

106: Management Responsibility **Medical Devices**

(Course length: 1.0 Hours, 2 Graphics, 33 Pages)

Purpose: To learn about the role of QC in the support of manufacturing drug products

Objectives

- State the requirements demonstrating management responsibilities regarding
 - Quality Policy, Plan and Objectives
 - Organization
 - Responsibility and Authority
 - Resources
 - Management Representative
 - Management Review
 - Quality System

Topics and Activities

- 1. Introduction**
GMP opener activity
- 2. Management responsibility**
Quality policy, plan, and objectives
Organization
Responsibility and authority
Resources
Quality system
Quality system definition
Quality system regulation FDA
expectation
Management reviews
- 3. Do we have an effective quality system**
Do we have one
Is it effective
Review of quality system requirements
for management
- 4. Wrap up**
Quiz
Company problems
GMP Closer activity
Wrap up

