

## Analysis and Control of Variation: Quality Risk Management and Variability Reduction



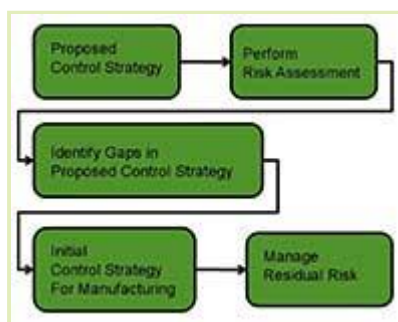
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### KEY POINTS DISCUSSED

The following key points are discussed:

- Quality risk management (QRM) is a key part of quality by design.
- Guidance for QRM is provided by ICH Q9.
- QRM is intimately linked with the pharmaceutical control strategy for a product.
- Risks represent the potential for variability in the process or product.
- QRM can help reduce variability in the following two ways:
- By ensuring the initial control strategy does not lead to high levels of variability.
- By helping the quality systems work better when the process is in operation and product is being delivered to the patient.
- Just as there will always be some level of variability in a process or product, there will always be some risks associated with the process or product.

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