

# Staff Training

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April 5, 2006



# CFR Requirements

- 21 CFR 211.25(a)
  - Each person engaged in the manufacture, processing, packing or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned function
    - Specific operations (procedures/protocols)
    - GMP

# CFR Requirements

- 211.25(a)
  - Training in cGMP shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them

# CFR Requirements

- 211.25 (b).
  - Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training and experience to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that is purports or is represented to possess.

# Definition of personnel

- Directly involved in manufacturing product
- Laboratory support personnel
- Laboratory Medicine (testing)
- Facilities
- Housekeeping
- Shipping and Receiving
- Human Resources

# Staffing Process

- Identification (job description)
- Screening/selection (interview)
- Orientation
- Training
- Competency – proficiency
- Re-evaluation/feedback

# Job Description

- Identify Personnel
  - Skills
  - Experience
  - Education
- Identify expectations
  - Tasks
  - Responsibilities
  - Output
- Identify Conditions
  - Salary
  - Organizational chart
  - Environmental

# Levels of GMP Training

- Orientation
- Job-Specific duties
- Continuous education



# Orientation training

- Keep it simple stupid (KISS)
- Videos
  - Institutional policies
  - Department videos with lab personnel
- Self- study
  - SOPs
- Interactive sessions
- cGMP/cGTP Training

# Job specific Training

- Modular format
  - 30-40 minutes each dealing with specific topics or specific SOPs
- Case studies
  - Deviations
- Interactive
- Games

# Job Specific Training

- Training Program (plan)
- Be specific and detailed
- Allow time for questions
- Observation/Supervised performance
- Evaluate competency
- Evaluate training program

# GMP Training Requirements

- Description of training
- Time
- Trainer
- Trainee
- Date
- Documentation of all of it

# How do you document training

- Checklists
- Sign-in sheets
- Quizzes
- Certificates

# **TRAINING OBJECTIVES**

**Procedure 12.22.3: Operation and  
Maintenance of the Sebra Sealers**

# Goals of Training

Employee: \_\_\_\_\_

Training Start Date: \_\_\_\_\_

**Goal:** To be able to heat seal tubing properly and perform the required maintenance.

## **Required Reading:**

Operation and Maintenance of the Sebra Sealers

Review/Initials \_\_\_\_\_ Date: \_\_\_\_\_

Manufacturer's Instruction Manual

Review/Initials \_\_\_\_\_ Date: \_\_\_\_\_

# Objectives:

Upon completion of the training employee will be able to:

| Task  | Discussed/Observed<br>Initial and Date |        | Performed<br>Initial and Date |            |
|---|--|--------|-------------------------------|------------|
|   | Employee                               | Mentor | Employee                      | Supervisor |
| Demonstrate an understanding of the procedure by explaining the principle of operation. |  |        |                               |            |
| Perform 3 successful tubing seals.  |  |        |                               |            |
| Explain the troubleshooting steps in case of tubing leak.                               |  |        |                               |            |
| List 1 example of each tubing size (small, medium, large).                              |  |        |                               |            |
| Perform the weekly & as needed maintenance.   |  |        |                               |            |

Processed products or other supportive documents (if applicable):

BMT# / Date:

BMT# / Date:



# Acknowledgement of Training

## **Employee Statement of Competence:**

I have read and understood the above objectives and am competent to perform the procedure indicated.

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## **Supervisor Statement of Competence:**

This employee has been instructed in the above objectives and is competent to perform the procedure as indicated.

Supervisor Signature:

\_\_\_\_\_ Date: \_\_\_\_\_

# Competency

- Retraining
  - Continuing education
    - Staff are responsible for keeping it up to date
    - Supervisor reviews on a monthly basis
  - Update reading list and SOPs
  - Mandatory Training
    - Safety
    - Biohazard

# Ongoing Training

- Case studies
- Modular
- Fun time
  - Games
  - Puzzles
  - Bulletin Boards

# How do you document competency

- Direct observation of performance
- Quizzes
- Review of procedures
  - Results
  - QC
- Review track record
  - Safety issues
  - Problems

# Support staff

- Facilities
- Environmental Monitoring
- Housekeeping
- Human resources
- Shipping and receiving
- Emergency services

# Support Staff

- Internal or External?
- Internal Benefits
  - Know the people
  - Cost
  - Can respond quickly to emergency
- Internal Disadvantages
  - Understanding of cGMP requirements
  - Advisory capacity
  - A little reading can be dangerous...

# Support Staff

- Tours
- Informal lectures
- Interdepartmental meetings periodically
- Worked hard to make them feel part of the team
  
- Threats

# Challenges for Training In Cell Therapy Product Manufacturing

- Supervisory and senior personnel have limitations on their time
- Procedures are complex
- Source material not available for training
- Reagents and supplies are expensive



# Conclusion

- Continuous Education
- Continuous Partnerships
- Continuous Monitoring