Pharmaceutical Facility Design

PhEn-602
J. Manfredi
Section 102 (Wed.)
Pharmaceutical Facility Design – PhEn 602

Syllabus

Term: 2009 Spring Semester

NJIT Course Title: Pharmaceutical Facility Design

NJIT Course Number: PhEn 602, Section 102 (Wed.)

Course Instructor: Joseph J. Manfredi
Adjunct Professor
New Jersey Institute of Technology
Department of Chemical Engineering
University Heights
Newark, NJ 07102-1982

Instructor’s Telephone & Fax: Ph: (973) 575-4990 Fax: (973) 808-9201

Instructor’s E-Mail Address: JJM1152@AOL.com

Instructor’s Office Hours: As an adjunct faculty member, Prof. Manfredi does not maintain an office on campus. Students may contact him, preferably by email, to schedule a meeting, to pose questions, or to request clarifications regarding course materials. Responses will be handled as quickly as possible, subject to scheduling, travel and other prior commitments. Phone calls should be limited to emergencies only. Prof. Manfredi will generally be available prior to and after each class for discussion.

Grader/Assistant: None

Course Day and Time: Wed. (Sect. 102) 6:00 – 9:05 p.m.

Location: NJIT, Newark, NJ, Kupfrian Hall, Room 110
Course Prerequisites: Graduate Standing
PhEn-601 – Principles of Pharmaceutical Engineering
PhEn-603 – Pharmaceutical Processing and Manufacturing
Permission by the Instructor or the Program Director

Course Description: This course provides students with a basic understanding of the challenges faced by engineers and designers when designing a pharmaceutical manufacturing facility. The course will focus on the sterile manufacturing facility design model, although many of the principles discussed will apply to all other types of Pharmaceutical facilities. Pharmaceutical facilities are required to meet Good Manufacturing Practices (GMP) regulations, while at the same time, must be in compliance with all governing codes, laws and regulations. The main objective of the course is to provide students with a solid understanding of the key principles of facility design. The course blends practical applications, with the underlying theory behind basic concepts, so that the student obtains a balanced understanding of the topics. The course is intended to 1) teach students the basics of facility design, 2) highlight the major challenges faced by designers and engineers, 3) provide helpful “do’s” and “don’ts” concerning design options, and 4) present important operational, testing and construction considerations that impact design decisions.

Course Requirements:
- Examination: Two exams, i.e. a midterm exam and a final exam
- Quizzes: Four quizzes as scheduled by instructor

Grading Policy:
- Midterm exam..............................30%
- Final exam....................................30%
- Quizzes.........................................40% (10% each quiz)

Course Final Grade: a tentative guideline for the assignment of final grades is provided below:
Cumulative Points | Overall Grade
--- | ---
90-100% | A
88-89% | B+
80-87% | B
78-79% | C+
70-77% | C
<69% | F

The grade of “D” is not assigned to students taking graduate courses.

*Please remember that this is only a guideline designed to help the students understand how they are performing in the course.*

Exams:
- A calendar of the exams is included in the Course Outline given below;
- All exams are typically 3 hours long unless otherwise stated;
- All exams are open book and open notes, unless otherwise announced;
- The final exam will include all material covered throughout the course (although the main emphasis of the exam may be on the material covered after the midterm exam);
- Make-up exams will only be given to students who cannot attend the regular exam time, **and** only under documented and extraordinary circumstances. In any case, no student will be allowed to take a make-up exam unless he/she has the **prior** consent of the instructor. If a student fails to take an exam as scheduled, the exam grade will automatically be zero.

Quizzes:
- A calendar of the quizzes is included in the Course Outline below.
- Quizzes are typically 1 hour long unless otherwise stated.
- Quizzes may be open or closed book and notes. Format will be announced.
- Quizzes will typically cover material from immediately preceding classes.
- Make-up quizzes will only be given if approved in advance for documented and extraordinary circumstances.
**Class Attendance:** As for all graduate courses at NJIT, attendance is not mandatory, but **strongly** recommended. Experience shows that students who do not regularly attend class typically perform poorly in the course. In addition, discussions and material provided by any guest lecturers will not be covered in the notes. In any case, students are responsible for all material covered in class. Interwise access is anticipated for students unable to attend class in person due to travel or other business related activities. Details for accessing Interwise will be provided at the first class session.
Important Dates on the NJIT Calendar (Spring 2009) – visit NJIT’s website

