

Facility Design



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Outline

- o Facility Design Considerations
- o Choices & Design Tips
- o The Baylor GMP/GTP Facilities



Considerations

- o Type & Volume of Products
- o Manufacturing Time
- o Potential for Contamination & Cross-Contamination
- o Budget
 - Building
 - Operations



Type & Volume of Products



- Turnaround time
- Likely number/year
- Specialized handling & equipment
- Fresh or Cryopreserved



Choices



- Clean room environment
- Air handling design
- Single or "Clean" and "Dirty" corridors
- Many small rooms or fewer larger rooms
- Campaign or non-campaign manufacturing



Clean Room Environment



- Not mandatory
- More expensive to install & maintain
- Pressure relationships
- Air handler redundancy
- Single pass or recirculated air
- Number of air changes per hour
- Gowning strategies



Facility Design Tips

Corridor design



- Clean & Dirty
 - Typical for pharmaceutical GMP
 - Uses a lot of space
 - More expensive to maintain
- Single corridor
 - Mixed traffic patterns
 - Potential for contamination & cross-contamination
 - More space efficient




Facility Design Tips



Room Design

- Number & size
 - Smaller: allows product isolation
 - Larger: more efficient use of equipment
 - Variety and flexibility is optimal
- Finishes
 - Easily cleanable – epoxy painted
 - Removable cabinetry – stainless steel
 - Sealed & covered flooring
 - Minimal ledges and dust traps

Facility Design Tips

- Adequate space for incoming, quarantined and released supplies
- Adequate cold storage
 - Centralized or within rooms
- Nitrogen bank inside or outside of the controlled area
- Common and shared equipment areas
- Computer access



Facility Design Tips

- Controlled access
 - Irradiator present?
- Well designed gowning areas
 - Clean & dirty sides
 - Adequate storage for gowning materials
- Adequate space for cleaners & cleaning supplies



Facility Design Tips



- External gas cylinder storage
- Automated switchover systems
- Minimal N₂ transfer distances



Facility Design Tips

Alarm and Monitoring Systems

- Wired or wireless
- Notification systems (phone, e mail etc.)
- Web-based access
- Remote response capabilities
- Calibration and validation costs
- Compatible with institutional IS policies



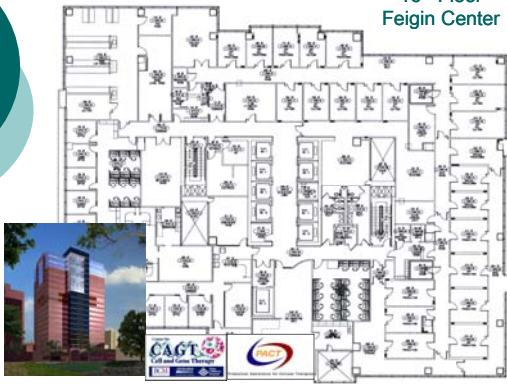
Baylor College of Medicine
Center for Cell & Gene Therapy



GMP/GTP Cell Processing Facilities



16th Floor
Feigin Center



Cell Processing Main

