QUALITY BY DESIGN

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Editor's note: Unless indicated otherwise, all quotations are the result of personal interviews or correspondence

Inside Apple's notoriously secretive lab on its Cupertino, California, campus, quality is an attribute that is not discussed; it just exists. It is what drives the computer manufacturer to obsess over materials, fit and function.

Born from the love of perfection that company cofounder Steve Jobs and design chief Jonathan Ive developed separately, an ocean apart, the devotion to quality processes stemmed from Jobs's relationship with Joseph Juran, formed while Jobs was leading NeXT Computer. Along with legendary designer Paul Rand—who developed iconic logos for IBM, UPS and others—and investor Ross Perot, Juran was one of a handful of renowned advisors Jobs turned to as he struggled to reassert his identity after his ouster from Apple in 1985. As his former company floundered under the leadership of John Scully, Jobs sought to create a product that would be set apart by beautiful design and remarkable functionality.

By turning to Juran—a Romanian-born engineer—Jobs embraced one of the gurus of modern quality management. During a stint with Western Electric, Juran had developed a theory that everyone involved in the manufacture of a product played a critical role in its success. Expressed in his 1951 book, *Quality Control Handbook*, his theory is credited with adding the human factor to the focus on quality in manufacturing, which had its roots in Frederick Winslow Taylor's work on productivity in the early 1900s and Walter Shewhart, who developed a theory of statistical control of manufacturing processes.

The 1996 PBS documentary *An Immigrant's Gift* told the story of Juran's life and groundbreaking work. As part of the project, director Jack Schatz asked Jobs to describe the importance that Juran's influence had on his thinking while he was trying to repeat his initial Apple success at NeXT. Jobs said that Juran showed him the importance of approaching business practices scientifically and questioning why they are done the way they are rather than following the traditional way of simply repeating what had been done before.

Photo courtesy of Matthew Yohe.

"That single shift is everything," Jobs said. [1]

Along with Iowa native William Edwards Deming (see "Quality's Midwife"), a Shewhart acolyte who had also passed through Western Electric, Juran played a major role in rebuilding and reshaping Japan's industrial system in the 1950s, moving the devastated country into a new era of manufacturing excellence.

Turning Theory Into Gold

Deming was the first to take his work to Japan, arriving in 1947 as part of a team of Americans assigned to develop a national census. Once there, his work in translating Shewhart's theories into practical approaches to control and management attracted the attention of the Japanese Union of Scientists and Engineers (JUSE). In 1950, the organization retained Deming to teach a series of classes in statistical control. Among his students was Akio

Morita, co-founder of the fledgling Tokyo Telecommunications Engineering Corporation, which would change its name to Sony five years later. Deming's focus in these lectures was the relation between quality controls, reduced expenses and increased market share. It was a lesson that Morita took to heart.

When Deming refused to accept royalties from the publication of his lectures in Japan, the board members of JUSE decided to create an award in his name—a prize that remains the most widely recognized and revered in the field of quality.

In 1952, JUSE extended the invitation to Juran to conduct a similar series of lectures, focusing on middle and senior management. Among the corporations that sent representatives were the Takeda Pharmaceutical Company, which had been operating in Japan since the 18th century, the chemical engineering giant Showa Denko, which had won the first Deming Prize in 1951, and Nippon Kögaku, which later changed its name to Nikon Corporation, after its most well-known product line.

The combined effects on Japanese manufacturing and engineering—and, by extension, the rest of the business world—are difficult to overstate.

Within 20 years, Japan was recognized as the pacesetter for implementing quality measures into all spheres of manufacturing, but particularly automobile manufacturing—a realm where the U.S. "Big Three" (General Motors, Ford and Chrysler) had previously been unassailed.

"By the 1970s, Americans were going over to Japan to take a look at how they were manufacturing," says Tripp Babbitt, a management consultant at the 95 Method in Fishers, Indiana, and a member of the Deming Institute. "Can you imagine an American manufacturer opening up their operation to Japanese visitors who wanted to see how things ran?"

Babbitt says Deming's influence was most strongly felt at Toyota, "but it was not limited to Toyota. It was much broader in steel, consumer products, watches, electronics and many more."

The Quality Boom

By the 1980s, the decline in Western manufacturing fortunes had reached crisis proportions, and quality proponents like Juran, Deming and Armand Feigenbaum began to be sought out by companies as well established as Ford and as nascent as NeXT. Deming's 1982 book *Quality, Productivity and Competitive Position* became required reading by corporate executives, who began to espouse the importance of total quality management (TQM) a set of management principles inspired by Feigenbaum's book Total Quality Control along with the work of Kaoru Ishikawa, a JUSE member who had championed the concept of quality circles among Japan's major industries and translated the works of Deming and Juran.

