What do Pharmaceutical Engineers do?

Pharmaceutical engineers are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, where they also are involved in the conception, design, scale-up, manufacturing, and labeling and packaging processes in the conversion of chemical and biological materials into valuable pharmaceuticals and pharmaceutical therapies. They have to implement FDA regulations, validation assurance (VA), quality control, and maintain Good Manufacturing Practices (GMP) compliant facilities. In addition to the safety of the end product, they have to maintain a level of personal and environmental safety.

Careers

Opportunities for jobs are international and there is a high demand for pharmaceuticals and the engineers who produce and manufacture them. There are a wide variety of careers in each sector of the industry including research of new drugs and drug delivery systems, scale-up process, manufacturing, labeling and packaging, facility design, management, sales, and education. Although many job inquiries are not listed as pharmaceutical engineering positions, they may be listed under several different engineering and science positions, such as chemical engineering, bioprocesses engineering, chemistry, and biochemistry, among others, depending upon education and experience, as well as the job description.

Skills needed to become a Pharmaceutical Engineer

A good standard to go by is the Certified Pharmaceutical Industry Professional™ (CPIP™). CPIP™ is a credential awarded to an individual based on competency in the pharmaceutical industry. It is awarded by the International Society for Pharmaceutical Engineers (ISPE). The following are the necessary areas by which the credential is given:

- Technical Knowledge: broad industry knowledge and experience including
  - Product development
  - Production systems
  - Facilities and equipment
  - Information systems
  - Supply chain management
  - Quality systems
  - Regulatory compliance
- Leadership and Professionalism: cost-effective, risk-based
- Integration/Innovation/Change Advocacy
- Quality and Continuous Improvement Focus

By remaining updated with information about pharmaceutical engineering and its closely related industries, and by taking the necessary steps to obtaining a degree in pharmaceutical engineering or a related field with the addition of courses, a certificate, or relative work experience in the pharmaceutical engineering industry, a satisfying career in pharmaceutical engineering can be found.

Companies

The 2005 Top 20 Pharmaceutical Companies, based on 2004 pharmaceutical revenues

1. Pfizer (USA)
2. GlaxoSmithKline (UK)
3. Sanofi-Aventis (France)
4. Johnson & Johnson (USA)
5. Merck & Co. (USA)
6. AstraZeneca (UK-Sweden)
7. Novartis (Switzerland)
8. Bristol-Myers Squibb (USA)
9. Roche (Switzerland)
10. Eli Lilly & Co. (USA)
11. Wyeth (USA)
12. Abbott Laboratories (USA)
13. Takeda (Japan)
14. Boehringer-Ingelheim (Germany)
15. Schering-Plough (USA)
16. Bayer (Germany)
17. Novo Nordisk (Denmark)
18. Schering AG (Germany)
19. Sankyo Co. (Japan)
20. Merck KGaA (Germany)

The 2005 Top 10 Biopharmaceutical Companies, based on biopharmaceutical revenues

1. Amgen (USA)
2. Genentech (USA)
3. Serono (Switzerland)
4. Biogen Idec (USA)
5. Genzyme (USA)
6. Gilead Sciences (USA)
7. MedImmune (USA)
8. Chiron (USA)
9. Millennium (USA)
10. InterMune (USA)

U.S. Department of Labor Wage Estimates

Architecture and Engineering Occupations

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Wage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petroleum Engineers</td>
<td>$92,840</td>
</tr>
<tr>
<td>Aerospace Engineers</td>
<td>$83,620</td>
</tr>
<tr>
<td>Chemical</td>
<td>$78,030</td>
</tr>
<tr>
<td>Electrical Engineers</td>
<td>$75,540</td>
</tr>
<tr>
<td>Biomedical</td>
<td>$74,150</td>
</tr>
<tr>
<td>Mechanical Engineers</td>
<td>$69,480</td>
</tr>
<tr>
<td>Civil Engineers</td>
<td>$68,280</td>
</tr>
<tr>
<td>Health and Safety Engineers</td>
<td>$66,750</td>
</tr>
<tr>
<td>Environmental Engineers</td>
<td>$69,200</td>
</tr>
<tr>
<td>Industrial Engineers</td>
<td>$67,820</td>
</tr>
<tr>
<td>Materials Engineers</td>
<td>$70,700</td>
</tr>
</tbody>
</table>

Life, Physical, and Social Science Occupations

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Wage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials Scientists</td>
<td>$73,270</td>
</tr>
<tr>
<td>Biochemists and Biophysicists</td>
<td>$72,160</td>
</tr>
<tr>
<td>Medical Scientists</td>
<td>$68,240</td>
</tr>
<tr>
<td>Chemists</td>
<td>$62,400</td>
</tr>
</tbody>
</table>

This information is based on the mean hourly wage for that particular occupation.