01/21/09  First Class PhEn-602 Section 102
02/02/09  Last Day for a Refund Based Upon A Partial Withdrawal
Ck. Registrar  Last Day for a Refund Based Upon a Complete Withdrawal
03/18/09  No Class – Spring Break
03/30/09  Last Day to Withdraw from Course(s) (No Refund)
04/29/09  Last Class-PhEn-602-102
05/06/09  Reading Day
05/13/09  Final Exam PhEn-601 (Finals 12/15-19/08)
05/14/09  Grades Due in Registrar’s Office
PHARMACEUTICAL FACILITY DESIGN (PhEn-602)

Wk #1 (1/21)  Introduction & Planning
   A) GMP’s, CFR, FDA
   B) Project planning

Wk #2 (1/28)  Design Considerations
   A) Regulations
   B) Building & Zoning Codes
   C) Support Utility Requirements
   D) Bldg. Materials & Finishes
   E) Safety

Wk #3 (2/04)  Types of Manufacturing
   A) Sterile / Aseptic
   B) Non-Sterile
   C) Liquid vs Dry
   D) Cross-Contamination
   E) Cleaning
   F) Single vs Multiple Products
Quiz #1 (Tentative)

Wk #4 (2/11)  Classified Spaces & Controlled Environments
   A) Clean Rooms
   B) ISO vs FSA
   C) Air Flow
   D) Exchange Rates

Wk #5 (2/18)  Environmental Issues & Monitoring
   A) Microbial.
   B) Air & Liquid Discharge
Quiz #2 (Tentative)

Wk #6 (2/25)  Architectural
   A) Materials & Finishes
   B) Service / Maintenance
      a. Interstitial & Mech. Rooms
| Wk #7 (03/04) | Midterm Examination |
| Wk #8 (03/11) | Heating & Ventilation  
| | A) Equipment  
| | B) Configuration  |
| Wk #9 (03/25) | Air Conditioning  
| | A) Equipment  
| | B) Configuration  
| | Quiz #3 (Tentative)  |
| Wk #10 (04/01) | Moisture  
| | A) Humidification / Dehumidification  
| | B) Related Problems  |
| Wk #11 (04/08) | Utility Sizing  
| | A) Heating & Cooling Loads  
| | B) Psychometrics  |
| Wk #12 (04/15) | Critical Utilities  
| | A) Water  
| | B) Steam  
| | C) Gases  
| | Quiz #4 (Tentative)  |
| Wk #13 (04/22) | Layout  
| | A) Adjacencies  
| | B) Materials Flow  
| | C) Personnel Flow  |
| Wk #14 (04/29) | Semester Review  |
| Wk #15 (05/13) | Final Examination  |
Course Notes, Textbooks, and Other Reference Material:

- **Notes**: *Pharmaceutical Facility Design Course Notes*. These notes are duplications of the presentations used in class. The Notes will be posted on the NJIT website:
  
  http://web.njit.edu/~armenant/PhEn602-102

- **Textbook**: (Optional)
  

Reference material:

3. “Good Design Practices for GMP Pharmaceutical Facilities”, Andrew Signore and Terry Jacobs, Taylor and Francis
5. “Validation of Pharmaceutical Processes”, Carlton and Agalloco, Marcell Dekker, Inc.
ISPE Guides
ISPE

- Excellent Resource
  - Publications: Guides, PE, JPI
  - Networking
  - COP’s (Community of Practice)
  - Educational Programs
  - Student Programs
Class Notes

Notes can be found at:

http://web.njit.edu/~armenant/PhEn602-102

THIS ADDRESS IS CASE SENSITIVE
Housekeeping

- The email address listed with the official class roster will be used as needed to communicate with the class. Check this regularly, especially during periods of inclement weather.

- Guest lecturers &/or tours may be scheduled as available and class schedule adjusted accordingly.
  - Novartis Tour 2/25/09

- Text is optional and will not impact performance.

- 30 Minute Policy for instructor absence.

