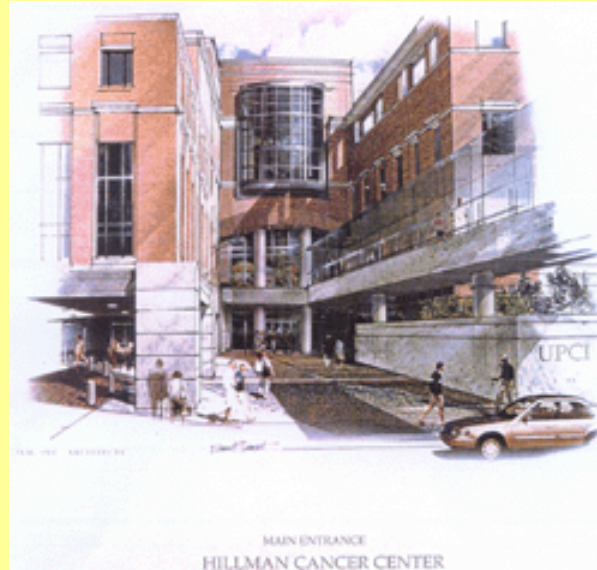


Pitt Facilities



Hillman Cancer Center
University of Pittsburgh Cancer Institute
University of Pittsburgh Medical Center



Cell manufacturing labs

- ↳ Facilities at the University of Pittsburgh consist of two separately run but interconnected laboratories
 - ↳ IMCPL
 - ↳ HSCLab
- ↳ Share QA Manager
- ↳ Long history of interaction – both labs have been in continuous operation for over 20 years
- ↳ Both are GMP
- ↳ Manufacture different therapeutic products



Cell manufacturing labs

Cellular Products Laboratory (CPL) in IMCPL

- Provides cell manufacturing for a variety of clinical trials with internal and external investigators, specializing in cell culture

Hematopoietic Stem Cell Laboratory (HSCLab)

- Provides cell processing for the stem cell transplant program and other programs, specializing in cell separation



IMCPL & HSCLab at the Hillman Cancer Center

- ↳ Built in 2003
- ↳ Share a single Class 100,000 air-handling system that in static operation functions closer to 10,000.
- ↳ Share same facilities management, clinical engineering, administrative support
- ↳ Under the umbrella of the Pathology Department of the UPMC
- ↳ Inspected for GLP by CAP



Environment

- ↳ Designed after discussions with the FDA
- ↳ Stainless steel casework
- ↳ Coved sprayed resin floors with a seamless join with the wall
- ↳ Solid ceilings
- ↳ Water-resistant epoxy paint
- ↳ Preliminary and terminal HEPA filtration
- ↳ Positive and negative air pressure areas
- ↳ Temperature and humidity controlled
- ↳ Secured area with restricted access



Facility Design

- ↳ Separate, defined areas for each operation of the laboratories:
 - ↳ Accessioning of products
 - ↳ Product labeling
 - ↳ Processing
 - ↳ Storage of products, short-term and long-term
 - ↳ Waste disposal
 - ↳ Supply and reagent storage
 - ↳ Testing
- ↳ Interlocked anterooms between outer labs and cleanrooms
- ↳ Surfaces are non-shedding and non-porous
- ↳ Card-key access to authorized-user areas



IMCPL

- ↳ CPL consists one large testing laboratory with several smaller attached labs and two cleanrooms
- ↳ Main laboratory contains
 - ↳ Flow Cytometer
 - ↳ Centrifuges
 - ↳ Incubators
 - ↳ Microscopes
 - ↳ Refrigerators & Freezers
 - ↳ Controlled-rate Freezers



IMCPL

- ↳ CPL consists one large testing laboratory with several smaller attached labs and two cleanrooms
- ↳ Cleanrooms contain
 - ↳ Biological safety cabinets
 - ↳ Centrifuges
 - ↳ Incubators
 - ↳ Microscopes
 - ↳ Elutra
 - ↳ Aastrom Replicell System
 - ↳ CliniMax



HSCLab

- ↳ The HSCLab consists of a main testing lab and a long cleanroom
- ↳ Main testing lab contains
 - ↳ Hematology Analyzer
 - ↳ Flow Cytometer
 - ↳ Incubator
 - ↳ Microscopes
 - ↳ Centrifuges
 - ↳ Serifuges



