

CLIENT: North Carolina Research Campus

DATE: 2006

LOCATION: Kannapolis, North Carolina

COST: \$8MM

PROJECT: Core Laboratory Building

SCOPE OF WORK: Design of cGMP Laboratory Space



The North Carolina Research Campus is a private-public venture created to foster collaboration and further advancements in the fields of biotechnology, nutrition and health. Once completed, NCRC will offer more than a million square feet of state-of-the-art lab and office space.

IDEA was given the challenge of creating a plan for the cGMP pre-clinical manufacturing portion of the campus' Core laboratory keeping in mind the goals and objectives of the Core Lab and the Campus as a whole.

IDEA's program includes 4 discrete laboratories of 2,500 ft each for the bulk manufacture of pre-clinical and clinical Phase I material. These core development laboratories were intended to be utilized as business opportunities in the biopharmaceutical and food science product development arenas. It is proposed that any required product finishing would be done elsewhere. The project team designed the laboratories to accommodate the following process types:

- Biological
 - ◇ Mammalian cell culture (principally recombinant)
 - ◇ Microbial fermentation (natural & recombinant)
 - ◇ Terrestrial plants (natural, recombinant & transgenic)
 - ◇ Aquatic plants (natural & transgenic)
 - ◇ Animal tissues (natural & transgenic)
- Chemical
 - ◇ Liquid phase synthesis
 - ◇ Solid phase synthesis

The manufacturing development capacity is intended to accommodate the Core Labs as a bridge from the bench top to the larger scale clinical and commercial manufacturing capability.

The manufacturing development labs will be completely equipped to allow client companies to develop and optimize their manufacturing processes (both upstream and downstream) to suit their particular needs, perform scale-up studies, and produce reasonable amounts of purified product for pre-clinical studies among other things.



IDEA — NORTH CAROLINA RESEARCH CAMPUS

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Project Features:

- cGMP Design / Validated Process
- Microbiology/Cell Culture Labs
- QA/QC Labs
- Cold Room
- Portable Lab Bench Units
- Process utilities
- Mechanical utilities
- Bulk product quarantine & release
- Materials shipping
- Metrology lab
- Office space for production staff



Deliverables:

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| <ul style="list-style-type: none"> • Room and area listing with approximate square footage • Preliminary process descriptions and diagrams • Utility requirements • Detailed equipment list • Block diagrams of areas • Process and clean utility equipment list • Process and Utility flow diagrams • Function of each room • Utility demand summary and Basis of Design • Equipment flow diagram • Raw material flow diagram | <ul style="list-style-type: none"> • Room pressurization scheme • Room classification scheme • Equipment layout of each room • Room criteria sheets • Basis of Design, HVAC • Basis of Design, Electrical • Basis of Design, Instrumentation & Control • Timeline for manufacturing design • Analyses of cell culture requirements • Analyses of fermentation requirements • Analyses of equipment technologies |
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Utilities:

It was planned for utilities to be provided to each of the Manufacturing Development Labs (MDLs) including:

- Hot and Cold Potable Water
- High Purity Process Water
- Ultra High Purity Process Water
- Clean Steam
- Chilled Water Supply and Return
- Chilled Glycol Supply and Return
- Compressed Air
- Central Vacuum System
- Specialized Gasses

