**Components of QbD Adoption**

**PEOPLE**

- Skilled risk management professionals dedicated to support portfolio

**PROCESS**

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

**TOOLS**

- Electronic system to facilitate consistent approach across the enterprise

**CULTURE**

- Clinical trial quality is OWNED by the study team

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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.

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

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.