HSCLab

- ↳ The HSCLab consists of a main testing lab and a long cleanroom
- ↳ Cleanroom contains
 - ↳ Biological safety cabinets
 - ↳ Floor model centrifuge
 - ↳ Cell Separator
 - ↳ Cell Washer

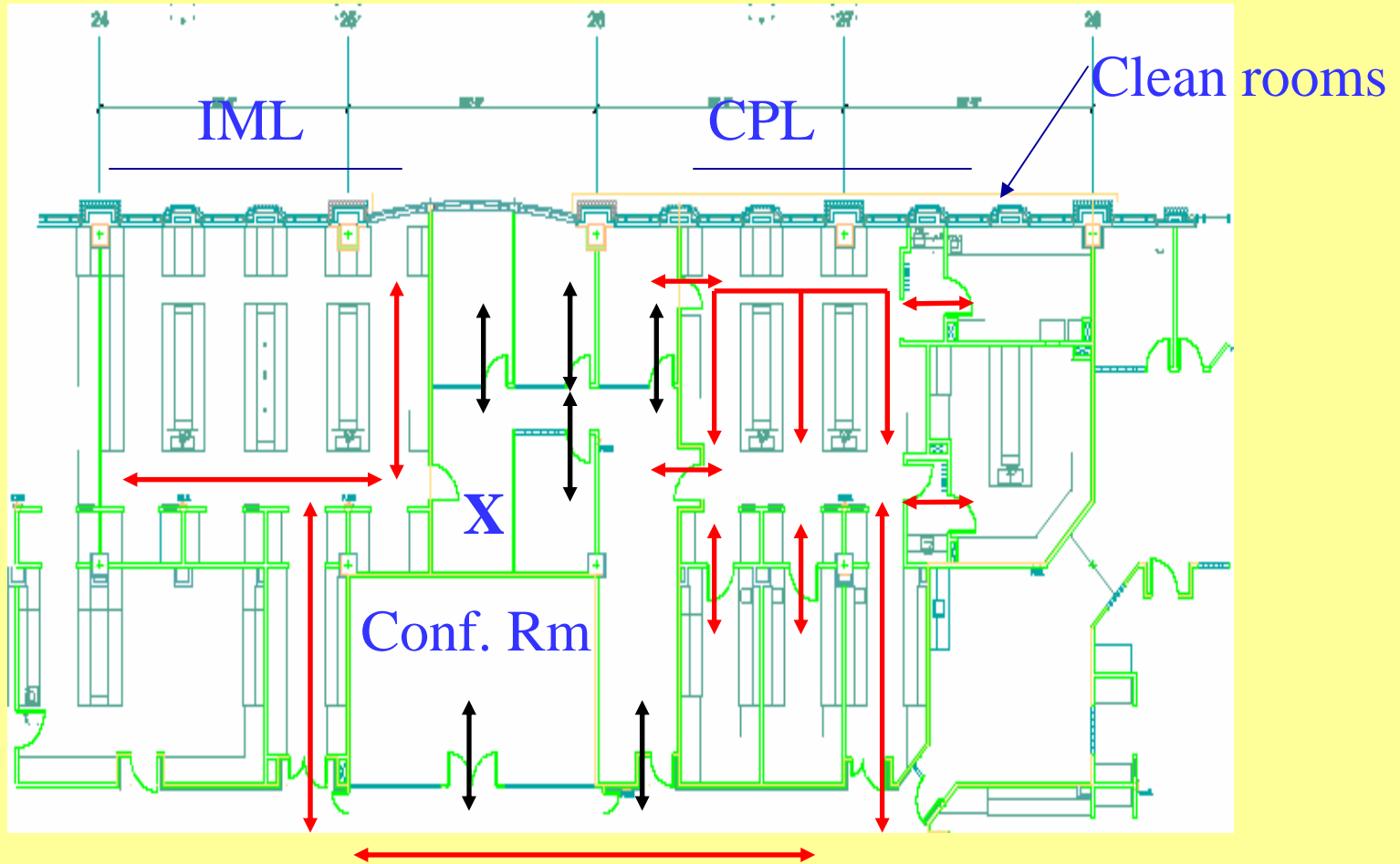


CPL Workflow



Personnel Workflow

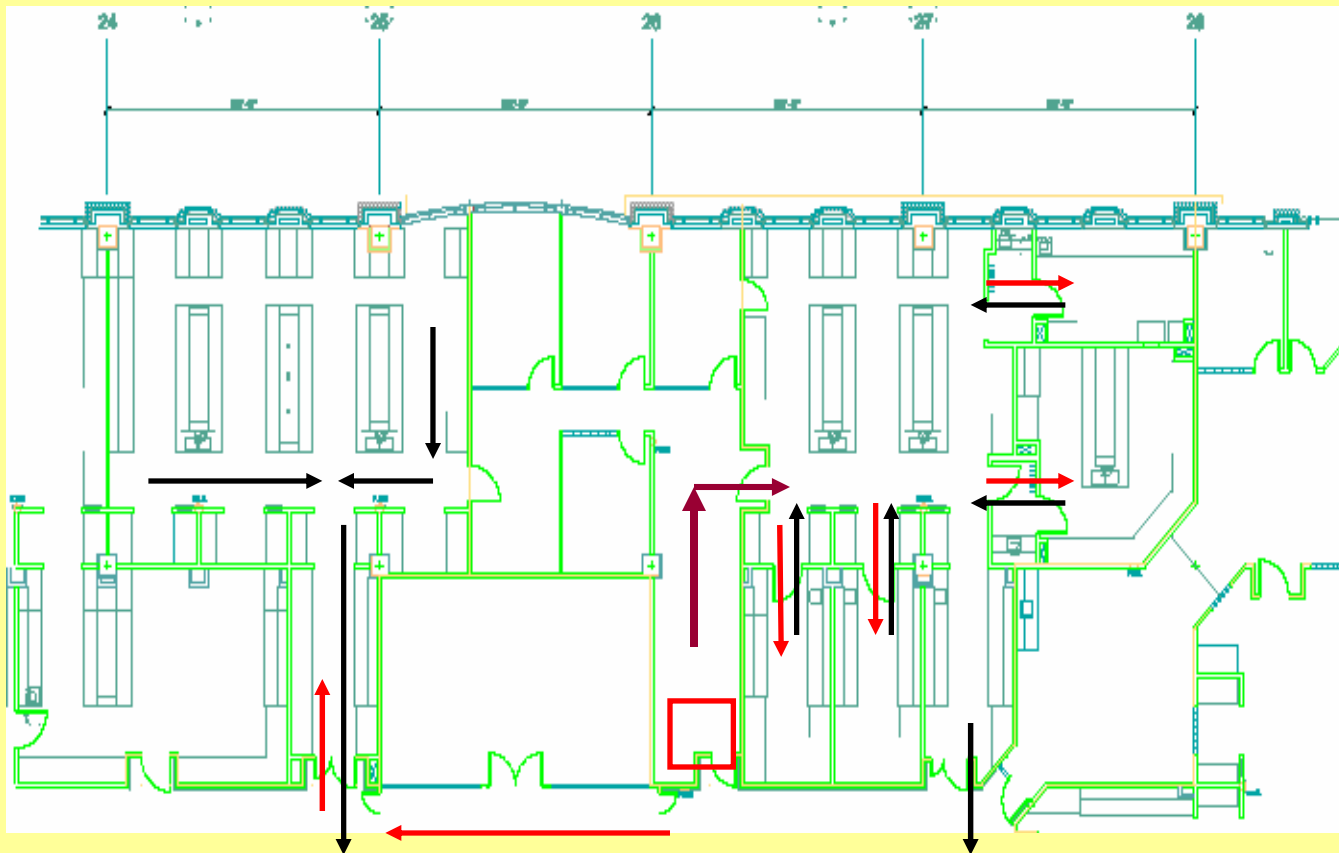
Lab Staff Office Staff



CPL Workflow

Supply and Waste Workflow

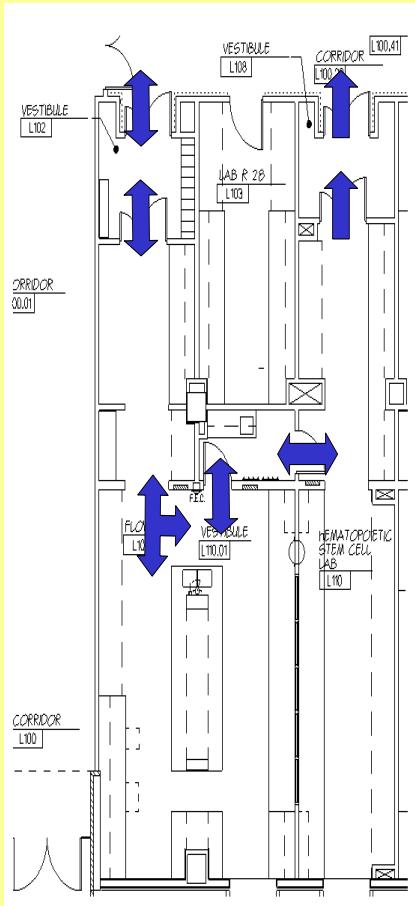
Supplies Waste Supplies reception



