Oxford BioMedica Manufacturing site 2 starting up a biopharmaceutical facility for Gene Therapy products

Christie J July 2012

Facility history

- Facility purchased January 2011.
- Facility conceptual design planning and refurbishment programme planning between Feb 2011 – June 2011.
- Facility refurbishment initiated July 2011 and completed Nov 2011.
- Facility underwent commissioning Nov 2011 – Feb 2012
- MHRA inspection April 2012 and May 2012
- MHRA approval for the Manufacture of Bulk Drug for supply to Clinical trials May 2012

Manufacturing facility overview

Facility ~ 1700m2

Two floors : Ground Floor and First Floor**.**

Ground Floor : Fill Finish, 1x manufacturing, office accommodation

First Floor : 2x manufacturing, QC labs, Process Development suite and central service area

The facility is multi-product or can be dedicated to a single product if required.

The facility also supports a GMP warehouse, central offices , board room and meeting rooms.

Current staff levels = 18

Key Code

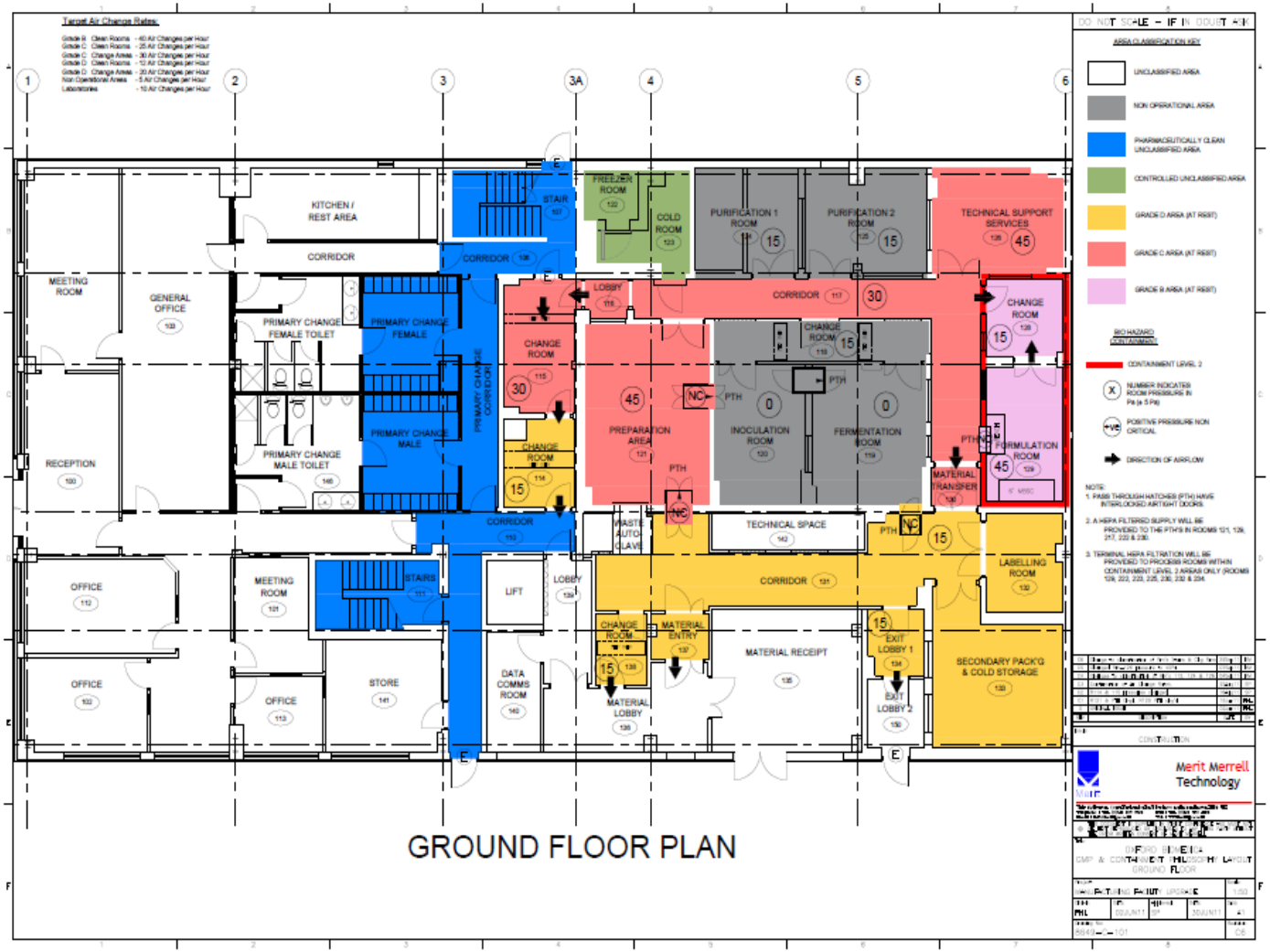
GRADE B

GRADE C

GRADE D

Controlled Unclassified

Pharmaceutical clean unclassified



Start up of a biopharmaceutical facility for Gene Therapy

There is one key overriding organising principle that must GOVERN the entire process

TIME TO CLINIC/MARKET

3 key stages in start up

1. Staff for success
2. Funded
3. Planned

and all these 3 factors are designed to optimise the regulatory, quality and financial aspects of the programme.

