

# Quality Management System

ISO 9000

# What is ISO 9000?

A series of standards that outline the requirements for a quality management system.

# The ISO 9000 Series

- ISO 9000 - Quality Management and Quality Assurance Standards - Guidelines for selection and use
- ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing
- ISO 9002 - Quality Systems - Model for Quality Assurance in Production and Installation
- ISO 9003 - Quality Systems - Models for Quality Assurance in Final Inspection and Test

# ISO 9000 Versus cGMP

ISO 9000

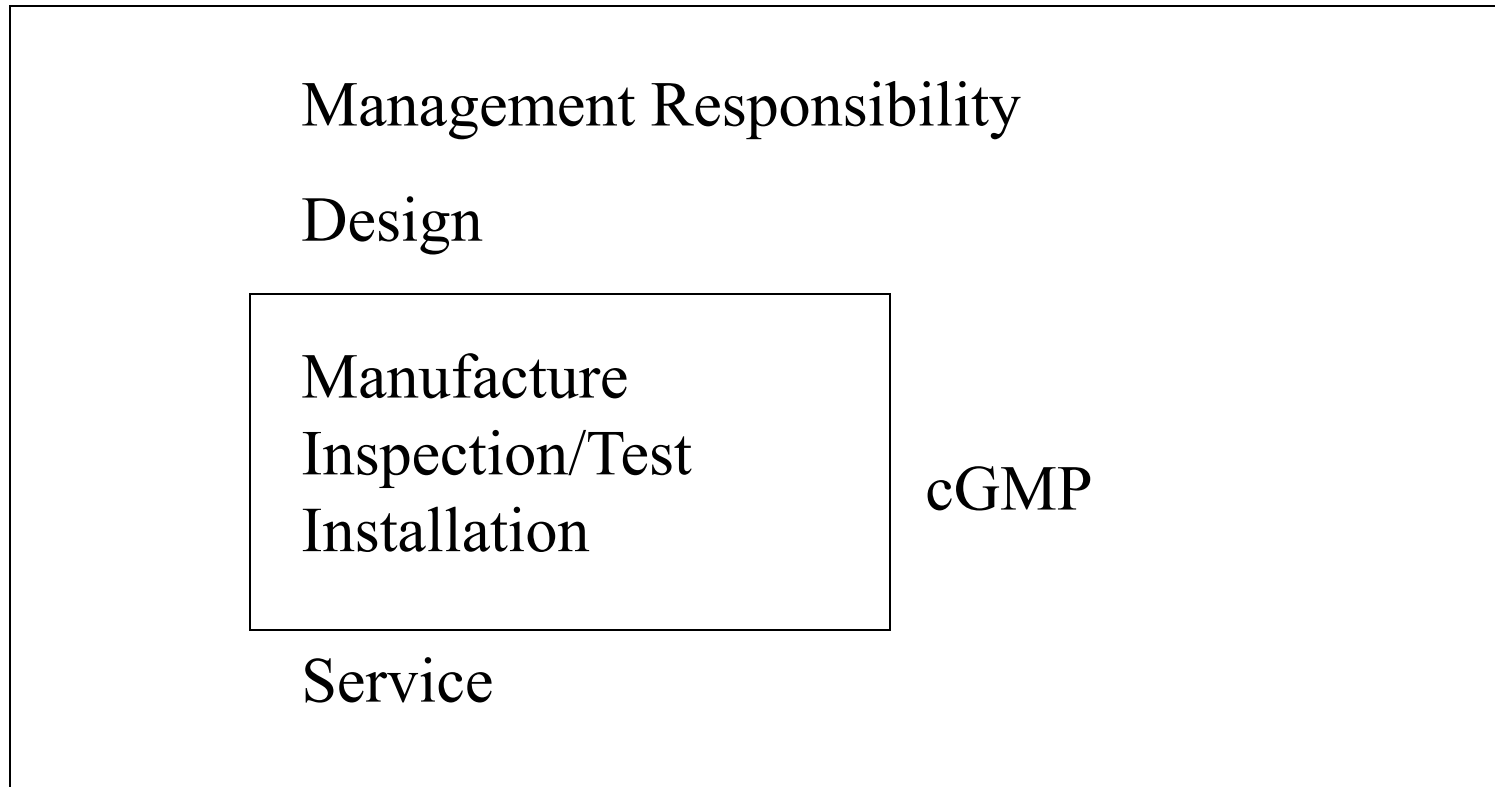
Management Responsibility

Design

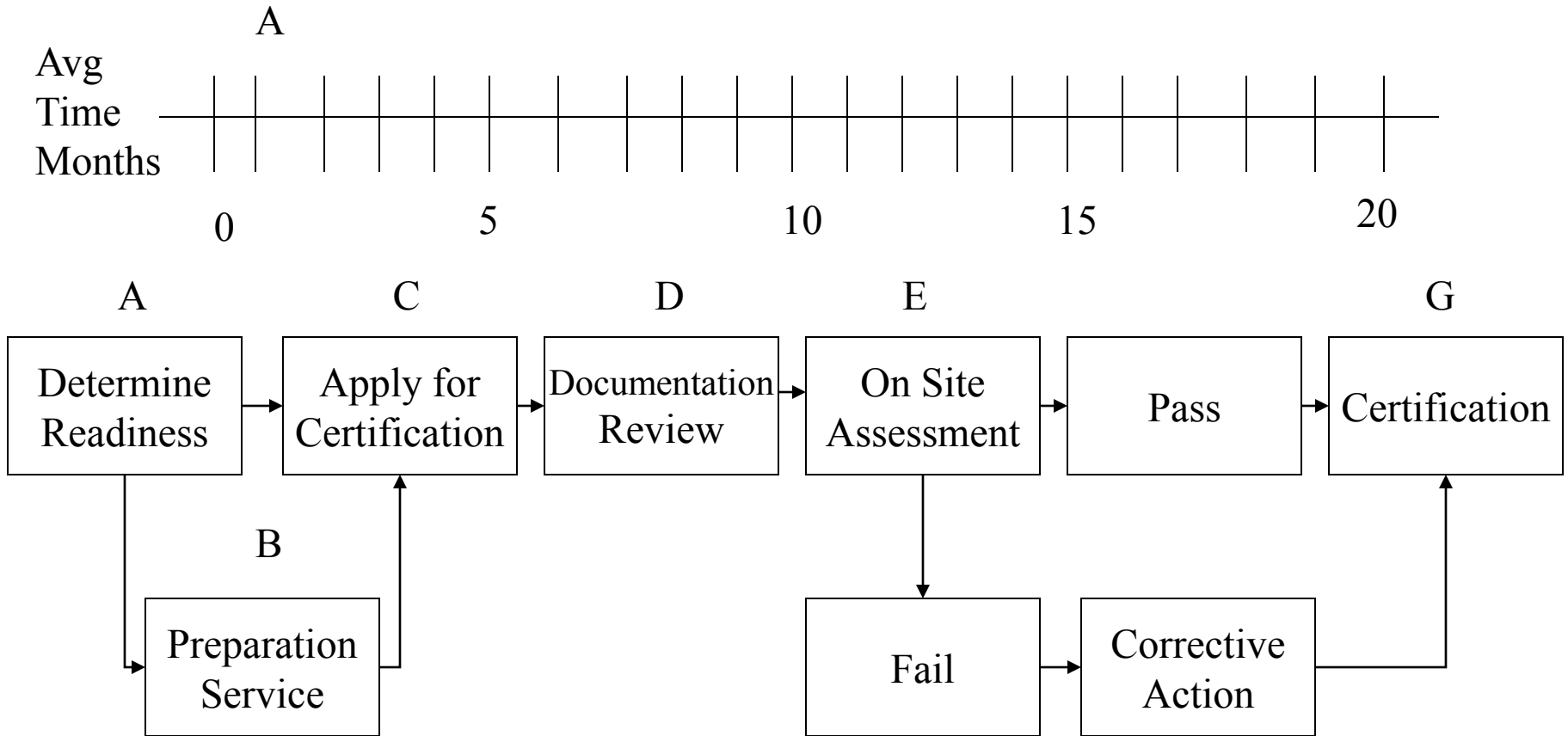
Manufacture  
Inspection/Test  
Installation

cGMP

Service



# Certification Time Line



# Certification Maintenance

- Initial Certification
- Semi-Annual Audits
- 3 -Year Recertification

# Benefits of ISO 9000 Certification and Registration

- Use of Recognized Certification Label in Marketing and Promotions
- Registered in dept of Trade and Industry Directory
  - Accessibility to EC Market
  - Visibility
- Overall Improved Competitiveness

