

Prescriptions for Excellence in HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON SCHOOL OF POPULATION HEALTH AND LILLY USA, LLC

A Message from Lilly In Pursuit of a Quality Culture

By *Fionnuala Walsh, PhD*

Being in the business of discovering, developing, manufacturing, and marketing medicines is a privilege. At Eli Lilly and Company, we understand that we must earn this privilege—and the trust of our customers—every day.

A relentless focus on quality is one of the most important ways we earn this trust. While historically our quality organization has been associated mainly with manufacturing, in recent years we have set a course to establish quality systems throughout our enterprise.

Our goal is nothing less than making quality an integrated and permanent part of our culture in every part of our business. Key to this transformation is the widespread use of science-based principles such as risk management and quality by design.

For a pharmaceutical company, quality by design can be described in 2 steps. First, you must design your products to meet specific targets—in this case, targets of clinical performance as defined by your customers and patients. Then, you must design all of your processes, from R&D

through post-marketing, to consistently deliver a product that meets the attributes necessary for this performance.

It is not hard to see how the use of quality tools in a truly integrated fashion can result in improved patient safety and better outcomes. In fact, we are implementing a Safety and Efficacy Quality System to span clinical development, marketing, and pharmacovigilance. Our goal with this system is to create global quality standards wherever possible, then integrate them across boundaries. While this effort is still relatively new, already many organizations and hundreds of people are involved, from clinical research physicians to the leaders of our marketing affiliates to business partners and vendors to regulators.

Of course, manufacturing remains integral to providing products that are safe and high quality. Within our global manufacturing network, which includes more than 20 sites, 10,000 employees, and numerous contract manufacturing organizations, we have moved beyond “basic” quality practices and into a continuous improvement

mode. Having seen tangible improvements among the metrics for manufacturing excellence (these metrics include deviations, backlog items, and factory losses), we have demonstrated effectiveness. Now, we are challenging ourselves to achieve efficiency as well.

More than 30 years ago, a Lilly advertisement appearing in popular magazines depicted a bottle of pills beneath the headline, “The one you take is never tested.” This rather provocative statement was our way of expressing confidence in the quality of every step we take leading to the moment when our products reach their intended audience.

Today we are working to reestablish this same level of confidence by building a quality culture. The key differences between then and now are that we have better tools at our disposal, a stronger commitment to enterprise-wide quality, and, perhaps most important, the knowledge that quality can and does lead to better outcomes for patients.

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