The Development of a Pharmaceutical

- Drug discovery
  - Target identification
  - Lead candidate identification
- Pre-Clinical Studies/Preformulation
  - Toxicology
    - Select or reject lead candidate
    - Select dose
  - Pharmacology in animals (2-3 species including one rodent and one non-rodent)
    - Absorption, distribution, metabolism, excretion
  - Analysis of physiochemical parameters
  - Dosage form development chart
  - Basic Preformulation Studies
    - Solubility, pKa
    - Partition coefficient
    - Chemical stability
    - Size, shape, surface area
    - Crystal properties
- Investigational New Drug (IND) Application with FDA
  - Results of Pre-clinical testing
  - Chemical Structure
  - Side affects in animals
  - Preliminary Manufacturing plan
  - Detailed clinical studies plan approved by the Institutional Review Board (IRB)
  - Annual reports to FDA and IRB
- Clinical Studies/Formulation
  - Clinical Studies
    - Phase I Clinical Studies
      - 20-100 healthy volunteers
      - 6 months to 1 year
      - Determine safe does range
      - Pharmacokinetics
      - Duration of affect
    - Phase II Clinical Studies
      - 100-500 volunteers with disease of interest
      - 6 months to 1 year
      - Placebo-controlled
      - Establish efficacy of treatment
      - Determine optimal dose strength and schedule
      - Note side effects
  - Phase III Clinical Studies
    - 1000-5000 volunteers
    - 1 to 4 years
    - Randomized, double-blinded treatment
    - Close monitoring for efficacy and side effects
- Formulation
  - Dosage Forms
    - Solid dosage form
    - Liquid dosage form
    - Semisolid dosage form
    - Special drug delivery technologies
  - Synthesis Methods
    - Emulsification
    - Coacervation
    - Extrusion
    - Polymerization
  - Delivery Methods
    - Parental
    - Oral
    - Buccal
    - Nasal
    - Transdermal
    - Needle-free injections
    - Cellular Implants
    - Inhalants
  - Formulation Studies
    - Physical and chemical stability
  - Scale-up and Manufacturing Plans
    - Freeze-thaw
    - Lypophilization
    - Filling
    - Labeling and Packaging
    - Accessories
    - Costs
- New Drug Application (NDA)
  - Analyzes of all data
  - File with FDA if candidate is safe and effective
  - 100,000 plus pages detailing every step of the processes
- Validation and Regulation
  - Drug information
  - ICD and DRG
  - Stability tests of drug substances and products (FDA)
  - Stability tests of new drugs and products (ICH)
  - Analytical procedures
  - Bioanalytical methods of human studies
  - Specifications for new drug substances and products
- NDA Application and Classification to Market a New Drug
- Post-approval Surveillance
  - Phase IV/Post-Market Studies
    - Continued evaluation of long-term effects

en.wikipedia.org/wiki/Pharmaceutical_company
http://www.biopharm.com/
http://www.phrma.org/
Organizations

**Controlled Release Society (CRS)**
CRS is an international society geared towards discovering methods for drug delivery. Members can attend workshops, short courses, and receive newsletters with updated information in drug delivery and release systems.

**The Institute of Biological Engineering (IBE)**
IBE revolves around three categories that integrate engineering with life sciences: Bioprocessing/Biotechnology, Biomedicine, and Environment. Pharmaceutical engineering falls under the first two categories. IBE promotes collaboration in education, research, and industry; exchange of technical knowledge; professional standards; scholarships; and public understanding and responsible uses of biological engineering products.

**The International Society for Pharmaceutical Engineering (ISPE)**
ISPE is a non-profit international organization that supports the pharmaceutical engineering and manufacturing industries through education, training opportunities, conferences, and technical publications. It aids in international collaboration and the exchange of ideas and experience among its members. The members of ISPE represent many disciplines in the industry from engineers and scientists to regulatory personnel, academia, suppliers, and sales representatives.

**Pharmaceutical Research and Manufacturers of America (RhRMA)**
RhRMA is involved in research and innovation of new treatments for disease, in addition to advocacy of public policy to allow for continued research by pharmaceutical and biotechnological companies.

**The Society of Manufacturing Engineers (SME)**
An organization that addresses issues in manufacturing processes and machinery. It maintains gatherings and conferences to promote information exchange, education, and networking.

**The Surfaces in Biomaterials Foundation**
A non-profit organization that focuses on educational, networking, and marketing opportunities, as well as creative solutions to problems in research, development, and manufacturing of biomaterials and in biomedical and diagnostic research. Professionals from the areas of engineering, scientific research, academia, and clinical and regulatory sectors are involved in this foundation.

**World Health Organization (WHO)**
WHO is the health agency of the United Nations aimed at the attainment of complete physical, mental, and social-well being of all people.

Journals

**Biomaterials**
An international journal dedicated to the science and engineering of biomaterials for clinical practice including drug delivery systems and implantable medical devices.

