

Components of QbD Adoption

PEOPLE



Skilled risk management professionals dedicated to support portfolio

The cross-functional study team is responsible to understand the factors that 'matter most' to quality and to proactively identify, prioritize, and mitigate the key risks to quality in their study.

PROCESS



End-to-end process for clinical trial QbD and Quality Risk Management

Development of study QRM plans should take place concurrent with protocol development. Quality control and improvement efforts should occur throughout study conduct with the objective to ensure protection of trial participants and credibility of the results.

TOOLS



Electronic system to facilitate consistent approach across the enterprise

Tools are not essential for Quality by Design or for quality risk management but may be useful to enhance process efficiency or effectiveness.

CULTURE



Clinical trial quality is **OWNED** by the study team

Create a culture where quality is a priority, on par with time and cost considerations, and the importance of discussing risks and issues is emphasized.