This tutorial is designed to enhance knowledge of biotechnological/pharmaceutical processes. The topics covered within this tutorial will give preliminary explanations and conclusions. However, references for more in depth study will be provided. It is strongly suggested that you investigate these references.
Overview

Introduction
- Description of facility design and why it is important to chemical engineers.

Equipment
- This section will describe equipment considerations during facility design.

Utilities
- This section will describe implications of facility design concerning facility utilities.

Waste Systems
- This section describes the role of waste disposal when developing a facility.

Storage
- This section will discuss the impact of raw materials and final product storage on facility design.

Conclusions
Introduction

The overall goal of process development is to implement a conceptual design into a manufacturing scale. For this reason, chemical engineers have to consider the implications of facility design.

In facility design, the manufacturing process concept is transformed into a physical process within a facility. For this reason, a detailed block flow diagram (BFD) should be created. The facility can be designed from this BFD.

This tutorial will describe a few of the aspects that should be taken into consideration when designing a facility for a pharmaceutical/biotech product.
The pharmaceutical/biotech industry is regulated by Food and Drug Administration (FDA). The FDA in turn sets guidelines for facility design, but these are only broadly define acceptable limits. The manufacturer ultimately decides how to implement these regulations.

The main regulations for facility design comes from the US Federal Standard 209E (FED-STD-209E). This document specifically sets the standards for air handling within the facility. It defines the amount permissible per particulate size. This limit in turn determines the classification of the process rooms within the facility.
Facilities must also comply to current Good Manufacturing Processes (cGMP). cGMP is a system of good manufacturing procedures and techniques that ultimately protect the patient. As the name implies, the standard are periodically updated to reflect changes within the industry. For facilities, the regulations are defined in the US Code of Federal Regulations, specifically, 21 CFR 211.42 - 211.58.
Equipment

One of the main considerations for the development of facility is the equipment needed for the manufacturing process. One should assess what is needed based on the BFD.

Since this project is a retrofit of an existing facility, consideration should be taken into what existing equipment can be utilized. If the equipment meets the specifications for the process, one should considering using them. This will save the company money and time.

However, many times equipment cannot be used for various reasons (out of spec., intrinsic problems, etc.). At this point, new equipment should be purchased and incorporated into the facility.
When incorporating this new equipment certain consideration should be made. Can the equipment physically be moved into the building? Is the facility processing room(s) big enough for the equipment? Is construction needed to build or refurbish the facility in order to accommodate the equipment.

These are just a few of the consideration a engineer must take into account with process equipment. Other will arise pending on the specific piece of equipment. The facility should be designed around these aspects.
Utilities

Engineers should also consider the facility utilities during conceptual design. Since the nature of the product is pharmaceutical/biotech, many specific systems have be considered.

The systems include, but are not limited too, water for injection (WFI), clean in place/steam in place (CIP/SIP), HVAC, compressed air, etc. (Explanations and references are given in the ‘Information’ section of this website). HVAC and CIP/SIP are needed to ensure human safety and minimal product contamination. Whereas WFI and compressed air are used in the manufacturing process.

Since this situation involves a retrofit, these systems may already be in place. But are they accessible for the equipment? Do they meet the specifications of the process? Will any system need to be updated or modified? These are just a few of the questions that should be considered.
Once again, since this product is biological, there may be special regulations that exist to guide this process. In addition, engineers should make sure waste treatment facilities are safe for man as well as nature.

It is certain that the manufacturing process will generate significant wastes associated with fermentation and purification. The facility must be able to dispose of these wastes effectively and safely.

For biotech industries the main concern of waste treatment is the recombinant host. This organism may pose health threats if it is released untreated into the environment. Methods of disposal vary pending on the organism. This should be kept in mind when design the waste treatment facility.
So, where will these wastes go? Are there facilities already existing that can handle these wastes? Are they sufficient in size and capacity? Are a few more questions that should be assessed when designing the waste treatment section of the facility.

Broad guidelines exist for waste systems as documented by the US Code of Federal Regulations (CFR). As mentioned earlier these codes include:

- 40 CFR Part 261
- 40 CFR Part 264
Storage of raw materials and products also has special consequences in the pharmaceutical/biotech context. These materials have to be quarantined when raw materials are received and after product packaging. This ensures that the materials avoid contamination while also minimizing human exposure. During this time, the new materials are properly labeled and tested before dispensing into the facility. The packaged product, on the other hand, awaits shipping.

When the facility becomes functional, these raw materials and final products will need a place for storage. This is yet another consideration an engineer must make during facility design.

Do these storage rooms already exist? Can existing room(s) be modified to accommodate these materials? Is there a need to build a new storage facility? An engineer should ponder these questions.
The design of a biological facility is multifaceted. Implementation of the processing equipment is just the first step in designing an effective facility. The aforementioned information is a starting point for considering decisions about facility design. Ultimately, particular decisions will be based on manufacturing needs, the BFD, and the existing facility.
Resources

   – 21 CFR Part 211:
     http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
     – FED-STD-209E

[2] Waste treatment regulations:
   – 40 CFR 261
   – 40 CFR 264
