



Quality Management Systems: History and Evolution

**4th APEC-Funded Seminar on
Harmonization of Medical Device Regulation
Kuala Lumpur
March 5-7, 2008**

**Gunter Frey
Vice Chair SG3**

Introduction

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



What is a quality management system for medical devices?

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
- Regulatory variations (US FDA CFR 21 Part 820), Japanese MHLW Ordinance No. 169, 2004, etc.)
- “Full” quality management system includes design and development (mandatory for highest risk devices)
- “Production” quality management covers all activities except design and development



What is a quality management system for medical devices?

Quality Management System

“management system to direct and control an organization with regard to quality.

ISO 9000:2000, Clause 3.2.3.

Quality

“degree to which a set of inherent characteristics fulfils requirements”

ISO 9000:2000, Clause 3.1.1



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

- 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



Evolution of Quality – No Quality Efforts

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



Evolution of Quality – Quality Control

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)

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

- 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

Management has greater commitment to and responsibility for:

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



Summary

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

