

him in the '80s to help turn around their fortunes. By then, he was well into his career teaching statistics at New York University, and on his way to working out his last great contributions to management theory: the System of Profound Knowledge and 14 Points for Management—which were published in *The New Economics for Industry, Government, Education* just prior to his death in 1993.

Babbitt, while admittedly biased, says Deming's philosophy continues to be relevant for manufacturers in all areas, but he warns that patience is required. "It's a challenge to adopt Deming's philosophy, especially in larger organizations that are tied to the

stock market. Their decisions are oriented around stock prices and reports, and their thinking only goes out 90 days. You need to look longer term to make longer term decisions about your organizational systems." ■

References

- [1] Ballard, John. *Leadership, Management, and Life in the Workplace*. "Steve Jobs on Improving Processes." 16 November 2012. <http://www.johnballardphd.com/blog/category/juran/2>.
- [2] Hunsaker, Phillip L. and Anthony J. Alessandra. *The Art of Managing People*. New York: Fireside, 1991.

GOOD BUSINESS IS GOOD QUALITY

At Bristol-Myers Squibb, A Culture of Quality Starts at the Top

Scott Fotheringham, PhD

For people in Bristol-Myers Squibb's manufacturing organization, delivering on the company's mission "to discover, develop and deliver innovative medicines that help patients prevail over serious diseases" has never been more significant.

As the New York-based BMS sharpened its R&D focus around fewer and more serious disease areas, getting it "right first time" on the manufacturing floor has become even more important to the company – and to the patients who depend on its medicines.

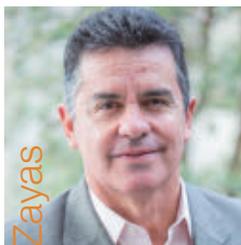
"This industry has traditionally equated the concept of quality with being compliant with regulatory authorities," says Donna Gulbinski, BMS's senior vice-president of global quality, who is responsible for the quality and testing of commercial products. "At



BMS, we've been focused on accelerating a culture of quality that transcends compliance. We know that driving right first time, reliability and predictability in manufacturing directly contributes to getting our medicines to the patients who need them faster. Every action of every employee counts."

For BMS, strengthening a culture of quality starts at the top.

"Our Leadership Team has established a strong focus on developing and maintaining a culture of quality throughout the company," says Ricardo Zayas, the company's vice president of pharmaceutical operations.



That focus is reinforced by a governance structure and resources, and is entrenched in the company's commitment to "fostering the continuous, proactive improvement of our production and process capabilities... (to uphold) the highest standards of quality for BMS medicines."

To support the concept of a quality culture and mindset, BMS has adopted five key elements:

- aligned vision and expectations;
- quality objectives linked to company goals;
- management reviews;
- quality unit independence; and
- transparency and openness, so that significant events can be escalated.



The company has also embraced the tenets of lean manufacturing, continuous improvement and the emphasis on the elimination of waste, theories that were developed at the Toyota Motor Company in the decades following World War II. Gulbinski says BMS has developed a deep understanding of lean quality and the relationship between eliminating waste and improving quality.

"Good business is good quality," she says. "The lean quality motto of 'right first time' is key for us."

The company started implementing the tenets of lean manufacturing at just a couple of its sites, including one in Ireland, where the company was able to more closely understand and learn how to maximize its efforts.

"When we were ready to roll it out more broadly, we were much more familiar with aspects of lean quality, and that made the rest of the rollout better. We had a proven standard and time-tested technology," says Zayas.

The rollout was not without some resistance, he admits, adding that change always takes time to accept.

"It's a different way of doing things, but once employees understand that it's a better way to work, a more organized way to work, they adopt into it. When people learn the benefits of well-planned work, they're grateful and they like it. In the pharma industry, we plan production processes well—for example, every bottle we fill, every tablet we make. But we're not great at planning lab operations, which require a demand-and-supply schedule, and that people know what's needed tomorrow and also what the work schedule will be six to 12 months from now."

Zayas says the big advantage of adopting a culture of quality within the pharmaceutical sector is the focus on prevention.

"There needs to be a significant shift in the paradigm of our industry. With programs like product robustness, reliability excellence, process engineering, and equipment and operational excellence, it can take a lot of convincing leaders in pharma that these things are necessary. Well, guess what—if you have a good program in each of those areas you're going to be focusing more on prevention. You're going to have less total cost of quality and fewer back orders that represent lost revenue, because they're usually driven by deviations in your processes."

