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Quality Desert: How An Academic Minor In Quality Could Be The Key To Quenching Industry's Thirst For QA Professionals

by [Shawn M. Schmitt](#)

The medtech industry is facing a quickening problem of older workers retiring, leaving holes to fill in quality departments around the globe. In response, a Medical Device Innovation Consortium (MDIC) "Quality as a Career" workgroup partnered with Pathway for Patient Health to create a Quality Science Education framework that can be used by any university or college in the world free-of-charge. The program, packaged as an academic minor, includes six quality-focused courses for students to complete. Xavier University in Cincinnati, OH, recently became the first school to use the program curriculum.

In 2007, a Thoratec vice president groused about the shallow pool of educated professionals to take on quality assurance roles at the Pleasanton, CA-based device firm – and in industry at large.

"It just seems like there aren't enough people to fill the funnel. There's a big gap," Don Middlebrook, VP of corporate RAQA, told *Medtech Insight* at the time. (Also see "[Device Firms Struggle To Find Qualified Quality Assurance Professionals](#)" - Medtech Insight, 15 Jul, 2007.)

"If you look at the people who have the big [QA] jobs at the moment, they're all baby boomers, and as they retire and the shifts occur and people are moving around and filling those jobs, it's creating a vacuum at the lower level," said Middlebrook, who still works at the manufacturer of ventricular-assist devices.

"What we need to do is reach out to universities and colleges," he offered. "I think that's what's really going to aid in filling that [QA] funnel."

Fast-forward 12 years, and the medtech industry still faces the same – if not quickening – problem of older workers retiring, leaving holes to fill in quality departments around the globe.

But an ongoing "Quality as a Career" initiative from the Medical Device Innovation Consortium (MDIC) – under the auspices of the [Case for Quality](#) – is looking to turn things around in part by doing what Thoratec's Middlebrook suggested all those years ago: reaching out to schools to train the next generation of quality professionals.

"Awareness of quality as a career is dependent on us figuring out what's cool." – Pamela Goldberg

"When I came to the quality department at Baxter [International Inc.] four years ago, I was assessing the talent, and what I found was that I had a bunch of history and English majors who fell into quality because they had nowhere else to go," said Jackie Kunzler, a chief quality officer for the device firm, and a former co-leader of the Quality as a Career workgroup. (Baxter's Kim Killackey and Becton Dickinson's Adrienne Brott – both quality experts at their respective companies – are the current co-leaders.)

While several universities offer majors in regulatory affairs, only a handful – many of them lesser-known online schools – offer a focus on quality.

Such an education deficiency "is why we need to establish a quality discipline at the university level to educate students about the benefits of making quality part of their future career," Kunzler said at a June Case for Quality forum in Arlington, VA.

To make that happen, the Quality as a Career group partnered with [Pathway for Patient Health](#), a relatively new organization that's the brainchild of Marla Phillips, director of Xavier Health at Xavier University in Cincinnati, OH.

"I started Pathway for Patient Health so I could do things more globally outside of Xavier, and one of those things is developing a quality curriculum that any university in the world can adopt," Phillips said at the forum.

She further explained: "Five different companies approached me in 2017 from all over the world asking if they could hire my students because they assumed, because of my work at Xavier Health, that Xavier University had students who were getting an education in quality. But Xavier

didn't have any of those programs."

After Phillips was approached the fifth time by a firm looking to hire graduates with an education in quality, she decided to act, launching Pathway for Patient Health and linking up with the Case for Quality group to get the ball rolling on creating a Quality Science Education (QSE) framework that could be used by any university or college in the world free-of-charge. (That's right: free. More on that in a bit.)

A 6-Course Quality Minor

To set the parameters of the QSE program, Pathway for Patient Health leveraged the experience of a panel of 13 chief quality officers from high-profile companies that cut across the device, pharmaceutical, consumer health and animal health industries, including Boston Scientific Corp., Eli Lilly & Co., Thermo Fisher Scientific, Gilead Sciences Inc. and Abbott Laboratories Inc.

"We were originally thinking about creating a quality science major until one of those chief quality officers said, 'I still need them to be scientists first, not just a quality major.' That was eye-opening," Phillips said. "So, now we want them to be chemists, biologists, engineers, data scientists, polymer scientists – whatever they need to be to function in these companies – and then have quality as a minor."

