

## **Educating the Medical Device Professional**

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### Abstract

The medical device industry is robust and thriving in Minnesota, particularly in the Minneapolis-St. Paul metropolitan area. Education on medical device issues is available to employees of the larger corporations, but not readily available for smaller medical device company employees and professionals from other industries that want to enter this area.

To address this situation, several years ago we began offering a course in medical device FDA regulations in our graduate program. Demand was high, and this single course has now evolved into a series of courses ranging from pre-market approval of devices to anatomy and physiology for engineers. These courses are offered in our evening part-time graduate program and can be taken as individual courses, be combined into a graduate certificate or used toward one of our Master's degrees.

The wealth of resources provided by adjunct faculty who are practicing and keeping up to date in this rapidly changing area have resulted in a high-quality, readily available program that has attracted students from a variety of companies and backgrounds and created opportunities for job enhancement and professional growth.

### History and Background

The medical device industry had worldwide revenues of \$195 billion and US revenues of \$95 billion in 2003 and is growing at 6% per year. The industry employs 1 million or more people in the US, Europe and Japan. Ten companies control 35% of the US market, with five of those companies located in Minnesota.<sup>i</sup> There are 800 registered medical device firms and more than 520 FDA approved medical device establishments currently in Minnesota.<sup>ii</sup> About 2,500 medical device related patents were registered to Minnesota companies between 1997 and 2001, and Minnesota has the nation's highest number of investigational medical devices and FDA premarket approvals of medical devices per 100,000 residents. Medical device employment increased 31% between 1992 and 2002 in Minnesota compared to 10.2% nationwide. Minnesota

ranks second only to California in the medical device industry.<sup>iii</sup> Minnesota ranks fourth in the country relative to the revenue produced by the number of workers in the health care industry.<sup>iv</sup>

Minnesota companies and research institutions have been first in developing many medical devices, from implantable cardiac pacemakers and artificial heart valves to in-the-ear hearing aids and implantable drug transfusion pumps.<sup>v</sup>

While giants like Medtronic, Guidant, 3M and Boston Scientific dominate the news, there are dozens of medium size and several hundred small size medical device companies as well. The average firm has 87 employees, with 66% of those firms having fewer than 50. While product education and some on-the-job training are available to employees of larger corporations, medical device training and education is rarely available to other employees and those wanting career changes. Hence our interest in developing programs to provide continuing education for employees of the smaller medical device firms, as well as for employees of supplier companies and those without medical device experience who want to enter the industry.

### Students

As noted above, Minnesota has many medical device manufacturers as well as a vibrant environment for new ventures. Much of this activity is concentrated in the metropolitan Minneapolis/St. Paul area. Education in the common elements of the medical device business tended to be available only through “on the job” training. With the prominence of this industry in the region, and the promising future for medical technologies with an aging population and new scientific discoveries, it is critical to provide continuing education to constantly update the skilled workforce needed to grow this industry.

The University of St. Thomas School of Engineering identified the need for an additional source of learning experiences in medical device design and manufacturing for a wide spectrum of individuals new to the field or with new responsibilities in the industry. As with any rapidly growing industry, applied education that covers fundamentals applicable to the long term, but that can be put to use immediately, is vitally important. The medical device curriculum does just that, offering applied education in areas of medical device design, development and manufacturing.

The program has been designed for engineers and managers in the medical device industry, suppliers to the industry, professionals taking new assignments or positions, team members wanting to understand the broader scope of their projects, venture capital executives and professionals interested in career change. The program has also attracted senior undergraduate engineering students who are interested in entering the medical device industry.

Students range from company presidents, marketing and sales leaders to engineers, scientists, program managers and regulatory personnel to nurses. About 30% are from large companies while the other 70% come from smaller firms in the medical device business, plus some from hospitals and the University of Minnesota Health Center. Some are in the process of making a transition from other industries into the medical device industry.

## Faculty

Our graduate programs rely on many adjunct faculty. They bring the real-life experiences to the classroom that are the hallmark of our applied graduate programs. The medical device courses are no different. With the wealth of talent in medical device companies in the Twin Cities, outstanding adjunct faculty have been attracted to the program. In the medical device courses we draw faculty from large corporations such as Medtronic and Guidant, and from emerging companies like Alliancz, Acorn Cardiovascular and VenturiGroup. All are experienced professionals in the medical device industry, bringing relevant and current knowledge to the classroom.

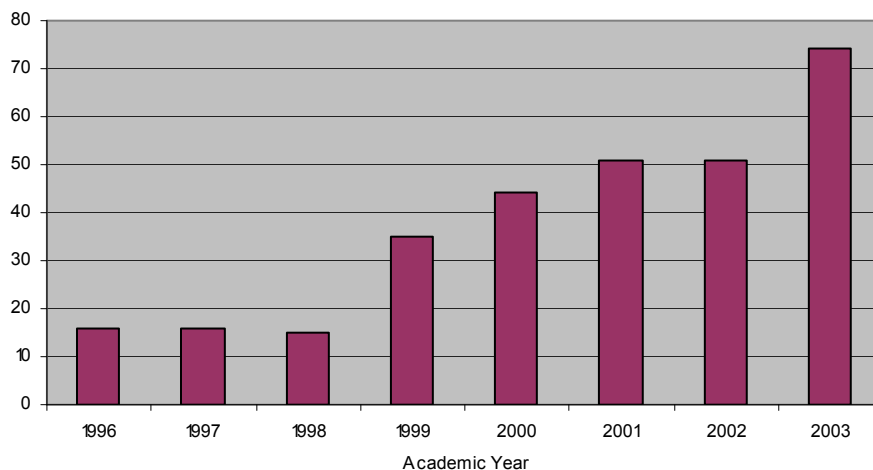
## The Medical Device Option

Since its inception, an advisory board of faculty and industry advisors has guided the medical device curriculum. Their experience in the industry, coupled with the emerging needs of prospective students, has been invaluable in identifying the course content that is relevant. This group has guided the program through rapid growth and change, and will so into the future.