**Journal of Controlled Release**
The official publication of the Controlled Release Society and the Japanese Society of Drug Delivery systems. It is focused on all aspects of release systems for drug therapy and other biologically active agents.

**Pharmaceutical Engineering Magazine**
The publication of ISPE that gives information on pharmaceutical facilities, plant systems, process equipment, and instrumentation.

**Process Magazine**
Caters to professionals in the chemical and pharmaceutical industries. It has editions in German, English, and Chinese.

**World Pharmaceutical Frontier**
Aimed at executives in the pharmaceutical industry regarding purchasing, research and development, and manufacturing.

Websites

[www.pharmaceuticalonline.com](http://www.pharmaceuticalonline.com)
Directed towards pharmaceutical engineering, scale-up, manufacturing, and processing; contract manufacturing; and contract services.

[www.pharmaceutical-technology.com](http://www.pharmaceutical-technology.com)
Provides updated news and press releases; international coverage of pharmaceutical projects and developments; listings of pharmaceutical contractors and suppliers; and catalogues of products and services.

[www.pharmamfg.com](http://www.pharmamfg.com)
In-depth research on current trends and progress, product announcements, news, Q&A opportunities, career center, and a topic-based archive of articles, research, products, and news.

[www.worldpharmaceuticals.net](http://www.worldpharmaceuticals.net)
Focuses on the business aspect of the pharmaceutical industry, providing information to stay competitive.
Example Job Positions

As a large pharmaceutical company, Merck & Co., Inc. describes four of its positions in the industry.

**Pharmaceutical Research & Development**

Engineers develop formulations and drug delivery systems for new products. Working with chemical engineers and others trained in physical chemistry, pharmaceutical sciences and materials sciences, the group develops and scales-up processes that transform active pharmaceutical and biological products into final dosage form.

**Pharmaceutical Technology & Engineering**

This group supports Pharmaceutical Manufacturing. Engineers provide technical support to enable technology transfer and address technical issues with local manufacturing groups. This group also is involved in process engineering and works to improve and expand existing pharmaceutical and sterile processing systems.

**Chemical Engineering Research & Development**

Here engineers produce bulk pharmaceutical compounds used in safety assessment and clinical trials. Engineers handle synthetic organic processes using complex organic chemistry and advanced separation technology to recover products. They monitor and evaluate new chemical processing technologies, while also working with other process research and developmental areas. This work provides the foundation for the ultimate manufacturing process.

**Bioprocess Research & Development**

Engineers in this department link basic research with the commercial production of biologically derived products, such as antibiotics, natural products, proteins and vaccines. Here is where Merck's leadership in biochemistry, biochemical engineering, immunology and molecular genetics comes to life.

Example Job Posting

**Pharmaceutical Process Engineer**

Two Roads Professional Resources (San Dimas, CA)

**Overview**

Works on the design, modifications, and maintenance of manufacturing equipment, facilities and processes. Works on engineering planning, financial justification, start-up activities, scale up processes, implementation, process improvements, and validation. Performs evaluation studies of manufacturing equipment and systems.

**Requirements**

Must have a working knowledge in aseptic processes, process controls, and equipment design. Must have a working understanding and application of principles, concepts, practices, and standards along with full working knowledge of industry practices. Must be able to develop solutions to semi complex problems. Utilizes as necessary, established precedents and polices. Strong verbal and written communication skills and interpersonal skills are required. Knowledge of UBC, NEC, NEC codes is a bonus.

Specific Education and Experience Requirements Typically requires a BS degree in Engineering and minimum 6 years of relevant experience in related field. A MA/MBA degree can be substituted for 2 years of related experience.

**Responsibilities**

Performs trouble shooting on manufacturing equipment and systems. Generates and reviews required engineering and manufacturing documentation. Provide accurate budget estimates for capital equipment and projects. Independently resolves manufacturing engineering issues of complex scope. Independently manages assigned projects through completion. Participates on cross-functional project teams. May coordinate contract personnel through completion of assignments. May provide guidance to other manufacturing engineers. Purchases machinery, equipment, tools, raw materials, packaging materials, parts, services, and supplies necessary for the operation of a pharmaceutical organization. Compiles and analyzes statistical data to determine the feasibility of buying products and to establish price objectives. Compiles information from periodicals, catalogs, and other sources to keep informed on price trends and manufacturing processes. Centers with vendors and analyzes vendors' operations to determine factors that affect prices and determines lowest cost consistent with quality, reliability, and ability to meet required schedules. Reviews proposals, negotiates prices, selects or recommends suppliers, analyzes trends, follows up on orders placed, verifies delivery, approves payment, and maintains necessary records. Works on semi complex problems where analysis of situations or data requires an evaluation of intangible variables. Exercises independent judgment in developing semi complex methods, techniques and evaluation criteria for obtaining results. Provides leadership and guidance to non-exempt employees. EOE M/F/V/D