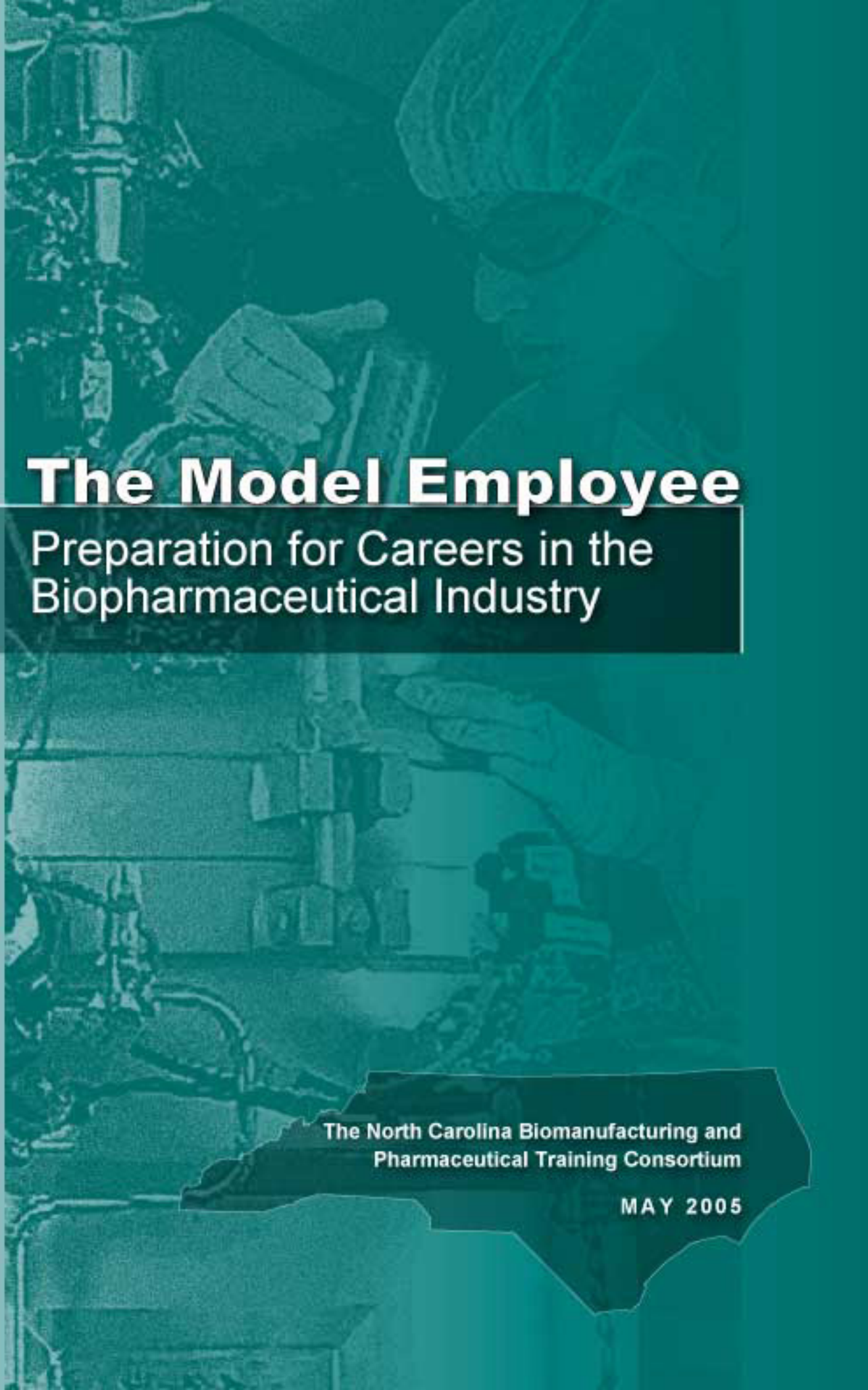


The Model Employee

Preparation for Careers in the Biopharmaceutical Industry

The North Carolina Biomanufacturing and Pharmaceutical Training Consortium

MAY 2005

The Model Employee

Preparation for Careers in the Biopharmaceutical Industry

Prepared by the North Carolina Biotechnology Center
For the North Carolina Biomanufacturing and Pharmaceutical Training Consortium

May 2005

This study was prepared by:

John Balchunas, Workforce Training Manager
Kathleen Kennedy, Vice President
Education and Training Program
North Carolina Biotechnology Center

To obtain additional copies of this report, contact:

North Carolina Biotechnology Center
Education and Training Program
PO Box 13547
Research Triangle Park, NC 27709
(919)541-9366

This study was prepared in collaboration with and on behalf of the Industrial Curriculum Committee (ICC) of the North Carolina Biomanufacturing and Pharmaceutical Training Consortium (BPTC). Activities of the Industrial Curriculum Committee as well as other industry participation in the BPTC are organized through the North Carolina Bioscience Organization (NCBIO).

ICC Chair: Hal Price
Biotech Manufacturing Forum
North Carolina Bioscience Organization
PO Box 20296
Raleigh, NC 27619

Table of Contents

Acknowledgements

The Industrial Curriculum Committee created the central idea for this report–that of using job descriptions as a framework within which to gather and organize industry needs for the education and training of future as well as current employees. We are grateful for the continuing guidance and support of individual ICC members during this study. Members of the ICC are listed in Appendix II.

We are indebted to the employees of North Carolina biopharmaceutical and pharmaceutical manufacturing facilities who served as advisors in this study. Participants in all the focus group meetings convened for this research, and other contributors to the Model Employee Job Descriptions are listed in Appendix III.

Similarly, we wish to thank all the employees of North Carolina companies who contributed their time and insights to Center staff in the course of surveys and interviews that formed the basis for two previous studies of employment needs in the bioprocessing industry: *Window on the Workplace* (1995) and *Window on the Workplace 2003*. The data and insights about industry needs gained from those earlier studies informed the design of the present work, and the interpretation of information gathered.

Executive Summary

The biomanufacturing sector of the biotechnology industry in North Carolina has exhibited strong growth over the last several years, with an annual average increase of 10% in number of employees. Most of our industrial activity in this sector is in biopharmaceutical manufacturing—the use of living cells to make a new generation of therapeutics. With an increasing number of new biopharmaceuticals in the FDA approval pipeline, drug companies worldwide are building new production capacity.

With the third largest concentration of biotechnology companies in the US, a strong base of traditional pharmaceutical manufacturing companies, and a growing cluster of service providers to the industry, North Carolina is well-positioned to compete for this new business. An essential factor in decisions on plant locations is the availability of a well-educated and trained workforce.

To support North Carolina's competitive position in attracting new biomanufacturing facilities, as well as to meet the needs of growing biomanufacturing companies already in the state, businesses and academic institutions have collaborated to envision and build a unique asset that will give North Carolina the edge in developing the right workforce: the Biomanufacturing and Pharmaceutical Training Consortium (BPTC).

Start-up of the Consortium is funded by a $60 million grant from Golden LEAF and is supported by more than $5 million in donations of equipment and employee time by the industry. Consortium member institutions include:

- **North Carolina State University.** NC State will be home to the Biomanufacturing Training and Education Center (BTEC) to be located on Centennial Campus. This 100,000 sq. ft. bioprocessing pilot plant will provide training for community college and university students from around the state as well as industry employees.
- **North Carolina Central University.** New facilities, undergraduate, and graduate degree programs will comprise the Biomanufacturing Research Institute and Technology Enterprise (BRITE). A new building will house biotechnology and biomanufacturing research laboratories and classrooms.
- **North Carolina Community College System.** BioNetwork is a statewide initiative providing education and customized workforce training for the biotechnology and pharmaceutical industry, providing a mechanism to swiftly respond to market demands.

To ensure that these new education and training programs are on target, industry needs for the knowledge and skill base of employees must be an essential input to curriculum development. To this end, the Consortium formed an Industrial Curriculum Committee to gather industry input. This report is the first step in the Committee's efforts.

The framework for this industry input is a series of detailed job descriptions for common entry-level positions that represent most of the major manufacturing functions in the industry, ranging from Process Technicians with community college certificates or AAS degrees to Process Development Scientists with PhDs. The job descriptions depict what ideal job candidates should know and be able to do.

Designing curriculum to meet industry needs is a challenging task, both because potential target audiences for the BPTC are diverse, and because the knowledge base is highly interdisciplinary. The spectrum of knowledge required by employees in the industry ranges over many areas, including:

- Basic preparation in biological sciences, chemistry, engineering, and mathematics, as well as business software usage;
- Cultivation of career skills such as communication and project management;
- Knowledge of the FDA-mandated guidelines (GMP) that govern work in the pharmaceutical industry, and common practices for implementing these guidelines;
- Industry-specific technical knowledge and practical training in manufacturing processes, as well as chemical and biochemical analytical methods for characterizing products;
- In-depth understanding of principles underlying these processes, as well as knowledge of emerging technologies, to provide the foundation for design and validation of new processes.

This diversity of topics is a challenge to curriculum design in academic institutions, but community college and university instructors are already actively developing new approaches.

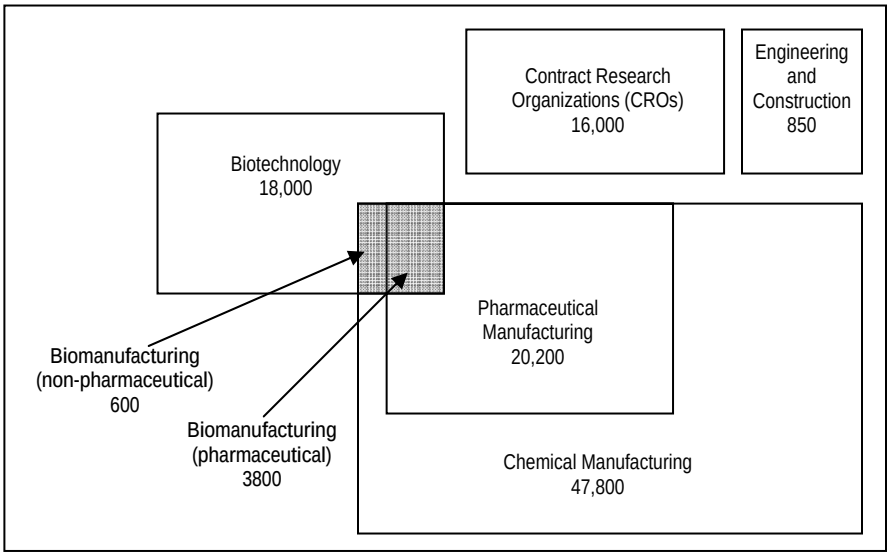
The Industrial Curriculum Committee will continue to provide more information and support to educators, build a broader base of support and engagement by a variety of biomanufacturing and pharmaceutical companies across the state, and carry out detailed analyses of needs to inform the curriculum development process.

Preface

Bioprocess and Pharmaceutical Manufacturing

Industry Overview

North Carolina ranks among the top three biotechnology regions in the United States,[1] with a statewide biotechnology employment of over 18,000 that continues to expand.[2] In addition, North Carolina has long had a significant pharmaceutical manufacturing presence. This manufacturing sector, including both biopharmaceutical and traditional pharmaceutical production, employs over 20,000 people.[3] Average salaries are among the highest in North Carolina manufacturing. Over time, this industry has stimulated significant growth in contract research organizations and consulting firms that provide services manufacturing, clinical trials management, engineering, regulatory compliance, and other areas. Nearly 17,000 employees in these kinds of firms contribute substantially to North Carolina's growing pharmaceutical/ biopharmaceutical cluster.[4]



The figure at right illustrates employment in North Carolina's biomanufacturing and related industry groups.

In traditional pharmaceutical manufacturing, the active pharmaceutical ingredient—a relatively small organic molecule--is usually made by chemical synthesis. This compound is then mixed with other ingredients and further processed to yield the final product, which might be in the form of tablets or capsules or injectible solutions. In *bioprocess* manufacturing living cells make the product, which is then extracted and purified from the cells. Products made in this way include many different kinds of molecules, from simple ones like citrate, a common food additive, to complex ones like the human proteins that are the newest kind of drugs to treat disease, or vaccines to prevent infectious disease.[5]

The majority of North Carolina's bioprocess manufacturers make these kinds of pharmaceutical products (called *biopharmaceuticals*), and this part of the industry is growing at a rapid pace due to the number of new products of this type in the FDA approval pipeline. The need for rapid expansion of manufacturing facilities to make these new products creates significant economic development opportunities for North Carolina, with its already solid traditional pharmaceutical manufacturing base and associated service providers.

