



International North America

Client

Human Genome Sciences

Location

Rockville, MD, USA

*" Governor Robert L. Ehrlich Jr.
...praised the facility, indicating it
'bodes well for the future of
bioscience in Maryland.'
...C. Robert Eaton, president of the
bioscience association MdBio Inc.,
also hailed the new plant. 'Anytime
you add such a world-class facility,
it is a great thing for our industry,'
Eaton said."*

The Gazette, Sept. 23, 2005



Design of a Large-Scale Biologics Manufacturing Facility

Project Description

CH2M HILL Lockwood Greene provided the detailed design of a large-scale biologics manufacturing plant at Johns Hopkins University's Belward Research Campus in Rockville, Maryland. The 300,000-square-foot, world-class, multiproduct facility houses a cell culture process train, as well as integral bulk fill operations to support both clinical trial and large-scale production requirements.

Human Genome Sciences (HGS) is a biopharmaceutical company with a pipeline of novel protein and antibody drugs directed toward large markets that have significant unmet medical needs. Due to the worldwide shortage of biologics manufacturing capacity, HGS considers this facility to be a vital asset both to the company and to the public.

The cell culture process in the new facility is based on two 20,000-liter production bioreactors. Recovery and purification operations include centrifugation, depth filtration, chromatography, ultra-filtration, and nano-filtration.

Bulk product filling, freezing, and frozen bulk storage areas are integrated with the rest of the plant. Flexible process operations were designed to accommodate a large pipeline of monoclonal antibody therapies. Process support functions include central weigh and dispense, media prep, buffer prep/buffer hold, and dedicated glass wash areas.

The facility design incorporates large-scale material handling and includes fully integrated clean-in-place/sterilize-in-place (CIP/SIP) technology. A uniflow system of clean and return corridors was designed to comply with stringent manufacturing requirements and to minimize the risk of cross-contamination. Dedicated air-handling units provide appropriate air classifications for FDA-regulated manufacturing as well as for Biosafety Level 1 biocontainment.

The three-story facility also contains process support and warehouse areas, quality assurance/quality control laboratories, and administrative offices. An 18-MW standby emergency diesel generator and an uninterruptible power supply system ensure that power to critical systems can be maintained at all times.

Clean process utilities include fully redundant, clean steam generators, clean air and process gases, and generation and storage of water for injection. Wastewater treatment is located inside the building, including continuous biowaste inactivation and process waste neutralization.

HGS's goal is to build a global biopharmaceutical company that discovers, develops, manufactures, and markets gene-based protein and antibody drugs to treat and cure disease. The new facility will play a significant role in helping HGS attain its goal by providing additional capacity for advanced clinical trials and by supporting the commercial launch of products emerging from the company's product pipeline.