

# *Requirements of ISO 13485*

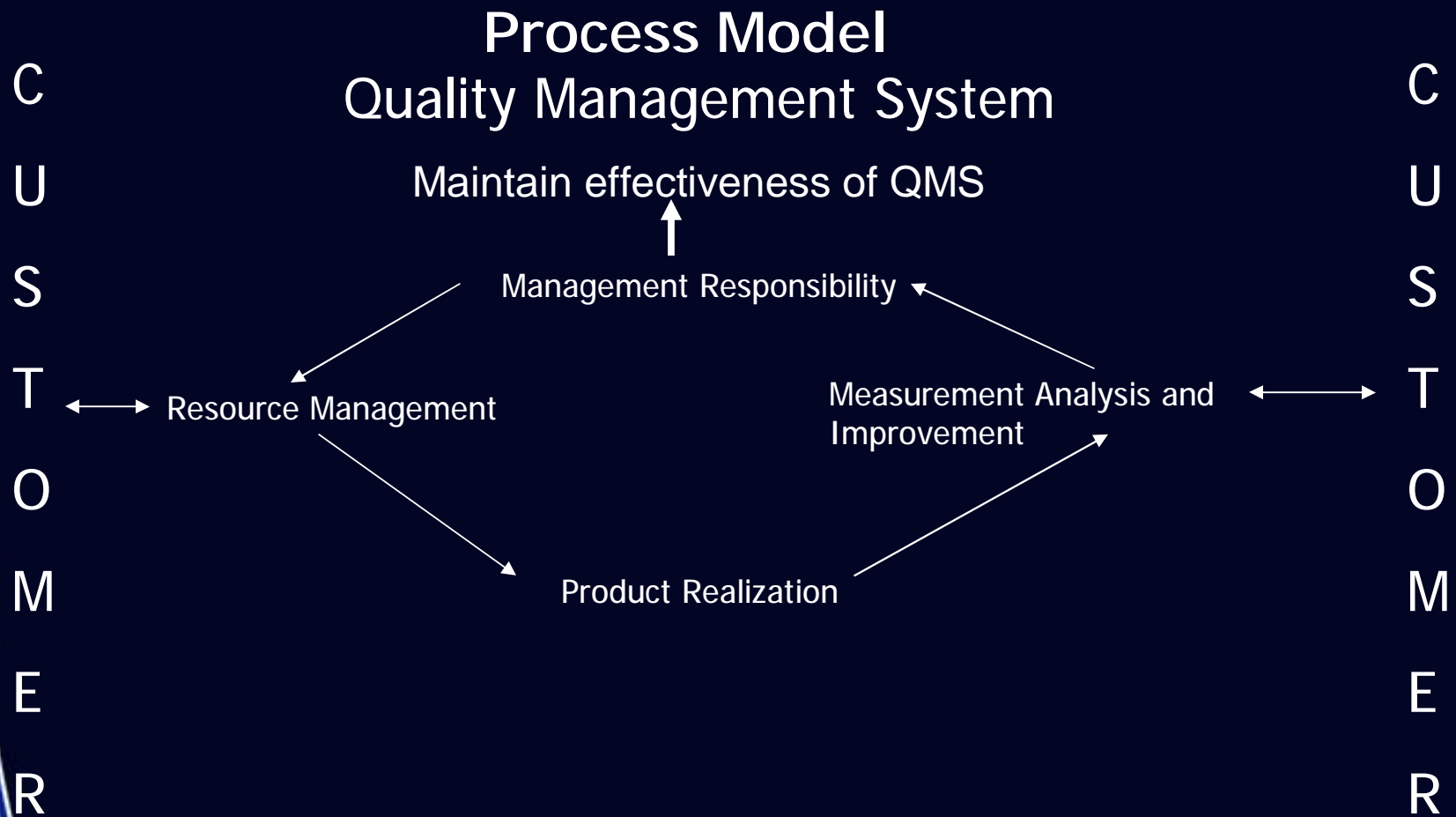
**In the following slides, the ISO 13485 Standard is paraphrased for instructional purposes. Please refer to the standard for the actual text.**

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# *What is ISO 13485?*

- ISO 13485 is a standard that represents the requirements of a comprehensive quality management system for the design and development of medical devices.
- The ISO 13485 standard was designed by representatives from many different countries
- These elements are good business practice

# *The Process Model*



## *4.2 Documentation Requirements*

- Control of Documents
  - You must have a system in place to control your documents- your quality manual, procedures and work instructions
  - Establish a process to approve documents, control the revision and distribution of the documents, and control changes to the documents
  - You must make sure that people are working from the current, correct document.

## 8.5 *Improvement*

- Establish a corrective action procedure that includes:
  - Identifying nonconformities with the quality system, product, processes
  - Handling customer complaints
  - Identifying root cause, action to take to prevent reoccurrence
  - Implementing the action and following up to determine effectiveness of the action
  - Record results of corrective action