Staffing for success

- The right people can mean the difference between success and failure
- The Project manager :
  - Tried and tested
  - Project professional
  - Knowledgeable
  - Experienced in start up
  - Can handle the difficult situations

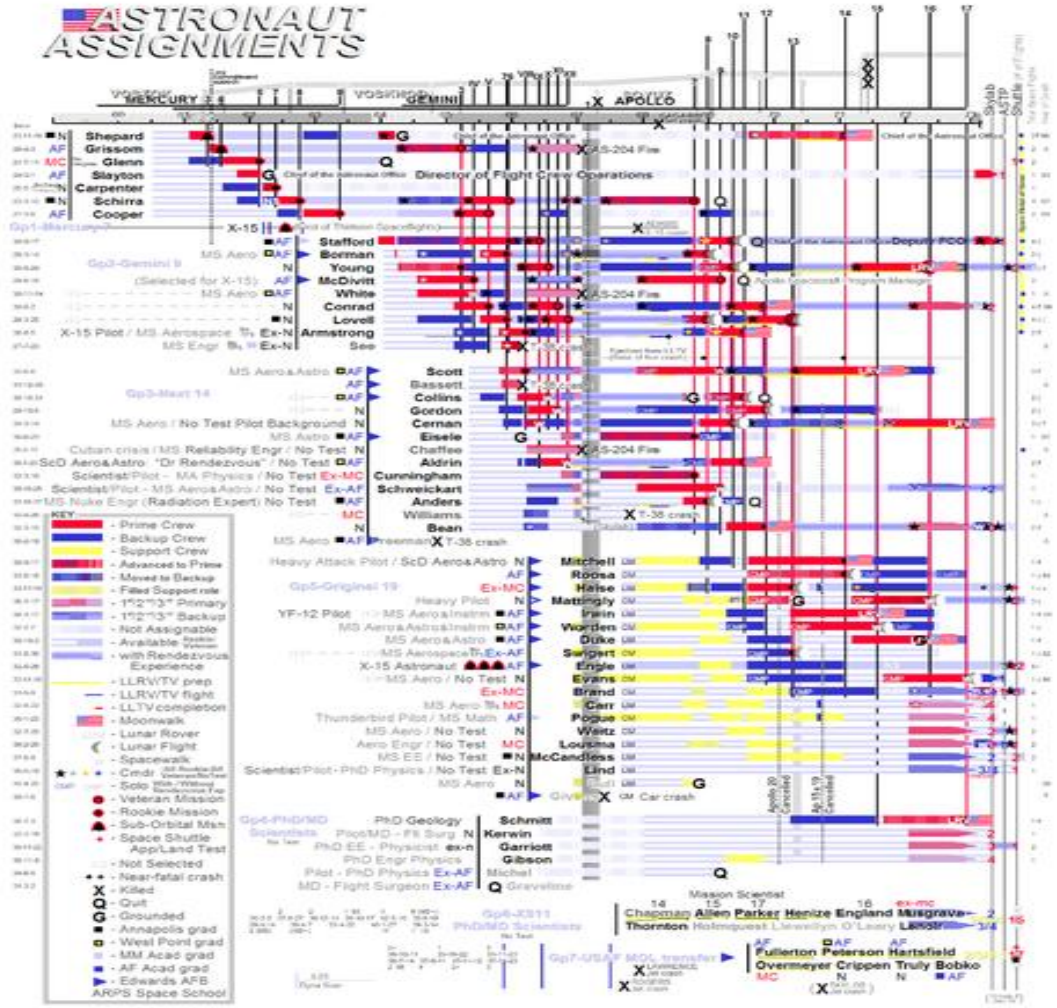
Staffing for success

The start up team

- Regulatory affairs
- Quality systems
- Operations
- Engineering
- Validation specialist
- Financial cost controller

The above functions need to be in place at the correct time and place against the programme BUT are interdependent of each other as they operate in delivering the project. However they must hold the "MANTRA" that they do what is best for the programme/project and not for self interest.