HSClab Workflow

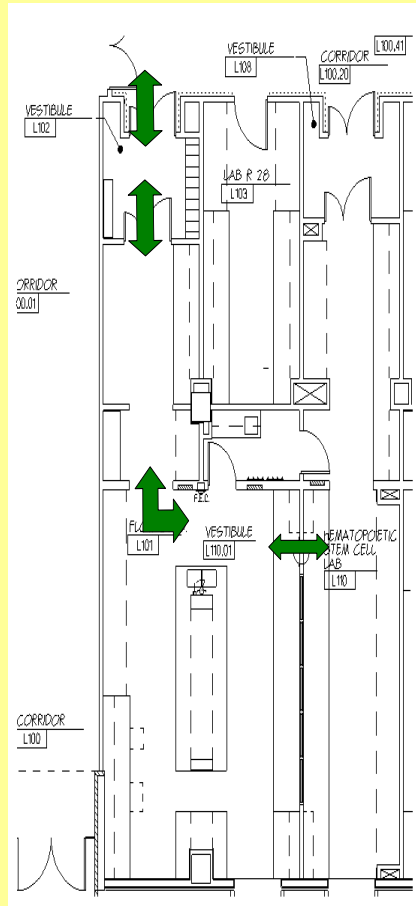


HSClab Personnel Traffic Pattern



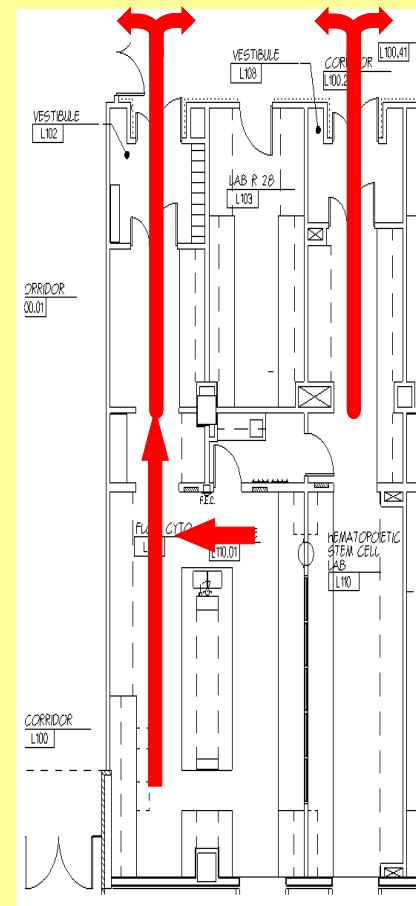
ADD DLG 102903

HSClab Product Traffic Pattern



ADD DLG 102903

HSClab Waste Traffic Pattern



ADD DLG 102903

Liquid Nitrogen Storage System

- Four “Closets” that contain the LN₂ Banks
- Manifold system that supplies the LN₂ to the vessels
- Freezer room with LN₂ vessels set up for both vial storage and bag storage
- 24 hours monitored alarm systems



Unique features

- Small, very busy facilities (400 products/year for HSCL and about 200 for CPL)
- In CPL, one cleanroom is the designated to HIV, adeno or retroviral work, the other (larger) to culture of all other non-viral cultures
- Production requests must be scheduled in the CPL: currently services 9 clinical trials
- Geared to efficient use
- Connected to the immune monitoring lab

