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# Quality Management Systems: History and Evolution

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# Introduction

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

## Why should a manufacturer comply with a quality management system standard?

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- 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

# What is a quality management system for medical devices?

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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

# Evolution of Quality – No Quality Efforts

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1. Design † manufacture † distribute  
† Result: **product may fail** †  
**customer complains**

## Evolution of Quality – Quality Control

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2. 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)

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

## Evolution of Quality – Quality System

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4. 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

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Management has greater commitment to and responsibility for:

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

# Summary

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- What is a quality management system?
- Evolution of quality practices