

The Behavioural Science of Risk Management

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PDA CHAPTER OF THE YEAR



“...achieving a shared understanding of the application of risk management among diverse *stakeholders* is difficult.”



“... the protection of the patient by managing the risk to quality and availability, when availability risks arise from quality/manufacturing issues, should be considered of prime importance.”



by providing a proactive means to identify and control potential quality issues during development and manufacturing

“Subjectivity can directly impact the effectiveness of risk management activities and the decisions made.”



Proactive Prevention Through People



- Quality risk management should include **systematic processes** designed to coordinate, facilitate and **improve science-based decision making** with respect to risk.
- by providing a **proactive means to identify and control potential quality issues** during development and manufacturing

Balancing The Level of Effort

Achieving a Better Balance between *the level of effort* Prospective Risk Management and Proactive Prevention and Continual Improvement



Our mission at the Quality Risk Management Institute is to promote, facilitate and empower Risk Excellence across the biopharmaceutical sector



What do we mean by Risk Excellence?

Risk Excellence is achieved when *every person* involved in *creating value* in their organisation is also actively engaged in *protecting that value*.

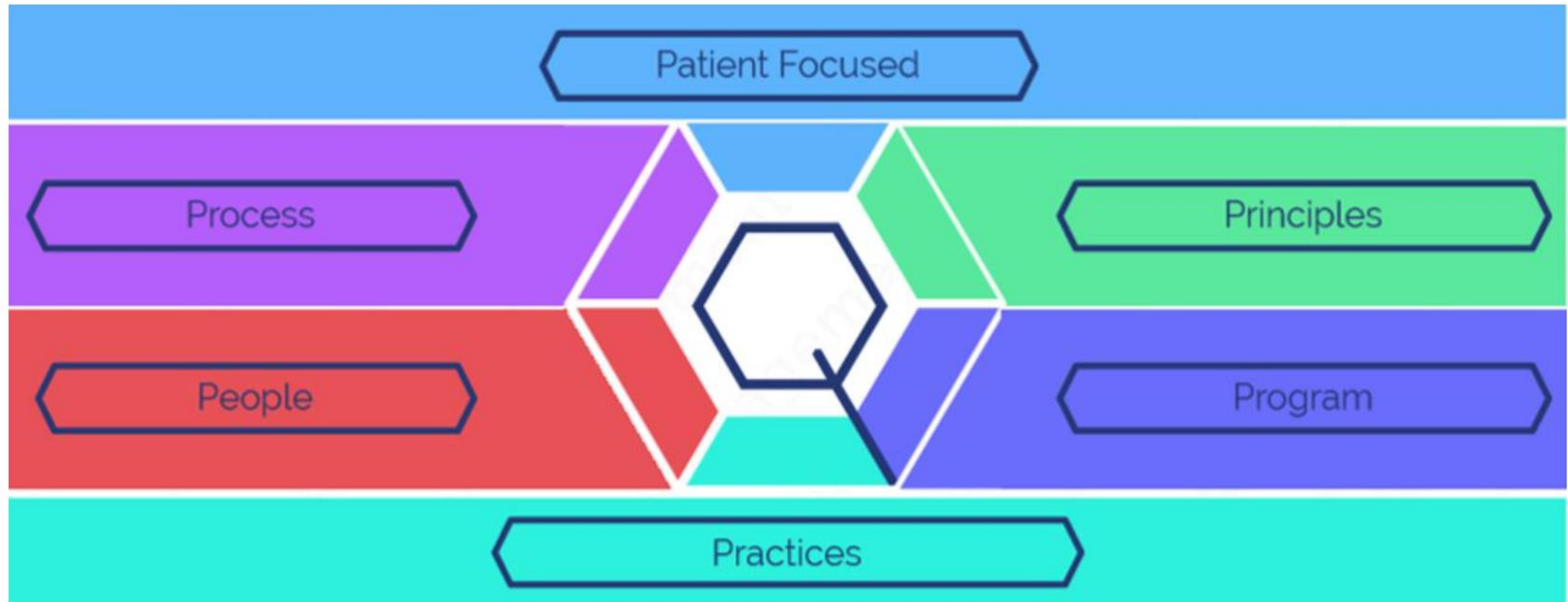
- managing, preventing and reducing risks,
- making timely decisions,
- setting and achieving objectives,
- relentlessly focused on improving performance.

“Risk management is often thought of as a negative, constraining function. We think it's quite the opposite: good risk management is empowering.”

—Robert S. Kaplan

Source: Kaplan, R.S., Mikes, A., A Better Way to Manage Risk, HBR, June 2012

Using the 6Ps to Achieve Better Balance



6P Model of Risk Excellence

Enables evaluation of current Principles/Policies, Program, Processes, People and Practices to assure Patient Focused Excellence

Two sides of one coin

Quality Risk Management is integral to an effective pharmaceutical quality system.

It can provide a proactive approach to identifying, scientifically evaluating and controlling potential risks to quality.

It facilitates continual improvement of process performance and product quality throughout the product lifecycle. (ICH Q10)

The practice of Continuous Improvement within a GxP environment is a proactive form of Risk Management.



Crowdsourcing Proactive Risk Prevention...

The Power of Many



Mobilise the power of the entire workforce.

*Excellence can't be commanded from above. It must be made contagious, individual to individual. **The trick is in knowing how to transfer the right mindsets and best practices without "voltage loss" as they spread.***

Dr. Robert I. Sutton, Scaling Excellence