She noted that packaging the QSE program as an academic minor "gives the student an idea that they're heading toward something with this, and it's also something that faculty can talk about with the parents of potential students. They can say, 'Your child can enter this quality program and this is where it can lead.'"

After it was decided to follow the academic minor track for the QSE program, [six courses were identified](#) for students:

MDIC Prez Weighs In

In an interview with *Medtech Insight*, MDIC president and CEO Pamela Goldberg weighed in on the Quality as a Career initiative:

"The schools that are already offering degrees and courses in quality are doing a great job, and we just want more institutions to follow that good example. And so, we're trying to get the word out.

"Someone said, 'Oh, we'll have "Quality" T-shirts on every college campus.' Well, I'm not so sure that T-shirts are the answer, but I do think that awareness of quality as a career is dependent on us figuring out what's cool. What is going to get people excited about doing this?

"Ultimately, students have to see that there is a career pathway for them if they're going to start taking these subjects, and the academic institutions have to expand their offerings."

- Global Regulatory and Legal Requirements of Quality, focused on why global regulations were adopted, as well as the evolution of quality systems;
- Business Acumen, to teach financial concepts and applications, such as operating and capital expenses, fixed assets and liabilities, cash flow, profit, and net worth;
- Product Development, Specifications, Process and Validation, to include criticality of inputs, risk controls and assessment, specifications, testing, clinical trials, transfer, scalability, yield, and validation;
- Risk and Failure Analysis, focused on investigation processes and writing scientifically justified conclusions linked to lab experiments; and
- Microbiology Course and Microbiology Laboratory, focused on controls, testing and aseptic techniques.

On 20 August, Xavier University became the first school to offer the Global Regulatory and Legal Requirements of Quality curriculum. The class is being taught on Tuesdays and Thursdays by subject-matter experts from device-makers Procter & Gamble Co., AtriCure Inc. and Sotera Wireless Inc.

Xavier allowed the course to proceed as a so-called "experimental class." That's because it can generally take one to three years for a university to approve a new academic minor.

"If we waited for a quality minor to be approved, then Xavier would not [have been] able to start the curriculum this year," said Phillips, who added that it's "very positive" that more than 20 students signed up for the inaugural class. "And while the experimental class is going, we're taking the steps to get the quality minor approved – that should take about a year."

"Just think about the graduates who don't have this [quality education] background coming into your company – they're making decisions, and that's a risk you're taking on." – Marla Phillips

At a separate Association of Food and Drug Officials (AFDO) annual meeting in June in Atlanta, GA, Phillips claimed device manufacturers could save time on employee training and avoid risk

by hiring a person who successfully completes the Quality Science Education program.

"Everyone we've asked has indicated that this kind of education in quality would shave one to three years off of onboarding training," she said. "Just think about the graduates who *don't* have this background coming into your company – they're making decisions, and that's a risk you're taking on. That's pretty key."

Phillips told *Medtech Insight* in a 19 August interview that Pathway for Patient Health and the Quality as a Career group have reached out to nearly 90 universities, both inside and outside the US, to gin up interest in the program.

"We have five schools that are seeking internal approval right now, and we have 12 schools that have attended virtual information sessions twice a month, which shows that they're interested enough to learn more," she said, noting that 90% of the schools that were approached are in the US.

"Quite a few of them are very large schools and are very recognizable. And we are targeting some schools that are smaller and diversified, as well."

Industry And FDA Internships

A key component of the Quality Science Education minor will be a paid internship for students at either a device company or at the US Food and Drug Administration.

Students will be matched up with paid internships (and after graduation, potential jobs) that will be posted on an online portal that's currently under development (but should be ready by next month).

"Once a student says, 'I am participating in these quality science courses,' we will send them a user license so they can build their profile in the portal," Phillips said. "We're planning in September to teach our Xavier students on how to build those profiles so they can be eligible for internships this winter and next summer."

4 Ways To Teach QSE Classes

The Quality Science Education program can be taught in one of four ways:

1. Live: Subject-matter experts (SMEs) will come to a school campus to teach, or teach online.
2. On Demand: Educational videos that feature SMEs can be used by universities on their own online platform.
3. On Demand via Pathway for Patient Health (with School Backing): Students can take the on-demand video classes through the organization's website and gain credit from their school after they

She said the portal will help make quality-related internship opportunities more visible for students and universities.