Industry Needs

In a 2002 survey of the industry[6], industry representatives noted several characteristics that they think are critical for programs established to train the biomanufacturing and/or pharmaceutical workforce:

- Operation in a GMP-like manner
- Provision of hands-on experience with production equipment, at least at pilot scale, as well as laboratory equipment
- Training in aseptic manufacturing processes and clean-room work
- Instruction by faculty with prior experience in the industry
- Industry input into the content and development of curricula

In 2002, the Biomanufacturing and Pharmaceutical Training Consortium (BPTC) was established in North Carolina to meet these needs.

The Biomanufacturing and Pharmaceutical Training Consortium (BPTC)

The goal of the BPTC is to create a state-wide life-science training network to meet the workforce development needs of life science companies in North Carolina.

The BPTC is a collaboration among:

- The University of North Carolina System;
- The North Carolina Community College System;
- The North Carolina Bioscience Organization, representing industry;
- The North Carolina Biotechnology Center, for facilitation and coordination

North Carolina's Golden LEAF has committed $60 million to fund construction and initial operation of the new facilities, equipment, and programs at North Carolina State University, North Carolina Central University, and community college campuses around the state. Industry has donated over $5 million in equipment and in-kind services to support this initiative.

Members of this consortium are working together to develop targeted programs to provide education and training at all levels for new employees, incumbent workers, and college graduates in life sciences, chemistry, engineering, and applied science degree programs.

Activities of the educational institutions are described in more detail below.[7]

North Carolina State University

NC State will be home to the **Biomanufacturing Training and Education Center (BTEC)** to be located on Centennial Campus. This 100,000 sq. ft. bioprocessing pilot plant will provide training for community college and university students from around the state as well as industry employees.

The BTEC will give students hands-on experience with large-scale equipment, cGMPs, cell-culture, fermentation, purification, quality control, aseptic processing operations, and other related bench-scale education and training. Through its distance learning capabilities, the BTEC will bring real-time operational data and educational content to universities, community colleges, and other satellite locations throughout North Carolina.

Additionally, the BTEC will allow graduate students and faculty to pursue scholarship and develop technologies in emerging fields such as transgenics, novel design of reactors and downstream processing, cell therapy and engineering, protein engineering, and molecular discovery.

North Carolina Central University

New facilities and degree programs will comprise the **Biomanufacturing Research Institute and Technology Enterprise (BRITE).** A new building will house biotechnology and biomanufacturing research laboratories and classrooms. BRITE will offer new undergraduate and graduate degree programs relevant to biomanufacturing and process development.

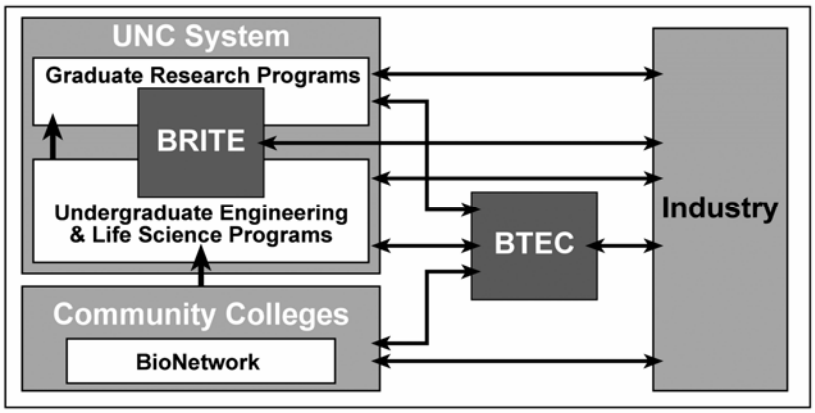
North Carolina Community College System

BioNetwork is a statewide initiative providing education and customized workforce training for the biotechnology and pharmaceutical industry, providing a mechanism to swiftly respond to market demands. Features of BioNetwork include:

- **BioNetwork Centers.** Each of the six centers is housed at a different community college and has a statewide focus. Each is charged with developing specialty curriculum for different aspects of the biotechnology and pharmaceutical/biopharmaceutical manufacturing industries. The Center descriptions follow.
    - BioNetwork Capstone Center, dedicated aseptic suite space located at the Biomanufacturing Training and Education Center at North Carolina State University. This Center was jointly developed by a consortium of all seven Research Triangle Area Community Colleges and is led by Wake Technical Community College. Students and incumbent employees who receive the bulk of their training at local community colleges can experience capstone training with industry-scale process equipment at this Center.
    - BioNetwork Bioprocessing Center, at Pitt Community College
    - BioNetwork Pharmaceutical Center, jointly developed by Forsyth Technical Community College and Guilford Technical Community College
    - BioNetwork BioAg Center, Robeson Community College
    - BioNetwork BioEd Center, Gaston College
    - BioNetwork BioBusiness Center, Asheville-Buncombe Community College
- **Other programs.** Over a dozen colleges throughout the state offer Associate Degrees in a variety of programs that support relevant industry training needs. These include Biotechnology, Laboratory Technology, Chemical Technology, Bioprocess Manufacturing, Chemical Process Technology, Industrial Pharmaceutical Technology, and Nanotechnology.
- Several colleges also offer ***BioWork***.[8] *BioWork* is a 128-hour course that provides individuals with the foundational knowledge necessary to seek employment as process technicians.

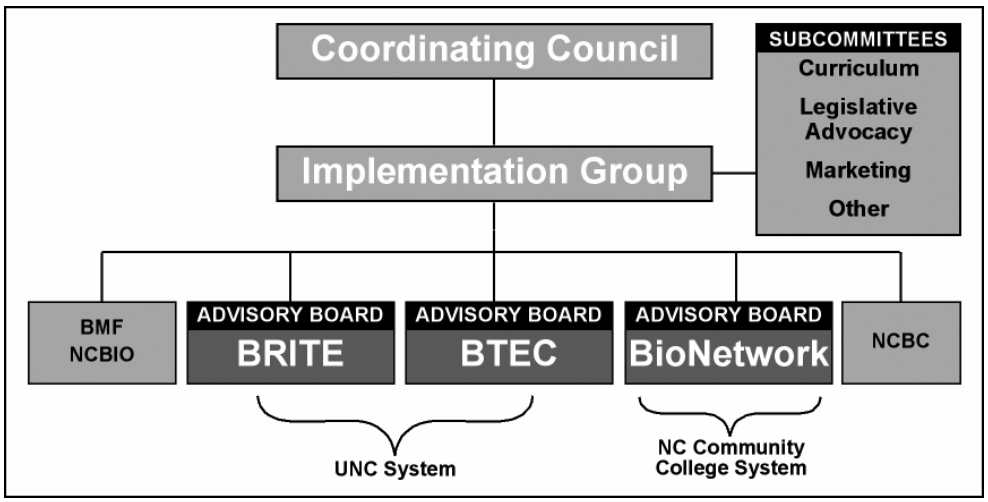
Student Flow

One of the most important and unique features of the BPTC is the coordinated goal of the community colleges and universities to create a vertically integrated, fully articulated set of degree programs. In the figure presented below, black arrows indicate the variety of ways in which students can flow through this system. Industry, in addition to hiring new graduates from the educational institutions, will benefit from short courses available for continuing-education training for the existing workforce. The goal is that incumbent employees can eventually weave short courses into a framework leading to a formal degree.



BPTC Organization

The BPTC is headed by a **Coordinating Council**, which includes the Presidents of the community college and university systems, chancellors of NCSU and NCCU, presidents of two community colleges (Wake Technical Community College and Asheville-Buncombe Technical community College), industry leaders, and the President of the North Carolina Biotechnology Center. A number of working groups, each consisting of representatives from both industry and the educational institutions, manage and ensure coordination for the many activities required to develop this educational enterprise. A summary of the BPTC organization is presented below:



Acronyms:

BMF -- Biomanufacturing Forum
NCBIO -- North Carolina Bioscience Organization
BRITE -- Biomanufacturing Research Institute and Technology Enterprise
BTEC -- Biomanufacturing Training and Education Center
NCBC -- North Carolina Biotechnology Center

Industrial Curriculum Committee

The Industrial Curriculum Committee (ICC) is one of several subcommittees working to ensure the success of the BPTC. Comprised of representatives from biomanufacturing and pharmaceutical companies as well as the educational institutions that make up the BPTC, the overall mission of the Industrial Curriculum Committee is to support institutional curriculum development for the Consortium.

To carry out this mission, major goals are to:

- Gather and disseminate information relevant to curriculum development
- Facilitate communication among partners in the BPTC

A complete list of the ICC's current membership is included in Appendix II.

Purpose of this Document

As major curriculum development efforts are required to implement BPTC goals, the Industrial Curriculum Committee's first project was to provide educators with detailed information about the pharmaceutical and biomanufacturing workforce in order to support necessary curriculum development efforts. This document presents the results of a study conducted under the guidance of the Industrial Curriculum Committee to develop industry-representative "Model Employee" descriptions. It is the Committee's hope that this study will become a fundamentally important reference for educators developing new curriculum.

References

1. *Resurgence: The Americas Perspective–Global Biotechnology Report 2004*
   Ernst & Young
2. Kennedy, Kathleen. *Window on the Workplace 2003*. North Carolina Biotechnology Center, 2003.
3. Ibid.
4. North Carolina Biotechnology Center Company Directory., 2005
5. Kennedy, Kathleen. *Window on the Workplace*. North Carolina Biotechnology Center, 1997.
   Kennedy, Kathleen. *Window on the Workplace 2003*. North Carolina Biotechnology Center, 2003.
6. Ibid.
7. For more information on the BPTC partners, contact:

   BioNetwork
   Ms. Susan Seymour
   Director, BioNetwork
   North Carolina Community College System
   Phone: 919.807.7155
   Email: seymours@ncccs.cc.nc.us
   URL: www.ncbionetwork.org

   Biomanufacturing Training and Education Center (BTEC)
   Dr. Peter Kilpatrick
   Director, BTEC
   North Carolina State University
   Phone: 919.515.7121
   Email: peter-k@eos.ncsu.edu

   Biomanufacturing Research Institute and Training Enterprise (BRITE)
   Dr. Ken Harewood
   Director, BBRI and Professor of Biology
   North Carolina Central University
   Phone: 919.530.7025
   Email: kharewood@wpo.nccu.edu
   URL: www.nccu.edu/research/brite.shtml
8. *BioWork* was developed and produced by the North Carolina Biotechnology Center's Education and Training Program, in conjunction with the North Carolina Community College System and the biomanufacturing industry.

The Model Employees in Context

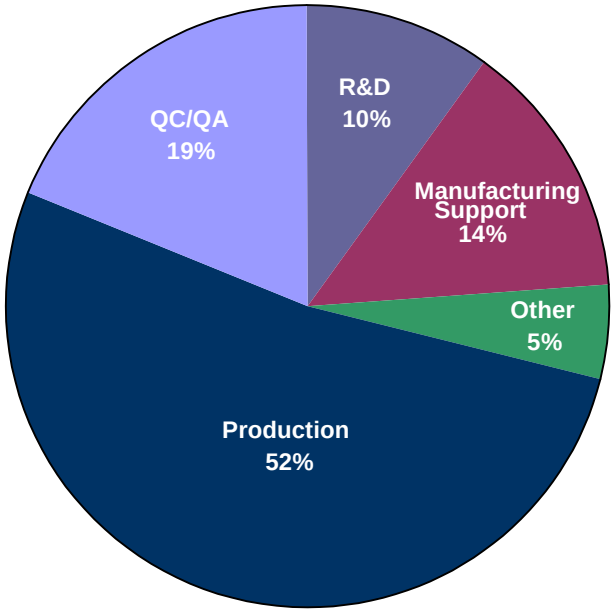
In this section we provide an overview of the pharmaceutical manufacturing enterprise, and describe the roles that the Model Employees presented in this report play in manufacturing.

These positions were selected because they are common across the industry, and because they represent the major functional areas in manufacturing. Also, all these positions are defined as *entry-level*; that is, companies are willing to hire persons with the appropriate education but *without* prior experience in the pharmaceutical industry (although job candidates with such experience have a distinct advantage in the market).

To put the jobs described in this publication into perspective, we present here data from the Center's 2002-2003 survey of the bioprocess and pharmaceutical manufacturing industry in North Carolina (*Window on the Workplace 2003*).

The Pharmaceutical/Bioprocess Manufacturing Workforce

Bioprocessing and traditional pharmaceutical manufacturing sites in North Carolina have a total employment of nearly 21,000. About 85% of the employees in biomanufacturing operations and about 65% of employees in general pharmaceutical manufacturing operations require at least some degree of scientific or technical education and training, and are the employees of interest in this report. As will be detailed later in this report, educational requirements for this workforce span a broad range of knowledge of science, technology, engineering, and regulatory topics.



The specific training individual employees need depends on the type of work they do. Common manufacturing functions can be summarized under the broad headings indicated in the figure at right, which shows the percentage of employees requiring scientific and technical education who work in each division.

