From Quality Management to Quality Business Leadership: The critical role of leadership, employee engagement and trust for innovation and continuous improvement

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Preface :

From Quality Management to Quality Business Leadership:
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trust for innovation and continuous improvement

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1.   Introduction

This edition of the Journal of Applied Pharmaceutical Regulatory Science showcases the importance of leadership in pharma and includes contributions from the Quality Business Leadership (QBL) Summit which took place on 1st May 2024 in TU Dublin, Ireland. The QBL summit brought together senior global leaders, from Academia, Industry and Regulatory organisations to explore what they have described as a "wicked problem of ongoing drug shortages, quality defects, product recalls and a lack of innovation" (11). With the proliferation of quality manufacturing issues and recalls of medicinal products contributing to drug shortages (4), the QBL explored the critical role of Quality Business Leadership in driving innovation and continual improvement to address the problem. The summit explored how the pharmaceutical industry can transition from a focus on Quality Management to Quality Business Leadership, individual and collective.

Contributions from an international panel of experts explored how the industry can engage every part of the organisation to ensure that everyone from CEO to the shopfloor is engaged in continuously improving quality and ensuring that quality is owned by all.

QBL Summit Agenda themes, 01 May 2024 TU Dublin:

- How quality can be owned by all employees in the organization
- Ways to actively engage employees in quality improvements
- Learning to speak compliance in financial terms
- How the quality system can be turned into an engine of value creation
- How confidence and trust in quality management can be improved

From Quality Management to Quality Business Leadership

Organisations are systems that are typically structured for inertia and stability (13), the pharmaceutical industry even more so, operating in a highly regulated environment. However, to meet the ever changing and growing patient demands for drug products, the industry must be creative, innovative and agile to implement change, and therein lies the wicked problem. The 2019 FDA report (4) highlighted that 62% of drug shortages between 2013 and 2017 were associated with manufacturing or product quality issues, despite using qualified equipment, validated manufacturing processes and trained staff in a highly regulated environment. This would indicate that it is time for a different approach and the 2024 QBL summit explored how to engage every employee in solving these industry challenges.

QBL Summit speakers outlined the need to redefine Quality Management and for the industry to transition from Quality Management to Quality Business Leadership. To effectively make this transition, an understanding of the difference between *Management* and *Leadership is necessary.* Management involves planning, controlling, complying and evaluating performance against agreed goals (12) and is critical for operational effectiveness. Leadership is the enabler, creating the culture and context in which work gets done (7) and is critical for whether employees can and will engage. Leaders and leadership style play a critical role in individual (1) and organisation (5) behaviour and performance. Scholars and practitioners alike often promote a transformation leadership stye (2) where the leader inspires and supports others to deliver a shared vision. This can enable a culture of psychological safety (3) and trust (14) where employees have the confidence, competence and support to be creative, innovative, and to drive change (6).

Transformational leaders influence and inspire others to engage with a vision through inspirational motivation and intellectual stimulation. They enable a psychologically safe (10) and trusting environment where individuals are supported to share knowledge, to take controlled risks to innovate without fear of reprimand, and if they fail, they are supported through a culture of learning from mistakes and encouragement to try again. Transformational leadership is an important approach to enable the pharmaceutical sector to make the transition from Quality Management to Quality Business Leadership. In helping to define Quality Business Leadership, the Quality Business Administration (QBA) has identified 6 Quality Business Leadership Traits:

1. Visibly demonstrate responsibility for Quality
2. Advocate that quality is owned by all through developing senior management partnerships
3. Engage employees to continuously improve quality
4. Make risk-informed decisions that benefit patients
5. Promote quality as a value-driven financial advantage
6. Lead the path to one global quality regulatory framework

These traits align with a Transformational Leadership style and enable a culture of trust for creativity and innovation (Figure 1.0).

