

106: Management Responsibility

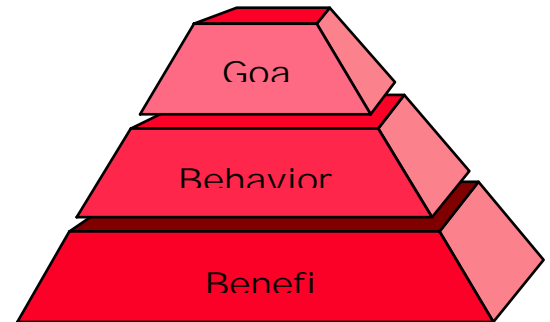
Pharmaceutical and Biotechnology

(Course length: 2.0 Hours, 19 Graphics, 57 Pages)

Purpose: To learn about the role of management in the support of manufacturing drug products and the quality system

Objectives

1. Summarize the citation trends
2. Explain the components of the quality policy
3. Explain upper management's responsibilities
4. Demonstrate setting compliance expectations
5. Explain the role of Quality Assurance in facilitating a recall
6. Describe FDA's expectations



Topics and Activities

1. Introduction

- ◆ Purpose
- ◆ Objectives
- ◆ Agenda
- ◆ *Activity: Opener*
- ◆ The Regulations
- ◆ Definitions

2. Citations Trends

3. The Quality Policy

- ◆ Goals
- ◆ Overview
- ◆ Organization
- ◆ Responsibility and Authority
- ◆ Resources
- ◆ Management Representative
- ◆ Management Review
- ◆ Quality Planning
- ◆ Quality Systems
- ◆ Consequences of Non-compliance

4. The Managerial Role

- ◆ Recall Classifications
- ◆ *Activity: Communicating Expectations*
- ◆ Discussion Overview
- ◆ Frame of Mind
- ◆ Why Compliance?
- ◆ Theme of Care and Concern

5. Responsibility and Accountability

- ◆ Feedback
- ◆ Managing Employee Resistance
- ◆ Building Cooperation
- ◆ *Activity: Feedback and Resistance*

6. Quiz

7. Wrap-Up