The most public display of the adoption of quality procedures and standards among the manufacturing sector was the sudden display of ISO certification, which became as ubiquitous in the early '90s as publicly displayed URLs were a decade later. Giant signs proclaimed that various organizations had met standards criteria set by the Swiss-based International Organization for Standardization. Formed in 1947, and built on the model of the International Federation of the National Standardizing Associations, which had been founded in the 1920s and suspended in 1942.

The rebirth of the organization in the years following World War II made perfect sense since the concept of standards certification was to level the field between countries, and assure other businesses and consumers that products had been manufactured to the same exacting metrics, using similar processes.

The ubiquity of ISO certification began in 1987, in parallel with the publication of ISO 9000, which codified the eight management principles that form the pillars of quality standards and contained three "models," including ISO 9001—which applies to organizations that design, develop or service new products. Today, more than one million companies around the world hold ISO 9001 certification.

ISO 9001 arrived just in time to bolster the sagging fortunes of America's most important industry.

After suffering record losses, and losing market share to foreign competitors, Ford recruited Deming to study its processes, and by 1986 the company had not only turned around its slumping sales figures, it had surpassed rival GM for the first time in six decades. Ford chairman Donald Petersen attributed the company's turnaround directly to Deming's teachings and told the industry bible *Autoweek Magazine* that Ford was building a "quality culture." [2] An ISO rating was just the thing to prove it was true.

After his return to Apple, and the company's improbable, inexorable rise from near bankruptcy in 1997 to the world's most valuable company—and the first U.S. company to be valued at more than $700 billion—Jobs also trumpeted an enterprise-wide culture of quality.

Growing a Culture

Success breeds imitation, and today, the adoption and nurturing of a quality culture is viewed as a business necessity. Seventy-five percent of senior executives surveyed by Forbes Insights and ASQ in April 2014 said their organizations had a culture of quality, and 20 percent said their quality programs were world class or state of the art. Among the key findings, according to Quality Progress, ASQ's official publication:

- Knowing your market—and, most importantly, your customers—are key to fuelling an organization's commitment to quality;
- Incentive programs tied to quality metrics and focusing on innovation and risk-taking allow organizations to nurture a culture of quality;
- Leadership is critical in setting the tone for an organization's culture of quality; and
- Leaders must provide examples and ensure that the principles of quality are understood and communicated throughout the organization.

Many organizations today embrace quality at the top levels, says Jordan Freed, director of performance excellence at Curtiss-Wright Controls Defense Solutions, whose products are found throughout the U.S. military. "More often than not," he says, "the senior executives get it, and place a high level of importance on it. The further up you go in an organization, the more connected they are to their customers. Reliable performance is essential to customers; it comes from quality systems."

Where you encounter problems, he says, is when middle management—often more concerned on a short-term basis with profit and loss—does not buy in or the quality staff is undersized. Quality is a long-term process, he says, and keeping an eye on overall goals is critical.

He says that in regulated industries like pharmaceuticals the head of quality is often also responsible for regulatory compliance. "Regulatory bodies are one of the stakeholders that pharma companies have to please. If you don't have a quality system that is responsible to compliance, you won't succeed in business."

Joseph FitzGibbon, president of Orion Canada, which consults on issues of quality with organizations throughout North America, says that support and involvement throughout the management chain is essential for quality principles to be effective.

"The present ISO 9001:2008 standard calls for a management representative to champion a QMS (quality management system) within the organization," FitzGibbon says. "This person does not have to be a member of top management, but—for purposes of ISO 9001—does have to have a direct line to top management. It requires the involvement of top management to ensure that ownership of the QMS does not center around a single individual. This requires that QMS processes are established and maintained, that reporting of QMS performance and the promotion of customer requirements across the organization can now be assigned to any role or split between many roles. These roles must be clearly defined."

FitzGibbon says that discipline, consistency and limiting variation in how things are done are all essential elements to ensure quality. "Some people doing day-to-day work say, 'I don't need procedures; I know what I'm doing,' but with the turnover of workers you need those procedures to ensure consistency"

Return On Investment

The need for consistency is something that is echoed by Christopher Kincer, president of Lexington, Kentucky-based ISO Experts. "If you look at successful organizations," he says, "they've reduced or eliminated variation in their processes. To be consistent, you want processes that are consistent. Identify what is variation and deal with it."