- Class Breaks will be discussed and a format selected, however this will remain at the instructor’s discretion.
Library Research

- [http://www.library.njit.edu/staff-folders/slutsky/PharmTutorial/Pharmtutorial.html](http://www.library.njit.edu/staff-folders/slutsky/PharmTutorial/Pharmtutorial.html)

- **Important Announcement for Users of Scifinder Scholar** - The Web version became available to NJIT on January 20, 2009
March 17-19, 2009
(Spring Break)
Jacob K. Javits Center
New York, NY

PhEn602-Pharmaceutical Facility Design-Spring 2009
PhEn-602
Pharmaceutical Facility Design

Week 1

GMP’s

Project Approach

Design and Validation
Good Manufacturing Practice (GMP’s)

Food, Drug and Cosmetic act gives FDA authority to enforce legal requirements in manufacturing, processing, packing and holding of drugs.

- These requirements are found in 21CFR Part 211

Subpart C relates to “Buildings and Facilities”
§ 211.42 Design and construction features.

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination.

The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

(c) Operations shall be performed within specifically defined areas of adequate size.
§ § 211.42 Design and construction features.
There shall be separate or defined areas for the firm's operations to prevent contamination or mixups during:

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

(2) Holding rejected components, drug product containers, closures, and labeling before disposition:

(3) Storage of released components, drug product containers, closures, and labeling;

(4) Storage of in-process materials;

(5) Manufacturing and processing operations;

(6) Packaging and labeling operations;
§ § 211.42 Design and construction features (cont).

(7) Quarantine storage before release of drug products;
(8) Storage of drug products after release;
(9) Control and laboratory operations;
(10) Aseptic processing, which includes as appropriate:
(i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
(ii) Temperature and humidity controls;
(iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;
(iv) A system for monitoring environmental conditions;
(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;
(vi) A system for maintaining any equipment used to control the aseptic conditions.
§§ 211.42 Design and construction features.

(d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.
Note:
The GMP Regulations specify what a particular requirement is (i.e. what is to be controlled), not *how* that requirement is to be achieved.
What does FDA look for in a facility?

Buildings and Facilities

1) Is the facility suitable for the operations being carried out?
2) Is the facility readily cleanable?
3) Are there proper controls against cross-contamination?
4) Is there adequate ventilation while still keeping out sources of contamination?
5) Are there adequate sanitary facilities?
6) Are there operational areas separate to prevent mix-ups and cross-contamination?
7) What is the source of the water supply?
8) Are there adequate systems for the handling and disposal of waste?
What does FDA look for in a facility?

Materials handling and storage

1) Is there proper segregation between incoming and released components?
2) Are environmental factors, such as temperature and humidity, monitored and controlled properly?
3) Is there adequate storage space under the required environmental conditions?
4) Are in-process materials properly stored?
5) Are containers suitable for raw materials and intermediate product?
What does FDA look for in a facility?

**Equipment**

1) Is the facility equipment suitable for its intended use?
2) Is equipment designed to facilitate cleaning?
3) Are there proper filtration systems adequately designed and properly functioning?
4) Does equipment design prevent contamination from external sources?
5) Is equipment clearly and uniquely identified?
Pharmaceutical Facility Design

**Pharmaceutical Facility Project Sequence**

*Design*

*Good Engineering Practice*

*Validation*
There must be a compelling reason for pursuing a new or renovated facility.

- Sales of existing products have surpassed the capabilities of the current facility and an expansion is necessary.
- New products have been identified which require different types of facilities.
- Existing facility does not meet current regulatory requirements (e.g. FDA, EPA or other agency)

From J. Odum, Sterile Product Facility Design and Project Management
There must be a compelling reason for pursuing a new or renovated facility.

- Economic or business advantage associated with relocation to a new or existing site.
  - Improved labor pool
  - Cost of upgrade, renovation, or change
  - Cost of manufacturing and/or shipping
  - Tax incentive
  - Lower labor rate
  - Reduced cost of employee benefits

*Not From J. Odum, Sterile Product Facility Design and Project Management*
Establish Goals

Prepare the Business Case

- From the business case we develop a plan for manufacturing, and then proceed into the Facility Planning stage
"Exceptional facilities don’t just happen…they are planned to be functional, efficient, cost effective, and compliant to all regulations. They are planned to meet market demands for product…to be environmentally pleasing to those that work in them on a daily basis…and they are planned to be safe, protecting the workers and the outside environment."

