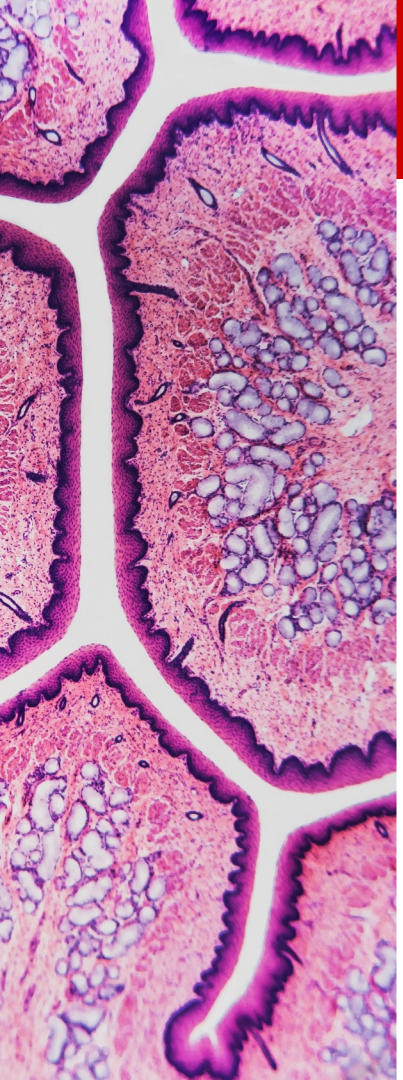
NC STATE Comparative Medicine Institute

Centennial Biomedical Clinical Manufacturing Facility

Facility Manager: Jay Xie



Facility Overview

This facility has been developed to produce novel products under controls consistent with US FDA current Good Manufacturing Practices (cGMP).

Work in the facility focuses on isolation and expansion of human cells.

Following the manipulation of these cells under cGMP controls, the cells will be of appropriate quality for use in Phase I, first in human, clinical trials in accordance with the written Investigational New Drug (IND) protocol controlling the work.

Why We Are The Best Choice

OUR FACILITY WAS DESIGNED WITH EARLY STARTUPS IN MIND.

WE PROVIDE THE HIGHEST QUALITY GMP, THE GREATEST FLEXIBILITY AND THE BEST POSSIBLE RATE.

WE WANT TO HELP YOU DE-RISK YOUR APPLICATION.

We work with your technical experts.

This drastically reduces costs and allows you to ensure that the protocol is being implemented by an expert.

Our charges are based a low daily fee and on time inside the facility.

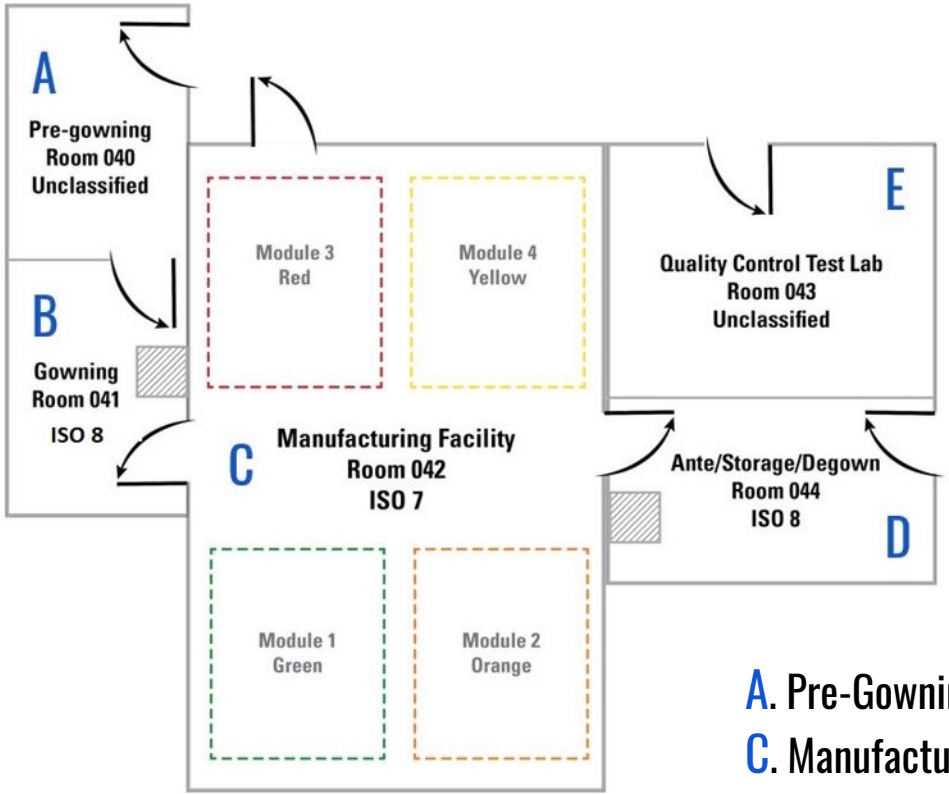
Most GMPs will charge a high 24/7 fee for the duration of the campaign. Our model drastically reduces costs.

