

# Facility Cleaning



## **GTP Regulations (5/25/05): 21CFR Part 1271.190**

- Maintain facility in clean, sanitary & orderly manner
- Establish & maintain procedures for facility cleaning
  - Assign responsibility for cleaning
  - Maintain records for 3 years
- Environmental monitoring where appropriate





# GMP Regulations: 21 CFR Part 211.66

- Maintain facility in a clean & sanitary condition
- Written procedures assigning responsibility for sanitation & describing:
  - Cleaning schedule
  - Methods
  - Equipment & materials
- Written procedures for use of pest control, cleaning and sanitization agents.



## Classified or Non-Classified Space?

- If you set classification you must meet it!
  - Particle counts
  - Viable counts
  - Alert and alarm levels specified with actions to be taken
  - Formal Cleaning Validation



# Setting the Bar Too High?

- No products are handled in an open room – Biological Safety Cabinet
- Majority of products are terminally tested for sterility
- Many products are irreplaceable
- Little evidence of clinical sequelae from using positive products
- Need for Class 10K facilities?



## Every Facility Should Have:-

- **SOP for Cleaning Procedures**
  - Agents to be used
  - Frequency of Cleaning
  - Who is to perform cleaning
  - Training records
- **Monitoring if appropriate**
- **Changeover procedures**





# Choices

## ↪ Cleaning agents

- ↪ Know potential contaminants
- ↪ Check with institution infection control
- ↪ Rotate regularly to prevent resistance
- ↪ Ensure proper use

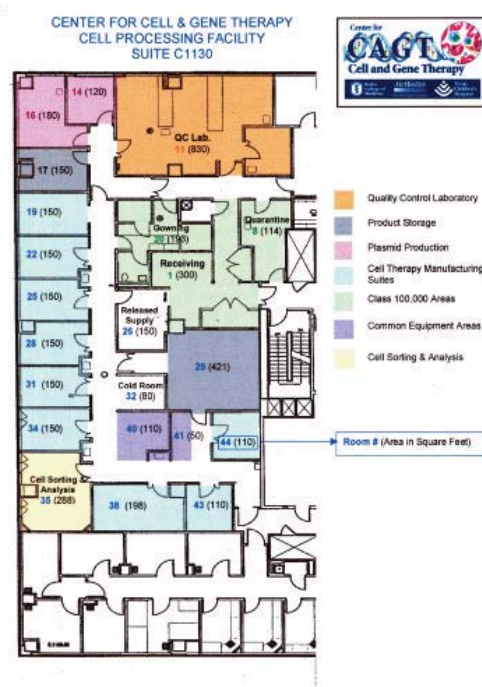
## ↪ Schedule

- ↪ Be prepared to explain!

## ↪ Monitoring plan?



# CAGT Cell Processing Facility

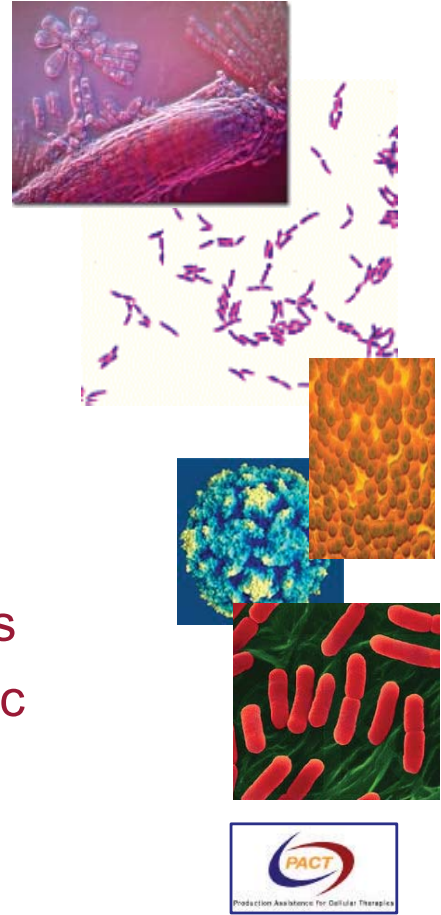


- ↪ Class 10,000  
Except gowning area
- ↪ 11 Processing  
Suites
- ↪ Dedicated product  
areas
- ↪ Multiple products  
per room