The pages that follow describe the kinds of work done and the educational levels of the workforce in each division; and identify the Model Employees from each division that are characterized in detail in this report.

Research and Development

Much research and development (R&D) in the pharmaceutical industry is devoted to the drug discovery process. However, that is not an emphasis for the Biomanufacturing and Pharmaceutical Training Consortium. In the manufacturing context, R&D refers to applied research at the interface between the basic research that leads to a new product idea and commercial production.

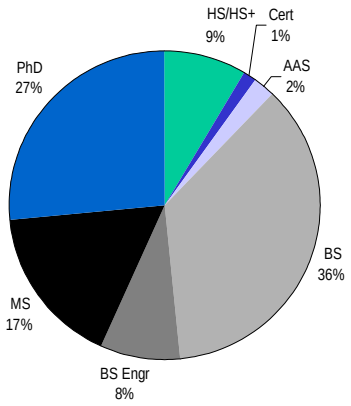
Process development research focuses on scaling-up a laboratory process for making a new product to commercial production, as well as optimizing and trouble-shooting new production processes. Manufacturing processes often are quite different than in the laboratory, and scaling-up requires experienced judgment as well as knowledge of scientific and engineering principles.

Most employees in this kind of work are engineers and scientists, many with advanced degrees. They work in laboratories and pilot plants as well as in large-scale production areas. Example tasks might include optimizing feed and agitation rate in bioreactors, developing new product assays, or executing validation protocols for a new purification process.

Educational Summary: R&D Related to Manufacturing

This chart presents the educational distribution for all employees in positions manufacturing-related Research and Development, including the model employees highlighted in this publication as well as all other positions not described.

The HS/HS+ population contains workers with only a high school diploma (or GED) and those with some additional college education or specialized certificates. Additional appropriate work experience and/or education beyond high school are now generally required for employment in this industry.



Model Employees

Process Development Scientist	PhD (no experience) or MS (with 2-5 yrs experience) Degrees are typically in biological sciences, or chemical or bioprocess engineering. These scientists and engineers are responsible for the design and execution of experiments associated with development, improvement, and scaling up processes; as well as analysis and interpretation of data.
Process Development Associate	AAS with 2-5 yrs experience; or BS with no experience These experienced and knowledgeable laboratory or process technicians assist scientists in the execution of process development experiments.

Production

Pharmaceutical manufacturing processes often are multi-step, lengthy operations.

Synthesis. The first step is preparation: cleaning and when necessary sterilizing equipment, measuring and mixing chemicals, and--for bioprocess manufacturing--growing small seed cultures of cells. Then the product itself is synthesized, either by through chemical reactions for traditional pharmaceuticals or through cell culture for bioprocess manufacturing.

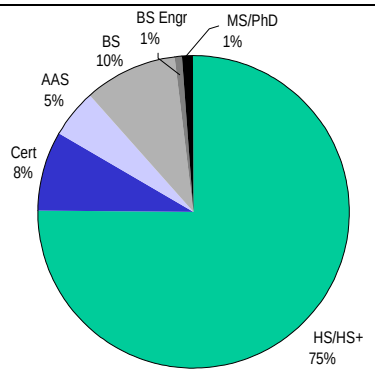
Purification. After the desired product is synthesized, it has to be purified. That means separating it from the other chemicals in a reaction mixture, or from the living cells and cellular nutrients and byproducts resulting from bioprocess manufacturing. The end result is called *bulk product*.

Formulation, Fill and Finish. For pharmaceuticals, final dosage forms can be solid (e.g., tablets or capsules), liquid, gels or creams, or aerosols. Biopharmaceuticals are almost always sold as sterile liquids or sterile dry powders. Formulation involves chemical mixing operations to blend the active pharmaceutical ingredient with other materials such as granulating agents, or buffers. The formulated preparation is put into final form, dispensed into containers, labeled, and packaged.

Educational Summary: Production

This chart presents the educational distribution for all employees in the Production division, including the model employees highlighted in this publication as well as other positions not described.

The HS/HS+ population contains workers with only a high school diploma (or GED) and those with some additional college education or specialized certificates. Additional appropriate work experience and/or education beyond high school are now generally required for employment in this industry.



Model Employees

Process Technicians	HS/GED plus relevant work experience or training is required. Additional relevant community college education including certifications (e.g. BioWork), short courses, and AAS degree programs is often required. These technicians monitor and operate a wide array of manufacturing equipment, and prepare media and chemicals for the various stages of production, and transfer materials from one unit operation to the next. Process technicians are the largest group of employees.
Process Engineers	BS or MS degree in Biochemical, Bioprocess, Chemical, or Mechanical Engineering; or in Food Science curricula emphasizing engineering. Engineers are involved in the design, operation, supervision, and on-going improvement of manufacturing processes, equipment, and facilities.

Quality Control (QC) and Quality Assurance (QA)

The standards are high in pharmaceutical manufacturing because the stakes are high. Poor quality products can harm or even kill consumers. Companies generally ensure product quality through their quality control, quality assurance, and validation functions.

Quality control employees sample and assay raw materials as well as the product during every phase of its manufacture. They utilize a wide variety of chemical and biological assays in addition to an array of analytical instrumentation.

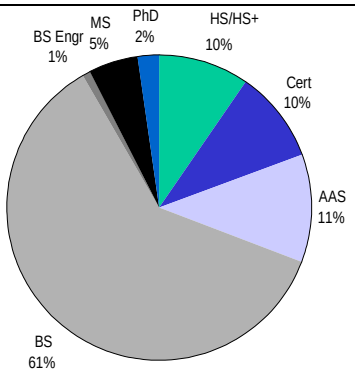
Quality assurance involves setting up and checking the systems of standard operating procedures and documentation that assure the quality of the product. Much broader than quality control, quality assurance focuses on insuring that the overall system of manufacturing will reliably produce products to the required standard and meets all regulatory requirements.

Validation is the experimental documentation that standard operating procedures carried out with specified materials and equipment will consistently result in a product of specified quality. The operation of every part of a plant has to be validated: manufacturing equipment, utilities, the chemical and biological assays used to characterize the product, and even computer data processing/storage systems. Companies organize the validation function differently. A few have specialized validation departments; but most distribute validation responsibilities across several departments. For example, process technicians might be asked to run equipment for validation protocols. Quality control technicians may need to validate a laboratory assay.

Educational Summary: QC / QA

This chart presents the educational distribution for all employees in the QC/QA division, including the model employees highlighted in this publication as well as other positions not described.

The HS/HS+ population contains workers with only a high school diploma (or GED) and those with some additional college education or specialized certificates. Additional appropriate work experience and/or education beyond high school are now generally required for employment in this industry.



Model Employees

Quality Control Assistant or Associate	*QC Assistant:* Depending on the specific nature of the position, ranges from HS/GED plus relevant work experience or training (community college certifications or short courses) to requiring AAS in scientific discipline with no experience. *QC Associate:* BS in scientific discipline with no experience or AAS in scientific discipline plus two years work experience. Carry out chemical analyses, biological assays, and instrumental analyses of raw material and product; monitor controlled environments.
Quality Assurance Associate	BS in biological science, chemistry, or engineering and no experience; or AAS with 2 years experience. QA employees audit and review SOPs, validation protocols, and every aspect of documentation of manufacturing processes.

Manufacturing Support

A variety of functions are required to support manufacturing. Most common are:

Maintenance. A pharmaceutical production plant is complex, and there is usually a department of technicians and engineers who ensure that all the utility systems and production equipment are in working order, and install new equipment.

Instrumentation and Control. Process control technicians and engineers design, program, and maintain the extensive automated instrumentation and control systems that run the processes.

Model Employees in this study are chosen for the above functions. Other functions that some companies organize in specific departments include those listed below. Employees from these groups were not chosen for study.

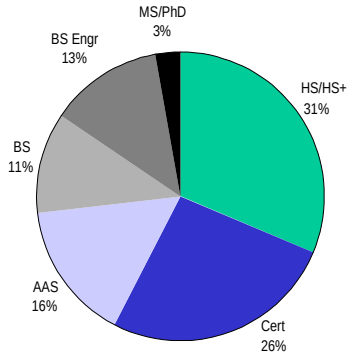
Examples of other manufacturing support functions:

- Process Optimization and Trouble-shooting
- Waste Management
- Documentation

Educational Summary: Manufacturing Support

This chart presents the educational distribution for all positions in the Manufacturing Support division, including the model employees highlighted in this publication as well as other positions not described.

The HS/HS+ population contains workers with only a high school diploma (or GED) and those with some additional college education or specialized certificates. Additional appropriate work experience and/or education beyond high school are now generally required for employment in this industry.



Model Employees

Maintenance Technician	HS/GED plus relevant trade certifications (refrigeration, HVAC) is required. Additional relevant community college education such as certifications and short courses is preferred. Responsible for repairs and preventive maintenance on equipment and utilities systems.
Instrumentation/Calibration Technician	Associate's degree in relevant program (Industrial Maintenance, Instrumentation, Industrial Systems Technology) is required. Additional relevant community college education such as certifications or short courses is preferred. These employees monitor, troubleshoot, calibrate, and install process instrumentation and process control systems.

Further Notes

Choice of positions to analyze

A number of entry-level positions were considered, but were not included in this study. They were:

- **Research Associate/Scientist.** In keeping with the general mission of the BPTC, the Committee decided to focus on process development but not drug discovery research.
- **Validation Specialist.** The Committee recognized that validation is an important field within the biopharmaceutical industry. However, as noted above, the validation function is handled differently among companies. The relatively small number of companies that have dedicated validation departments could hire entry-level validation specialists; though many validation department personnel could be expected to be more experienced employees. Therefore, the knowledge and skills involved in validation have been incorporated into all six model employee descriptions as appropriate. For example:
    - Process Technicians should be familiar with *executing* validation protocols.
    - Process Engineers should be familiar with *designing* validation protocols.
- **Documentation Specialist.** As scientific and industry-specific technical knowledge requirements are minimal for documentation specialists, they have not been included in this study.
- **Customer Support Specialist.** These employees are the interface between the company and its customers. Jobs typically require a BS in science or communications. These positions are not directly related to manufacturing. Related positions, also typically requiring a BS degree, are in Sales.

Engineering Positions

Engineers work in most of the major manufacturing areas: Process Development (R&D), Production, Manufacturing Support, Quality Assurance, and Validation. In this report, we have described in detail only the Process Engineer. The knowledge and skill base required for engineers in other areas is similar. An exception may be engineers responsible for supervising facility maintenance—they often have BS degrees in mechanical or electrical engineering, rather than bioprocess or chemical engineering.

Overview

The Industrial Curriculum Committee (ICC) was formed in Spring, 2004. Its initial task was to ensure industry input into the curriculum development processes for the BPTC, in order that graduates of new programs would be well-prepared for employment in the industry. The Committee wanted industry representatives serving as advisors to educational programs to be able to speak with a common voice about industry needs. To this end, the Committee conceived the idea of job descriptions for the most common and important entry-level positions as a useful framework within which to gather and organize information from companies about their education and training needs. While we have used the title "Model Employee" for these descriptions, in fact they are descriptions of "Model Candidates" for hiring into the positions.

The Model Employee Job Descriptions that follow later in this report contain detailed information about the selected positions including the academic education required, tasks and responsibilities, career pathways, and the ideal foundation of job knowledge and skills that successful candidates for these positions should possess.

Job Description Format

Basic Job Description

The Basic Job Description provides a summary of the position as might be found in a company posting. Components include:

- **Job Title.** Identifies common job titles associated with the position.
- **General Description.** Provides a snapshot overview of the typical job functions and the employee's role within a company.
- **Qualifications / Requirements.** Education and work experience required for hiring.
- **Organizational Responsibilities.** Describes the employee's interactions with others in the company, with respect to training or supervising others and interactions outside the employee's unit.

Quality Assurance Associate

Job Title

Quality Assurance Associate

General Description

Responsible for ensuring product quality and company compliance with relevant regulations, industry standards, and internal procedures and policies by reviewing and approving GMP documentation supporting operations such as production, quality control, and validation. Document areas include:

- Batch Records
- Laboratory Records
- Change Control
- Deviations, Exceptions, and Out-of-Specification (OOS) results
- Investigations
- Validation and other protocols

Other duties include informing internal and external clients how Quality Assurance works with other departments to ensure quality, performing incoming raw material/reasonable inspection, conducting internal and external audits, and providing initial and annual GMP training for new hires, incumbent employees, and contractors.

Qualifications / Requirements

Educational Experience

- Minimum: AAS + two years' experience in industry (in production, quality control, engineering).
- Preferred: BS degree (science or engineering). Experience not required but one to two years preferred.

Work Experience

Relevant industry experience (production, quality control, engineering) is beneficial.

Organizational Responsibilities

Supervisory responsibilities:

N/A. Would report to QA supervisor/ QA manager.