Proper planning is the key.....having a sound project management process is crucial

In order to properly plan the facility, a significant amount of information is needed, such as project goals and objectives, product volumes, schedule, budget costs, utility requirements, safety requirements, etc., etc. This information is typically gathered during the facility programming portion of the conceptual design phase.
Pharmaceutical Facility Design

Project Approach – 9 stages

1. Conceptual Study
2. Functional Design/Preliminary Engineering
3. Request for Funds Approved
4. Detailed Engineering
5. Procurement/Bidding
6. Construction
7. Commissioning
8. Validation/Qualification
9. Turnover to Owner
PhEn-602 will focus on:

- Design (1, 2 & 4)
- Commissioning, Validation/Qualification (7 & 8)

1. Conceptual Study
2. Functional Design/Preliminary Engineering
3. Request for Funds Approved
4. Detailed Engineering
5. Procurement
6. Construction
7. Commissioning
8. Validation/Qualification
9. Turnover to Owner
Pharmaceutical Facility Design

Three phases to the Design Process

- Facility Programming
- Business Objectives
- Conceptual Design
- Preliminary Engineering
- Detailed Design
Conceptual Design - Basic Elements

- Establish goals and objectives, and discuss how GMP requirements will be met
- Conduct facility programming, with extensive data gathering - Very important!
- Conceptual layout and Accommodation Schedule
- Prepare “Basis of Design” (statement of criteria)
- Establish design philosophy: e.g. state-of-the-art or leading edge?
- Heating, Ventilation and Air-Conditioning philosophy
- Major equipment list
- Budget estimate (often prepared for management review)
Conceptual Design – Facility Programming

<table>
<thead>
<tr>
<th>Process</th>
<th>Company Z</th>
<th>( \text{Pharmaceutical Facility Design-Spring 2009} )</th>
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</thead>
</table>

### Conceptual Design – Facility Programming

#### Process Company Z

- Laboratory
- Office / Amenities
- General Support

#### Preliminary Program

- Single Level Manuf./Pkg. Facility with Mezzanine

#### Functional Unit Title/ Space Description

<table>
<thead>
<tr>
<th>Unit Title/ Space Description</th>
<th>2008</th>
<th>2013</th>
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<tbody>
<tr>
<td><strong>Net</strong> SF</td>
<td><strong>Net</strong> SF</td>
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#### PROCESS

**Manufacturing**

- Pharmacy: 120 units, 480 net SF, 620 net SF
- Drying: 400 units, 960 net SF, 1,600 net SF
- Blending: 300 units, 2,700 net SF, 3,600 net SF

**Packaging**

- Compression: 480 units, 13 net SF, 6,240 net SF
- Encapsulation: 480 units, 2 net SF, 960 net SF
- Coating: 400 units, 5 net SF, 2,000 net SF

**Support Areas**

- Dirty Equipment Staging: 600 units, 1 net SF, 600 net SF
- Equipment Wash: 600 units, 2 net SF, 1,200 net SF
- Clean Equipment Storage: 200 units, 1 net SF, 200 net SF
- Tool Storage: 400 units, 1 net SF, 400 net SF
- Tool Inspection: 400 units, 1 net SF, 400 net SF
- Instrumentation Shop: 300 units, 1 net SF, 300 net SF
- In-Process Test: 250 units, 1 net SF, 250 net SF

**Situation Prep**

- 250 units, 50 net SF, 50 net SF

**Enlargement**

- Men’s Lockers: 12 units, 80 net SF, 960 net SF
- Women’s Lockers: 12 units, 80 net SF, 960 net SF

### Manufacturing Admin

- General Admin - Office: 64 units, 3 net SF, 192 net SF
- General Admin - Workstation: 120 units, 10 net SF, 1,200 net SF
- Engineering - Office: 64 units, 20 net SF, 1,280 net SF
- Engineering - Workstation: 120 units, 3 net SF, 360 net SF
- Purchasing - Office: 64 units, 3 net SF, 192 net SF
- Purchasing - Workstation: 120 units, 2 net SF, 240 net SF
- Health, Safety & Environment - Office: 120 units, 2 net SF, 240 net SF
- Maintenance - Office: 120 units, 6 net SF, 720 net SF
- Production Planning - Office: 120 units, 3 net SF, 360 net SF
- Support Areas: 150 units, 55 net SF, 8,250 net SF

