

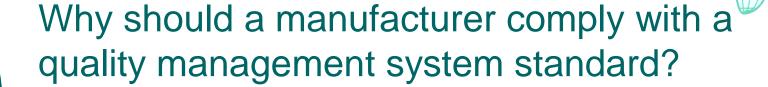
Quality Management Systems: History and Evolution

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Introduction

- Why comply with quality management system standard
- What is a quality management system?
- Evolution of quality practices



- Provides high degree of assurance that manufacturer will consistently produce medical devices that:
 - Are safe
 - Perform as intended
 - Comply with customer requirements
 - Comply with regulatory requirements
 - Have the appropriate degree of quality

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- Based on ISO 9001, and contains additional requirements
- "Full" quality management system includes design and development (mandatory for highest risk devices)
- "Production" quality management covers all activities except design and development

CHUE



Evolution of Quality – No Quality Efforts

Design t manufacture t distribute

र Result: product may fail र

customer complains



Evolution of Quality – Quality Control

Design & manufacture & test & discard rejects # distribute accepted product & Results: Fewer failing product are distributed, but design problems may arise & Customer complains. Manufacturer is unhappy about rejects and waste

Evolution of Quality – Quality Assurance & Good Manufacturing Practice (GMP)

Design & build quality into manufacturing steps & control manufacture † test † discard rejects Result: Fewer product rejects due to manufacturing. Manufacturer is happier, but design problems may still arise. Customer complains.

CHUE



Evolution of Quality – Quality System

Build quality into design & build quality into manufacturing † control manufacture † Test † Discard rejects ♣ Distribute accepted product ♣ Results: Better-designed products satisfy customers. Manufacturer is happy with fewer rejects and fewer customer complaints



Evolution of Quality – Quality Management Systems

Management has greater commitment to and responsibility for:

- establishing effective quality system,
- providing adequate resources
- periodically evaluating quality system
- making changes and adjustments



Summary

- Why comply with a quality management system standard?
- What is a quality management system?
- Evolution of quality practices