The Plan


ASTRONAUT ASSIGNMENTS
MERCURY
GEMINI
APOLLO
Director of Flight Crew Operations
AS-204 Fire
Shepard
Grissom
Glenn
Slayton
Carpenter
Schirra
Cooper
X-15
Stafford
Borman
Young
McDivitt
White
Conrad
Lovell
Armstrong
Scott
Bassett
Collins
Gordon
Cernan
Eisele
Chaffee
Aldrin
Cunningham
Schweickart
Anders
Williams
Bean
T-38 crash
Mitchell
Roosa
Haise
Mattingly
Irwin
Worden
Duke
Swigert
Engle
Evans
Brand
Carr
Pogue
Weitz
Lousma
McCandless
Lind
Car crash
Schmitt
Kerwin
Garriott
Gibson
Michel
Grayeltine
Mission Scientist
Chapman Allen Parker Henize England Musgrave Thornton Holmquest Llewellyn O'Leary Lenoir
Fullerton Peterson Hartsfield Overmeyer Crippen Truly Bobko
KEY
- Prime Crew
- Backup Crew
- Support Crew
- Advanced to Prime
- Moved to Backup
- Filled Support role
- 1st/2nd/3rd Primary
- 1st/2nd/3rd Backup
- Not Assignable
- Available
- with Rendezvous Experience
- LLRV/TV prep
- LLRV/TV flight
- LLTV completion
- Moonwalk
- Lunar Rover
- Lunar Flight
- Spacewalk
- Cmdr
- Solo
- Veteran Mission
- Rookie Mission
- Sub-Orbital Msn
- Space Shuttle App/Land Test
- Not Selected
- Near-fatal crash
- Killed
- Quit
- Grounded
- Annapolis grad
- West Point grad
- MM Acad grad
- AF Acad grad
- Edwards AFB
ARPS Space School

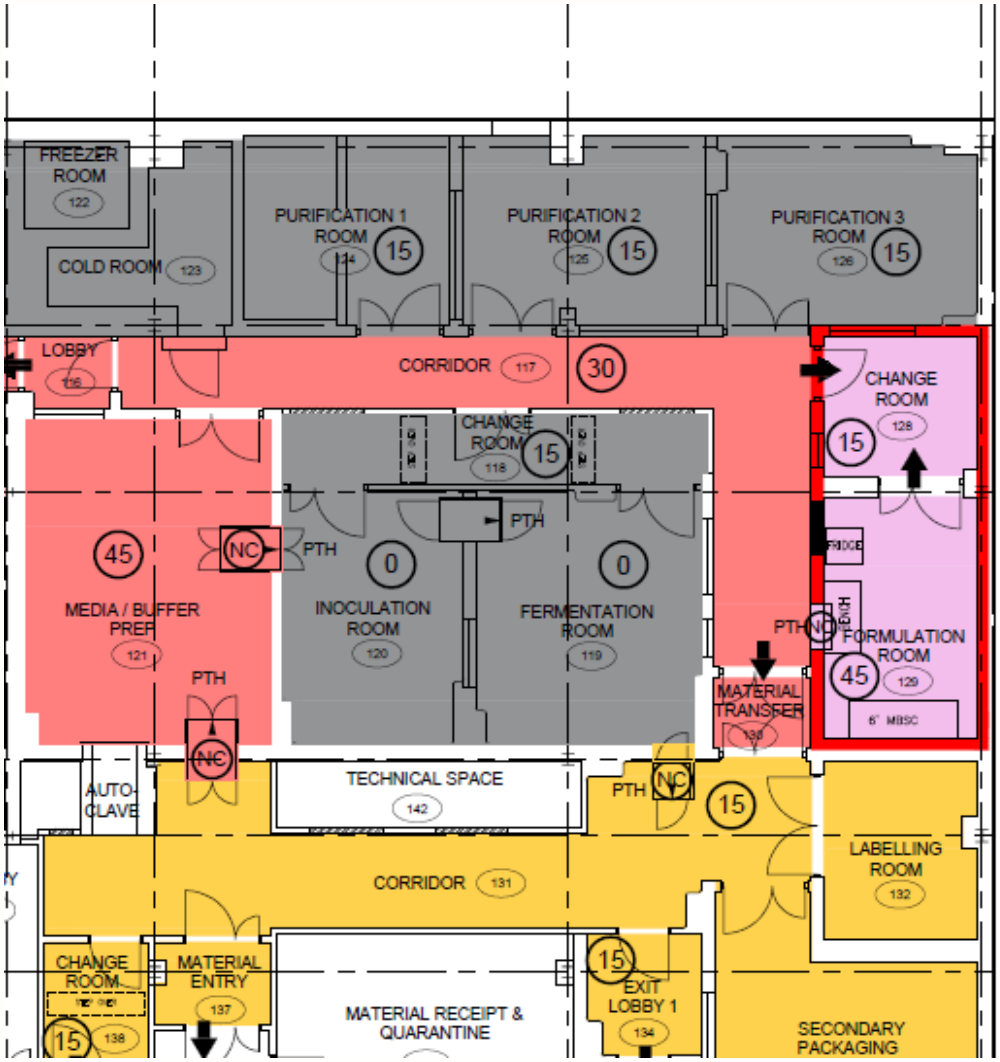
Considerations in build for Gene Therapy facility

Typical considerations

- Health and Safety paramount in any approach to both design and construction
- OBM decided to put the clear roles of principle contractor and Designer under one roof
- Site control was with principle contractor
- Build a risk log of project
- Containment Vs GMP

GMP Vs Containment considerations

- Fill finish



Summary

- Staff for success
- Plans NEED to be translational (We are not all Astronauts)
- Regular project meetings
- Understand your process and its implications on standard GMP practices
- Build your relationship with the regulator right from the start of the programme

Thank you