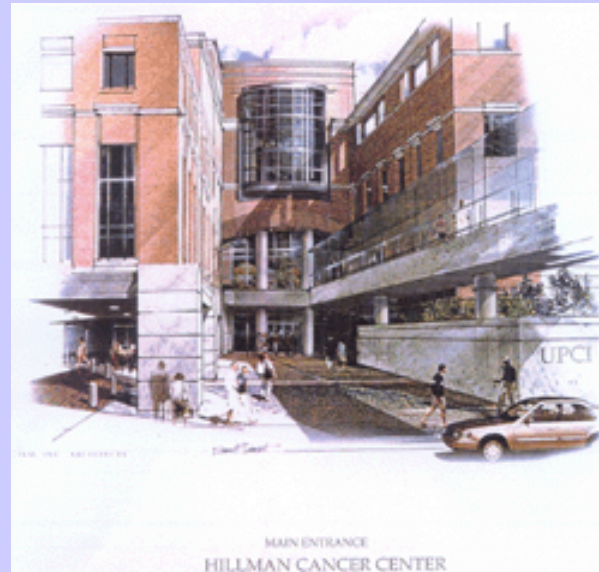


Staff Training



Deborah L. Griffin

Manager, Quality Assurance for Cellular Therapies

Hillman Cancer Center

University of Pittsburgh Cancer Institute

University of Pittsburgh Medical Center



Overview

- ↪ Facilities at the University of Pittsburgh consist of two separately run but interconnected departments
 - ↪ IMCPL
 - ↪ HSCLab
- ↪ Long history of interaction – both labs have been in continuous operation for over 20 years
- ↪ Currently share some training



Hospital Provided Training

- ↪ Orientation
- ↪ Blood borne Pathogens
- ↪ Formaldehyde Safety
- ↪ Laboratory Safety
- ↪ Fire Safety/Fire Extinguisher Training
- ↪ Radiation Safety
- ↪ Infectious Materials Shipping

Lab Specific Training

- ↻ Lab orientation
- ↻ Training on individual SOPs and processes
- ↻ In Services

Lab Specific Training Documentation

- ↻ Detailed forms
- ↻ Training on individual SOPs and processes recorded
- ↻ In Services described and recorded

Competency

- ↳ Once competency is established, it is monitored once a year.
- ↳ Assayed for KEY aspects of processing
- ↳ Form has key elements to review during actual processing and the corresponding steps in the procedure.

↳ FIND NEW COMPETENCY FORMS

Retraining

- If staff is not found to be competent in an area, retraining is necessary. The individual is prohibited from processing in that area until successful completion of the retraining plan
- A deviation management form is completed with the short term corrective action being the creation of a retraining plan for the individual
- The retraining plan details the steps to retrain and the acceptance criteria
- The plan is followed and steps in the plan are documented as to trainer, trainee, date/time and work performed. A short report is created.
- Successful completion of the retraining plan and review of the report is determined by the Laboratory Director or designee and the individual is now released for processing.

Aseptic Technique

↳ A pattern of behaviors rather than following a procedure.

HSCLab

- ↳ Special courses offered to all Stem Cell Transplant staff through the hospital
- ↳ Once every six months
- ↳ Full day course for new staff
- ↳ Topics include
 - ↳ Special needs of the HSCT patients
 - ↳ Chemotherapy
 - ↳ Mobilization
 - ↳ Adverse Events



IMCPL

- Monthly in services covering new testing or processing techniques
 - ELISPOT
 - Cytokine Flow Cytometry
 - Regulatory T Cells
 - IL-12 Assays

Webinars

 Pathology

 ITxM

 PACT

Alternative In Services

- We have a large number of possibilities for in-services
 - Grand Rounds
 - Weekly Cancer Center Seminars
 - Tumor Board
 - Journal Club
- Tend to be rarely used by the labs due to the workload in the labs.

Employee Records

- All documentation describing the employee's education training and experience is maintained in a secure location
- Available for review by FDA or PA inspectors or accrediting agencies
- Employee evaluations are NOT kept with the above documentation due to confidentiality issues and are maintained in a locked cabinet in a secure area

Employee Records

- ↳ Binder containing:
 - ↳ CV at time of hire or as updated
 - ↳ Training forms completed by trainee and trainer
 - ↳ Training certificates provided from vendors or continuing education programs
 - ↳ Yearly competency evaluations
 - ↳ Continuing education forms
 - ↳ Any additional training or continuing education materials that the employee wants to include

Future Plans

- Standardized GMP Training Program
- Developed as a Medical Curriculum Course Project
- Development as an Online GMP Training Program offered through PACT



Training Program Development

- ↳ Module Development Fall 2006 to present
 - ↳ Module topic identification and characterization
 - ↳ Module development
 - ↳ Exploration of different methodologies for presenting the program to the public
 - ↳ Abstract completion regarding development
 - ↳ Program summary
 - ↳ Preparation of expedited IRB submission for human subject research
 - ↳ Discussion with AABB to ensure that modules would complement rather than overlap the AABB certification program currently in development



Training Program Development

- ↳ Program Development present to April 2007
 - ↳ Completion of modules
 - ↳ Creation of pre- and post-test documents
 - ↳ Completion of program evaluation document
- ↳ April 2007 to Oct 2007
 - ↳ Randomization of subjects for evaluation segment of the program development
 - ↳ Administration of the program
 - ↳ Abstracts regarding evaluation and implementation
 - ↳ Modification of the program based on outcomes
 - ↳ Budgeting for PACT and preparation of presentations for web usage



Technologist Program Content

- ↳ Technologist
- ↳ GxP and the History of the FDA
- ↳ Regulatory
- ↳ Deviation management
- ↳ Inspections
- ↳ Batch Records and Document control
- ↳ Audits
- ↳ Informatics
- ↳ Adverse events and Donor Eligibility
- ↳ Testing and release criteria
- ↳ Facilities
- ↳ Equipment
- ↳ Supplies and Reagents

Conclusion

- ↳ Keep documentation on all of your employees from the moment you hire them
 - ↳ Hospital-based training
 - ↳ Laboratory training records
 - ↳ Competency, continuing education and new skills
- ↳ Resources available
 - ↳ Hospital or university based educational programs
 - ↳ In-services
 - ↳ Webinars
- ↳ Future plans
 - ↳ Development of GMP training program