

**Production Assistance for
Cellular Therapies**

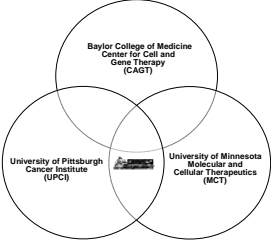
Welcome to the

**Educational Web Seminar
“Effective and Result-based Training”**


**November 06, 2008
12:00 Noon - 1:00 PM ET**

PACT

A National Heart Lung and Blood Institute-funded initiative



- PACT manufactures quality cell therapy products on behalf of investigators with funded clinical trials requiring support in product development
- PACT's educational training focuses on three general areas: translational development/scale-up and manufacture of cell therapy products, quality assurance, and regulatory issues
- Workshops (onsite)
- Web Seminars

 National Heart Lung and Blood Institute

**Today's Education Web
Seminar**

“Effective and Result-based Training”

Larry Midgett, PhD
National Seminars Group

Diane Kadidlo, MT ASCP SBB
University of Minnesota

The presentation slides for this web seminar
are available publicly on the main page at:
www.pactgroup.net



Web Seminar

Description

Effective training, organizational techniques, and measurements of success that could be implemented across any discipline will be presented. An overview of GMP requirements for training and a training session example that has been used in the GMP cell processing laboratory will be discussed.

Objectives

- Learn how to select and use appropriate training resources and activities to facilitate training
- Learn to select and arrange crucial information in a logical order that will ensure the transfer of learning
- Learn to assess competency adequately and evaluate the effectiveness of your training



Faculty Disclosure Information

Faculty	Disclosure	Nature of Relationship	Manufacturer/Provider
Diane Kadloff	None	PACT member	University of Minnesota
Larry Midgett	None	non-PACT member	National Seminars Group
Lisa Davis	None	PACT member	The EMMES Corporation
Nathan Kassalow	None	PACT member	The EMMES Corporation
Karin Quinnan	None	PACT member	The EMMES Corporation
David Styers	None	PACT member	The EMMES Corporation
Debbie Wood	None	PACT member	The EMMES Corporation



Faculty Disclosure

The Accreditation Council for Continuing Medical Education (ACCME) is the governing body that accredits AABP to provide continuing medical education credits for physicians. In accordance with the ACCME Standards for Commercial SupportSM, all faculty for this event have signed a conflict of interest form in which they have disclosed any significant financial interests or other relationships with the industry relative to the topics they will discuss during this program.





How to Be a Dynamic Trainer

Welcome:
Rockhurst College Continuing Education
Center, Inc.

Presented by:
Larry Midgett Ph.D.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc.



■ WIIFM – *What’s in it for me?*

■ WSIDI – *Why should I do it?*

■ WIBF – *Will it be fun?*



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ²



“For learning to take place with any kind of efficiency students must be motivated. To be motivated, they must become interested. And they become interested when they are actively working on projects [tasks] which they can relate to their values and goals in life.”

— Gus Tuberville, President,
William Penn College



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ³

LEARN

Vision

Long Term Goal

Objectives Objectives


STG- STG-STG-STG

 **National Seminars Group** A Division of Rockhurst University Continuing Education Center, Inc. ⁴

LEARN

*“Personally, I am always ready to learn,
although I do not always like being taught.”*


— Winston Churchill

 **National Seminars Group** A Division of Rockhurst University Continuing Education Center, Inc. ⁵

LEARN

*“I never teach my pupils;
I only attempt to provide
the conditions in which
they can learn.”*

— Albert Einstein

 **National Seminars Group** A Division of Rockhurst University Continuing Education Center, Inc. ⁶



Adult learners are not just kids that
have gotten bigger



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ⁷



*"The biggest enemy to learning is the
talking teacher."*

— John Holt



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ⁸



*"Never let the fear of striking out get in
your way."*

— Babe Ruth



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ⁹



"Humor is a rubber sword – it allows you to make your point without drawing blood."

– Mary Hirsh



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ¹⁰



Storytelling

- Understand storytelling takes time to develop.
- Read.
- Listen.
- Look at time-tested stories.
- Rehearse.
- Be a student of storytelling.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ¹¹



Create a Flow Chart

- Menu slide, branch to one main point, return to menu slide and review, continue to next main point...



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ¹²



Consider Using Colors That Coincide With Each Point

Match color with perceptions to increase retention:

- Green - Money
- Red - Love or strong emotions
- Dark blue - Seriousness or formality
- Neon colors - Informality



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 13



Consider Using Animation That Coincides With Each Point

- Good transition effects mimic eye movement.

Examples:

- Use “blinds down” to introduce material, “blinds up” to remove it.
- Use “wipe right” to introduce, and “wipe left” to remove.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 14



“Before you become too entranced with gorgeous gadgets and mesmerizing video displays, let me remind you that information is not knowledge, knowledge is not wisdom, and wisdom is not foresight. Each grows out of the other, and we need them all.”

— Arthur C. Clarke



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 15



Visualize yourself achieving the outcome you're after, building mental muscles, increasing your endurance, flexibility and effectiveness. This decreases your likelihood of being distracted by negative emotions or energy under pressure.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 16



Icebreakers allow trainees to share an experience or a challenge, while creating a sense of accomplishment



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 17



"Retention is best when the learner is involved."

— Edward Scannell, Director,
University Conference Bureau, Arizona



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 18



Other Questioning Tips

- Develop questions in advance and review these questions before training starts.
- Ask questions at specific intervals throughout training.
- Use questioning as a means of summary at the end of a module or session.
- Rather than provide information, present it as a question.
- Provide questions in a list form for specific cases and exercises.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 19



The **cohesiveness** of a group refers to the ability of the members to get along; *their loyalty, pride and commitment to the group.*



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 20



“Constant kindness can accomplish much. As the sun makes ice melt, kindness causes misunderstanding, mistrust and hostility to evaporate.”

