

CLIENT: North Carolina Research Campus

DATE: 2007

LOCATION: Kannapolis, North Carolina

COST: \$88MM

PROJECT: Biologics CMO Building

SCOPE OF WORK: Design of Small Scale cGMP Bioprocessing Manufacturing Facility



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

IDEA was an integral part of the design and development of an 80,000 square foot cGMP bioprocessing manufacturing plant that was incorporated into the North Carolina Research Campus (NCRC) in Kannapolis, North Carolina. The purpose of this facility is to add much needed regulatory compliant manufacturing capacity to the biopharmaceutical and food sciences industries. This facility will produce material for human clinical trials among other things.

NCRC's bioprocessing manufacturing plant includes a three story (plus basement) clinical manufacturing facility designed to operate as a Contract Manufacturing Organization (CMO) catering to the bioprocessing and food science industries. The plant will accommodate pre-clinical and clinical Phase I and Phase II material manufacturing with the ability to increase production for Phase III biopharmaceuticals, if needed. The scope of the building includes:

- One dual headed 500L Mammalian cell culture train
- One 1,000L scale microbial fermentation train
- Multi-product downstream purification suites
- One 500L food-plant based processing train
- One 500L food non-plant-based processing train
- ISO Class 5, 7 & 8 Clean Rooms
- Meets FDA, EU and ICH requirements
- Maximum use of modular process and process support systems



IDEA — NORTH CAROLINA RESEARCH CAMPUS

HEADQUARTERS:
Merritt Corporate Woods
612 Wheelers Farms Rd.
Milford, Connecticut 06461
203.951.4100

IDEA ENGINEERING, INC.

NORTH CAROLINA OFFICE:
2100 Gateway Centre
Suite 120
Morrisville, North Carolina 27560
919.380-5700

Project Features:

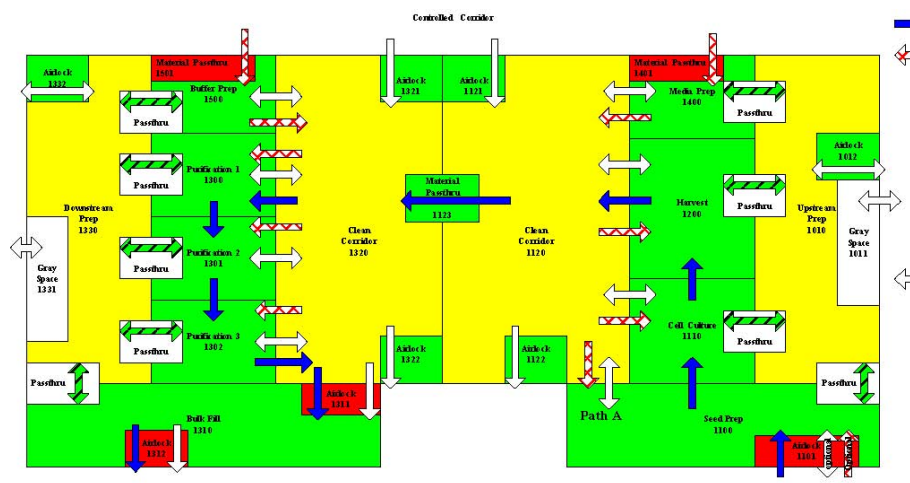
- cGMP Design / Validated Process
- Microbiology/Cell Culture Labs
- QA/QC Labs
- Cold Room
- Portable Lab Bench Units
- Upstream and downstream manufacturing suites
- Innovative use of "single use" technology
- Separate Final Bulk Fill area
- Biopharmaceutical Cell Banking
- Process utilities
- Mechanical utilities
- Bulk product quarantine & release
- Materials shipping
- Office space for production staff

Deliverables:

- Facility Overview
- User Requirement Specification (URS)
- Process Flow Diagrams
- Preliminary Equipment List
- Utility Systems Specifications
- Preliminary Adjacency Diagrams
- Preliminary Space Programming List
- Preliminary General Arrangement Drawings
- Material, Personnel, and Waste Flow Diagrams
- Preliminary Electrical Area Classifications
- Process Control Strategy
- HVAC Systems
- Room Pressurization Diagrams
- Modular Clean Room Strategy
- Building Shell Requirements
- Contract and Project Delivery Strategy

Plant Utilities:

- Hot and Cold Potable Water
- High Purity Process Water
- Ultra High Purity Process Water
- Water-For-Injection System (WFI)
- USP Water
- Clean Steam
- Chilled Water
- Compressed Air
- Central Vacuum System
- Specialized Gasses
- Liquid Process Waste Collection
- High Nitrogen Process Waste Collection
- Clean-In-Place (CIP) Systems
- Fire Protection
- Back-up Electrical Power Generation System



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