

103: Contamination Control **Medical Devices**

(Course length: 2 Hours, 13 Graphics, 34 Pages, \$600)

Purpose: To learn about our personal roles and responsibilities in assuring a pure and safe product.

Objectives:

1. Explain personal responsibilities in controlling contamination
2. Explain how personal hygiene practices control contamination: hygiene, clothing, restroom, and clean room practices
3. Explain the role of cleaning procedures: SOPs, documentation, logs, and trash
4. Explain the role of cleaning documentation practices



Topics and Activities:

1. Introduction and GMP opener activity

2. Regulatory issues

3. Sources of contamination

- ◆ Plant food rules
- ◆ Live sources
- ◆ Personal contamination rules
- ◆ Contamination categories
- ◆ Activity: *Contamination Sources*
- ◆ Penicillin contamination

4. Personal hygiene

- ◆ Aseptic or clean room activities
- ◆ Rest rooms and hand washing
- ◆ Illness and lesions
- ◆ Clothing to be worn

5. Environmental monitoring

- ◆ What gets sampled and tested
- ◆ Sampling and testing issues
- ◆ Major influences

6. Cleaning

- ◆ Procedures
- ◆ Level of equipment cleaning
- ◆ Work space cleaning
- ◆ Refuse and trash

7. Documentation

- ◆ Major and minor equipment
- ◆ Logs

8. Wrap up

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

9. Glossary