



New master's degrees fill critical gap for medical device makers

WHEN DAVID DEGROOTE LEARNED THAT MEDICAL DEVICE makers in Minnesota were struggling to fill critical positions, he headed straight to his computer to find out whether he could help.

DeGroote, dean of St. Cloud State University's College of Science and Engineering, was at a meeting of the Science Initiative of Central Minnesota, an economic development group, when an industry expert pointed out the shortage of regulatory affairs professionals to help new products gain federal approval.

"I came back to my office that night and started searching the Internet for what regulatory affairs professionals did for medical device companies," DeGroote said.

His search found no programs for regulatory affairs focused on medical devices. That was in 2005. DeGroote and industry executives hammered out a curriculum for a new master's degree program in regulatory affairs and services at St. Cloud State University that was launched in 2007. The program prepares students to navigate the Food and Drug Administration's complex approval process.

MEDICAL DEVICE MANUFACTURING SPECIALISTS NEEDED

The state's medical device manufacturing industry employed more than 29,000 people in 2007, according to a report from the

state Department of Employment and Economic Development. That amounts to 1 percent of total jobs in Minnesota, the report said, and employment is expected to continue growing.

But a lack of seasoned professionals can affect medical device companies regardless of their size, from giants such as Medtronic and Boston Scientific to fledgling startups.

"We got feedback that in some ways their business growth is hindered by a lack of adequate talent in these fields," said Brian Rembish, president of management consulting firm MedTech Leadership. "Programs like this can help the industry be healthier and grow faster."

Directing the regulatory affairs master's program is Chuck Swanson, who headed the regulatory affairs department at Fridley-based Medtronic Inc. for nearly 30 years and helped shape many FDA regulations on medical devices.

"We got started because there just aren't enough experienced people around," Swanson said. "Everybody wants somebody with three to five years' experience. The only way you get that is to rob somebody from a competitor. It's a game of musical chairs. Our goal is to increase the population, and we've had a lot of industry support for that."

The regulatory affairs program began with 13 students in its first year and has about 20 students each in its second and third



Building the biosciences workforce

Numerous bioscience-related programs are offered throughout the Minnesota State Colleges and Universities system for current workers and those pursuing a career in the medical device and biomedical field.

In addition to bachelor's and master's degrees, shorter-term educational opportunities are available in programs such as biomedical technologist, clinical research professional, biotechnology laboratory technician, bioinformatics and clinical research coordinator.

For more information, visit www.mnscu.edu.

years. A job fair for regulatory affairs graduates and students drew representatives of nine medical device companies last summer, Swanson said. Many students get hired while they're still in the program. "That's probably the biggest surprise to me," Swanson said. "That indicates how strong the need is."

NEW CLINICAL RESEARCH DEGREE INTRODUCED

This fall, DeGroot and the university launched another program – a master's degree in applied clinical research to train professionals who design, conduct and evaluate clinical trials in medical devices. Such research is critical to developing safe and effective medical devices, providing scientific validation for new products under strict scientific and ethical standards.

This fall, the new applied clinical research program enrolled 15 students when classes convened at St. Cloud State's Twin Cities Graduate Center in Maple Grove. Rembish, who currently is the program director, said, "We expect this number to increase as word on the program gets out to the industry."

Because clinical trials are much more labor intensive, the clinical research program eventually could dwarf the regulatory affairs program, Swanson said, estimating that the industry would need to fill four times more clinical jobs than regulatory affairs positions.

Both master's degree programs are believed to be the first of their kind in the nation to focus specifically on medical devices, which can range from everyday products such as contact lenses to high-tech equipment such as pacemakers, stents for treatment of peripheral artery disease in legs, devices to treat obesity, neurological devices and wireless transmitters of abnormal heart rhythms.

DeGroot and Rembish met with senior managers at four device companies to have the regulatory affairs curriculum reviewed by the people who would

potentially hire the graduates of this program. A similar approach led to the applied clinical research curriculum.

"Who better to ask what it is in terms of skills and competencies that the next generation of employees should have than the people who are going to hire them?" DeGroot said.

DEMAND FOR GRADUATES ANTICIPATED

Diane Sahr, president of Twin Cities consulting firm Perceive Medical, said hiring experienced clinical professionals was a struggle when she was director of clinical affairs for American Medical Systems, a Minnetonka medical device maker.

"The need for the program is tremendous," said Sahr, who was a member of the group that helped develop the clinical research master's program. "I think there will be even higher demand with health care reform and as devices advance. The level of skills these graduates are intended to display can take several years to learn through the industry route on the job, so we're hoping to shorten that curve."

Kathy Lundberg, former chief compliance officer at Boston Scientific and now consultant to startup companies, said the programs are just what the medical device industry needs. The clinical research program is one of few in the country that covers the unique skill set necessary to design and manage clinical research through the stages leading to approval, she said.

A regulatory affairs graduate, Waylon Vanderpoel, said the program provided a new professional opportunity at a time when he needed one. He had worked in a plant that produced thermoplastics for boats and recreational vehicles, and the chemicals were causing him severe allergy problems. Like some other students, he got a job in regulatory affairs with a medical device company while he was still a student.

"You make a positive impact on the world while you make a nice living, and you feel good when you go home," Vanderpoel said. ■