The curriculum has been designed for multiple purposes. For those interested in earning graduate transcript credit, but not wanting to pursue a Master's degree, a five-course Medical Device Certificate is available. This certificate has a core of three courses that provide a common foundation, and two electives that allow each student to tailor the curriculum to meet their individual needs.

Students can also apply these courses as electives to one of our three Masters degree programs. This is happening at an increased rate, with particular interest in our Master of Science in Technology Management degree.<sup>vi</sup> The design of this degree is particularly appropriate for the fast-paced, competitive medical device industry.

Medical Device Class Enrollment



The curriculum began in 1996 with one course and 16 students, and has grown to over seven courses and 70 students each year. See growth chart above

The program has gained a national and international reputation. We have had requests to offer courses from the program in Europe. Within the United States, we have had various inquiries, and recently a student moved to the Twin Cities from Utah just to attend the program.

Courses now offered in the curriculum include

- Design and Manufacturing in the Medical Device Industry
- Designing Corrective and Preventive Action Systems (CAPA)
- Medical Device Quality Systems
- Medical Device Regulatory Submissions
- Medical Device Clinical Studies
- Automation in the U.S. and Overseas
- Anatomy and Physiology for Medical Devices
- Biomaterials in the Design and Reliability of Medical Devices
- New Venture Strategies

Class sessions take on a collegial atmosphere, with the expertly experienced faculty and seasoned students engaging in rich dialogue. The pragmatic instructional approach includes projects and presentations by students actively engaged in the learning experience. Class sessions also often include guest speakers from industry, on-site visits to companies and even tours of operating rooms. Details on these courses can be found on our website.<sup>vii</sup>

### Observations

We have found in all of our graduate programs that industry has the need for applied engineering leadership programs. These needs may be “unarticulated”, however, and it takes experienced professionals to sort out the needs from the fads. Our experienced adjunct faculty and industry advisors have done an excellent job at identifying the real needs, and of transforming ideas into practice. This is particularly true in the area of medical device graduate education. In fact, students have also helped in shaping the program. The clinical studies class, for example, emerged as a need that was identified by students who wanted structured learning in this topic.

One large advantage of the graduate classroom is the ability of many individuals with vast experience to come together in an environment that encourages the exchange of ideas. Even if the subject matter were offered within a company, there is an advantage of neutral territory with no hidden agendas that is provided by the university classroom.

Surveys have identified many of the benefits students receive from the program. Among those are

- A comprehensive understanding of the medical device business
- Understanding how to put together different functions to take a product to market
- Learning other facets of the medical device industry outside their own specialty
- Understanding the development process and its requirements

- Understanding FDA regulations and how they drive actions at work
- Creating an increased awareness of all the complexities and aspects in bringing a medical device to the marketplace
- Letting management know they are serious about advancement in the industry
- Meeting other people who work in the medical device industry

## The Future

The medical device industry is growing rapidly and changing daily. With the guidance of our medical device advisory board, we have been making changes in anticipation of the need. The board is now evaluating how our program should change in the next few years. With the aid of surveys and focus groups, new and modified courses are being evaluated. Just this fall we introduced a new Finite Element Analysis course that focuses on medical applications. This course is offered to graduate and upper division undergraduate students. The ongoing integration of the medical device and pharmaceutical industries, with drug coated stents and drug delivery pumps, will require new course topics be covered. The recent purchase of Guidant by Johnson & Johnson will further fuel that need. We expect more technical courses to be added in the near future, based on our strong electrical, mechanical and manufacturing systems engineering curriculum. As noted earlier, we will also be exploring the need for on-site programs in corporations, online components for distance delivery and as enhancements to classroom experiences, and collaborations with industry on projects.

We anticipate continuing growing needs locally, and based on interest from around the country and the world, expanding needs in a broader market.

## Bibliography

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  - iii Ibid
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  - v <http://www.deed.state.mn.us/facts/PDFs/BioTechFctsht.pdf>
  - vi <http://www.stthomas.edu/engineering/graduate/mstm.asp>
  - vii [http://www.stthomas.edu/technology/grad/cert\\_meddevice.htm](http://www.stthomas.edu/technology/grad/cert_meddevice.htm)

RONALD J. BENNETT is Founding Dean of the School of Engineering at the University of St. Thomas. He holds a Ph.D. in Metallurgical Engineering and an MBA. With a background of 20 years in industry, Bennett teaches and publishes on diverse topics including materials engineering, technical innovation, technology transfer and engineering education. He is an EAC of ABET program evaluator and is currently Chair of the Graduate Studies Division of ASEE.