Other responsibilities

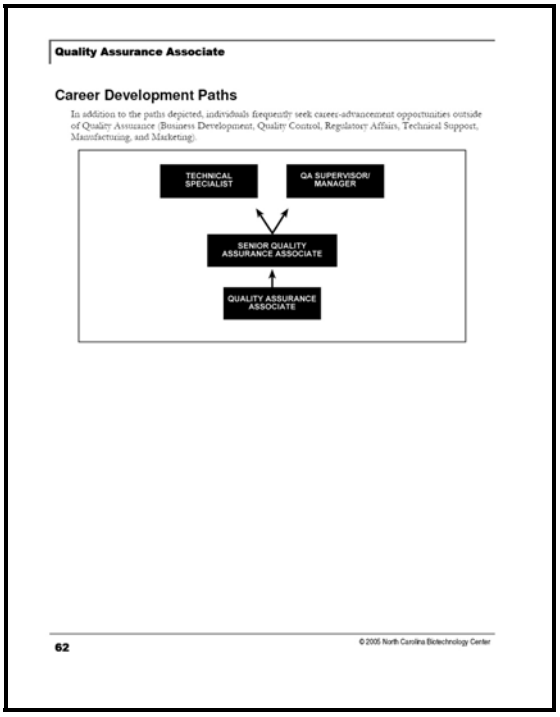
After training period, has signature/approval authority on certain documents.

61

Career Development Paths

The Career Development Paths portion of each description provides a map of the typical career progression for the employee, from entry-level to advanced positions.

Note: We found that individuals often seek employment opportunities in other functional areas within a company. These opportunities have not been shown on the career maps, but are indicated in explanatory text where applicable.



Quality Assurance Associate

Career Development Paths

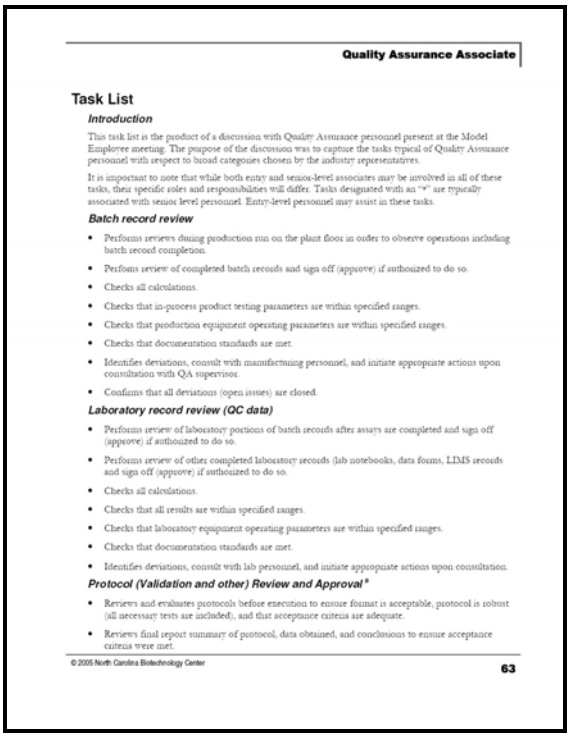
In addition to the paths depicted, individuals frequently seek career-advancement opportunities outside of Quality Assurance (Business Development, Quality Control, Regulatory Affairs, Technical Support, Manufacturing, and Marketing).

62

Task List

The Task List that is included in each of the descriptions provides a detailed breakdown of the types of activities or projects that an employee might carry out. Task descriptions provide examples of how specific knowledge is applied on the job and types of skills employees need.

Note: In most cases, the task list presents a range of activities that are typical of the position described. While an entry-level employee may not be responsible for all of these tasks, they will likely assist senior staff in some manner.



Quality Assurance Associate

Task List

Introduction

This task list is the product of a discussion with Quality Assurance personnel present at the Model Employee meeting. The purpose of the discussion was to capture the tasks typical of Quality Assurance personnel with respect to broad categories chosen by the industry representatives.

It is important to note that while both entry and senior-level associates may be involved in all of these tasks, their specific roles and responsibilities will differ. Tasks designated with an "*" are typically associated with senior level personnel. Entry-level personnel may assist in these tasks.

Batch record review

- Performs reviews during production run on the plant floor in order to observe operations including batch record completion.
- Performs review of completed batch records and sign off (approve) if authorized to do so.
- Checks all calculations.
- Checks that in-process product testing parameters are within specified ranges.
- Checks that production equipment operating parameters are within specified ranges.
- Checks that documentation standards are met.
- Identifies deviations, consult with manufacturing personnel, and initiate appropriate actions upon consultation with QA supervisor.
- Confirms that all deviations (open issues) are closed.

Laboratory record review (QC data)

- Performs review of laboratory portions of batch records after assays are completed and sign off (approve) if authorized to do so.
- Performs review of other completed laboratory records (lab notebooks, data forms, LIMS records and sign off (approve) if authorized to do so.
- Checks all calculations.
- Checks that all results are within specified ranges.
- Checks that laboratory equipment operating parameters are within specified ranges.
- Checks that documentation standards are met.
- Identifies deviations, consult with lab personnel, and initiate appropriate actions upon consultation.

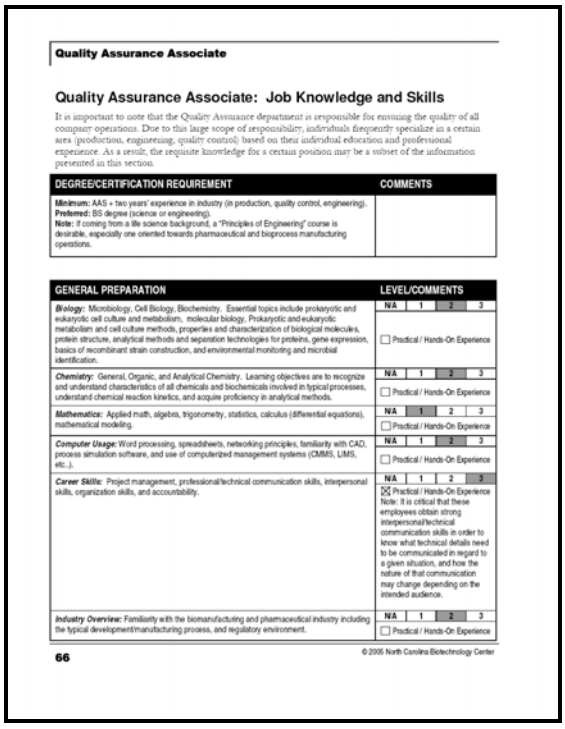
*Protocol (Validation and other) Review and Approval **

- Reviews and evaluates protocols before execution to ensure format is acceptable, protocol is robust (all necessary tests are included), and that acceptance criteria are adequate.
- Reviews final report summary of protocol, data obtained, and conclusions to ensure acceptance criteria were met.

Job Knowledge and Skills

The Job Knowledge and Skills portion of each description provides a detailed listing of the technical knowledge required. Components include:

- **Degree and Certification Requirements.** A summary of typically acceptable degrees and/or certificates for the position described.
- **General Preparation.** This includes courses and/or topics now typically found in many academic programs.
- **Knowledge and Skills.** A detailed list of the scientific and technical knowledge and skill required for the position described.



Quality Assurance Associate

Quality Assurance Associate: Job Knowledge and Skills

It is important to note that the Quality Assurance department is responsible for ensuring the quality of all company operations. Due to this large scope of responsibility, individuals frequently specialize in a certain area (production, engineering, quality control) based on their individual education and professional experience. As a result, the requisite knowledge for a certain position may be a subset of the information presented in this section.

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
Minimum: AAS + two years' experience in industry (in production, quality control, engineering). **Preferred:** BS degree (science or engineering). **Note:** If coming from a life science background, a "Principles of Engineering" course is desirable, especially one oriented towards pharmaceutical and bioprocess manufacturing operations.	

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, Biochemistry. Essential topics include prokaryotic and eukaryotic cell culture and metabolism, molecular biology. Prokaryotic and eukaryotic metabolism and cell culture methods, properties and characterization of biological molecules, protein structure, analytical methods and separation technologies for proteins, gene expression, basics of recombinant strain construction, and environmental monitoring and microbial identification.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Learning objectives are to recognize and understand characteristics of all chemicals and biochemicals involved in typical processes, understand chemical reaction kinetics, and acquire proficiency in analytical methods.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, trigonometry, statistics, calculus (differential equations), mathematical modeling.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, networking principles, familiarity with CAD, process simulation software, and use of computerized management systems (CMMS, LIMS, etc..).	N/A 1 2 3 ☐ Practical / Hands-On Experience
Career Skills: Project management, professional/technical communication skills, interpersonal skills, organization skills, and accountability.	N/A 1 2 3 ☒ Practical / Hands-On Experience Note: It is critical that these employees obtain strong interpersonal/technical communication skills in order to know what technical details need to be communicated in regard to a given situation, and how the nature of that communication may change depending on the intended audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A 1 2 3 ☐ Practical / Hands-On Experience

66

Methodology

Identifying Information to Gather

After identifying the job descriptions most representative of the spectrum of employment in the industry, the Committee outlined the components to include in each job description, as illustrated in the Overview given in the preceding section of this report.

As a starting point, and to test the feasibility of this framework, members of the ICC then drafted job descriptions for each the positions as identified below:

- **Process Technician**
  Kathleen Kennedy and Susan Seymour
- **Process Engineer**
  Peter Kilpatrick
- **Process Development Associate/ Scientist**
  Kathleen Kennedy
- **Quality Control Assistant/Associate**
  Timothy Kelly
- **Quality Assurance Associate**
  John Balchunas
- **Maintenance and/or Instrumentation Technician**
  John Balchunas

North Carolina Biotechnology Center staff put all drafts into a common format and added necessary information compiled from prior studies of the industry, current research, and real job descriptions provided by industry. These draft job descriptions were used as starting material for focus group meetings of industry professionals.

Focus Group Meetings

Center staff then convened and facilitated focus groups for each position to authenticate the draft descriptions, obtain further information where needed, and ensure industry consensus.

Focus group participants included managers, directors, and senior employees in relevant areas, as well as technical trainers and a few incumbent employees in the positions being described. The majority of participants represented biopharmaceutical companies, so knowledge and skill lists may reflect this emphasis. In order to ensure data collected is useful in shaping curriculum development, academic observers from community colleges and universities were also invited. All focus group participants are listed in Appendix III.

Focus group meetings were not held for Process Technician and Quality Control Assistant/Associate, as a substantial body of knowledge exists for both positions from past research. In both of these cases, data was gathered in informal interviews and discussions with industry representatives. In the case of the Process Technician, the basic knowledge and skill foundation for this position has been extensively described in the learning objectives for *BioWork*, an introductory course for process technicians in the chemical, pharmaceutical, and bioprocess manufacturing industries. The North Carolina Biotechnology Center developed *BioWork* (launched in 2001) in cooperation with North Carolina companies and the North Carolina Community College System. Formal Work Keys job analyses support the course content.

Compiling and Authenticating Results

Center staff compiled, consolidated, and formatted new draft job descriptions from data gathered in focus group meetings, and circulated the descriptions to focus group participants for an initial review. Once these results were incorporated into the Model Employee Job Descriptions as presented in this publication, ICC members, focus group participants, and a few additional subject matter experts reviewed the entire publication.

A "Living" Document

In order to encourage feedback that will clarify, expand upon, and further develop the findings presented in this report, the ICC determined that this publication should be a "living document," with an established mechanism for collecting feedback from readers. Appendix IV contains instructions and contact information for submitting comments for consideration in future editions of this publication.

Essential Career Skills

Introduction

While a solid foundation in an appropriate scientific/technical discipline will help new graduates get an interview, this foundation alone will not ensure employment. Hiring managers in the biomanufacturing and pharmaceutical industry want individuals who demonstrate strong career skills and personal attributes. These skills and attributes:

- Help an employee effectively perform the tasks required by their position.
- Provide an employee with a foundation to continuously learn new skills.
- Enhance an employee's ability to adapt to change.

This section introduces the general skills and attributes that will ensure qualified candidates get a job and excel in the industry.

Attributes for Success

Despite the diverse range of physical job aspects in the biomanufacturing and pharmaceutical industry, a number of personal attributes are critical for any employee to succeed in a heavily regulated GMP (Good Manufacturing Practices) environment. Put into place to ensure products are safe, pure, and effective, these regulations address issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, change control, and complaint handling.

All employees in the pharmaceutical industry must learn to work within these guidelines that mandate specified procedures for almost every action. Even in companies that do not manufacture pharmaceuticals, other comprehensive quality systems are in place, and students that learn the GMP "mindset" should readily adapt to the meticulous habits of documentation and consistent work practices that are common to both.