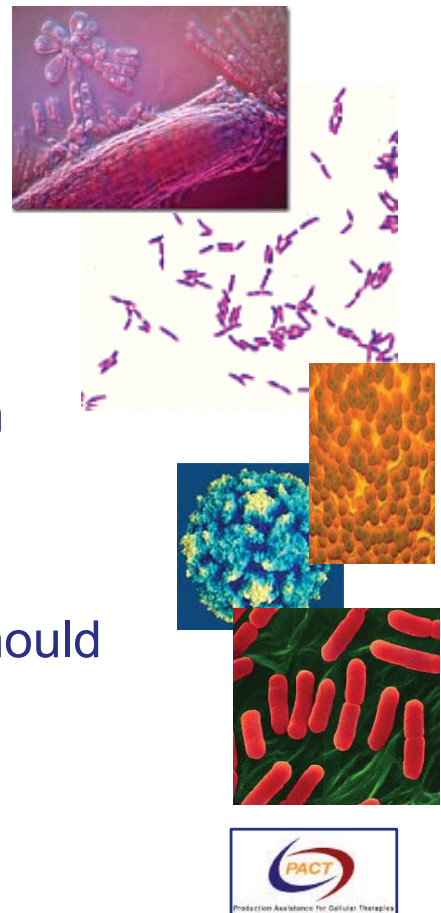
# Contaminants - 1

- ↳ Sampled surfaces using RODAC plates
- ↳ Included tacky-mats
- ↳ Speciated contaminants
- ↳ (Confirmed that contaminants could be detected with Bactec system)



# Contaminants - 2

- ↳ Predominantly skin flora
  - ↳ Coagulase-negative staph
  - ↳ Diphtheroids
  - ↳ Dematiaceous / Hyaline mould
  - ↳ Bacillus species





# CAGT Selection of Cleaning Agents

- ↪ Met with Infection Control to review organisms
- ↪ Selected IC-approved agents with appropriate activity (virus, bacteria, fungus)
  - ↪ Vesphene
  - ↪ Process LpHst
- ↪ Rotated monthly +/- 5% bleach
- ↪ Equipment – 3MQuat, 70% ethanol



## Cleaning Staff - Selection

- ↪ Institutional staff
  - ↪ Need to establish authority
  - ↪ Extensive training required
  - ↪ High staff turnover
  - ↪ Provide incentives for type of cleaning
- ↪ Contract cleaning company
  - ↪ Can select one with experience
  - ↪ Can hire and fire!
  - ↪ Needs institutional approval
  - ↪ Expense



# CAGT Cleaning



- ↪ Dedicated hospital staff – report to CAGT
- ↪ Trained by QC staff and audited
- ↪ SOPs in English/Spanish
- ↪ Formal cleaning schedule with sign-off
  - ↪ Regular clean – floors and counters
  - ↪ Complete clean – walls, ceilings, windows
- ↪ Continuous process – room in constant use
- ↪ Equipment – GMP staff



## CAGT Validation of Cleaning Agents

- ↪ Skin organisms main contaminants
- ↪ “Dirty” handprints onto surfaces
- ↪ RODAC plates before and after cleaning
- ↪ Reduction in colonies after cleaning
- ↪ Viral validation (more complex)
- ↪ Checked sterility of cleaning solutions
- ↪ Monitor water used for cleaning
- ↪ Use clean room disposable mops



# Monitoring Challenges for Classified Space



## ↪ What data to collect?

- ↪ Huge quantities of information
- ↪ Results may take days to obtain
- ↪ How to relate and manage data?

