

# Effective Training for Cell Therapy Laboratories

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# Training

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## □ Personnel

- Biggest resource of an organization
- Reflect the quality of an organization
- Key to an organization success

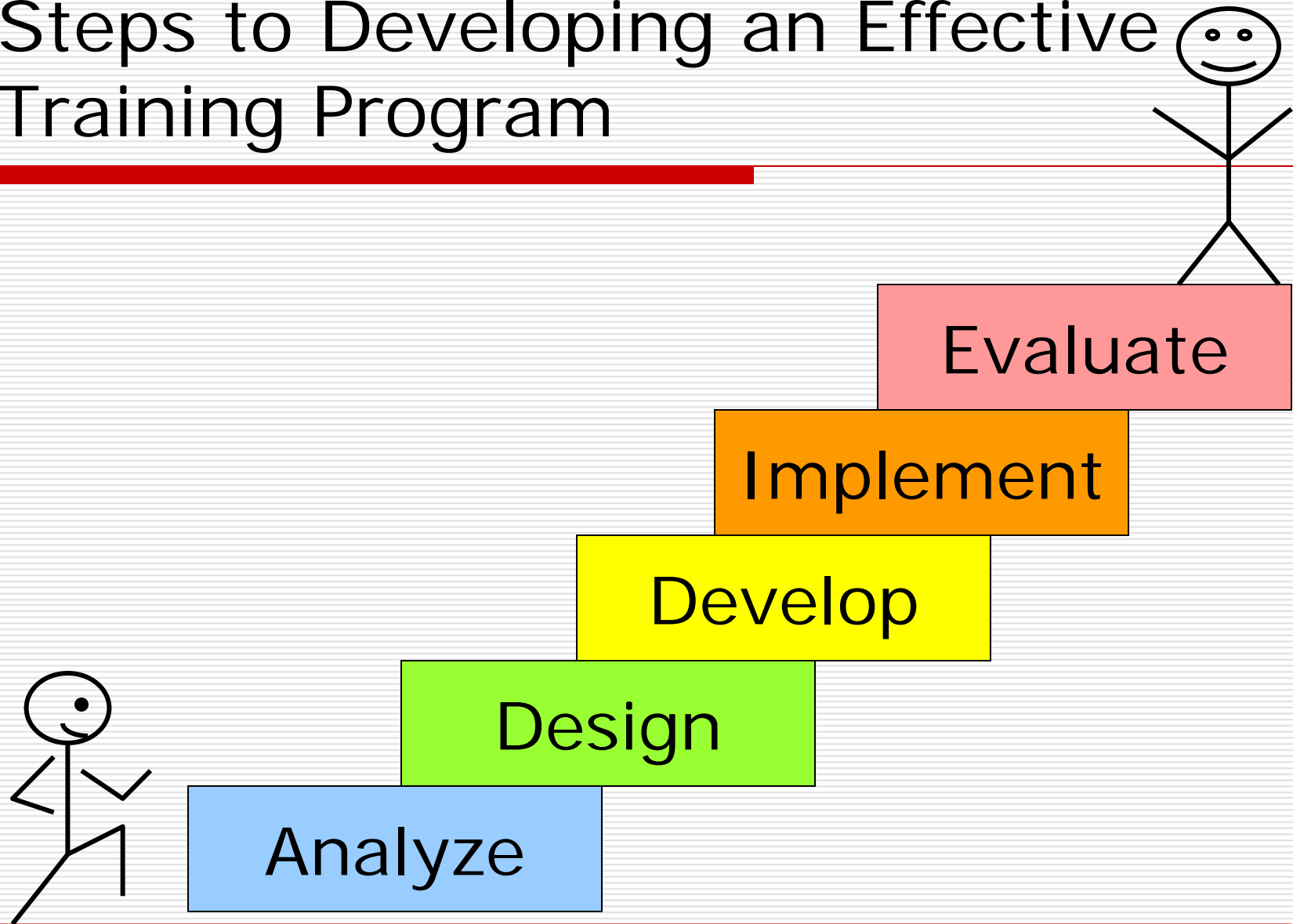
## □ A well designed training program leads to

- Employee satisfaction
  - Increased productivity
  - Retention
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# Steps to Developing an Effective Training Program

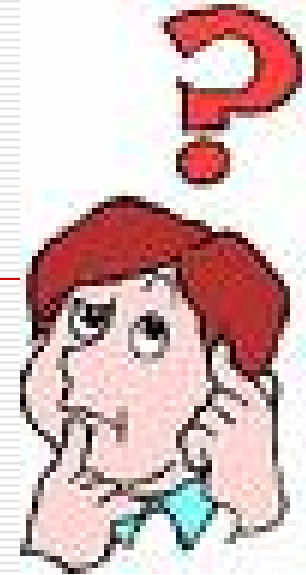
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# Analyze Training Needs

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- Evaluate job task
  - Job description
- Regulations
- Key learning
- Organization requirements