We are a one-stop shop.

We can help you from starting and preparing your **IND** application, to generating the GMP-compliant Phase I material.

We have an extensive scientific network that can help you optimize your protocol, design improved manufacturing solutions, and address scale up issues.

Facility Layout



A. Pre-Gowning room B. Gowning room

C. Manufacturing suite ≈ 620 sqft with 4 modules ≈ 150 sqft each

D. Anteroom/De-Gowning room E. Quality Control testing laboratory

Facility Operations

Clients /Sponsor of GMP Projects → Facility Manager → GMP Panel/ISRC (Required by NC State)

Facility Manager

Client/PI supplies technicians to perform operations → Technicians

Outsourced Quality Assurance

Compliance Review
Review by QA independent of production

Clients /Sponsor

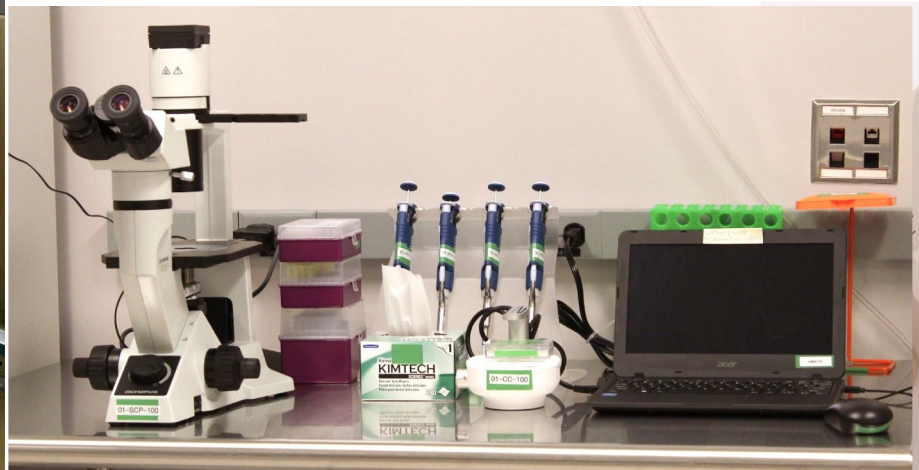
Final Release

Subjects

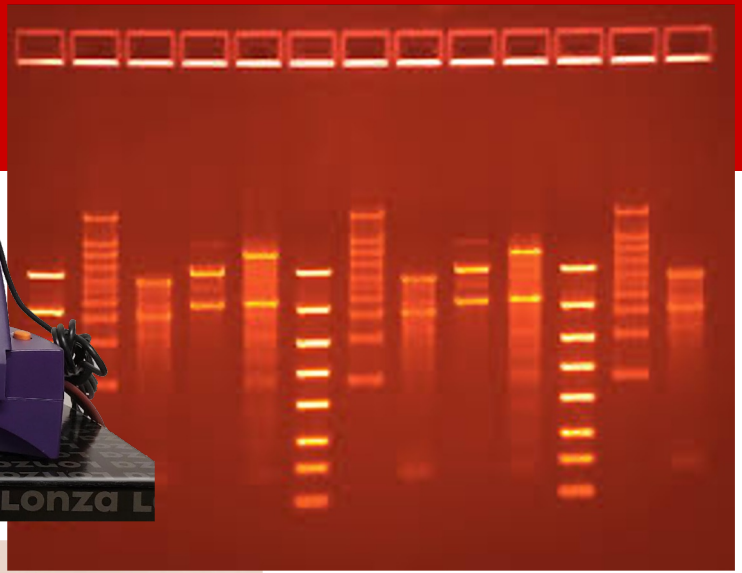
Client has ultimate responsibility for release