# Elements of ISO 9001 - 4.1

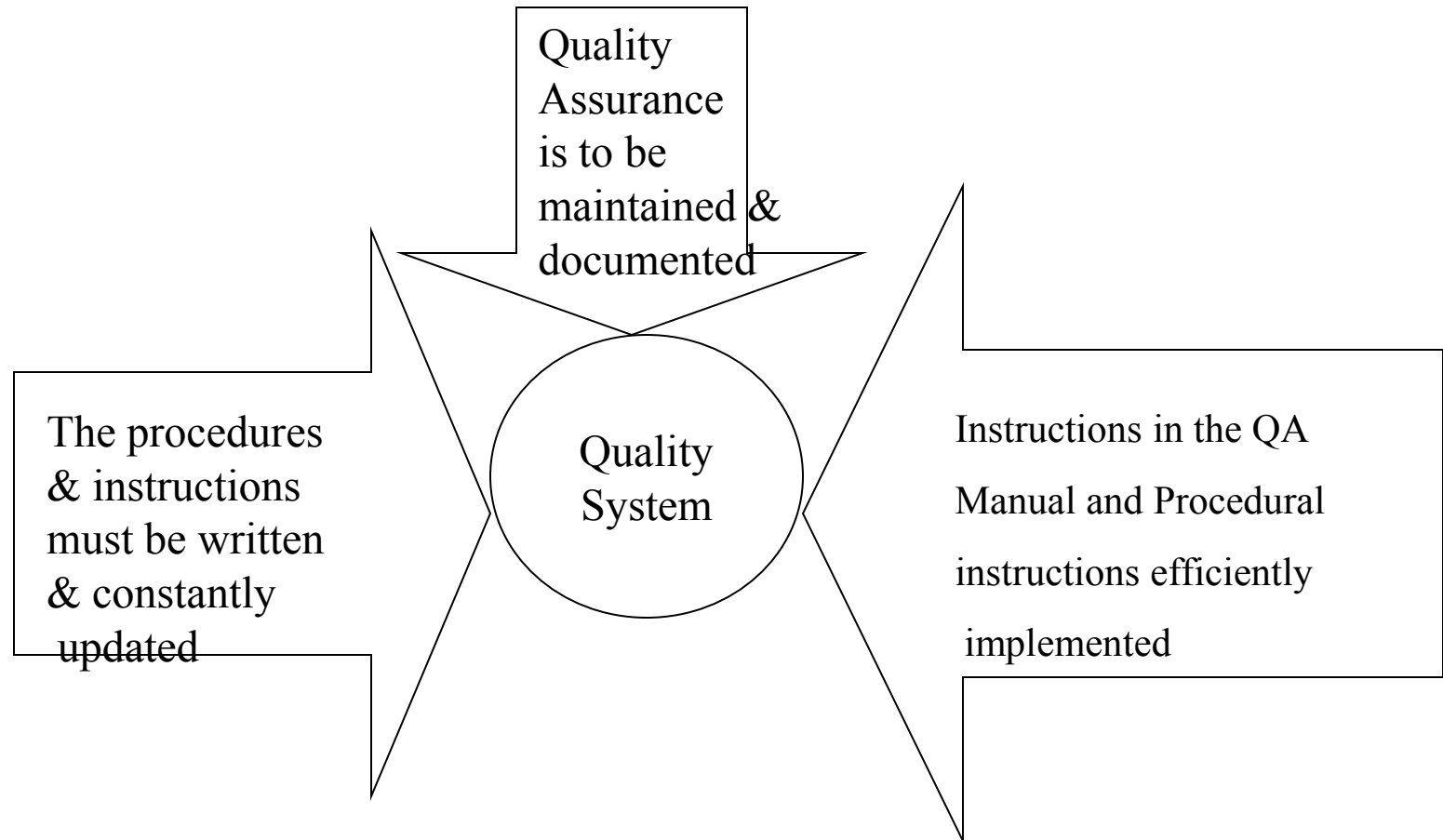
## Management Responsibilities

- Are there established quality policies & are they communicated to all employees?
- Who has the responsibility & authority for quality?
- Are people trained to perform their function?
- Are people responsible for implementing & maintaining standards?
- Is management involved with quality issues?



# Elements of ISO 9001 - 4.2

## Quality System



# Elements of ISO 9001 - 4.3

## Contract Review

- Are contracts reviewed for intent and capability?
- Are there records maintained to verify this review?
- Is there a system for resolving differences?

# Elements of ISO 9001 - 4.4

## Design Control

- Are there procedures for controlling and verifying product or service design?
- Are the design reviews performed by an independent source?
- Does the design output satisfy the design input?
- Is the design properly controlled?
- Is software design controlled?

# Elements of ISO 9001 - 4.5

## Document Control

- Who is responsible for issue & review of all documents?
- Are current documents in place, where they are needed?
- Is there a master list of documents?
- How are documents reviewed and changed?
- Is there control of temporary changes?

# Elements of ISO 9001 - 4.6

## Purchasing

- Are there specifications for all purchased goods and services?
- Is there a system to insure they conform to requirements?
- Is there a system for selection and control of suppliers?
- Are requirements clearly defined on the contracts/PO's?
- Are contracts/PO's reviewed to insure requirements listed?
- Can customers verify that the supplier meets requirements?

# Elements of ISO 9001 - 4.7

## Purchaser Supplied Product

- Is there a system for controlling materials supplied by customers?
- Is there a system for recording & reporting loss, damage and defects?