# Job Description

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- Identifies the experience, skills and educational background necessary to perform the job.
  - Specifies the expectations, responsibilities and conditions of employment.
  - Employees must be trained and evaluated to the duties identified in the job description
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<b>Clinical Manufacturing Scientist</b>	
<b>Core Competencies</b>	<b>Knowledge, Skills and Abilities Needed</b>
<p>Performs a wide variety of complex biologic processing and quality control testing</p> <ul style="list-style-type: none"> <li>• Functions independently in performing a wide variety of complex biologic manufacturing and testing</li> <li>• Performs biologic manufacturing procedures including: positive and negative cell selection, mononuclear cell separation, cell depletion or purification, cryopreservation, cell culture, vaccine preparation, cell activation, expansion and retroviral transduction.</li> <li>• Operates laboratory instrumentation and information systems</li> </ul>	<p>Knowledge of cell biology.            Demonstrates aseptic techniques            Ability to operate variety of lab equipment            Working knowledge of instrumentation and ability to take corrective action.</p>
<p>Recognizes problems and takes appropriate measures to resolve them.</p> <ul style="list-style-type: none"> <li>• Acts as a resource for problem solving, corrective action and troubleshooting for procedures and unexpected events</li> <li>• Initiates proper safety or emergency responses.</li> <li>• Consults with management if unable to resolve issues.</li> </ul>	<p>Knowledge of safety protocols,            Knowledge of emergency and other relevant policies and procedures.            Problem solving skills            .</p>
<p>Evaluates testing results and processes for accuracy and appropriate intervention.</p> <ul style="list-style-type: none"> <li>• Determine if test results or process fall within normal parameters and reporting protocols.</li> <li>• Correlates data based on clinical knowledge, technical expertise and other conditions affecting test results or process outcome.</li> <li>• Takes appropriate action to recheck abnormal, discrepant, or unexpected results.</li> <li>• Directly communicates abnormal and critical results to appropriate parties</li> </ul>	<p>Critical Thinking</p> <p>Knowledge of laboratory testing and significance cell therapy.</p> <p>Knowledge of relevant factors which can influence testing results.</p>
<p>Demonstrates understanding of and commitment to Quality Assurance, Performance Improvement and Compliance Programs</p> <ul style="list-style-type: none"> <li>• Documents deviations and action taken.</li> <li>• Recognizes and communicates values and trends that exceed the QC decision levels. Takes action to resolve and consults with supervisor as needed.</li> <li>• Documents compliance with regulations of governmental or voluntary regulatory agencies</li> <li>• Collaborates with the customers to promote customer satisfaction.</li> </ul>	<p>Knowledge of policies and procedures that are based on FDA, AABB, FACT, CAP standards, as appropriate to the work setting.</p> <p>Knowledge of quality assurance principles and practices.</p>

# FDA/AABB/FACT

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- GMPs 21 CFR 211.25
    - Personnel must have necessary education, experience or combination thereof to perform assigned functions.
    - Training shall be in assigned function & GMPs
    - GMP Training on a continuing basis
  
  - GTPs 21 CFR 1271.170
    - Necessary education, experience & training to ensure competent performance
    - All personnel must be trained and retrained as necessary
  
  - AABB/FACT
    - Policies & procedures for training
    - Trainer qualifications
    - Annual competency
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# Master Training List

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- ❑ Orientation – HIPAA/HR issues/General Lab policies
- ❑ Safety – Fire/Chemical/Disaster
- ❑ Technical Processes
- ❑ GMP/GTP
  - Aseptic Processing
  - Facility Design
  - Equipment Management
  - Environmental Monitoring
  - Supplies & Containers
  - Quality Assurance Unit
  - Process Controls
  - Donor Eligibility
  - Labeling
  - Product packaging
  - Document Control
  - Product Testing and Release
  - Storage
  - Deviations
  - Recordkeeping
  - Complaints
  - Adverse Events
  - Distribution





# Training Plan

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- Scope
  - Types of training (technical, safety, GxP)
  - Responsibilities
  - Personnel to be trained
  - Timeframe for training (initial & ongoing)
  - Role and responsibility of Quality Unit
  - Learning plans and development process
  - Qualification of instructors
  - Documentation and record retention
  - Learning assessments & corrective plan
  - Program evaluation
  - Reports to management
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# Technical Training: Lesson Planning

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*What makes a lesson complete?*

- Introduction
  - Core
  - Conclusion
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# Lesson Planning: Introduction

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- Motivation
    - Why trainees need to learn
    - Tailor lesson to individual's skills
  - Objectives
    - Performance goals
    - Means for evaluation
  - Overview
    - Main ideas and lesson structure
  - Review of past
    - Trainee reminded of what they know and how to use those skills
  - Agenda
    - Lesson schedule
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# Lesson Planning: Core training

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- Information
    - Gather & compile in logical sequence
  - Demonstration
    - Showing the trainee an application of knowledge
  - Practice
  - Feedback & Refinement
    - How well did they perform
    - Identify improvements
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# Instructional Tools

