

# Staff Training & Competency



## GTP Regulations: 21CFR Part 1271.170

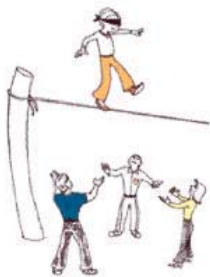
- Sufficient personnel to ensure compliance
- Necessary education, experience and training to ensure competent performance of assigned functions
- Train (and retrain as necessary) all personnel to perform assigned responsibilities adequately





# 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)

**An Introduction to the Cell & Gene Therapy GMP Facility**

- The GMP Facilities are located on the 11th floor of the Feigin Center at Texas Children's Hospital
- These facilities are used to prepare therapeutic cells (the Cell Generative Facility—CGF) and vectors (the Vector Facility—VPF) to patient
- This manual provides Practice

**Gowning**

- Special clothing must be worn in the facility
- Lockers can be assigned for your street clothes and valuables
- The gowning procedures are different for the CPF and VPF
- You must read the specific gowning SOPs for the facility in which you will be working

**Biohazardous Material**

- All sharp objects (needles, pipets, Pasteur pipets etc.) must be placed into the red plastic buckets
- All fluid must be aspirated into plastic containers in the red buckets

**What is GTP?**

- GTP is a proposed new system that deals specifically with cells and tissues that are used therapeutically
- It is basically GMP applied to cells & tissues
- GTP proposals are available thru SOPTrak - see later

**GMP Quiz 2005**

What do the words GMP stand for?

What do the following activities entail (all are made 100%)

Blue rooms (cell prep)	100	100
Autoclave (WIP) processing	100	100
CTP processing	100	100
Manufacture manufacturing	100	100
Occupation	100	100
Product control	100	100
Quality	100	100
Equipment maintenance and calibration	100	100
Facility housekeeping	100	100
Quality	100	100
Facility of safety	100	100
Quality	100	100
Facility of safety of equipment	100	100
Facility maintenance	100	100
Facility maintenance	100	100
Facility maintenance	100	100

**PACT**  
Production Assistance For Cellular Therapies

## 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

**PROSPECTIVE AND RETROSPECTIVE TRAINING DOCUMENTATION**

Form # 10 (REV 01/04)

NAME: \_\_\_\_\_

DATE: \_\_\_\_\_

REVIEWED BY: \_\_\_\_\_

DATE: \_\_\_\_\_


**REQUIREMENTS**

REQUIREMENT	DATE	STATUS	REMARKS
Read SOP & review with supervisor	10/10/05	Completed	
Observe procedure	10/10/05	Completed	
Perform under supervision	10/10/05	Completed	
Take quiz	10/10/05	Completed	

**EXAMPLE**

# 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**

<b>Q</b> <b>CAGT</b> <b>Program</b>	<b>AW03.04.2B</b> <b>SOP Training</b>	
Send to: All GMP Lines <input checked="" type="checkbox"/>	<input type="checkbox"/> Liver Cells	<input type="checkbox"/> Islet Cells
Send to: Stem Cell Processing <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Cord Cells <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: CTLs <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Tissues/Vaccines <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Vectors <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Flow Cytometry <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Monoclonal Antibodies <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: QA/QC <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Send to: Transplant Physicians <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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									
WJW01	WJW02	WJW03	Origin Class	WJW04	Plasma Depletion	WJW05	WJW06	WJW07	WJW08
100.0	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08
40.0	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08
The Recovery for this procedure					Total Procedures performed using this method				
CD34 Recovery					Mean % Recovery				
87.8%					99.9%				
87.8%					99.9%				
87.8%					99.9%				

PERIPHERAL BLOOD									
WJW01	WJW02	WJW03	WJW04	WJW05	WJW06	WJW07	WJW08	WJW09	WJW10
100.0	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08
40.0	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08	2.00E+08
The Recovery for this procedure					Total Procedures performed using this method				
CD34 Recovery					Mean % Recovery				
87.8%					99.9%				
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87.8%					99.9%				

Procedure: Manual PB, 2002 Page 1/2



## 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

