolished the army here, so all of that money is vested in education. Also, people here are very interested in technology."

Costa Rica's military was disbanded in 1948 following civil war.

"I believe the people here are very passionate. That doesn't mean we want to do things right and people in other countries don't want to do things right," Grünwedl said. "But Costa Ricans are very passionate to make things happen, to solve the issues – to make things different. We love challenges, so if we have a challenge, that's something that motivates us to do things to raise the bar. I believe that, based on that, we are having a very good reputation right now regarding audits and inspections.

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To help meet the demand in manpower at device firms, local universities have incorporated studies in quality and regulatory geared toward medtech manufacturing.

"Locally, we are looking to have quality technicians ready – to know the statistics, to know about quality and quality tools," Grünwedl said. "That's something we're managing with universities here. They include programs for quality, manufacturing supervising, English – that's a big topic at the universities. And there's microbiology mixed with some engineering. These are new programs to align to the needs of the medical device industry."

For example, *Tecnológico de Costa Rica* in Cartago offers degrees in medical device engineering, while *Universidad Técnica Nacional*, with campuses situated around the San Jose area, offers a diploma in quality control, as well as a bachelor's program in process and quality.

UTN also boasts a Center for Productivity and Quality. Launched in 2008, the center "provides consulting, advisory, technical assistance and training services focused on improving the productivity and quality of companies," the school says.

'Intégrate a Coyol' Trains Quality Technicians

Despite the educational opportunities presented by Costa Rica's more traditional universities, Medtronic's Grünwedl and Creganna Medical's Corrales say their biggest quality challenge is finding people with adequate education and experience.

Coocoo For Costa Rica

Since the mid-2000s, ever-larger manufacturers have been making the leap to

Manufacturers "need a person in quality who knows about suppliers, compliance, operations, and such. It's not easy to get those types of people," Grünwedl said. "Some people will know, say, about validation activities, but not so much about operations, for example. Trying to maintain quality assurance people is difficult."

Device-makers must also deal with competitors poaching employees.

"It's difficult because more and more firms are coming to Costa Rica. There's competition to attract the right people, and it's getting worse," Corrales said. "Some people don't like the little device company they're in, so they jump to another one. Many companies are located close to each other. They just need to cross the street and go to another company. You can lose good people very easily."

To help meet the growing needs of the device industry, a program was designed by the Coyol Free Zone to train locals on the basics of becoming a quality technician.

The *Coyol Free Zone*, located in Alajuela, is Central America's largest business park. Hologic, a maker of diagnostic products, medical imaging systems and surgical products, was the park's anchor tenant when ground broke on the complex in 2007. The CFZ is now home to scores of device firms, including St. Jude Medical, Volcano, Abbott Vascular and Moog, to name a few.

Costa Rica, sometimes shuttering facilities in the US. Here's a selection of *Medtech Insight* reports tracking the rise of device-making in the country:

- 2005: "Hospira has announced it is to shut down its medical device manufacturing plant in Donegal, Ireland. Production at the Donegal site will be transferred to the company's other facilities in Costa Rica and the Dominican Republic." (Also see "*Hospira closes Irish factory, over 500 jobs axed*" - Medtech Insight, 9 Sep, 2005.)
- 2011: "Boston Scientific has indicated that it will cut 167 jobs at a manufacturing facility in Doral, Fla. The redundancies are part of an ongoing plan to relocate the Doral operation to Alajuela, Costa Rica, first disclosed in November 2009." [In 2015, Boston Scientific moved the production of many of its electrophysiology products from Northern California to Costa Rica.] (Also see "*Boston to make more redundancies as part of Costa Rica move*" - Medtech Insight, 25 Jul, 2011.)
- 2011: "Among other site location trends ... is the emergence of Costa Rica as the epicenter of the Latin American medical device industry over the last 10 years. More than 50 device firms currently operate facilities there, including St. Jude Medical, Allergan, Boston Scientific and Abbott Vascular. Key draws of Costa Rica include the country's high literacy rates, labor-training programs, green

The four-week long "*Intégrate a Coyol*" training program educates recruits on regulatory and quality issues, biosafety, asepsis, management of cold rooms, and technicalities in English, among other topics. Launched in 2016, the program is extremely popular amongst device manufacturers in the CFZ.

Intégrate a Coyol is "based on our need to train people from our influence zone so they become skilled candidates with the capabilities that businesses search for when it's time to recruit operative staff," María José Crespo, a service manager for CFZ, *told Costa Rica's Canal 3 TV* in March.

The program offers "subjects about the industry's employability; subjects about quality; subjects about production," she said. Recruits "need to understand all of the terminology that they are going to encounter when they work in [the device] industry."

Trainees also learn about work responsibilities and values, as well as occupational health.

"What we offer to people is to train them, to prepare them so they have all of the fundamentals, so when they have to face an interview or a recruitment process for a business, they already have a very big part of the process covered and have gained the knowledge to be a suitable candidate with the capabilities and the qualities that the businesses search for," Crespo explained.

hydroelectric power, free-trade zone industrial parks and the Panama Canal's upcoming expansion." (Also see "*Coastal States Among Most Costly Device Manufacturing Locales – Report*" - Medtech Insight, 11 Apr, 2011.)

- 2012: "Covidien is the latest medtech company to join the workforce cull as it plans to cut 595 full-time jobs with the closure of a facility in South Carolina. The closure is part of the company's plan to cut costs amid challenges brought on by pricing pressures and reimbursement issues. The closure of the Seneca facility is expected to be completed in three years and its operations will be transferred to another plant in Alajuela, Costa Rica." (Also see "*Covidien adds to medtech layoff toll with 600 job cuts*" - Medtech Insight, 14 Sep, 2012.)
- 2013: "'For the first time in our 25-year history ... we've been forced to look at manufacturing outside the US,' Cyberonics CEO Dan Moore said. 'It's primarily driven, first, by overregulation, and the second piece is the tax.' Until now, Cyberonics has done all of its manufacturing at its Houston-based headquarters. But recently, the firm broke ground on a manufacturing plant in Costa Rica. 'Every job that we put in Costa Rica is a job that we're not going to put here,'" Moore said. (Also see "*MDMA Will Focus On FDA Performance, Device Tax Repeal In 2013*" - Medtech Insight, 4 Feb, 2013.)
- 2014: "Volcano says it plans a limited

At Precision Concepts, which is a finished device manufacturer, quality technicians trained through Intégrate a Coyol are welcomed with open arms.

That's because "they know some basics around GMPs, how to enter the clean room, sterilization, and some other basics that operators need to know," Rivel said. This helps to bridge the gap "between the requirements of the medical device industry and the knowledge of some of the population that live around the [Coyol Free Zone]."

market release of the low-profile *Phoenix* system by the end of the year and a full launch in early 2015. The company will initially manufacture the device at AtheroMed's Menlo Park, Calif., facilities, but it will transition to Volcano's manufacturing site in Costa Rica by next year." (Also see "*Volcano Cuts Deeper Into Peripheral Market With AtheroMed Buy*" - Medtech Insight, 28 May, 2014.)

Grünwedl agreed. Students "learn how to behave in a controlled environment, and learn good documentation practices. Those things are very basic, but sometimes for untrained people it's very hard. They'll want to know, 'Why is documentation important? Why do I need to write this? Why do I need to sign like this?' So Intégrate a Coyol is a solution for those people to get involved and be ready if they are hired in the medical device industry."