

MD Anderson Cancer Center Department of Blood and Marrow Transplantation Cell Therapy Laboratory



PRODUCTS AND PROCEDURES

- ~ 1500 products processed per year
- ~ 700 products infused per year
- ~ > 800 Cord Blood Units banked (04/05-01/06)

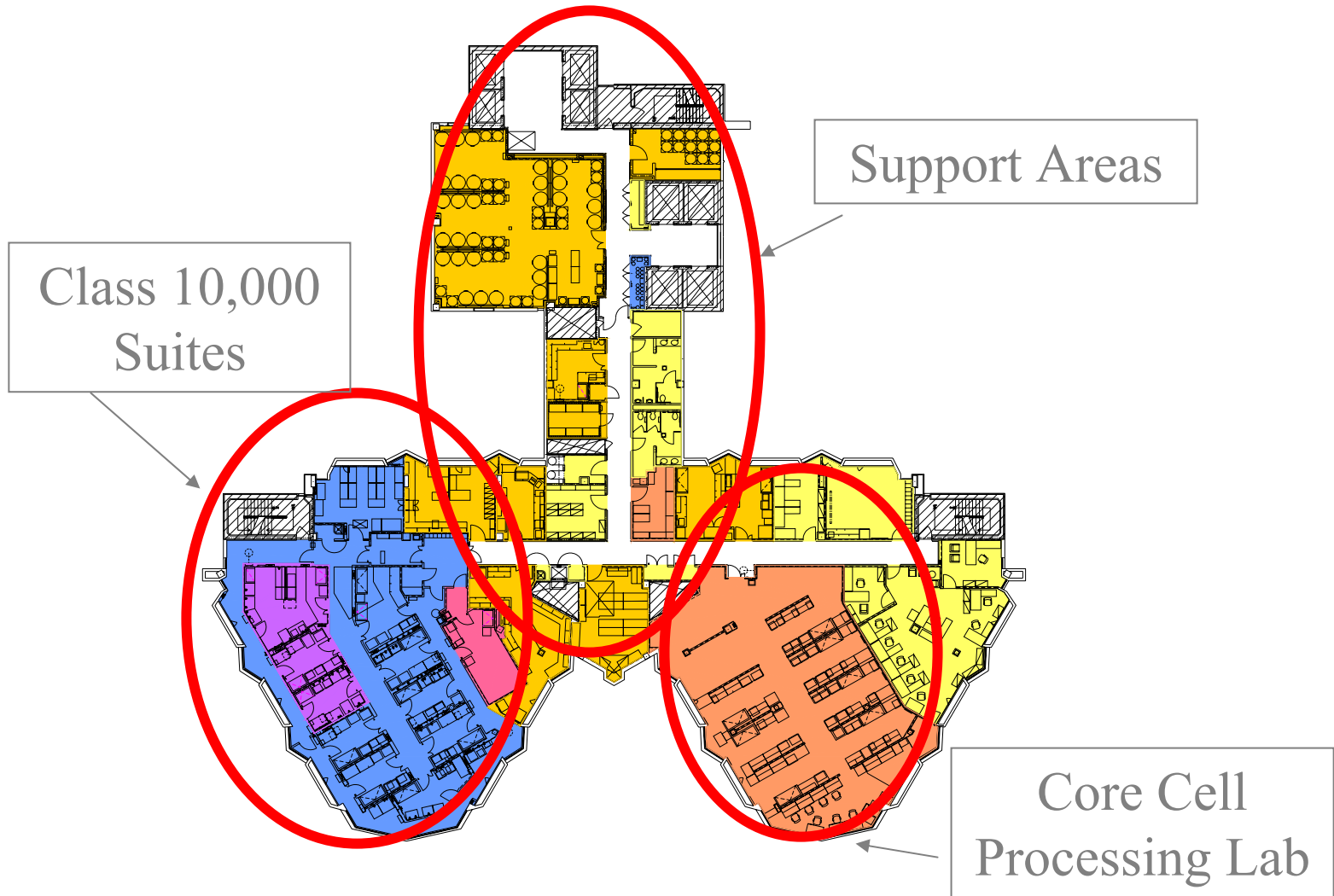
Cryopreservation and thaw

- Red cell and plasma depletion
- MNC preparation
- CD34 selection
- CB culture and expansion
- Dendritic cell culture
- TIL cell generation and expansion

700 infusions

- 50 Immunotherapy products
- 350 autologous HPC-A
- 350 allogeneic HPC
 - 200 related
 - 150 unrelated
 - 30 Cord Blood
 - 120 NMDP or donor registries
 - 100 Bone Marrow
 - 20 Mobilized peripheral blood