### Manufacturing Admin SUBTOTAL - NSF

- 20,420 net SF
- 22,240 net SF

### General Support - Manufacturing

- Warehouse - Unreleased Material: 6.00 units, 1168 net SF, 7,008 net SF
- Warehouse - Released Material: 6.00 units, 718 net SF, 4,308 net SF
- Warehouse - Manufacturing WIP: 6.00 units, 1080 net SF, 6,480 net SF
- Technical Services: 3.00 units, 5,927 net SF, 5,927 net SF
- Maintenance Shop: 5,000 units, 1 net SF, 5,000 net SF
- Consumable Storage: 1,200 units, 1 net SF, 1,200 net SF
- Filter Storage: 1,200 units, 1 net SF, 1,200 net SF
- Chemical Dispensing: 450 units, 1 net SF, 450 net SF
- Waste Drum Storage: 200 units, 1 net SF, 200 net SF

### General Support SUBTOTAL - NSF

- 8,250 net SF
- 12,300 net SF

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**Conceptual Design Basic Elements:**

1) **“Accommodation Schedule”** also called **“Bubble Diagram”**
2) **Defines adjacencies and high level flow of material and personnel**
3) **Performed prior to layout of area**
Functional Design – Basic Elements

Also called: "Preliminary Engineering", "Front-end Design", "Design Development"

- Establish a basis for detailed design
  - Prepare Basis of Design (BOD)
- Layout of production lines, location of equip't., building services/utilities defined
- Create process specifications, process flow diagrams, and P&ID’s (Process and Instrumentation Diagrams)
- Detailed cost estimate is generated
- Develop User Requirements Specifications (URS)
Detailed Design

- Prepare detailed engineering drawings to be issued for construction
- Create detailed equipments lists and instrument lists
- Develop construction strategy
- Set the basis for the Installation Qualification (IQ)
- Finalize layouts, size and routing of utilities
Pharmaceutical Facility Design

Note: A more developed design produces a more accurate estimate! Too often projects are estimated at the conceptual design stage....

Tip: If possible finish the functional design (preliminary engineering) before requesting funds to minimize submission of budget revisions.
Good Engineering Practice

“Established engineering methods and standards that are applied throughout the project lifecycle to deliver appropriate cost-effective solutions”...including:

- Professional and competent project management
- Professional and competent engineering design, procurement, construction and commissioning
- Full consideration of applicable safety, health and environmental statutory requirements
- Full consideration of operation and maintenance requirements
- Full consideration of recognized standards and guidance
- Appropriate documentation for ongoing operation and maintenance, and to demonstrate compliance with applicable regulations and codes
Commissioning

“A well planned, documented and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the End-User that results in a safe and functional environment that meets established design requirements and stakeholder expectations.”
Commissioning Plan

- Prepared and approved by Commissioning Team
- Approvers include Construction, Design, Quality, Validation and User Department Representatives.
- Includes list of systems and equipment to be commissioned, including process equipment and utilities.
- Can include schedule/timeline for the commissioning activities
- Often precedes validation
- ETOP (Engineering Turn-Over Package) is often a deliverable.
Commissioning Benefits

- Can streamline the validation, since thorough up-front testing is done to eliminate bugs
- Improved documentation in place prior to IQ can reduce IQ execution effort
- Provides a formal structured approach to testing and owner acceptance, ensuring a minimum level of acceptable documentation
- Provides a formal structured approach to testing and acceptance, for those systems that are not validated (non-GMP).
Validation – An Essential Part of GMP

Validation is the scientific study of a system:

- To prove that the facility system/equipment is consistently doing what it is supposed to do (i.e., that the process is under control)
- To determine the process variables and acceptable limits for these variables, and to set-up appropriate in-process controls.

Validation as defined by FDA:

"Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes."