Adopting the "mindset" required to thrive in this industry is critical for the entire biomanufacturing and pharmaceutical workforce. Employees in the biomanufacturing and pharmaceutical industry must understand and accept the responsibility and personal accountability of working in a federally regulated industry. Ultimately, it is the individual employee's personal integrity that ensures compliance.

In addition to being *responsible* and *accountable*, good employees in the biomanufacturing and pharmaceutical industry are:

- *self-motivated*
- *reliable*
- *continuously-learning*
- *resourceful*
- *punctual*

Educators must look for opportunities to reinforce, strengthen, and build upon these attributes within the context of the scientific and technical disciplines required for work in the biomanufacturing and pharmaceutical industry. For example: Accountability, documentation, and many aspects of the "GMP mindset" could be reinforced and practiced as a foundational part of lab work exercises.

Skills for Success

Professional/Technical Communication Skills

The ability to communicate clearly is critical to successful employment. In addition to technical expertise in communication-related software packages (word processing, spreadsheet, e-mail, presentations), employees must know what details need to be communicated in a given situation. Employees must also know how to shape communication depending on the intended audience. Examples:

Potential Audiences:

- *Coworkers / Supervisors / Managers.* Individuals likely share a common vocabulary and tacit understanding of a situation.
- *Cross-Functional Team Members.* Individuals may not share a common vocabulary or underlying awareness of a situation.

Modes of Communication:

- *Written.* Includes communication by e-mail, technical reports, work orders, and form completion.
- *Oral.* Includes one-on-one (in person and telephone) communication as well as formal and informal presentations.

Interpersonal Skills

Hand-in-hand with communication skills, employees in the biomanufacturing and pharmaceutical industry must be able to work effectively with coworkers and managers in a variety of interpersonal relationships. Successful employees are able to work well:

- Alone / Independently
- Jointly with a partner or helper
- As a member of a team

Employees in supervisory positions require additional experience in leading, coaching, and supervising individuals working in each of these situations.

Organization Skills

Employees in the biomanufacturing and pharmaceutical industry must possess strong organizational skills in order to effectively perform complex tasks. Among these organizational skills are:

- **Attention to Detail.** Employees need to be meticulous in attention to detail, reliable in carrying out routine procedures over and over.
- **Troubleshooting Ability.** Employees must be able to determine the cause of and resolve technical issues related to their job function.
- **Time/Task Management.** Employees must be able to multitask appropriately, prioritizing workloads based on company and project-specific needs.
- **Project management.** Employees must be able to plan projects appropriately, assembling a timeline, project plan, and necessary resources to complete tasks assigned.

Comprehensive final projects can give students the opportunity to develop and strengthen these skills by planning, managing, and presenting technical/scientific projects as part of a team or as individuals.

General Preparation

Certain areas of preparation are required for all the employees described in this report--to a greater or lesser degree, and with varying emphasis on specific topics for different positions. These areas are:

- Basic science (biology and chemistry)
- Mathematics
- Computer usage
- Business skills
- Pharmaceutical industry overview

All these areas except the last are currently taught in many community colleges and universities. As noted below, some standard courses are useful as generally taught now. However, particular topics could be recombined in new courses to make efficient use of time in specialized industry-oriented curricula.

NOTE: All relevant topics in these areas are listed in the Knowledge and Skill Master List in Appendix I. Selected topics of particular importance to specific positions are listed in the individual Job Descriptions.

Biology

The most relevant areas include Cellular and Molecular Biology, Biochemistry, and Microbiology. Examples of topics of interest are listed below. Other topics (mostly methodological) are included in the Knowledge and Skill Master List in Appendix I.

- Prokaryotic and eukaryotic metabolism and cell culture methods
- Properties and characterization of biological molecules
- Protein biochemistry
- Analytical methods and separation technologies for proteins
- Gene expression
- Basics of recombinant strain construction
- Environmental monitoring and microbial identification

Chemistry

Key courses are General, Organic, and Analytical Chemistry. Enough organic chemistry is required to inform the study of biochemistry, but organic synthesis methods are not relevant. Analytical methods—especially instrumental methods--are of key importance. Chemical reaction kinetics is an important topic for chemical and bioprocess engineers.

Mathematics

At minimum, Maintenance and Process Technicians need to know basic computational skills and dimensional analysis as usually taught under the rubric of "Applied Mathematics" or "Technical Mathematics." Algebra and statistics are the next most fundamental needs for all other employees; and also for Process Technicians if they are to advance into, for example, QC technician positions. Mathematical modeling is a useful concept for all scientific and engineering professionals. Calculus (differential equations) is required for engineers.

Computer Usage

Most employees need to be proficient with word processing and spreadsheet programs. Some need to be familiar with the basics of networking principles. These topics may be readily available in existing academic courses. There are other specialized kinds of software that certain employees need to use that may not be currently taught in existing courses. These are listed in Appendix I.

Career Skills

As noted above in the section on Essential Career Skills, many of these skills can be acquired in existing academic courses such as Technical Writing; others, such as project management, are often covered in existing continuing education courses.

Industry Overview

One of the most useful kinds of preparation students could have is a general appreciation for how the pharmaceutical industry works. Such an overview should describe the typical progress of a new drug from discovery to commercial production, including such topics as the regulatory environment and manufacturing methods, the kinds of jobs available in the industry, and expectations of employees. This kind of overview would give students much more realistic expectations about the kind of work they would do, and help them understand how what they are learning in other courses can be applied on the job. This overview can be more or less detailed and include lesser or greater depth in business and management-related topics depending on the audience.

Basic Science—General Comments

It is a common complaint among employers that many new college graduates often do not grasp three important fundamentals. With some re-design, these fundamentals could be conveyed within the context of many existing science courses. Students who engage in internships, undergraduate research projects, or part time lab assistant jobs are more likely to develop these skills simply because they spend more time in experimental work.

Laboratory Techniques

Often, employers say, graduates "don't know how to make solutions." That is, they do not seem to have had enough practice to become independently proficient at basic lab techniques. Perhaps this is because typically science course labs are designed to illustrate important concepts; and often most of the set-up is done in advance. The issue is time allocation. It takes time to allow students to practice the basic skills—time that faculty often prefer to allocate to learning new concepts.

Experimental Design

Although good experimental design is illustrated in many standard laboratory exercises, maybe students just don't get it—or more probably they are not challenged often enough to design experiments of their own.

Working in a Regulated Environment

Graduates are unfamiliar with and often resistant to the necessary disciplines of documentation and careful attention to detail required in an FDA-regulated environment.

Industry-Specific Knowledge and Skills

All the areas of knowledge and skill included in this study are included in the Master List in Appendix I. The knowledge base presented in this publication covers almost all the significant functional areas within a typical biomanufacturing company. Exceptions include:

- High level strategic business knowledge of the industry required by upper level executives or business development specialists;
- Emerging technologies, particularly in the area of biopharmaceutical cell culture and downstream processing; (focus groups tended to concentrate on current needs).
- Specific knowledge required for higher-level regulatory affairs specialists outside of typical quality assurance entry-level positions

We have subdivided the entire spectrum of industry knowledge and skill included in this study under the following headings (content summarized on the following page):

- Regulatory Compliance: Safety and Environmental
- Regulatory Compliance: FDA Requirements
- General Plant Operations
- Process Equipment and/or Facility Design and Scale-up
- Unit Operations and Manufacturing Methods
- Basic Laboratory Work
- Analytical Instrumentation and Methods

KNOWLEDGE AND SKILL CATEGORIES	
Regulatory Compliance: Safety and Environmental	All employees must be cognizant, at least at a basic level, of industrial safety precautions including those mandated by OSHA as well as federal, state, and local regulations governing plant emissions.
Regulatory Compliance: FDA Requirements	As noted above, the majority of North Carolina bioprocess manufacturers make pharmaceutical products and are subject to FDA regulation. FDA regulations, set forth in "21 CFR," part of the Code of Federal Regulations, are generally known as "Good Manufacturing Practice", or GMP. These regulations also encompass Good Laboratory Practice (GLP) that governs laboratory work related to clinical trials and process development; and Good Automated Manufacturing Practice (GAMP) that sets standards for automated process control systems. A considerable part of the knowledge base of pharmaceutical industry employees relates in some way to these guidelines.
General Plant Operations	This category focuses on the manufacturing plant environment and on technology that is common across the pharmaceutical industry regardless of the specific processes used to manufacture individual products. Examples: • Plant utilities, e.g., different types of water, steam, HVAC systems and controlled environments • Familiarity with basic kinds of equipment used in all types of chemical, pharmaceutical, and bioprocess manufacturing • Instrumentation and feedback control systems used to control processes • Engineering diagrams that depict process equipment and control systems • Fundamentals of working in controlled environments, i.e., those in which contamination must be reduced in order to manufacture sterile products.
Process Equipment and/or Facility Design and Scale-up	This category is specific to Process Engineers and deals with principles governing the design of manufacturing equipment and plants in the pharmaceutical industry.
Unit Operations and Manufacturing Methods	In this category we list all the methods used in general pharmaceutical and bioprocess manufacturing. Employees need to know (at different levels appropriate to their jobs) both the scientific concepts underlying the methods, as well as the kinds of equipment used to carry them out at commercial production scale.
Basic Laboratory Work	This category includes the fundamental techniques that students should master as a foundation for most other work of a more specific nature.
Analytical Instrumentation and Methods	Both raw materials and the product must be frequently assayed to determine chemical composition and/or biochemical characteristics, and purity. Included in this category are spectroscopic and chromatographic methods.

NOTE: All relevant topics in these areas are listed in the Knowledge and Skill Master List in Appendix I. Selected topics of particular importance to specific positions are listed in the individual Job Descriptions.

Translating Job Descriptions into Curriculum

Both the traditional mode of pharmaceutical manufacturing, relying on chemical synthesis of active therapeutic molecules, and biopharmaceutical manufacturing, that relies on culturing living cells and purification of the desired molecules from them, are based on a blend of science, engineering, manufacturing technology, and other specialized knowledge.

This presents a challenge to curriculum developers for the following reasons:

- An interdisciplinary (or interdepartmental) approach must be organized.
- While some traditional academic science courses are highly relevant, not all of their content is appropriate for every employee.
- Much of the knowledge base that industry employees need is specific to the industry and reference sources are not widely known to academic faculty.

Curriculum design must take into account the needs of the target audience. The employee types described in this report represent a wide range of educational levels. While different groups of employees may need to know about the same subject, they will probably need to know about different aspects of it, with different emphases and to different depths.

This chapter provides:

- An overview of the system that was applied to the knowledge and skill section to address these differences in the level of mastery required.
- A summary of the findings related to knowledge and skill level required for each of the model employees.
- An introduction to the ways in which this information could be used to develop curricula.

Level of Mastery

Some employees require knowledge of a particular subject in great depth, while others require only a general familiarity. For example:

- In order to design a biomanufacturing process that produces the desired product, a *Process Engineer* needs to have a thorough and detailed understanding of the relevant engineering principles and design issues.
- In order to transition a process from a research laboratory to production-scale manufacturing, a *Process Development Scientist* may simply need a good basic understanding of engineering principles and concerns.
- A *Quality Control Associate* does not need any knowledge of engineering and design principles in order to ensure the quality of the product being manufactured.

The Job Knowledge and Skills tables in the individual job descriptions indicate the level of mastery required for each knowledge category. The levels presented were achieved by obtaining a consensus among focus group participants and other industry reviewers. The levels are defined below:

Knowledge and Skill Levels

- **Level 1.** Basic introduction and overview of the subject matter and important terminology. It is important to note that topics assigned Level 1 are not less important than others. Rather, Level 1 topics are critical in building a foundation and contextual awareness of the industry necessary for successful employment.
- **Level 2.** Intermediate treatment of the subject matter with more exposure to the science involved, as well as a practical working knowledge of the subject sufficient to support basic troubleshooting.
- **Level 3.** Advanced treatment of the subject, with significant level of detail and scientific understanding to support high-level analysis and problem-solving.

An Example

The chart below illustrates the approach we have used in this report to define the level of knowledge required for different topics.

Level 1 - Basic	Level 2 - Intermediate	Level 3 - Advanced
Example: Gas flow in bioreactors		
• Cells need oxygen to grow. • Bioreactors have spargers to bubble air or oxygen through the growth medium. • Air supply to cells needs to be controlled.	In addition to Level 1 concepts: • Factors that increase DO include gas flow, reactor pressure, and agitator speed. • Process control circuits for a bioreactor • Basics of cellular metabolism	In addition to Level 1 and 2 concepts: • CO_2/NH_3 balance in mammalian cell cultures • Factors affecting O_2 demand • Metabolic pathway engineering • Diffusion theory • k_{LA} determination • Impeller design

Notations in the right-hand column in the Job Knowledge and Skills tables in the individual job descriptions indicate the level of mastery required for each knowledge category.

