



Pharmaceuticals & Biotechnology

Client
GeneMedix

Location
Tullamore, Ireland



Generic Biotech Production Facility

Project Description

GeneMedix is a generic biotech company and this was their first new production facility. It was built inside an existing unoccupied 1998 IDA "advanced factory" in an industrial park.

The project included 500 square meters of Grade C and D production areas; a warehouse area to receive goods, sample goods and store goods, including a cold room for media; and laboratories. A mezzanine was constructed to house the plant room, which contained six air handling units.



Other equipment included RO and WFI units; LPHW boilers, plant steam boiler, compressed air and gases, chilled water, and waste neutralisation systems; and Class II biosafety cabinets, incubators, autoclaves, LAFs, freezers and refrigerators.

The project was handled in a phased manner on a guaranteed maximum price basis under the I.Chem.E Green Book conditions. It took 13 months from the start of basic engineering to the plant opening ceremony, a truly fast-track project showing the benefit of the prebuilt IDA advanced factory concept.

A critical success factor was the high level of integrated teamwork between CH2M HILL IDC, GeneMedix, key suppliers and subcontractors. Services provided included:

- Project Management
- Engineering
- Systems Integration
- Procurement
- Construction Management
- Validation
- Regulatory Controls

The process produces a generic erythropoietin using a continuous mammalian cell process. To minimize piping and cleaning costs, the heart of the process uses portable bag technology. Sterile media is purchased in large bags and held in a cold room in the warehouse until required. A single bag is then moved to a second cold room where it is connected to the bioreactor. At this time a second (receiving) bag is also connected. Once the several week perfusion fermentation process is completed, the perfusate is concentrated using ultrafiltration. The cell free solution is then passed through a series of chromatographic columns. (The requisite buffers are made up on site using in-house WFI. Buffers are held in portable bags until required.) The final product is collected, transported to a Grade A hood where it is sterile transferred into a final receiver. It is then shipped for final dosage preparation elsewhere.



The building management system was based upon an Allen-Bradley control logix system with 500I/O and an RS view Scada system that was 21 CFR Part 11 compliant. IDC produced the URS, and performed loop checking, PLC programming, commissioning and validation.