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Validation Execution - Three primary elements

**DQ** – Design Qualification
Verifies the design is suitable/appropriate and will work

**IQ** - Installation Qualification
Verifies the system/equipment is supplied and installed correctly

**OQ** – Operational Qualification
Verifies that the system/equipment operates as specified, intended throughout all anticipated ranges

**PQ** – Performance Qualification
Verifies that the system/equipment performs as intended meeting predetermined acceptance criteria
When to begin planning?

- Validation needs must be incorporated in earliest stages of the project (DQ?)
- Should be considered during the design phase (DQ?)
- Validation cannot be thought of as the last hurdle.
- Ignoring validation early in the project will be disastrous!
Project Validation Plan

- Defines overall validation approach
- Defines validation activities to be performed; at a high level
- Defines roles and responsibilities
- Describes the phases to the validation effort
- Provides estimated timelines
- Must be approved by cross-functional team, with final approval by QA
The V-Model

- User Requirements Specification (URS)
- Functional Specification
- Detailed Design
- Implement/Build
- Performance Qualification
- Operational Qualification
- Installation Qualification

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User Requirements Specification (URS)

- Also called “User Requirement Brief”
- Describes what the system or equipment is supposed to do.
- Often sent to suppliers as part of the vendor solicitation process.
- Includes essential requirements \((\textit{musts})\) as well as desirable requirements \((\textit{wants})\)
- Normally written by user department, or engineer
Functional Specification (FS)

- Often written by supplier
- Describes what the system will do.
- Detailed functions are described.
- Links to an OQ, which tests all functions specified.
- The FS is a design output.
Detailed Design Specifications (DDS)

- Documents how the system will be built
- Like FS, is a design output
- Links to both IQ and OQ
- Based upon the detail design documents
Quality Plan

- A document setting out the specific quality practices, resources, and sequence of activities relevant to a particular product or process. It defines the general distribution of responsibilities for quality related tasks and the implementation of the Quality System elements.
### Project Planning & Schedule

Agreed by team members
Details phases, activities, and milestones
Gantt Chart most commonly used

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Putting it all together

The Compliance Pyramid

- Validation
  - Final Turnover and Acceptance
- Qualification
  - IQ
  - OQ
  - Installation Qualification
  - Operational Qualification
- Commissioning
  - Operability Function Tests
  - Factory Acceptance Tests
  - Operation Manuals
- Design Phase
  - User Requirements Specification
  - Quality Plan
  - Project Validation Plan
  - Project Plan
  - Compliance/GMP Review
  - Functional Design Specifications
  - Detail Design Specifications

Good Engineering Practice

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Project Life Cycle Discussion

- Who are the players that make everything happen?
The Project Team (Typical)

- Validation Team Rep
  - Name
  - Title
  - Name
  - Title
  - Name
  - Title

- Quality Assurance Rep

- Manufacturing Rep
  - Name
  - Title

- Facilities and Maintenance Rep
  - Name
  - Title
  - Name
  - Title

- Design Team Rep
  - A/E Firm
  - Architect
  - Mechanical
  - Electrical

- Construction Group Rep
  - MEP Supervisor
  - Planner/Scheduler
  - Purchasing

- Quality Control Rep

- Purchasing Rep

- Finance Rep

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Some unique aspects of Pharmaceutical Facility Projects

- Plants are very expensive to build, as compared to other industries.
- Procurement costs for process equipment are astronomical...can be 30% of overall project cost.
- Validation costs are very high...in some cases 15-20% of overall project cost.
- Very long timelines from start to finish, often due to two major issues:
  - Specialty equipment lead-time
  - Validation is extensive...up to 1 – 3 years in some cases, depending on size of project.
Pharmaceutical Facility Design

Summary:

- A structured project approach is required for successful implementation of Pharmaceutical Facility Projects
- A phased approach to the design is often used
- Good Engineering Practice and Commissioning play a key role in the project life-cycle
- Validation is an essential part of the facility system and must be considered at the earliest part of the project; during the design phase.
Documentation “Golden” Rules

■ If there is no documentation; the job wasn’t done
■ That which is written remains
Six Phases of a Project:

- 1) Enthusiasm
- 2) Disillusionment
- 3) Panic
- 4) Search for the guilty
- 5) Punishment of the innocent
- 6) Praise and honors for non-participants