



# **Establish Quality Management System in A Trading Company of Medical Device**

Alex Jiang

2013-06-06

# DECLARATIONS

- Information that is contained in this presentation reflects the integration of best industry practices, other than the direct copy of a specific company.
- Just share thoughts/practices in specific situation, which might not be suitable to the situation in other companies. Keep flexible!

# INTERPRETATION

*Establish*

Quality Management System

*in*

A Trading Company

*of*

Medical Device

# CONTENTS

- Functions of trading company
- What does quality mean?
- Quality management system
- Benefits?
- Key success factors
- Best practices vs. lessons learned

# FUNCTIONS OF TRADING COMPANY

- Basic functions
  - Country manager
  - Sales
  - Supply chain (incl. quality)
  - Finance
  - HR
- Extended functions
  - Marketing
  - Regulatory affairs
  - Quality assurance
  - Compliance
  - Government affairs
  - ...

# WHAT DOES QUALITY MEAN?

“**Quality** means the totality of features and characteristics that bear on the ability of a device (product) to satisfy fitness-for-use, including safety and performance”

*... wherever the term “product” occurs, it can also mean “service”.*

**➔ What does quality mean to trading company?**

# WHAT DOES QUALITY MEAN?



# QUALITY MANAGEMENT SYSTEM

A systematic approach to

- continuously meet customers' needs
- ensure safe and effective product are supplied to market
- improve efficiency

through

- clearly defined and communicated roles and responsibilities
- organic cooperation and/or independence between departments/functions

Simply, abbreviated as “QMS”



# QUALITY MANAGEMENT SYSTEM

- Standards:

- ISO 9001 (general)
- ISO 13485 (medical device)
- ISO 16949 (automobile)
- ...

- Regulations:

- 21 CFR 820 (US FDA GMP)
- 93/42/EEC (European Union)
- GMP for medical device (China SFDA)
- ...



# QUALITY MANAGEMENT SYSTEM - ISO 13485

- 4. Quality management system ✓
- 5. Management responsibility ✓
- 6. Resource management ✓
- 7. Product realization ✓
  - ~~7.1 Planning of product realization~~
  - 7.2 Customer-related processes ✓
  - ~~7.3 Design and development~~
  - 7.4 Purchasing ✓
  - 7.5 Production and service provision ✓
  - ~~7.6 Control of monitoring and measuring devices~~
- 8. Measurement, analysis and improvement ✓

# QUALITY MANAGEMENT SYSTEM – TRADING COMPANY

- General conception: Start from minimal scope and then extend
- Current focus: Quality assurance, Supply chain, Human resources
  - QA: system coordinator, quality control, PMS
  - SC: purchasing, storage, sales
  - HR: roles & responsibilities, competence & training

Open platform to accommodate or cooperate with other functions/departments

# BENEFITS?

- If QMS can make money? -> *No*
- If QMS can save money? -> *Yes*
- How to save money? -> *Reduce risks*
  - Proper control to guarantee product quality
  - Clear responsibility to shorten service time
  - Integrated process to facilitate cooperation

Do things right. Do things efficiently.

# KEY SUCCESS FACTORS

- Management supports
- Employee awareness
- Clear authorities and responsibilities
- Close collaboration between functions/departments
- Commitment to the approved/released procedures

# BEST PRACTICES VS. LESSONS LEARNED

- Case1:
  - Understand and illustrate why a QMS is critical and beneficial
  - Reason: ROI (Return of investment) is always a KPI of trading company

# BEST PRACTICES VS. LESSONS LEARNED

- Case 2:
  - Practice: Top-down approach
  - Reason: Management commitment is the key of success especially in an environment lack of quality awareness

# BEST PRACTICES VS. LESSONS LEARNED

- Case 3:
  - Practice: Continuous awareness (step-by-step)
  - Reason: We can not expect to achieve the goal within one night



# BEST PRACTICES VS. LESSONS LEARNED

- Case 4:
  - Lesson Learned: Lack of involvement of HR (key function)
  - Impact: non-HR person is required to take up HR role; disconnect the company HR policy to QMS HR section; limited effectiveness of QMS

# BEST PRACTICES VS. LESSONS LEARNED

## ○ Case 5:

- Lesson learned: Several in-parallel 'small' QMS, other than an integrated QMS covering the whole company
- Impact: Duplicate process & workload; Potential conflicts; Difficulty & high cost of later integration

# BEST PRACTICES VS. LESSONS LEARNED

## ○ Case 6:

- Lesson learned: Inexperienced or QA takes up the leadership role
- Impact: Waste of money & time; Go along the wrong way; Conflicts due to culture/background

RECAP

**Quality Management System**

**makes**

**both us and company**

**More compliant, More efficient**

THE END

THANKS  
THANKS