Hands-On Experience

In addition, the right-hand columns also contain a "Practical/Hands-On Experience" check box. When an "X" appears in this box, it indicates that students should have practical hands-on experience in using equipment. This practice should provide sufficient repetitions to give the student reliable competence in operations. Even when a particular topic is not designated as "hands-on", faculty may want to include some kind of limited practice or demonstration to facilitate learning.

While "hands-on" practice with other kinds of work such as reading diagrams or filling out and/or writing documents was often cited by focus group members as a valuable part of training, we have reserved this designation for practice with laboratory or manufacturing equipment.

Summary of Knowledge and Skill Requirements: by Subject Area

Understanding the spectrum of employees requiring education in a given area is useful in broad curriculum planning efforts. While this information is presented in much more detailed form later in this publication, the following charts provide a summary of the estimated average level of knowledge for each subject area. The order of these tables has been prioritized, with the subject areas requiring Level 2 and 3 treatment for the largest variety of employees coming first.

COMPLIANCE: SAFETY AND ENVIRONMENTAL

Maintenance/Instrument. Tech.	Level 2
Process Technician	Level 2
QC Assistant/Associate	Level 2
QA Associate	Level 2
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 2

A solid practical understanding of procedures related to safety, material handling, and environmental compliance is essential for all of the model employees discussed in this publication. Without this working knowledge, employees could be endangered and plant operations could be suspended.

COMPLIANCE: FDA REQUIREMENTS

Maintenance/Instrument. Tech.	Level 1
Process Technician	Level 2
QC Assistant/Associate	Level 2
QA Associate	Level 3
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 2

It is critical that all employees have a solid practical understanding of the realities of working in an FDA-regulated environment. Maintenance personnel need know how to work in controlled spaces and follow documentation related to their work. Quality Assurance personnel are specialists in this area.

UNIT OPERATIONS AND MANUFACTURING METHODS

Maintenance/Instrument. Tech.	Level 1
Process Technician	Level 2
QC Assistant/Associate	Level 1
QA Associate	Level 2
Process Dev. Assoc./Sci.	Level 3
Process Engineer	Level 2

All personnel in areas directly related to production should have at least a solid practical understanding of the various unit operations and manufacturing methods. Process Development personnel should have more advanced knowledge in this area in order to design experiments to optimize and scale-up specific operations.

GENERAL PLANT OPERATIONS

Maintenance/Instrument. Tech.	Level 3
Process Technician	Level 2
QC Assistant/Associate	Level 2
QA Associate	Level 1
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 2

All personnel in areas directly related to production should have at least a solid practical understanding of plant utilities, instrumentation, and reading engineering diagrams. Maintenance and/or Instrumentation personnel may need much more advanced training depending on their role at a company.

BASIC LABORATORY WORK

Maintenance/Instrument. Tech.	N/A
Process Technician	Level 2
QC Assistant/Associate	Level 3
QA Associate	Level 2
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 1

Most personnel in the industry have job functions that involve work in a laboratory setting, directly or indirectly. These employees should have a practical understanding of basic laboratory concepts. QC personnel rely heavily on a strong mastery of these techniques in performing more complex analyses.

ANALYTICAL INSTRUMENTATION AND METHODS

Maintenance/Instrument. Tech.	N/A*
Process Technician	Level 1*
QC Assistant/Associate	Level 3
QA Associate	Level 2
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 1

Those personnel working in a laboratory setting should have a practical understanding of some analytical instrumentation and methods used in the industry. A strong mastery of instrumentation such as HPLC or UV-VIS is essential for QC personnel.

* As Process Analytical Technology (PAT) becomes more integrated into manufacturing operations, this topic may become more important.

PROCESS, EQUIPMENT, AND OR FACILITY DESIGN AND SCALE-UP

Maintenance/Instrument. Tech.	N/A
Process Technician	N/A
QC Assistant/Associate	N/A
QA Associate	Level 1
Process Dev. Assoc./Sci.	Level 2
Process Engineer	Level 3

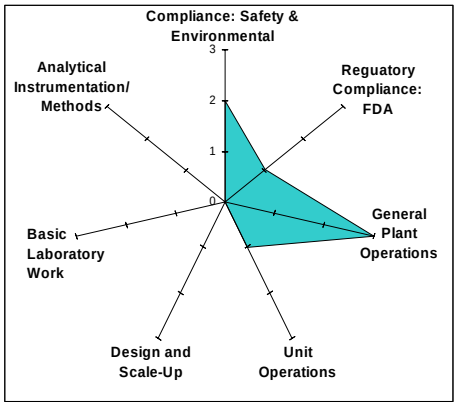
Knowledge of the engineering principles and design issues specific to biopharmaceutical manufacturing is critical for Process Engineers. Process Development Personnel should at least be familiar with basic engineering principles.

Summary of Knowledge and Skill Requirements: by Employee Type

While this information is presented in much more detailed form later in this publication, the radial diagrams that follow provide an informative summary of the knowledge and skill level requirements for each of the six Model Employees.

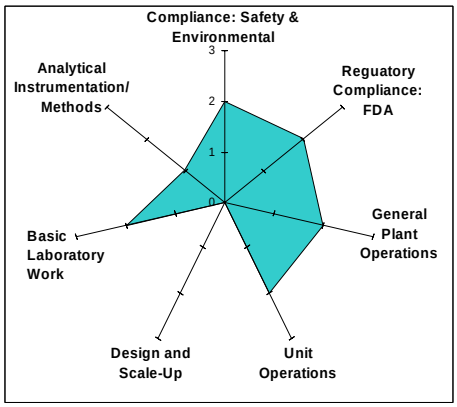
Maintenance/Instrumentation Technician

These personnel are responsible for troubleshooting, repairing, and performing preventative maintenance on production equipment, instrumentation, and utility systems. As a result, a strong level of mastery in general plant operations is required as well as basics of compliance issues (Safety, Environmental, as well as FDA regulations), and an introduction to unit operations to gain a general understanding of equipment they may have to maintain.



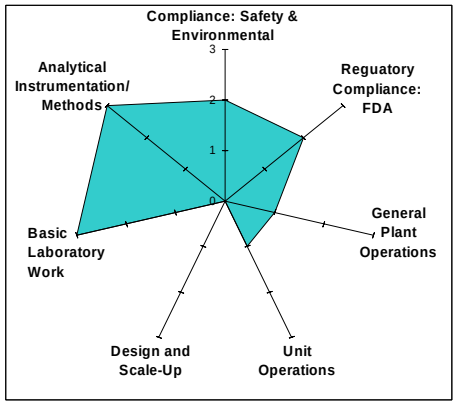
Process Technician

These personnel are responsible for monitoring and operating manufacturing processes. They also do in-process lab assays and must observe safety, environmental, and FDA regulations in all that they do. As a result, a solid foundation in most areas of the knowledge and skill list is required.



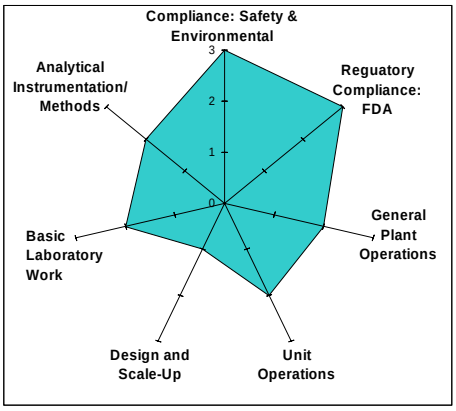
Quality Control Assistant/Associate

These personnel are responsible for conducting chemical and biological analyses of raw material, products, and the environment. As most of this work is conducted in a laboratory setting, a strong level of mastery in basic laboratory work and analytical instrumentation (HPLC and UV-VIS are essential) and methods is required, together with a general understanding of manufacturing methods.



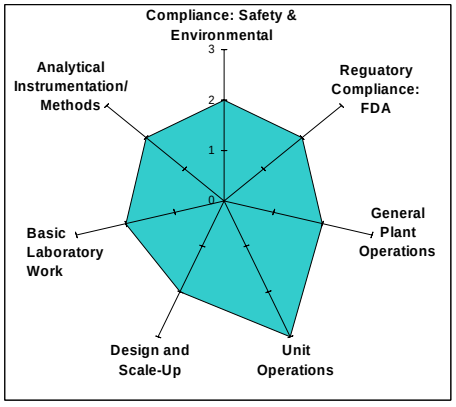
Quality Assurance Associate

These personnel are responsible for ensuring the proper function of the entire operation by reviewing SOPs, validation protocols, and all manufacturing documentation. They are responsible for ensuring compliance with regulatory agencies such as the FDA. As a result, a strong level of mastery in compliance areas is essential. As they are responsible for reviewing documentation from all other areas in the company, a solid knowledge of basic laboratory work and unit operations is also essential.



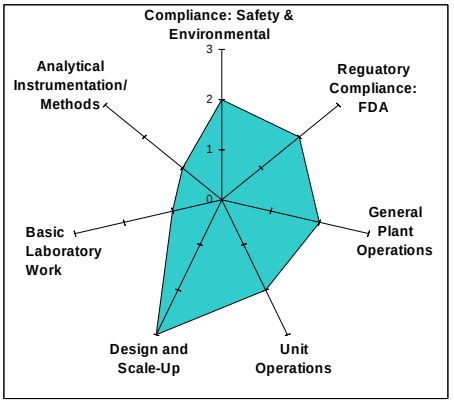
Process Development Assoc. / Scientist

These personnel are responsible for designing and executing experiments associated with the development, improvement, and scale-up of production processes. A high level of mastery of Unit Operations is necessary to perform these tasks. In addition, a very robust foundation in all knowledge and skill areas is critical as these personnel often interface between laboratory and engineering groups, and should be familiar with both engineering principles and analytical laboratory techniques.



Process Engineer

These personnel are responsible for designing, operating, and improving manufacturing processes, equipment, and facilities. In addition to a high level of mastery of engineering design and scale-up issues, process engineers need a strong foundation in all manufacturing-related knowledge and skill areas (Unit Operations, General Plant Operations, FDA Compliance).



Frequently Asked Questions

Are knowledge and skill areas assigned a Level 1 less important?
No. A topic about which job candidates need only a general familiarity (Level 1) can be a key part of their preparation. A broad understanding of all parts of the pharmaceutical manufacturing operation is essential for all employees to better understand their own role, facilitate learning, and facilitate communication with personnel in other areas.

Do job candidates really need to know everything that is in the Job Description Knowledge and Skill lists?
No. These lists capture all the information obtained from focus group meetings and other research. We asked focus group participants to think in terms of what employees in a particular position would be likely to need to know or would learn in their first six months on the job.

- For categories assigned a Level 1 (general familiarity), a broad introduction to all indicated topics would be useful.
- For categories assigned a Level 2 or 3, candidates would need more specialized knowledge on select topics – those most commonly applied across the industry or those most relevant to a particular local need. Obtaining this more advanced mastery of selected topics will enable students to better "master" new topics once on the job.

  For example, there are a number of topics listed under Analytical Instrumentation and Methods for Quality Control personnel. As each piece of instrumentation is very complex, it is not reasonable to expect students can be taught advanced knowledge regarding each instrument. However, industry focus group participants and reviewers have indicated that HPLC and UV-VIS are immensely useful to laboratory personnel. Students given the opportunity to reach a high level of operational and scientific knowledge of HPLC will be more employable and better able to master new instruments once on the job.

As an educator, how should I prioritize this information when developing curriculum?
Inevitably, class time constraints will force choices in the curriculum development process. Priorities will have to be set. Overall, our sense from the industry is that educational priorities rank as follows in their importance to the potential new graduate as a job candidate:

1. General career skills
2. Science, math, and computer skills
3. Industry overview and GMP basics
4. Industry-specific science, engineering, and technology topics

Of course, these priorities are very different for incumbent employees seeking greater proficiency or knowledge in certain areas, and item #4 above would probably be the highest priority for this population. As is always the case in course development, the needs of the intended target audience drives the design.

While the Job Descriptions included here are designed for entry-level employees, more senior employees in the same company divisions would require knowledge in the same topics listed, albeit in greater depth and detail, and with greater attention to theory. This indicates the direction for development of advanced continuing education modules intended for industry professionals.

How should I use the Career Development Pathways in counseling my students about career options?

The career pathways presented as a part of each model employee job description provide an introduction to typical career progressions. Generally speaking, as employees gain more and more experience on the job, they eventually choose between a technical career path or a managerial career path.

- **Technical career paths** include those positions requiring more specialization and subject matter expertise.
- **Managerial career paths** include those positions requiring the supervision of other employees and increased involvement outside of the employee's division.

While the career paths only show typical career opportunities within the appropriate division, employees often seek employment outside of the company division into which they were hired. These opportunities are summarized in the text preceding the career path. Additionally, as specific requirements for promotion (education and experience) differ from company to company, these requirements have not been indicated.