— Albert Schweitzer



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 21



“There are two ways of meeting difficulties: you alter the difficulties or you alter yourself to meet them.”
 — Phyllis Bottome



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ²²



Learning is just one factor in a set of factors that influence the outcomes of effective training.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ²³



Tips for Needs Assessment

- Focus on problems that training can solve.
- Focus on what is and what should be; measure how wide the gap is between current skills and desired skills.
- Focus on how to improve performance: how training can close that gap.
- Focus on simplicity.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. ²⁴



“Nothing is more terrible than activity without insight.”

— Thomas Cayle



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 25



Setting Clear Objectives

- Write all objectives so that the learner knows what to do.
- Write each objective so that it can be taught and learned in about 15 minutes.
- Be certain that your message for the objective has a clear business purpose.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 26



“Education is what survives when what has been learned has been forgotten.”

— B. F. Skinner



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 27



Think through the motivation the participants will have to learn and where that motivation originates.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 28



Remember

- While information about satisfaction may provide useful feedback on facilities, schedules, attitudes, and materials, measures of satisfaction do not correlate with levels of learning.
- Superior trainers are in the job to facilitate learning – not just satisfy the participant.



National Seminars Group

A Division of Rockhurst University Continuing Education Center, Inc. 29

Effective Training for Cell Therapy Laboratories

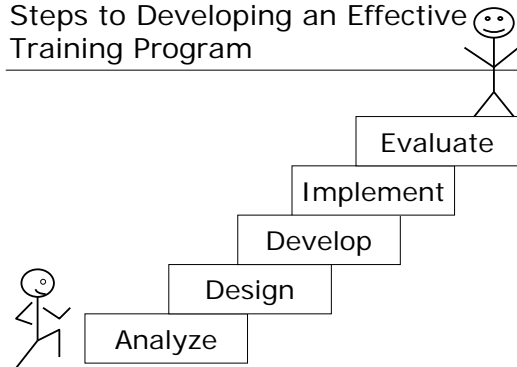
Diane Kadidlo MT(ASCP)
University of Minnesota
Molecular and Cellular Therapeutics Facility

Training

- 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
-



Steps to Developing an Effective Training Program

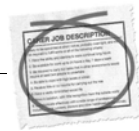


Analyze Training Needs



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

Job Description



- 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

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

FDA/AABB/FACT

- 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
-

Master Training List

- 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

- 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
-

Technical Training: Lesson Planning

What makes a lesson complete?

- Introduction
- Core
- Conclusion

Lesson Planning: Introduction

- 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

Lesson Planning: Core training

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

Instructional Tools

- 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
 - www.progenitorcelltherapy.com

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

- Summary
 - Reconstruct
 - Recall
 - Integrate
- Evaluation
 - Assess the trainees ability to meet established objectives
 - Assess the effectiveness and value of the training program

Competency

- 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

Competency Measurements

- 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



Progressive Cell Laboratory & St. Louis Cord Blood Bank
3612 Park Avenue, St. Louis, MO 63110, 314-268-2787

**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 bags				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Addition of HelaStarch				<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 (Request List, etc)				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
First incubation & spin - inv. 45 min. @ 400 rpm				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Calculate amount of red cells to dispense				<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, 3 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

- 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

- 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?

Records

- 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



Training & Competency Resources

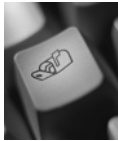
- Lee, C. *Personnel Training and Competency*. Cytotherapy, 1999: Vol.1, pp493-508.
 - ISCT cGMP Workshop, Orlando, FL, Dec. 2003.
 - Kelly, L., editor. *The American Society for Training and Development (ASTD) Technical and Skills Training Handbook*. New York, 1995.
 - Yelon, S., and Sheppard, L.. *Instant 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)
-

Questions?

“Effective and Result-based Training”



Speaker Contact E-mail



Larry Midgett, PhD
lrymgt@aol.com

Diane Kadidlo, MT ASCP SBB
kadid003@umn.edu



Web Seminar Presentation Slides

This web seminar presentation and presentations from previous web seminars are available publicly at

www.pactgroup.net

Select **Education** → **PACT Web Seminars**



CME Information

Physicians

AABB is approved by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians (Provider number 0000381). AABB designates this educational activity for a maximum of **1 hour of Category 1 credit** toward the AMA Physicians Recognition Award. Each physician should claim those credits that he/she actually spent in the activity.

California Clinical Laboratory Personnel

AABB is approved by the California Board of Clinical Laboratory Personnel to provide continuing education for California-licensed clinical laboratory personnel (Provider number 0011). AABB designates this education activity for a maximum of **1 credit**. California clinical laboratory personnel must provide a personal signature and other required information on the attendance log.

Florida Clinical Laboratory Personnel

AABB is approved by the Florida Board of Clinical Laboratory Personnel to provide continuing education for Florida-licensed clinical laboratory personnel (Provider number 50-4261). AABB designates this education activity for a maximum of **1 credit**.



CME Credit

If you are interested in obtaining CME credit for attending this web seminar, please note that each attendee must:

~Sign and fax roster to 240-306-2527~

~Complete the online survey~

PACT Web Seminar #12 Survey

(Survey link above embedded in the reminder email sent Wednesday 5th)

Note: Please complete within 48 hrs of the web seminar



AABB Live Learning Center

After the rosters have been processed, you will receive an email from AABB with instructions on how to print your CME/CE certificates for this web seminar



Thank you for attending!

To register for updates on upcoming web seminars, workshops, and PACT attended meetings visit us on the web at:
www.pactgroup.net