

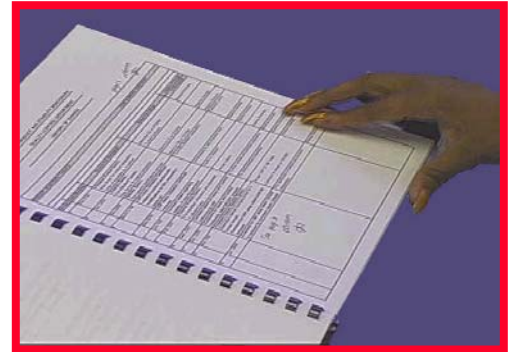
## **102: People and Procedures** **Medical Devices**

(Course length: 2 Hours, 13 Graphics, 45 Pages, \$675)

**Purpose:** The purpose of this program is to learn about the role and importance of people and procedures in assuring a quality product.

### **Objectives**

1. State the expectations for organizational structure
2. State the requirements for personnel and consultants working in plant facilities
3. State the training requirements
4. State the value, origin and need to comply with procedures
5. Describe the considerations for writing procedures
6. Explain the purpose of investigations



### **Topics and Activities:**

#### **1. Introduction and GMP opener activity**

#### **2. Organization and personnel**

- ◆ Organization chart
- ◆ Personnel training
- ◆ Training audit
- ◆ Consultants and contractors
- ◆ Staffing

#### **3. Standard operating procedures**

- ◆ SOPs Defined
- ◆ Quality Assurance responsibility
- ◆ Titling procedures
- ◆ General format
- ◆ Writing guidelines
- ◆ Writing, revisions, review, and approval
- ◆ Review frequency
- ◆ Activity: Writing Procedures
- ◆ Optional Activity: House Building

#### **4. Investigations**

- ◆ Investigation overview
- ◆ Deviation investigation
- ◆ Investigation documentation
- ◆ Returned product investigations
- ◆ Complaint investigations

#### **5. Wrap up**

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer activity
- ◆ GMP wrap up activity
- ◆ Change history

#### **6. Glossary**