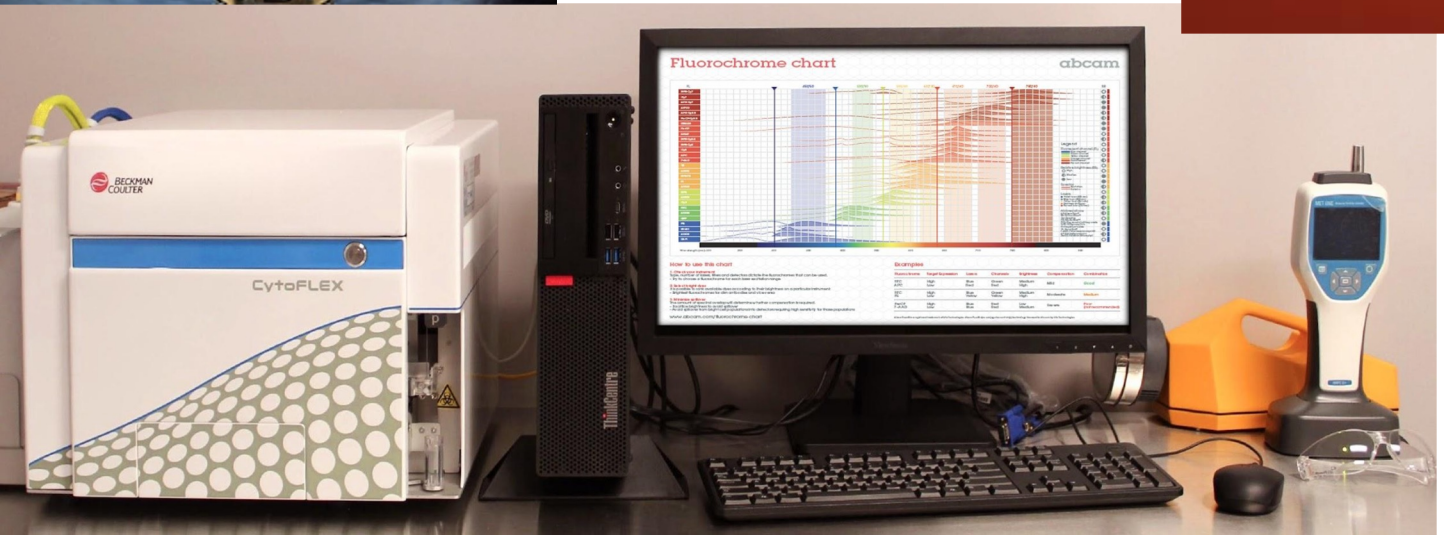
GMP Facility Equipment

Biological Safety Cabinets (BSL-2)
Incubators
Microscope
Automated cell counter (as well as a manual hemocytometer)
Centrifuge with interchangeable rotors and air tight lids
Bead bath
Aspirator



QC Lab Equipment





Electric Bunsen burner
Centrifuges
PCR thermocycler
Gel imaging
Flow cytometry

Services Offered

- We train all client employees working in the facility on proper cGMP.
- We convert client documents into a cGMP compliant format using the CBCM Facility template
- We supervise and provide assistance as needed for manufacturing and to ensure cGMPs are followed.
- We do initial Quality Assurance reviews, suggest edits as needed, then send to external QA for final review.
- We investigate protocol deviations and write Corrective Action Preventive Action (CAPA) plans and risk assessments.
- We safely maintain the originals of all documentation
- We provide consultation services related to GLP and GMP practices coupled to Phase 1 trials

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Contact facility Manager: Jay Xie at jxie24@ncsu.edu