## ↪ How often to clean?

## ↪ How to manage ongoing production

## ↪ How to respond to contamination?



Time	Location	Count	Species	Response
2010-01-15 10:00	Room 101	150	Particle	Alert
2010-01-15 10:05	Room 101	120	Particle	Alert
2010-01-15 10:10	Room 101	100	Particle	Alert
2010-01-15 10:15	Room 101	80	Particle	Alert
2010-01-15 10:20	Room 101	60	Particle	Alert
2010-01-15 10:25	Room 101	40	Particle	Alert
2010-01-15 10:30	Room 101	20	Particle	Alert
2010-01-15 10:35	Room 101	10	Particle	Alert
2010-01-15 10:40	Room 101	5	Particle	Alert
2010-01-15 10:45	Room 101	2	Particle	Alert
2010-01-15 10:50	Room 101	1	Particle	Alert
2010-01-15 10:55	Room 101	0	Particle	Alert
2010-01-15 11:00	Room 101	0	Particle	Alert

## CAGT Documentation

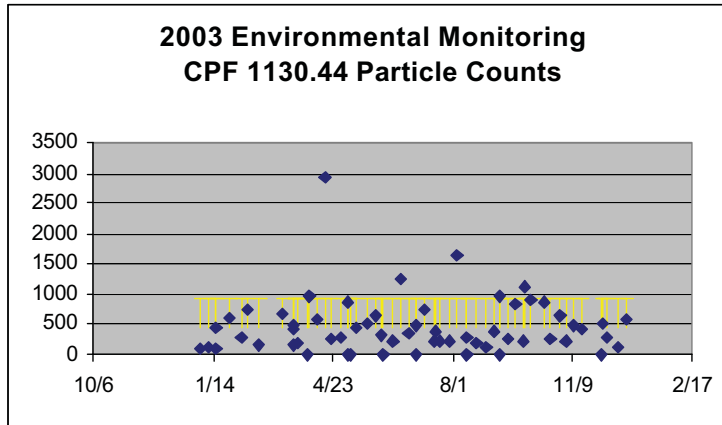
## ↪ Environmental monitoring database

- ↪ Date, type of cleaning, disinfectant
- ↪ Monitoring counts – particle & viable
- ↪ Results – alerts, alarms, species, responses
- ↪ Activities in facility or suite – dynamic & static
- ↪ Used for audits, follow-ups, door reports





# CAGT Audits & Tracking



Particle Counts  
Within Specifications

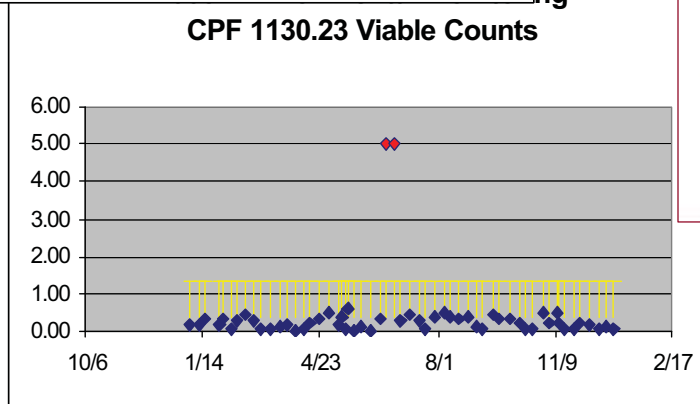
**CAGT** CENTER FOR CELL & GENE THERAPY  
GMP FACILITY  
FACILITY IDENTIFICATION NUMBER: 1130.44  
AUDIT REPORT NUMBER: 1130.44-001  
AUDIT DATE: 1/14/03  
AUDITOR: [Name]

Date	Time	Location	Results
1/14/03	10:10	Room 201	6.5
1/14/03	10:15	Room 202	6.0
1/14/03	10:20	Room 203	6.2
1/14/03	10:25	Room 204	5.8
1/14/03	10:30	Room 205	5.5
1/14/03	10:35	Room 206	5.8
1/14/03	10:40	Room 207	5.5
1/14/03	10:45	Room 208	5.8
1/14/03	10:50	Room 209	5.5
1/14/03	10:55	Room 210	5.8

Remarks: [Text]

Ongoing Door Charts

Viable  
Counts  
2 Alarm  
Readings



Ongoing  
Door  
Charts

## Take Home Messages

- Development & maintenance of a cleaning & monitoring system is possible
- It can be complex, costly & labor-intensive
- For classified space large amounts of information need to be processed and acted upon in a timely & consistent manner

