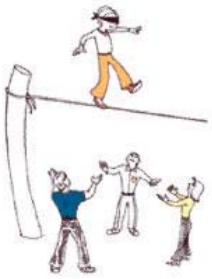
Staff Training & Competency

GTP Regulations: 21CFR Part 1271.170

- Sufficient personnel to ensure compliance
- Necessary education, experience and training to ensure competent performance of assigned functions
- Train (and retrain as necessary) all personnel to perform assigned responsibilities adequately

GMP Regulations: 21 CFR Part 211.25

- Each person engaged in manufacturing or processing shall have education, training and experience (or combination thereof) to perform assigned functions.
- Training shall be in particular operations performed and in cGMP practice
  - Conducted by qualified individuals
  - Continuing basis & sufficient frequency



General Training Program

- Basic GMP operations
  - Facility overview
  - Standard Operating Procedures
  - Worksheets/Batch Records
  - Laboratory behaviors

Facility Overview

- Description of Center and its purpose
- Types of Products made and their critical nature
- Regulatory oversight GMP vs. GTP
- Specialized way of manufacturing
- Importance of documentation

Standard Operating Procedures

- Their purpose, scope, structure, release and review
- Associated worksheets and batch records
- Access to SOPs & worksheets
- How staff are trained
- Variance and Incident reporting

Worksheets & Batch Records

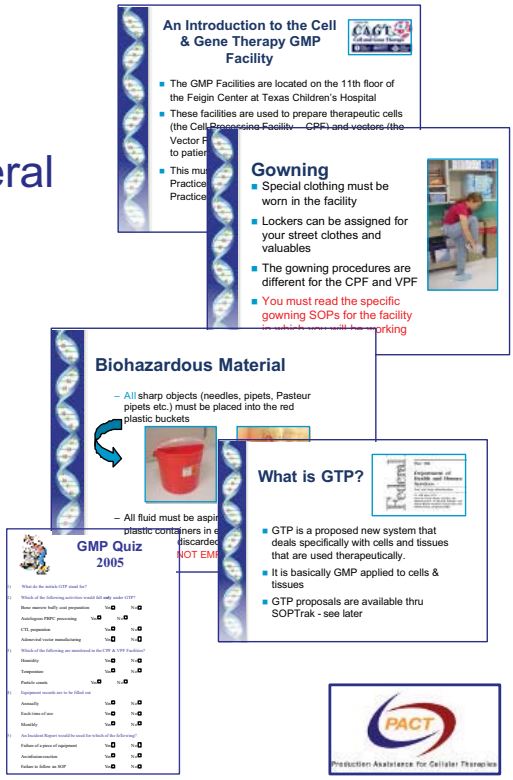
- How they are used
- Importance of completion
- Corrections and change management
- Associated records (C of A etc.)
- Review process
- Product release systems

Laboratory Behavior

- Gowning & degowning
- Eating & drinking
- Cosmetics, contact lenses etc.
- Protective equipment
- Safety & accidents
- MSDS
- Changeover procedure

Training Mechanisms

- Training Manual
  - Floorplans, copies of general SOPs etc.
- On-line training programs
  - GMP and GTP
  - Working in the Facilities
  - Tissue culture
- Quizzes (80% to pass)

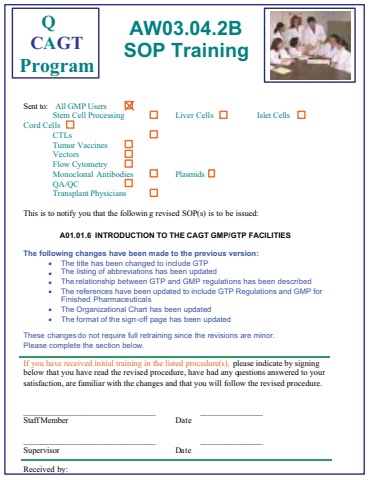


Initial SOP Training

- SOP for Training
- Prospective & Retrospective
  - Retrospective – documents previous experience
  - Prospective
    - Read SOP & review with supervisor
    - Observe procedure
    - Perform under supervision
    - Take quiz
- Reviewed by QA and filed

Retraining

- Annually – usually at SOP review or change
- Training notice sent with SOP renewal/change announcement
  - Lists changes (if any)
  - Confirms training is current
  - Confirms changes understood
  - Requires retraining
- Co-signed by supervisor & QA
- Copy to training records



Q CAGT Program

AW03.04.2B SOP Training

Sent to: All GMP Users ☒ Stem Cell Processing ☐ Liver Cells ☐ Islet Cells ☐ Cord Cells ☐ CTLs ☐ Tumor Vaccines ☐ Vectors ☐ Flow Cytometry ☐ Monoclonal Antibodies ☐ Plasmids ☐ QA/QC ☐ Transplant Physicians ☐

This is to notify you that the following revised SOP(s) is to be issued:

A01.01.6 INTRODUCTION TO THE CAGT GMP/GTP FACILITIES

The following changes have been made to the previous version:

- The title has been changed to include GTP
- The listing of abbreviations has been updated
- The relationship between GTP and GMP regulations has been described
- The references have been updated to include GTP Regulations and GMP for Finished Pharmaceuticals
- The Organizational Chart has been updated
- The format of the sign-off page has been updated

These changes do not require full retraining since the revisions are minor. Please complete the section below.

If you have received initial training in the listed procedure(s), please indicate by signing below that you have read the revised procedure, have had any questions answered to your satisfaction, are familiar with the changes and that you will follow the revised procedure.

Staff Member _____ Date _____

Supervisor _____ Date _____

Received by:

Training Binders

- For each staff member
- Include:
  - Job description
  - Curriculum vitae
  - Hepatitis/TB information
  - Color blindness test
  - Training records
  - Competency/Proficiency testing
  - Continuing education records
  - Universal precautions, fire & chemical safety

Competency & Proficiency

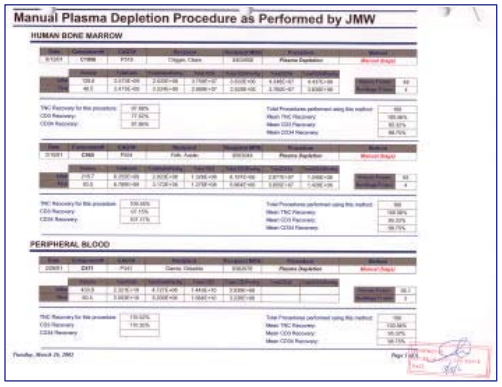
- Competency
  - The ability to perform procedures within acceptable limits of accuracy
- Proficiency
  - The ability to perform a task on which the person has been trained, and routinely achieve the expected results

Proficiency Testing

- External agencies
  - CAP, Stem Cell Technologies,AAB
- Hematology, CFU, CD34
- Devise collaborative program
- 3-4 times/year
- Perform testing as per SOP
- 80% benchmark

Competency Testing

- Annually or if evidence of problems
- Ability to achieve results indicated in SOPs
- Analyze aggregate data for procedure
- Compare results from each staff member
- Retrain if necessary


Manual Plasma Depletion Procedure as Performed by JMW

HUMAN BONE MARROW

PERIPHERAL BLOOD

Take Home Messages

- A comprehensive training program is required by GMP & GTP regulations
- Documentation is ALWAYS examined during an audit
- Training Programs generates a lot of data! Electronic tracking is useful
- Only limited proficiency testing is available – do something!
- Develop internal competency testing systems