"There are many universities that aren't on the companies' targeted internship lists, so the internships are never sought after. So, you may have an amazing rock-star program and student, but your school just isn't on a targeted list. The portal will change that," Phillips said.

Students "can build a profile in our portal, and by them selecting where in the world they would be willing to live and work, and what their major is, what year they are in school, what their GPA [grade-point average] is, how many of these quality courses they've taken, they will pull from a table of criteria that fits them, while industry is pulling from that same table of criteria, for what they're looking for," she said.

In other words, "it will be an automatic matchmaking service."

FDA internships will also be an element of the QSE program, but how that will ultimately work hasn't been ironed out yet.

"Through this program we're talking with universities about offering paid internships. But FDA can't pay students," Phillips said. "So, we thought that through Pathway for Patient Health, we could perhaps have a competition where maybe two students a year – we would fund them to have an internship opportunity at FDA. But we haven't worked out the details on that yet."

An internship at the FDA "could be about quality; it could be product-related. Of course, that's all linked to quality eventually, but it could be from a [new device] application standpoint – researching similar products or precedent, or adverse events of products that are similar – I just don't know how it will ultimately shake out," she said.

Who's Paying The Tab?

The Quality Science Education program is being offered to universities, colleges and students for free.

"Everything is free. The curriculum is free – we have the curriculum developed. We have slides per class, we have quizzes, homework, tests – all of that is developed and free," Phillips said.

complete the program.

4. On Demand via Pathway for Patient Health (without School Backing): Students who want to take the program courses but don't have buy-in from their school can take the on-demand video classes through the organization's website. Those who finish the program successfully will receive a certificate of completion from Pathway.

Nevertheless, developing a curriculum, web portal, and much, much more isn't cheap. And that's where the device industry will step in – by literally buying into the program.

Beginning next year, subscribing companies will have access to the portal and graduating students – visibility that would otherwise be difficult for firms to attain. The price of the annual membership will be based on company size.

So-called "micro" companies with fewer than 50 employees that want to participate will pay \$5,000 per year, while small manufacturers (51 to 1,000 employees) will be charged \$10,000. Medium (1,001 to 10,000), large (10,001 to 40,000) and "enterprise" (more than 40,000) firms will pay \$25,000, \$50,000 and \$75,000, respectively.

A firm's return on investment will come in the form of improved operational efficiency and effectiveness, and a reduction in the cost of poor quality, Pathway for Patient Health [says](#) on its website. Companies that take part might also see some economic benefits.

Part of that money from industry will allow "students to get their user license for the portal for free. We'll pay for it through Pathway for any student," Phillips said. "Now, this could one day be a very large program and require a lot of funding – but we're committed to making it free for students."

"We need to create the next generation of professionals to help our organizations continue to make a paradigm shift so we're not caught flat-footed in our quality departments." – Corlis Murray

Another way to ensure that the program remains free for students and schools is for companies to offer up their own subject-matter experts as teachers.

"Schools are shocked that it's free," Phillips said. "Somebody asked me, 'Do I need to sign a memorandum of understanding?' And I said, 'No. We just want to give it to you. Here's the curriculum. Here's the content. We'll give you the subject-matter experts to teach. We'll have internships. We'll have mentors. We just want to give it to you.'"

Remember Young Students, Abbott VP Says

While the current focus for Pathway for Patient Health and the Quality as a Career group is on college-age students, some say younger students shouldn't be forgotten.

"We need to create the next generation of professionals to help our organizations continue to make a paradigm shift so we're not caught flat-footed in our quality departments," said Corlis Murray, senior VP for quality assurance, regulatory and engineering services at Abbott Labs.

"So, we have to begin that process by reaching young people very early," she said at MedCon 2019 in May. "And I'm talking about middle school and high school. It's important to start making these investments early."

Murray speaks from experience: Abbott launched a science, technology, engineering and mathematics (STEM) internship program for high school students several years ago.

"Abbott is committed to that. Our STEM program is our way of trying to help bring these young people more exposure," she said. "And the students are in everything, from all aspects of the sciences. So they're in research and development; they're in cybersecurity; they're in quality; they're in regulatory."

"It's important that we as an industry continue to foster opportunities for our young professionals to learn how to think critically," Murray added. "We have to connect the dots if we're going to make this shift. We have to ground them in the fundamentals of the science of quality."