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- Reading Materials
    - SOP
    - Journals
    - On line presentations (AABB,NIH,ISCT,FDA)
  - Multimedia
    - Videos/CD
    - Self –Directed Training Modules
      - American Association of Blood Banks (aabb.org)
    - Video/Digital pictures of SOP
  - Mock products
    - Leftovers from buffy coat
    - Purchased cells
      - [www.lonza.com](http://www.lonza.com)
      - [www.progenitorcelltherapy.com](http://www.progenitorcelltherapy.com)
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Training: Beckman 300 Series pH Meter

Objective	Date Completed	Instructor
1. Review MCT3-636 with instructor		
2. Check level of saturated KCL and add more if needed		
3. Successfully standardize pH meter 3 times using standardization buffers		
4. Successfully perform pH analysis on 3 different samples		

Competency Questions:

1. How do you check the level of saturated KCL? What will result if level of KCL is not adequate?
2. Perform standardization procedure three times. Record results below.
3. What is the acceptable slope value for standardization? What action should be taken if slope value is out of range.
4. What is the usual pH resolution setting?

Training Objectives Met and Competency Questions Completed  
Successfully YES / NO

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

# Lesson Planning: Conclusion

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## Summary

- Reconstruct
- Recall
- Integrate

## Evaluation

- Assess the trainees ability to meet established objectives
  - Assess the effectiveness and value of the training program
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# Competency

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- ❑ Specific to job description
  - ❑ Emphasis placed on assessing those areas that are high risk, most critical to product safety, prone to mistake
  - ❑ Frequency
    - Initial
    - 6 months of employment (CAP)
    - Annually
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# Competency Measurements

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- ❑ Direct Observation of procedure, intermediate and final test results
- ❑ Daily performance – QC records, deviations, equipment PM
- ❑ Proficiency Testing
  - Interlab samples – hematology/Flow
  - CAP – Flow, Heme, (New) PBPC products
  - StemCell Technologies - CFU
- ❑ Written/Oral Exams



**TRAINING & COMPETENCY DOCUMENTATION,  
CORD PROCESSING I**

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

Observer Signature: \_\_\_\_\_

SKILL	Date Procedure Read / Reviewed	Training Date(s) Trainer/Tech Initials	Performance Observed Date, Trainer/Tech	Competency Level Achieved	Comments/ Follow Up Actions
Transfer of blood from collection to transfer bag				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Addition of Hetastarch				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Balance bags in centrifuge (inverted)				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Prepare syringes & tubes for post counts				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Prepare paperwork for file, (Reagent List, etc)				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
First incubation & spin - inv, 45 min, 4°, 420 rpm				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Calculate amount of red cells to deplete				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Drain off red cells				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Second centrifugation – upright, 1200 rpm, 13 min				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Express plasma, 5 ml plasma, 3 ml rbc				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Remove final product with 60 ml syringe				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Place 10 drops in plastic aliquot tube				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Document volumes on processing sheet				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Prepare 1 ml freezing cocktail per 4 ml product				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Order cultures and mom IDMs				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	

- 1 discussed / read – individual is only responsible for being aware of policy/procedure and understanding its role within the scope of the program
- 2 observed – the procedure has been demonstrated to the individual while being performed by another
- 3 performed / competent – the individual has met the objectives of a task and has demonstrated the ability to perform those tasks consistently and proficiently
- 4 competent with expertise – individual is able to train other employees

EMPLOYEE SIGNATURE: \_\_\_\_\_

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

# Corrective Action

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- ❑ Identify the problem
- ❑ Root cause
  - Clear instructions
  - Knowledge issue
  - Technical error
  - Documentation error
- ❑ Corrective action plan
  - Re-read
  - Review
  - Retrain
  - Re-test
  - Reassign



# Improving the Process

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- Continuing process improvement:
    - Scheduled review of the training & competency program
    - Review regulatory changes, institutional policies and organizational changes
  
  - Feedback from Trainee and Trainer
    - What worked? What didn't?
    - Was training adequate?
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# Records

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Keep on file:

- Job descriptions for all job classes
  - Employees
    - Resumes, curriculum vitae
    - Relevant degrees as required by job description
    - Training Records: initial, ongoing
    - Safety Training (annual)
    - Continued Education
    - Annual Competency
  - Keeping Track of Everyone
    - Database
    - Individual notebooks
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# Training & Competency Resources

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- ❑ Lee, C. *Personnel Training and Competency*. *Cytotherapy*, 1999: Vol.1, pp493-508.
  - ❑ ISCT cGMP Workshop, Orlando, FL, Dec 2003.
  - ❑ Kelly, L., editor. *The American Society for Training and Development (ASTD) Technical and Skills Training Handbook*. New York, 1995.
  - ❑ Yelon, S., and Sheppard, L., *Instant Lessons*. *Performance Improvement Quarterly*, 1998: Vol. 11, pp15-20.
  - ❑ ISCT
  - ❑ AABB
  - ❑ American Society for Quality (asq.org)
  - ❑ National Committee on Clinical Laboratory Standards (nccls.org)
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