Maintenance and/or Instrumentation Technician

Job Titles

Instrumentation/Calibration Technician, Levels I and II
Maintenance Technician (General Mechanic, Maintenance Mechanic), Levels I and II

General Description

Performs daily monitoring, repair, predictive and preventive maintenance activities on all production-related (process and critical utilities) equipment. Troubleshoots, installs and modernizes new and existing systems, which may include refrigeration equipment, water systems, HVAC systems, and electrical systems. Monitors, troubleshoots, calibrates, installs and modernizes process control instrumentation for production-related (process and critical utilities) equipment. Documents repairs, adjustments, and replacement of equipment and/or components per company, and regulatory standards. May also provide input and corrections to Standard Operating Procedures (SOPs).

Qualifications / Requirements

Maintenance Technician

HS/GED plus relevant trade certification (e.g. refrigeration, HVAC) is required. Additional relevant community college education such as certifications and short courses is preferred. Work experience is not required for entry-level, but military and other industry experience is desirable.

Instrumentation Technician

AAS degree in relevant program (Industrial Maintenance, Instrumentation, Industrial Systems Technology) is required. Additional relevant community college education such as certifications or short courses is preferred. Work experience is not required for entry-level, but military and other industry experience is desirable.

Organizational Responsibilities

Supervisory Responsibilities

N/A

Training responsibilities

Train fellow employees in areas of expertise, and actively learn about new systems and equipment.

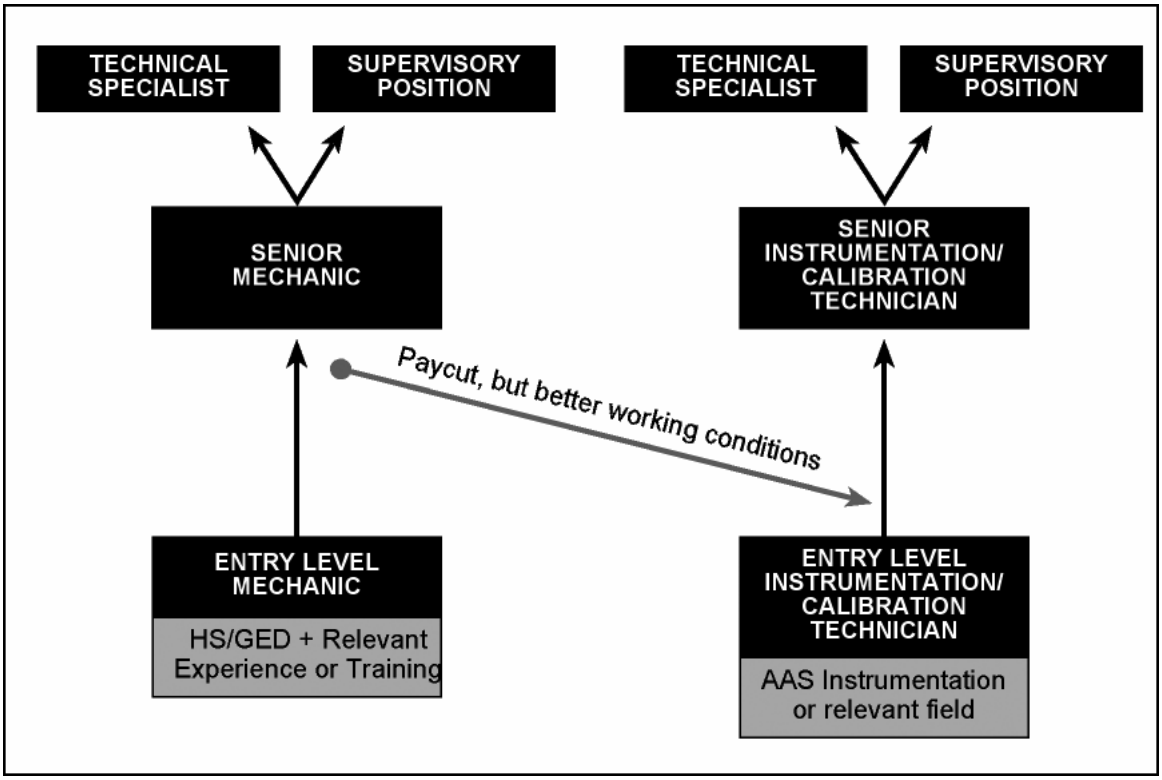
Work Environment

Shift work in plant environment

Career Development Paths

The following information comes from a focus group discussion of the various career development paths for both *Maintenance Technicians* and *Instrumentation Technicians*. Both positions follow a very similar path. It is worth noting that Maintenance Technicians routinely transfer to the Instrumentation Technician pathway, but not *vice versa*.

While at present these two types of technicians have distinctly different job responsibilities, there is a growing tendency within the industry to create combined positions, and hire individuals capable of both kinds of work. Instrumentation/Calibration technicians typically require a higher level of education.



Task List

Introduction

This task list is the product of a focus group discussion with Maintenance and Instrumentation personnel present at a Model Employee meeting. The purpose of the discussion was to capture the tasks associated with both Maintenance and Instrumentation personnel. In order to capture an industry-wide shift toward departments/employees capable of serving both maintenance and instrumentation needs, this task list contains tasks associated with both personnel.

It is important to note that while both entry and senior-level technicians may be involved in all of these tasks, their specific roles and responsibilities will differ. Typically:

- **Senior Level** technicians have responsibility for planning and executing maintenance projects, as well as leading cross-functional teams and communicating project status with individuals outside of the department.
- **Entry Level** technicians perform supervised work to assist senior personnel in executing tasks.

Note: Tasks with an "**M**" are typically associated with maintenance personnel. Tasks with an "**I**" are typically associated with instrumentation personnel. Tasks with an "**MI**" are associated with maintenance and instrumentation personnel.

Installation, Commissioning, Qualification, and/or Validation

- Assists in installing new equipment. **M**
- Assists in installing new instrumentation. **I**
- Assists in commissioning activities. **MI**
- Assists in executing validation protocols (IQ, OQ, PQ). **MI**
- Evaluates new equipment or technologies. **MI**

Operation

- Is familiar with the location and function of all plant utility systems, process equipment and control systems. **MI**
- Operates or accesses utility systems including steam, water, instrument air, process air, chilled water, waste water. **MI**
- Performs monitoring of system equipment status, condition and location. **M**
- Monitors process control systems to ensure proper operation. **I**

Predictive/Preventive Maintenance

- Performs chemical testing of steam and cooling water systems. **M**
- Performs corrective and preventive maintenance of systems and equipment (for example, basic lubrication and shaft alignment). **MI**
- Performs electronic maintenance for pressure, temperature, flow, and weight transmitters. **I**

- Prepares required documentation for the recording and notification of events and changes related to equipment such as maintenance logs, calibration certificates, deviations, out of tolerance reports and installation reports.MI
- Works with department supervisors to clarify service needs and identify problems.MI

Troubleshooting / Analysis / Repair

- Performs general mechanical repairs to all plant equipment and systems not to exclude: pumps, valves, agitators, fans, bearings, couplings, filters, belt drives, mechanical seals, hoists, hydraulics, pneumatics, on-off actuators, diaphragms, filters, fasteners, all types of electrical and pneumatic industrial control circuits and equipment, and any other special process equipment.M
- Troubleshoots and repairs electrical and/or PLC control logic and/or instrumentation in various types of process control systems including electromechanical, pneumatic, and hydraulic actuators, microprocessors, programmable logic controllers, and DCS devices.I
- Reads and interprets P&ID and other schematics as required.MI
- Works with maintenance planner to ensure materials required to do the job are on hand. Locates spare parts as necessary.MI
- Repairs or replaces equipment in most cost effective manner.MI
- Documents work as required per GMP and other regulatory standards.MI
- Communicates with vendors and service suppliers regarding equipment parts and supplies.MI
- Supports manufacturing in process-related troubleshooting.MI
- Troubleshoots and solves problems encountered by referencing previous work experience and education.MI
- Develops and recommends equipment improvements.MI
- Uses manuals and drawings to troubleshoot problems.MI
- Participates in root cause analysis, root cause verification, identification of solutions and development of solution implementation work plans.MI
- Leverages root cause/failure mode analysis into the plant processes, systems and equipment (very senior/engineering positions).MI

Safety-Related

- Follows all safety requirements and follows safe procedures, immediately notifying management or Safety when unsafe conditions or potential hazards are found; attends all required safety and health training, including LO/TO, confined space, fall protection, PPE, fire protection and response, and hazardous waste handling if necessary.MI

Calibration

- Adjusts and calibrates all types of control valves, actuators, and positioners.**I**
- Documents calibration activities per all applicable standards.**I**
- Troubleshoots and calibrates all types of process switching devices.**I**
- Performs electronic maintenance and calibration for pressure, temperature, flow, weight, pH, DO and other critical process parameter-measuring devices.**I**
- Evaluates calibration failures.**I**

Other

- Uses Computerized Maintenance Management System (CMMS).**MI**
- Trains fellow employees in areas of expertise, and actively learns about systems and equipment outside own expertise.**MI**
- Is able to support the plant operations during off-hours if needed.**MI**
- Maintains frequent communication with manufacturing personnel to be aware of their priorities and to communicate equipment repair status.**MI**

GMP

- Works to cGMP and ISO standards as required.**MI**
- Follows change control procedures.**MI**
- Completes training in, and maintains standard practices for gowning and work in controlled areas.**MI**
- Analyzes the need for technical instructions for various maintenance functions and originates standard operating procedures (SOPs).**MI**

Job Knowledge and Skills

It is important to note that focus group participants mentioned an industry-wide shift toward departments/employees capable of serving both maintenance and instrumentation needs. As a result, the Knowledge and Skills presented in this section represent a combined skill set for a Maintenance / Instrumentation Technician.

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
Maintenance Technician: HS/GED plus relevant trade certifications (e.g. refrigeration, HVAC) is required. Additional relevant community college education such as certifications and short courses is preferred. *Instrumentation/Calibration Technician:* AAS degree in relevant program (Industrial Maintenance, Instrumentation, Industrial Systems Technology) is required. Additional relevant community college education such as certifications or short courses is preferred.	Note: Candidates typically come into these positions based on prior work experience or certificate/degree programs in the technical trades that confer general mechanical savvy and an understanding of routine maintenance and repair procedures.

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: N/A	N/A 1 2 3 ☐ Practical / Hands-On Experience
Chemistry: N/A	N/A 1 2 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, and statistics.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, familiarity with CAD, process simulation software, process automation software, and use of computerized management systems (Computerized Maintenance Management System).	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Career Skills: Professional/technical communication skills, interpersonal skills, priority management skills, organization skills.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience Note: It is critical that these employees obtain strong communication skills in order to know what details need to be communicated, and how that communication may change depending on audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A **1** 2 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Lock-out/Tag-out procedures • Fall protection • Confined space entry • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience As Maintenance and Instrumentation personnel spend much of their time in the manufacturing and utility portions of the facility, a strong working knowledge of industrial safety is critical.
Environmental: General understanding of environmental regulations and plant waste processing systems.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience Note: Employees will benefit from more experience following SOPs. Assigned a Level 1 because the scope of documentation maintained is limited for these individuals at many companies.
Know how to access and use regulations from FDA and international agencies. See Appendix I for complete list.	**N/A** | 1 | 2 | 3 ☐ Practical / Hands-On Experience
Validation: • General understanding of validation principles • Principles and practices of commissioning and qualification	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience

Special Topics:
• Principles of ISO standards related to maintenance and repair functions
• Knowledge of typical types of documentation related to facilities and equipment. Examples include:
  • Maintenance logs
  • Calibration certificates
  • Out of tolerance reports
  • Installation reports
	N/A | 1 | **2** | 3
	☐ Practical / Hands-On Experience

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Utility Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • Chilled water • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Instrument and process air • Other gases • Electrical systems/power distribution • Waste collection and processing systems	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience
Reading P&IDs • Working knowledge of symbology • Ability to verify equipment location/installation using P&IDs • Ability to redline P&IDs appropriately	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience
Process Equipment: • Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing • Principles of piping and pump sizing • Characteristics of materials used in pumps, piping, tanks, and valves • Pipefitting: Fabrication, welding, and passivation; especially as the latter two methods are applied in pharmaceutical operations; other principles of sanitary piping installation	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience
Process Control: • Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO • Good operational understanding of process control systems • Statistical process control and trending analysis • Good operational knowledge of the calibration of process instrumentation	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience
Aseptic Processing: • Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience Note: Employees may need to gown up and work in controlled spaces.

