

# QUALITY BUSINESS LEADERSHIP MANIFESTO

REDEFINING QUALITY MANAGEMENT IN THE PHARMACEUTICAL INDUSTRY

We live in exciting times with many new medical and technological breakthroughs, **but** our quality systems and processes are *challenged* to catch up with the speed of change.

Our focus as Quality professionals is to improve and save people's lives, **but** we are *challenged* with significant drug shortages worldwide, which has put pressure on Quality Management.

We have for many years defined our measure of success by staying cGMP compliant in our operations, a target that is inadequate. Before us is an opportunity to be bold and aim higher.

***What if, we take up these challenges by turning Quality Management into a business advantage for our companies, enabling innovation and technological advances, while manufacturing uninterrupted supply of high-quality drug products for patients?***

To do so we must transition from Quality Management to Quality Business Leadership individually and collectively. And the best time to start is now.

As Quality Business Leaders we will not only demonstrate our responsibility for quality and cGMP compliance. We are also corporate players that are financially savvy and

- demonstrate leadership in our actions by nurturing a quality mindset in everybody, from CEO to the shopfloor. We advocate quality owned by all through partnerships and we engage all employees to continuously improve quality.
- keep the supply of quality products to patients in mind, balancing benefits and risks in every decision we make. We adopt new and continuously improved technologies with agility.
- advocate a science and risk-based approach towards a simplified global regulatory framework that facilitates continual improvement and innovation.
- constantly simplify our quality systems and processes.

From the level we are operating today, this may sound highly ambitious. It won't be easy and will test the commitment of all involved in shaping and delivering the pathway to Quality Business Leadership. Yet, it is said that everything is created twice, first in our mind and then in the physical world. So, here is where it starts.

This is our ambition. *Is it yours too?*