Figure 1.0 From Quality Management to Quality Business Leadership
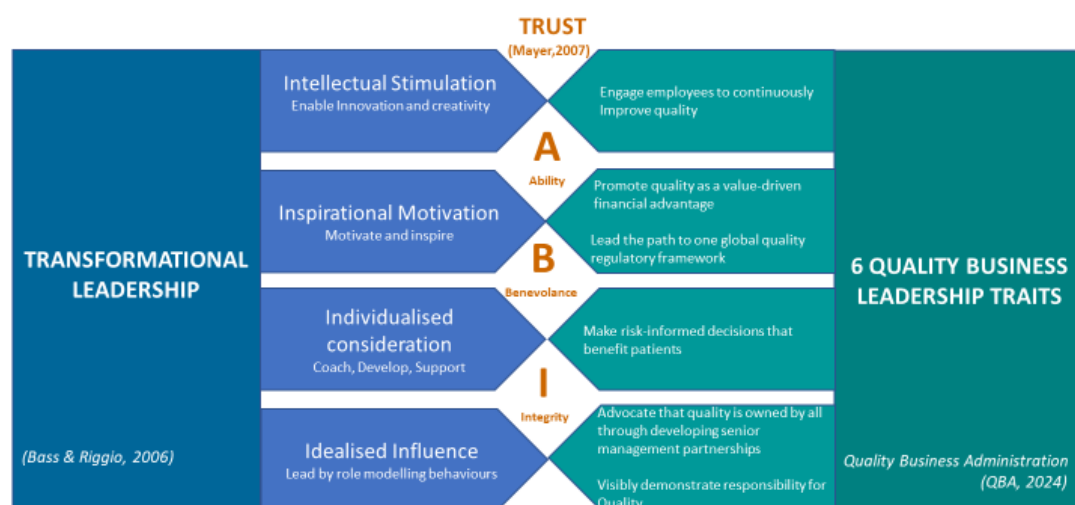
Quality Management ensures a culture of compliance, while Quality business Leadership creates a culture of courage and creativity.

Quality Management and Quality Business leadership are inextricably linked and you can't have one without the other. Quality Management provides the compliance, regulatory structures and clarity for employees to achieve operational excellence. Quality Business Leadership however, enables an innovative and learning culture where employees feel it is safe to question, challenge, to be innovative and to try new things for continuous improvement. Effective leaders can unleash the talent around them and bring it to life, creating a culture in which people feel comfortable to bring their full selves to work and to fully engage their talents. With an innovative and learning culture, employees can trust that their leader will support and not punish them even if innovations fail and that their leader supports a quality and learning mindset that continuously nurtures individual and organisation creativity. Quality Management ensures a culture of compliance, while Quality Business Leadership creates a culture of courage and creativity where people are encouraged to unlearn old and ineffective habits, to not just be reactive and effective problem solvers, but to also be future focused, innovative and continuously improving. It is clear from the QBL Summit that transitioning from a predominantly Quality Management mindset and culture to an individual and collective culture of Quality Business Leadership is critical for achieving the FDA's Vision for 21st Century Manufacturing.

"A maximally efficient, agile, flexible Pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight."

Dr Janet Woodcock, FDA's Vision for 21st Century Manufacturing

2. Current Edition Overview

This edition of the *Journal of Applied Pharmaceutical Regulatory Science* presents papers written based on presentations presented at the QBL Summit. The Agenda for the 01-May-2024 QBL Summit is shown in Figure 2.

Figure 2 – QBL Summit Agenda

The editors would like to thank IPQ for partnering with us in the dissemination of this important work.

Furthermore, picking up on the theme from Dr Woodcock, another element of 'Taking a Stand for Quality,' in addition to Quality Business Leadership, is ensuring the effectiveness of one's Pharmaceutical Quality System (PQS). This concept of 'PQS effectiveness' is a recurring theme across regulatory observations, including warning letters, which regularly cite ineffective quality systems. Indeed, much of the work by the PRST is focused ultimately on improving PQS effectiveness, such as progressing research on quality risk management (QRM), knowledge management (KM), operational excellence (OpEx), post-approval change management, and decision-making.

Post-summit, the PRST has advanced the theme of operationalising QRM and KM in unison, as a means for organisations to improve and demonstrate PQS effectiveness. An initial paper on this topic, entitled *Taking a Stand for Quality - Demonstrating PQS Effectiveness by Operationalising QRM and KM*, written by the editors, is included in this issue of the Journal of Applied Pharmaceutical Regulatory Sciences.

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