

CLIENT: Wyeth Pharmaceuticals

LOCATION: Andover, MA

PROJECT: Embrel Production Facility

SCOPE OF WORK: Commissioning Manager

DATE: 2002

COST: \$180MM



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A new 112,000 square foot building facility was constructed at the existing Wyeth BioPharma Andover site. This new complex is a both a production and multi-product development facility. The facility is used for drug development work, process scale-up, production trouble shooting, and clinical drug substance use. The process is designed to produce two products concurrently. Only CHO based drug substances are produced in this facility. No bacterial processes will be run in these process areas.

The unit operations were designed with the flexibility to run alternate product volumes. Sizing of the process operations and utilities were based on the worst case of these operations occurring concurrently. The facility was designed to operate independently from the process areas E/F commercial facility, also located in building B. Although, utility systems are shared between E/F process areas and ADF process areas, the systems are designed to allow for shut down/isolation of either process areas E/F or process areas ADF without affecting each other's operations. The scope, of this facility included:

- ◇ HVAC/MCC and other utilities on the penthouse
- ◇ Media prep, holding tanks and Buffer prep located on the fourth floor
- ◇ All the support equipment is in the interstitial space and the third floor.
- ◇ Titrant tanks and cell culture Bioreactors on the second floor.
- ◇ Permeate filtering and harvest on the first floor

COMMISSIONING OVERVIEW

The commissioning team developed a set of startup / commissioning packages to be used as a guide by construction to concentrate their efforts on finishing the systems in the sequence required to be able to commission, start and run the ADF facility. These packages were intended to be strictly a guide and did not in any manner replace or override the engineering design specifications, drawings, and other design engineering documents.

Commissioning was a planned, collaborative, and systematic process of checking, inspecting, and testing to confirm that a building or process, and its subsystems, performed as designed.

The ADF facility was commissioned by various means based upon the requirements of the building and process being constructed. The building and process components were broken down into systems with specific system numbers to be commissioned in a required sequential manner. The startup activities for certain systems were scheduled early while building construction was still in progress in order to meet the schedule requirements of the project. This necessitated that Wyeth BioPharma take over operation of systems that were commissioned to continue operation with building construction still ongoing.

The building systems defined as those that were turned over to Wyeth BioPharma based on completion by a subcontractor and as those that went through a startup by the commissioning team. The process areas have been defined in a similar manner with most systems being started by the commissioning team. The introduction of the automation systems for the various building and process systems were a key element of commissioning and were addressed within the plan.