Integration is another important factor, adds FitzGibbon. "Way back, a number of organizations considered (QMS) a parallel system to what they were already doing. There's more integration now with ISO 13485, which is focused on medical devices and regulatory requirements. Many of them are doing the same things you need to run a successful business. For example, 'Do we have enough resources to do the work?' 'Are the people sufficiently trained to do the work?' 'Do we have backup if these critical suppliers go out of business?' ISO 13485 sets this out as a requirement. It needs to be documented, and it's subject to audits."

"If you have an effective quality leader who is bringing this to the organization, that is the most cost-effective way of meeting the objectives of the business," says Freed. "The goal of a quality program is to prevent failure. How do you measure the total cost of quality? If you consider quality across an entire organization, you can allocate the cost of quality control into four buckets: the prevention of quality problems, through things like good design, training, good manufacturing processes; the cost of assessment, of screening out problems; the cost of internal failures; and the cost of external failures, such as product recalls. As you move through these buckets, it gets more and more expensive to address failure."

Despite the proven link between quality measures and the reduction of risk and associated costs of failure, Kincer says: "You'd be amazed at how many multimillion-dollar companies have not identified their objectives when it comes to quality. These are basic quality principles that many organizations don't take into account. They may deal with customer complaints in a non-

systematic way; not looking at the root causes of issues. They're wasting time. If they'd look at the problem in a systemic manner, look at the root causes, the problem wouldn't happen again."

Kincer says it all comes back to principles that Deming espoused: "Plan what you're going to do. Do it by following your plan. Then, check to make sure what you did was successful in meeting your objectives. If it was, then you have a happy customer. If it wasn't, you need to act and fix the problem.

"A company that is manufacturing a product or providing a service needs to ask, 'What is the customer ordering from me and what am I doing to provide that?' Any type of industry—no matter where you are in the supply chain—has to have a process where they are going to take something and turn it into something that you're going to sell. ISO 9000 dictates that you need to document the process. This allows you to meet the desired output. It has to be measurable. When you document or measure something, you can reduce variation."

Does this apply to pharmaceutical engineering and manufacturing? Absolutely, says Kincer. "If a company is not doing this, it's missing a great opportunity to improve performance, improve employee morale, and improve internal and external customer satisfaction."

He says systems must be simple to implement and easy to maintain. "I look at what a person is doing. I look at a process. We try to create a document that is easy to follow and effective in achieving the objectives."

> What is the customer ordering from me and what am I doing to provide that?

Without that level of simplicity and a long-term commitment to quality, experts say the results will be inconsistent, undermining the entire effort.

That is something that Steve Jobs and Jony Ive ensured was part of Apple's DNA. After the overwhelming success of the iPod and iPhone—when their company was moving from the break of insolvency to the top of the world—they did not take their foot off the gas, and they did not forsake their devotion to simplicity, consistency and quality for something less.

"When times are good, it's easy to ask, 'Why do we need all this quality stuff?' says Freed. "But manufacturing processes shift with time. It takes continual effort to maintain consistent quality."

Quality's Midwife

"W. Edwards Deming's influence is everywhere," says Babbitt. "His work is everywhere, or we see organizations moving naturally toward his philosophy."

Born in Sioux City, Iowa in 1900, Deming trained as an electrical engineer, but gravitated toward mathematical physics. His most significant early work was the development of scientific sampling, which continues to be used to extrapolate census and labor statistics in the U.S.

At 27, Deming encountered Walter Shewhart, a physicist, engineer and statistician who worked at Bell Telephone Laboratories and was developing a theory of statistical measures that would be published in his 1931 book, *Economic Control of Quality of Manufactured Product*. Shewhart's work pointed out the importance of reducing variation in a manufacturing process and the understanding that continual process adjustment in reaction to non-conformance actually increased variation and degraded quality. Consistency was key.

Deming saw that Shewhart's theory could be applied not only to manufacturing processes, but also to the processes by which enterprises are led and managed. He honed his expansion of Shewhart's ideas by editing a series of the older researcher's lectures into a 1939 book called *Statistical Method from the Viewpoint of Quality Control*.

It was Deming's own lectures—particularly one he delivered at Tokyo's Hakone Convention Center in August 1950—that changed the course of Japan's, and eventually the rest of the world's, manufacturing processes. Calling his theory "statistical product quality administration," he espoused four main principles:

- Better design of products to improve service;w
- Higher level of uniform product quality;
- Improvement of product testing in the workplace and in research centers; and
- Greater sales through side markets.

It was a case of the ideal prescription at the perfect time. Japan's industrial sector was crawling out of the wreckage of the war years and the devastation of two atomic explosions, and its senior managers were eager to find a way to jump-start their businesses.

Despite Deming's success in Japan, he was not widely recognized in his native country until the Ford Motor Company hired

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

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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.