THE HISTORY OF QUALITY AND THE EVOLUTION OF THE MODERN LEADER

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The Food and Drug Administration (FDA) report "Pharmaceutical Quality for the 21st Century: A Risk-Based Approach"[14] was an introduction to quality by design (QbD), the concept that quality should be built into a product. According to the FDA report "Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach," QbD involves a thorough understanding of the product and the process by which it is developed and manufactured, as well as a knowledge of the risks involved in its manufacture and how best to mitigate them.[1]

Three other agency Guidance for Industry titles:

- "PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance"
- "Q10 Pharmaceutical Quality System"
- "Process Validation: General Principles and Practices"

further describe this new thinking and introduce a regulatory framework intended to encourage development and innovation within the pharmaceutical industry.[2–4]

While intended for the twenty-first century, each of these documents reflect basic principles first proposed after World War II by Dr. Joseph Juran and Dr. W. Edwards Deming. As agency guidance is increasingly aligned with the principles of these founding fathers of modern-day quality, it is worth exploring Juran's and Deming's views on leadership and learning how they evolved from engineers to philosophers in management.

After World War II, Juran and Deming both traveled to Japan to help rebuild the country's economy. Their efforts helped revolutionize the quality system of Japan and started a quality revolution that the rest of the world could not help but notice. Evidence of Juran and Deming's work is present today in FDA guidance documents and regulations, as well as in other industries that have quality system regulations.

Leaders in the pharmaceutical industry must recognize that as quality systems have evolved, so too have the expectations and responsibilities they must fulfill. Quality cannot be an afterthought with any product, nor can it be the responsibility of any one department. Quality must be instilled within an organization and designed into processes and systems. Most importantly, perhaps, the culture of quality must begin with the leaders in the organization. These concepts are also detailed within the "Q10 Pharmaceutical Quality System" Guidance for Industry.[3]

JURAN

In 1925 Juran joined the Inspection Statistical Department at Western Electric, where he was in charge of integrating statistical sampling and control charting techniques into the system. At this time, quality management systems were focused solely on the end product. But Juran saw things differently. He recognized that this approach was missing something—the human element. Some of the biggest hurdles organizations faced, he realized, were human relations problems and employee resistance to change.[5] Rather than confining quality to a specific department, he said, "It is most important that top management be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below."[6]

Juran later moved on to management consulting, and by 1951 had written the first edition of his landmark Quality Control Handbook.[7] This publication attracted the attention of the Japanese and earned him an invitation to work with 10 manufacturing companies, including Takeda Pharmaceutical Company, the largest pharmaceutical company in Japan and Asia and one of the top 15 in the world.[8–9]

DEMING

Dr. W. Edwards Deming, who had a very similar philosophy to Juran's, also traveled to postwar Japan. He saw that the root cause of many quality issues came from top management. At that time quality issues were frequently attributed to the worker—and often are today, as well. Deming saw through this and identified organizational culture as a root cause.[10] Quality was not something that could be attained without first designing an entire organization and related processes around it; these concepts are reflected today within the FDA documents mentioned above.[2–4]

Deming began his career working for the US Department of the Census and the Bureau of Labor Statistics. Here he applied the principles of Walter Shewhart by integrating statistical process control to an operation. Shewhart identified problems in manufacturing as the result of either common or special variation. Common variation, which is inherently present in a process, represents the "noise" in a system. Special variation is assignable variation that results in a significant process change.[10]

Deming took this one step further and developed a philosophy of management based largely on Shewart's principles. Management, he said, can lead by understanding what he called his "System of Profound Knowledge":[11]

Appreciation for a system: *Understand the overall processes involving suppliers, producers, and customers (or recipients) of goods and services.*

In the pharmaceutical industry, this would translate to: What are the mechanisms of degradation, drug release, and absorption? How do product components affect quality? What are the critical material and process attributes relating to product quality?[2] Product and process

knowledge should be managed from development through the commercial life of the product up to and including product discontinuation.[3]

Knowledge of variation: *Know the range and causes of variation in quality, and use of statistical sampling in measurements.*

What sources of variability within the process are critical? How does the process manage variability?[2] What is the effect of variation on the process and ultimately on product attributes?[4]

Theory of knowledge: *These concepts explain knowledge and the limits of what can be known.*

In FDA guidance, this is a challenge to back up opinions with data to truly understand what is going on, learn, and thereby continually improve: This is reflected in the FDA PAT guidance, which explains that "Continuous learning over the life cycle of a product is important,"[2] and the Q10 guidance, which outlines a systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes, and components.[3]

Knowledge of psychology: *These are the concepts of human nature.*

In every industry, understanding psychology can allow a leader to create a culture of trust, relationship, interdependence, and pride in workmanship. The FDA Q10 guidance notes that "Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system."[3]

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In addition to his System of Profound Knowledge, Deming developed 14 points for the transformation of management.[12] These points are equally useful for developing an organizational culture of quality and compliance with regulatory expectations:

1. Create constancy of purpose toward improvement of product and service, with the aim to become competitive, to stay in business and to provide jobs.
2. Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.
3. Cease dependence on inspection to achieve quality. Eliminate the need for massive inspection by building quality into the product in the first place. ›

4. End the practice of awarding business on the basis of a price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
6. Institute training on the job.
7. Institute leadership. The aim of supervision should be to help people and machines and gadgets do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers.
8. Drive out fear, so that everyone may work effectively for the company.
9. Break down barriers between departments. People in research, design, sales, and production must work as a team, in order to foresee problems of production and usage that may be encountered with the product or service.
10. Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.
    a. Eliminate work standards (quotas) on the factory floor. Substitute with leadership.
    b. Eliminate management by objective. Eliminate management by numbers and numerical goals. Instead substitute with leadership.
11. Remove barriers that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality.
12. Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means abolishment of the annual or merit rating and of management by objectives.
13. Institute a vigorous program of education and self-improvement.
14. Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job.

QUALITY

As Deming stated, "There is no substitute for knowledge."[13] Without knowledge we are powerless and are at the mercy of variation within our processes. With knowledge we can achieve a predictable process that produces a product that meets all quality requirements. This is a large step away from quality control (or quality by inspection) and is consistent with current thinking that "Quality cannot be tested into products: It should be built-in or should be by design."[2]

While QbD provides better design predictions, there is also recognition that industrial scale-up and commercial manufacturing experience provides knowledge about the process and the raw materials used. FDA process validation guidance notes the need for companies to continue benefiting from knowledge gained, and continually improve throughout the process life cycle by making adaptations to correct root causes of manufacturing problems;4 these are also core principles of Deming's philosophy.

Deming said, "To manage one must lead. To lead, one must understand the work that he and his people are responsible for."[12] In its time this statement was not only radical but also largely ignored. What does a statistician really know about the management of people, anyway? Deming would go on to explain that 94% of troubles and possibilities for improvement belong to the system or are the responsibility of management while the remaining 6% are attributed to special causes.[12] In other words, today's leader must begin by taking responsibility for nearly all the problems facing his or her organization.

FOUNDATIONS

To truly understand Deming and Juran, one must first appreciate that their ideas for a quality system begin with a basic philosophy about why people go to work and what motivates them. Deming's 14 points reflect his idea that while workers want to do a good job and take pride in their work, leadership often robs them of this.

To take responsibility for problems in an organization a leader must begin by including every worker in the task as a shareholder. This requires effective communication and the belief that each worker brings enormous potential and the ability to improve the quality of not only the product but the organization. According to this philosophy, workers are not the source of quality problems or success. They are merely part of an imperfect system responding to variation.

Deming understood that to achieve remarkable results, an attitude of continuous improvement had to be present in every single worker. He believed that instead of holding workers responsible for production and quality problems that are actually the result of a poorly understood process or one that is subject to too much variation, workers should be trained and given opportunities to develop professionally.

Deming understood what many did not: Work is more than just collecting a paycheck. Leaders must resist the urge to find a scapegoat for problems that exist within their organization. Workers may often be the easiest assignable cause, but the real root of any quality problem is with the system in which it is produced.

Deming's 14 points were first published in the 1980s, but adopting and truly understanding them in relation to pharmaceutical manufacturing has always been a little opaque. For many leaders, taking responsibility for an organization's problems can be overwhelming. This responsibility can be shared, however, by creating a culture in which pride and ownership are present in every worker, and each individual is accountable.

The following is a modern-day take on Deming's philosophy and the leader's critical role in perpetuating it:

Know your employees. There is no shortcut for this step. To truly understand what motivates your employees to come to work every day, you must invest the time to learn what makes them tick and what brings them satisfaction in the workplace. By aligning employees with the tasks that give them the most satisfaction and helping them find ways to increase their satisfaction in other areas leaders can increase the happiness of both individual employees and the entire workforce. Today's leader must want to be a positive force within the organization as well contribute to the end product.

Be trustworthy. Say what you mean and mean what you say. Be clear and specific in your expectations and allow for open communication across your organization. A true leader must be an excellent listener.

Create a culture that fosters individual growth. If an organization is to improve continuously, so must its workforce. Investing in an employee shows that the organization values what the employee can contribute.

Allow employees to rise to challenges without fear and competition. Much of Deming's philosophy involves eliminating fear. At the time of his first publications this was a major stumbling block for leaders. By recognizing that each employee is human and that it is human nature to fail, we can appreciate that valuable lessons can be achieved through failure.

CONCLUSION

By creating a culture that fosters the philosophies of Juran and Deming, today's leader can create an organization that is more capable and driven than any seen before. Production capabilities and quality improvements will be the inevitable side effects and likely, Deming and Juran will look down from above and grin with approval. ‹›

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