CELL THERAPY LABORATORY



Cell Therapy Laboratory

Facility Requirements; Minimal Manipulation Lab

- Clinical use only
- One product per Bay at any time
- Shared equipment with
 - appropriate segregation
- Quarantine areas for all
 - supplies, reagents and products
- Validated supply area (separate from GMP)
- Designed so that it can be converted to Class 10,000 in future with minimum disruption to lab

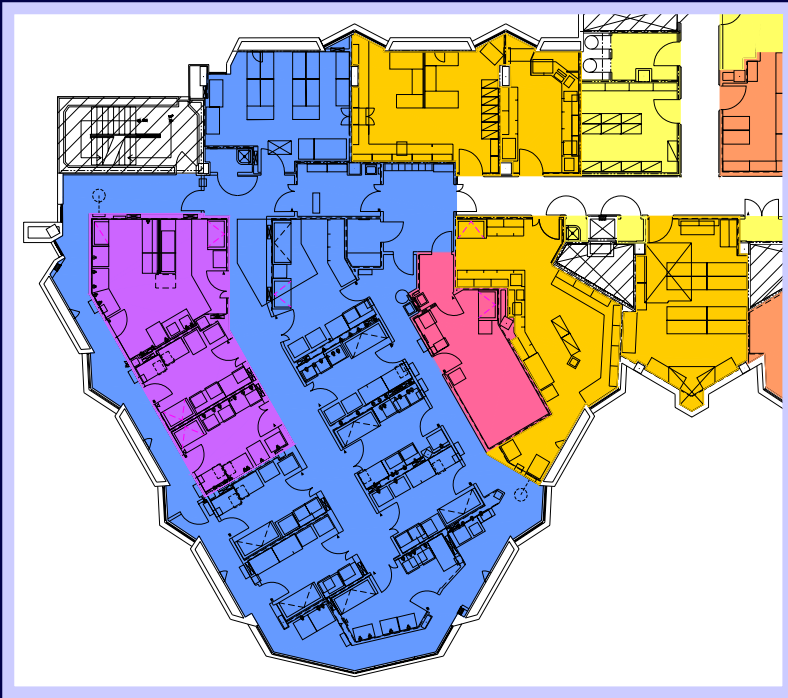


Facility Requirements: Class 10,000 Suites

- Clinical use only
- Class 10,000
- Unidirectional flow of products, personnel and waste
- One protocol per suite at any time
- Multiple patients per suite provided there is appropriate segregation
- Quarantine areas for all supplies, reagents and products
- Validated supply area
- Each suite must be self sufficient
- Pass boxes
- Manifold all rooms for 3 different gases

Class 10,000 Suites

- Total: 11
 - 7 Positive pressure
 - 3 negative pressure
 - 1 Cell Sorter
 - Airlock/Gowning
- Unidirectional
 - Entrance corridor
 - Exit corridor
- Single pass air
- Redundancy



Class 10,000 Suites

- Finishes
 - Hard surfaces for clean ability
 - Seamless vinyl floors with integral covered base
 - Hard ceiling in Production suites
 - Gasket ceilings in remainder of GMP
 - Stainless Steel work surfaces
 - No sinks/ Hands free



Systems Approach

- Quality
- Facility Management
- Equipment Management
- Material and Product Management
- Environmental Monitoring
- Rees Alarm

Quality Management

- SOP
- Training and Competency
- Review of all records by Supervisor and TD or designee
- Review of cumulative results of procedures to track for trends
- Quality Management Team that reviews all Events
 - Deviations
 - Determines reportability
 - Immediate actions that need to be taken
 - Quality Improvement

Facility Management

- Segregated bays - prevent mix-up
 - work on one product at a time in BSC
- Cleaning/documentation
 - Bays, BSC - CTL staff
- Cleaning of facility/removal of waste
 - MDACC Housekeeping
- Access to facility
 - Key card at the front door
 - Key card at the Core Lab Door
 - Key card at the GMP Lab Door
 - Key card at storage tank room

Equipment Management

New Equipment

- Electrical Check - ESI
- IQ/OQ - Manufacturer or QC Staff
- PQ & Validation - Technologist
- Review and Sign off
- SOPs - Staff, Approval by Directors & QA

In Service

- Daily, weekly, monthly, quarterly, semi-annually QC - Contractor or CTL staff
- Yearly PM - contractor

Out of Service

- QC Staff

Material and Product Management

- Material Management - Inventory Planner
 - Defined vendors in SOP
 - Supplies are placed in 'Quarantine' upon receipt
 - Release by IP upon documentation of meeting specifications
 - Green labels for release supplies

Material and Product Management

- Product Storage Management - CTL Staff
 - Before processing
 - Receipt log documents arrival time of all products and acceptability
 - Monitor temperature of room 24/7
 - Monitored refrigerator
 - Rees Alarm System

Material and Product Management

- Product Storage Management - CTL Staff
 - Liquid nitrogen
 - Monitor LN2 supply
 - Rees Alarm System

Questions