

New school of thought for teaching medical device skills

By **Steve Sawin** | FEBRUARY 04, 2014

When both Governor Deval Patrick and President Barack Obama focus on the same topic — job and skills training — as they did last week in their major addresses, it's a moment to take notice.

Bringing the issue close to home, we can take a look at the medical device sector. The US medical device industry and, by extension, the device companies in Massachusetts, have a lot to be proud of. More than half of the leading global medical device companies are based in the United States, employing more than 400,000 Americans. It's also one of the few US manufacturing industries to consistently export more than it imports.

However, with all its strengths, the sector faces some serious weaknesses — especially when it comes to human talent. According to a skills gap study by Deloitte Consulting LLP and the Manufacturing Institute, shortages and skill deficiencies in production roles (e.g. machinists, technicians, operators, etc.) are having a significant impact on manufacturers' ability to expand operations or improve productivity.

In addition to an insufficient supply of candidates with manufacturing-related skills, most medical device companies find it difficult to recruit skilled labor in the areas of quality, regulatory, research and development, and facilities. Each of these jobs tends to require specific skill sets and knowledge that are not developed in the current national education curriculum.

Moreover, candidates who do possess these skill sets, but have gained them in other industries, such as aerospace or automotive, are often perceived as being unqualified for a related position at a medical device company because they lack specific medical device experience.

Another issue that arises because of a shortage of qualified labor is employee poaching. In some areas of the country where the medical device industry is clustered, some companies get so desperate for skilled labor that they consistently lure employees back and forth between each other. Their main tactic is to offer more money to the worker, which ultimately drives up costs and creates a domino effect of additional problems.

To help the industry address its workforce supply deficiencies, the Obama administration and the US Department of Labor created the Medical Device Harmonization Initiative , a grant-based project that provides funding for the Community College Consortium for Biosciences Credentials. Two main objectives of this initiative are to:

- 1) Create a set of medical device industry standards for five functional areas: manufacturing, regulatory, quality, instrumentation, and engineering and R&D.
- 2) Develop curriculum for a national network of community colleges that will elevate the skills and knowledge base of entry-level workers.

This initiative is designed to supply medical device companies with applicants who have a solid foundation of knowledge and abilities in key areas where the needs are greatest. For example, most medical device companies need entry-level manufacturing applicants to have strong “basic skills,” which include reading comprehension, writing, communication, and basic math. They also need a good work ethic, a positive attitude, and an aptitude to learn.

In addition to basic skills, additional training could be obtained in areas such as management systems, current good manufacturing practice, and manufacturing and maintenance. Education that focuses on the competencies and capabilities most needed by the medical device industry will enable students to add more value to their employers. It will also reduce the amount of time and money that medical device companies need to spend training their new hires.

To establish the industry standards and develop a harmonized curriculum that will be universally recognized in community colleges across the country, the consortium and its

partners of medical device industry experts was assembled from various national organizations.

In its curriculum development process, the consortium is focused on two types of students:

- a) Individuals who are entering the workforce for the first time; and
- b) Individuals whose skill set is no longer relevant in today's job market and need to be "re-tooled" to meet the needs of growth industries.

The grant-based project will allow students to earn certificates that build upon other program elements in a pathway toward curriculum that meet industry needs. These certificate and program elements focus on one or more of the five functional areas: manufacturing, regulatory, quality, instrumentation, and engineering and R&D. In addition, students who want to pursue a more well rounded education can "stack" their certificates and earn an associate's degree.

A universally recognized and standardized curriculum means that community colleges in any state will be able to develop students with medical device-specific skills and knowledge. As a result, medical device companies will have access to a nationwide pool of qualified skilled labor, which would give them greater geographic flexibility over where they choose to headquarter or expand their operations.

The process of determining the specific skills and knowledge that need to be included in the curriculum for each functional discipline began in October, 2012, and is expected to be completed and rolled out in community colleges by September, 2016.

The hope is to finish the work so the medical device sector can get a boost in putting more people to work growing our leadership in this important manufacturing sector.

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