As Gulbinski explains, driving this kind of change begins with a strong presence on the shop floor, where operational excellence (lean quality) begins and ends. BMS helps to ensure buy-in with visual boards that express data like quality and safety performance to employees on the floor.

"If you want people to care, enabling them to understand how their work impacts the bigger picture really helps," she says. "What are we making today? What stage of manufacturing are we at? What issues do we have? What's our history look like? How are we doing against our targets? We hold daily huddles to discuss what's happening on the floor."

Another important component of the Toyota-led quality assurance movement that BMS has adopted is the Gemba Walk—one of the key lean principles.

"Walking around is a big part of what we do," says Zayas. "I do this when I visit sites, and more importantly, our site and area management people do this in a formal way."

"It starts with front-line supervisors," echoes Gulbinski.



“In addition, during my tenure, I met with all of the colleagues at the Mount Vernon plant,” says Espejo. “It took me nine months to complete. I called them 10-on-1’s and I’d ask two questions, ‘What do you like about working here? What things can we improve on?’ and I let the conversation go from there.”

“We also spoke about quality and safety at town hall meetings every month.” Said Espejo. Consistent messaging was a key element to instilling a quality culture.”

Another important concept that is central throughout Bristol-Myers Squibb is keeping patients at the center of everything.

“When I met with new employees, I told them, ‘What you do here, every single day, you’re ensuring quality for our patients, who could be your family (who consume pharmaceutical products), friends, your community members.’ It’s about the patient—you, your parents, brothers, sisters—who takes a prescription medicine. (I’d tell them) ‘You have their health in your hands when you come to work.’ That’s how you change the quality mindset from one of just compliance; you bring it to the human level.”

Espejo says that—while BMS’s business objectives were foremost—the human element of quality is a significant part of what resonated with employees.

“We didn’t focus on cost. The cost savings emerged but we focused on the potential impact on patients. We have quality products going to patients, and that’s the most important thing

One of those front-line BMS managers was Andrew Espejo, who is now an executive director of strategy on Zayas’s team. For a number of years, Espejo was a general manager at BMS’s Mount Vernon, Indiana, manufacturing facility, which is being transferred to AstraZeneca as part of the sale of BMS’s diabetes drug business to the UK-based company.



Espejo says the process was essential. “The most important thing for me was that they see us, and we hear them. From the Gemba Walks we implemented a ground-up 5S program (another primary methodology developed in Japan to ensure manufacturing quality). We were 30 miles from a major Toyota plant where many of our colleagues came from, so we decided to leverage what they knew about lean. It was truly amazing. We empowered the operators, gave them budgets and guidance about the strategy.”



we do. It's hard not to stress the human element because that's who we are. We have the processes in place, but people run the processes."

One of the things that stays with him from his time in Mount Vernon is a line adapted from the Rascal Flatts song "Every Day."

Says Espejo: "We coined the phrase, 'every day you help save a life.' When we did our site strategy engagement sessions we would close the sessions with videos of our people talking about what they do and what it means to their life... If you don't focus on people, on the patients we work for, quality gets lost in the compliance mire. When people make the connection to themselves, their loved ones, to patients – it brings it home: 'I'm not just making widgets. People are relying on the quality of the products I make help treat serious diseases.'"

Making that connection, says Espejo, was a huge part of ensuring that the culture of quality replaced the culture of compliance at BMS.

Zayas says that implementing that kind of transition throughout the industry represents a challenge, but it's possible if pharmaceutical manufacturers are committed to the change.

"It's like reprogramming a massive network," he concludes. "You've got to commit to these programs, provide the necessary resources for people to implement them and help them. A lot of support is required because it's a lot of work. But, once you turn that corner, you turn into a powerhouse operation because you don't have the events that create lost revenue.

"The change at BMS has been dramatic. We've turned that corner where our employees realize the focus is on prevention, not on reaction," concluded Zayas. ■

WALKING THE QUALITY CULTURE TALK

Acting Responsibly; Earning Customer Trust Every Step of the Way



François Sallans
Vice President, Quality & Compliance and
Chief Quality Officer, Johnson & Johnson

Regardless of industry, every organization has a culture. The degree to which quality is embedded in an organization's culture can mean the difference between success and failure. In some industries, such as healthcare, quality is more than a competitive advantage, it is a social responsibility.