

# *ICH Q8, Q9 and Q10*

## *An Opportunity to Build Quality into Product*

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# Sequence

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- Continuous improvement in product quality by **controlling variability**.
- Controlling variability through a **robust process**.
- Understanding of a robust process for changing a manufacturing site.
- Using ICH Q8, 9, 10 concepts to obtain a robust process.



# Concept for Continuous Improvement

Edwards Deming's concepts of *reducing variability* or Japanese *kaizen* for **continuous improvement** is well known in the auto, and electronic industries (e.g., Toyota, Sony).

“...understand your processes so well that you can predict the quality of their output from upstream activities and measurements.” (Edwards Deming's *Out of Crisis*, 1986)



# Reducing Variability is addressed in ICH Q8, Q9, Q10

**Q8 (Annex):** A comprehensive pharmaceutical development approach will generate process and product understanding and identify sources of variability. Critical sources of variability that can lead to product failures should be identified, appropriately understood, and controlled.

**Q9:** To decrease variability of quality attributes:

- Reduce product and material defects.
- Reduce manufacturing defects.

**Q10:** Product or process variability is explored using CAPA.

CAPA: Corrective Action and Preventive Action System



# Robust Process – the Key to Reduce/Manage Variability

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**Process Robustness:** Ability of a process to tolerate variability of materials, and changes in the process and equipment, without negative impact on quality.

**Q8:** An understanding of process robustness can be useful in risk assessment and risk reduction, and to support future manufacturing and process improvement, especially in conjunction with the use of risk management tools.



# Advantages of a Robust Process

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- Aims towards getting the product Right First Time, Every Time
  - Minimises market recalls.
  - Ensures supply reliability.
  - Reduces inventory, improves capacity utilization.
  - Reduces overall cost.
  - Transforms company from reactive through proactive to a predictive mode.



# Advantages (Cont'd)

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- Enhances regulatory compliance.
- Understanding of process robustness and site specific factors (equipment, etc.) helps in seeking site change (as a post-approval change). This is important for the outsourcing and supply chain management.



# How to get there?

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- Product quality (including robustness) greatly depends on the effort put into the pharmaceutical development.
- ICH Q8R, 9, 10 provide guidance on approaches to building quality into the product.
- Progress in this path could be incremental. The first important step is making the commitment to building quality into the product.
- Quality is everyone's business!





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# Thank you

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