GENERAL PLANT OPERATIONS (CONTINUED)	LEVEL/COMMENTS

Special Topics:
• Repair and maintenance of equipment and systems listed above or their components, including:
  • Valves, actuators, agitators, fans, bearings, couplings, belt drives, and mechanical seals
  • Hoists, hydraulic and pneumatic equipment
  • Electrical and pneumatic control circuits and actuators
• Calibration:
  • Good working knowledge of and ability to calibrate and adjust all types of control valves, actuators, and positioners
  • Good working knowledge of and ability to calibrate process instrumentation measuring common parameters including temperature, pressure, flow, level, weight/mass, pH, and DO
  • Understanding of NIST standards and their application in calibrating analytical instrumentation
• Troubleshooting principles applicable to instrumentation and control system hardware
	N/A 1 2 3
	☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Engineering economics:	N/A 1 2 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Familiarity with select unit operations and processing equipment. Maintenance technicians working in the biomanufacturing/ pharmaceutical industries need an overall view of the types of manufacturing processes in these industries, and the typical flow of unit operations. This foundation should enable technicians to learn quickly the specific operations in a given plant. Such a process overview gives the technician the background knowledge to inform judgment calls about how to respond in an emergency or how to prioritize among multiple repair jobs. See complete list of unit operations and specialized manufacturing technologies employed in the pharmaceutical and bioprocessing industries in Appendix I.	N/A 1 2 3 ☐ Practical / Hands-On Experience

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques.	N/A 1 2 3 ☐ Practical / Hands-On Experience

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation.	N/A | 1 | 2 | 3 ☐ Practical / Hands-On Experience
Familiarity with basic analytical methods.	N/A | 1 | 2 | 3 ☐ Practical / Hands-On Experience
Special Topics: • Chemical testing of steam and cooling water systems • Predictive technologies (vibration analysis, laser alignment)	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience

Process Technician

Job Titles

Process Technician, Chemical Operator, Manufacturing Associate, Process Operator, or Production Technician; Levels I and II.

General Description

Process Technicians are responsible for executing steps in the manufacture of chemical and pharmaceutical products. While specific duties vary depending on the employer, typical duties include:

- Operate, monitor, and control the production process.
- Receive, transport, and store materials.
- Collect and analyze materials used in production.
- Inspect and maintain the production equipment and control systems.
- Keep critical records on the process and product.
- Maintain company safety, health, and environmental standards.

Qualifications / Requirements

Educational Experience

HS/GED plus relevant work experience or training is required. Additional relevant community college education including certifications (e.g. BioWork), short courses, and AAS degree programs is often required.

Work Experience

A variety of types of experience may be considered a plus in hiring decisions including work in manufacturing facilities, shift work, military experience, clean room work, work with agricultural chemicals or in food processing, chemical manufacturing, laboratory work.

Organizational Responsibilities

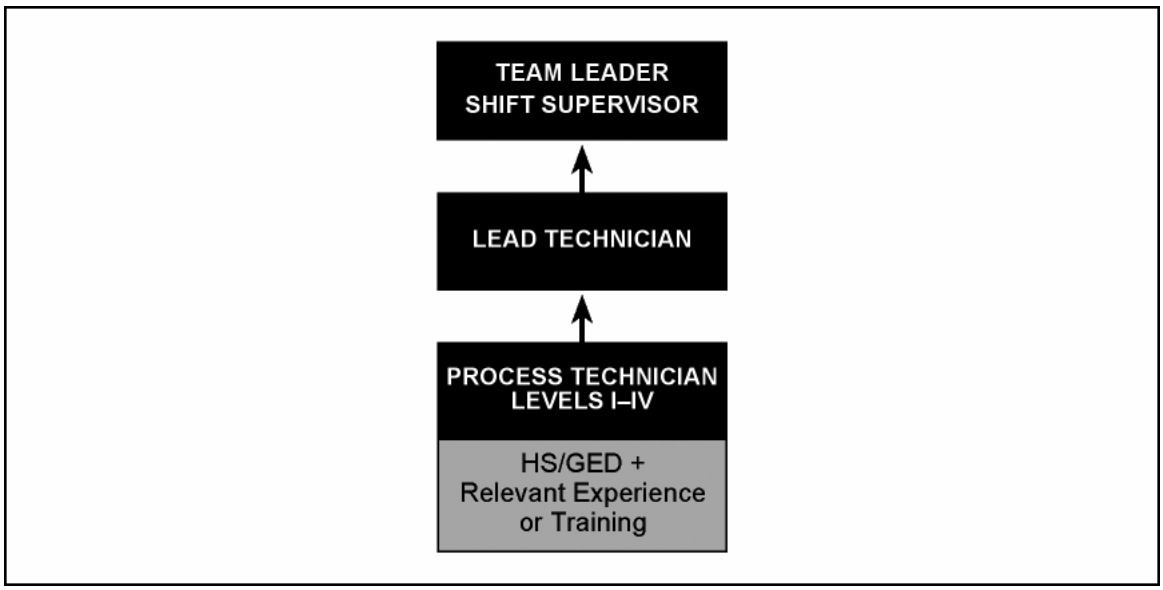
Supervisory Responsibilities

N/A

Other Responsibilities

N/A

Career Development Paths



Notes:

- **Employment of BS Graduates.** While BS graduates are not typically hired into these positions, certain companies may hire these graduates as process technicians in order to give them experience necessary for promotion into other areas.
- **Progression through Process Technician levels III-IV or V.** With these come more on-the-job training, cross-training and often formal in-house or academic coursework in topics such as: trouble-shooting; GXPs; corporate culture, expectations, and business considerations; supervisory skills, and team-building. Senior technicians at the highest level are expected to understand the theory and concepts behind the manufacturing process and be able to execute all processing operations. They take increasing responsibility in helping to train new hires, executing validation protocols, recognizing and trouble-shooting problems; and prioritizing and scheduling various production operations. They may also help to bring new processes or equipment on-line, write new SOPs; and contribute to process improvement.
- **Further progression to Lead Technician, Team Leader, or Shift Supervisor.** These positions entail supervisory responsibility over other technicians, including developing training plans.
- **Progression outside of Manufacturing.** As Process Technicians learn a tremendous amount about the manufacturing process and company operation, they often add value to other areas within an organization such as Quality Control, Process Development, Engineering, and Validation.

Task List

Operate, monitor, and control the production process.

- Executes steps in the manufacture of chemical and pharmaceutical products. See examples on following page.
- Operates, monitors and controls manufacturing equipment and processes.
- Assists with validation projects.
- Assists with waste treatment operations.
- Monitors and controls processes in a DCS environment.

Analyze, receive, transport, and/or store materials.

- Measures and prepares raw materials for use in production.
- Obtains in-process samples and may perform chemical and/or microbiological tests to ensure process and/or product are within specifications.
- Assists in environmental monitoring activities.

Maintain the production equipment and control systems.

- Prepares and calibrates probes.
- Cleans, sterilizes, inspects, and maintains production equipment.

Keep critical records on the process and product.

- Follows SOPs for all operations.
- Records process data and completes batch records as required.

Maintain company safety, health, and environmental standards.

- Follows SOPs for all operations.
- Carries out all operations with knowledge and attention to FDA-mandated Good Manufacturing Practices, OSHA and EPA regulations, and any other applicable state or federal regulations.
- Keeps work areas clean and safety equipment in order.
- Participate in all company safety training and audits as required.

Industry-Specific Examples.

- *Bioprocess Manufacturing:* Technicians must operate, monitor, and control bioreactors and bioseparation equipment, especially chromatography and filtration unit operations.
- *Aseptic Manufacturing:* Technicians must work in clean rooms, observing strict rules regarding personal hygiene, gowning, and behavior in controlled spaces.
- *Manufacturing Preparation:* Technicians are responsible for cleaning and sterilizing production equipment and glassware; and for making solutions and cell culture media.
- *Formulation and Filling Operations:* Technicians are responsible for mixing active pharmaceutical ingredients with other agents to produce the finished product. This may involve weighing, mixing, sterile filling, lyophilization, tabletting, or other operations.
- *Packaging:* Technicians use automated packaging systems to correctly label, inspect, document, and package finished product.

Job Knowledge and Skills

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
HS/GED plus relevant work experience or training is required. Additional relevant community college education including certifications (e.g. BioWork), short courses, and AAS degree programs is often required.	

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics are listed in Appendix I.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Essential topics are listed in Appendix I.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, and statistics.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, and process automation software.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Career Skills: Professional/technical communication skills, interpersonal skills, and organization skills.	N/A 1 2 3 ☐ Practical / Hands-On Experience Note: Responsible for communicating precise details of their work with other employees. It is critical that these employees obtain strong communication skills in order to know what details need to be communicated, and how that communication may change depending on the intended audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A 1 2 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Lock-out/Tag-out procedures • Fall protection • Confined space entry • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience As Process Technicians personnel spend much of their time in the manufacturing portion of the facility, a strong working knowledge of industrial safety is critical.
Environmental: General understanding of environmental regulations and plant waste processing systems.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience Note: Employees will benefit from more experience following SOPs.
Know how to access and use regulations from FDA and international agencies. See Appendix I for complete list.	**N/A** | 1 | 2 | 3 ☐ Practical / Hands-On Experience
Validation: • General understanding of validation principles	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience Note: Process Technicians may execute process validation protocols but would not often originate them.

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Process Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • Chilled water • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Instrument and process air • Other gases • Electrical systems/power distribution • Waste collection and processing systems	N/A 1 2 3 ☐ Practical / Hands-On Experience Note: Process Technicians do not typically operate utilities, but need to know enough about them to be informed end users; e.g., know utilities needs of the processes they control, when utility supplies are out of spec, and the consequences if they are out of spec.
Reading P&IDs • Working knowledge of symbology • Ability to verify equipment location/installation using P&IDs	N/A 1 2 3 ☐ Practical / Hands-On Experience
Process Equipment: • Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing	N/A 1 2 3 ☒ Practical / Hands-On Experience
Process Control: • Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO • Good operational understanding of process control systems • Statistical process control and trending analysis • Good operational knowledge of the calibration of process instrumentation	N/A 1 2 3 ☒ Practical / Hands-On Experience
Aseptic Processing: • Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A 1 2 3 ☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Engineering economics:	N/A 1 2 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Practical mastery of selected unit operations and processing equipment. See complete list of unit operations and specialized manufacturing technologies employed in the pharmaceutical and bioprocessing industries in Appendix I.	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience Note: Process Technicians will require Level 2 knowledge and hands-on training with particular methods, depending on the type of manufacturing facility they work in, and their specific job assignment.

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques including: • Glassware selection/preparation/use/cleaning • Making solutions/dilutions • Measuring pH/titration; conductivity • Basic equipment calibration • Colorimetric assays (manual and automated) • Microscopy • Culture methods (microbial and mammalian cell) • Sampling technique (as well as labeling/handling/storage of samples) • Adjusting pH • Sterilizing solutions by autoclaving and filtration • Disinfecting surfaces • Aseptic technique	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience Note: Process Technicians are often required to carry out in-process assays.

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation.	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience Note: A very general introduction is sufficient; emphasis would depend on which method(s) are used for in-process analysis.
Familiarity with basic analytical methods.	N/A | **1** | 2 | 3 ☒ Practical / Hands-On Experience Process Technicians often are required to carry out in-process assays. A foundation in basic laboratory techniques should enable technicians to quickly master particular assays applicable to their operations. Examples might include endotoxin assays or dry weight determinations.

Quality Control Assistant / Associate

Job Titles

Quality Control Associate, Quality Control Assistant, Quality Control Technician, Microbiology Technician, Chemistry Technician, Chemical Analyst

General Description

Performs chemical, microbiological, *in-vitro*, or *in-vivo* biological assays and routine analysis of raw materials, in-process intermediates, finished products, stability samples, environmental monitoring samples, process & cleaning validation samples, and packaging materials in support of pharmaceutical manufacture and clinical trial production in compliance with standard operating procedures, written test procedures, safety, FDA, cGMP and other regulatory body requirements, and approved license requirements.

Assistant

Technical know-how is necessary as well as the ability to perform routine tasks such as receiving samples, preliminary sample preparation, and glassware washing.

Associate

High level of technical and operational know-how is necessary. QC Associate is responsible for developing and performing assays as described above.

Qualifications / Requirements

Assistant

Depending on the specific nature of the position, ranges from HS/GED plus relevant work experience or training (community college certifications or short courses) to requiring AAS in scientific discipline (for example: industrial pharmaceutical technology, laboratory technology, biotechnology, chemical technology) with no experience.

Associate

BS in scientific discipline (for example: microbiology, chemistry, biochemistry) with no experience.

AAS in scientific discipline (for example: industrial pharmaceutical technology, laboratory technology, biotechnology, chemical technology) plus two years work experience.

Note: No pharmaceutical work experience is required for entry-level positions, but is always desirable. Laboratory experience in the following areas is beneficial: academia, research and development, hospital, clinical, healthcare, food science, cosmetics, agriculture, chemical, or environmental analysis.

Organizational Responsibilities

Assistant

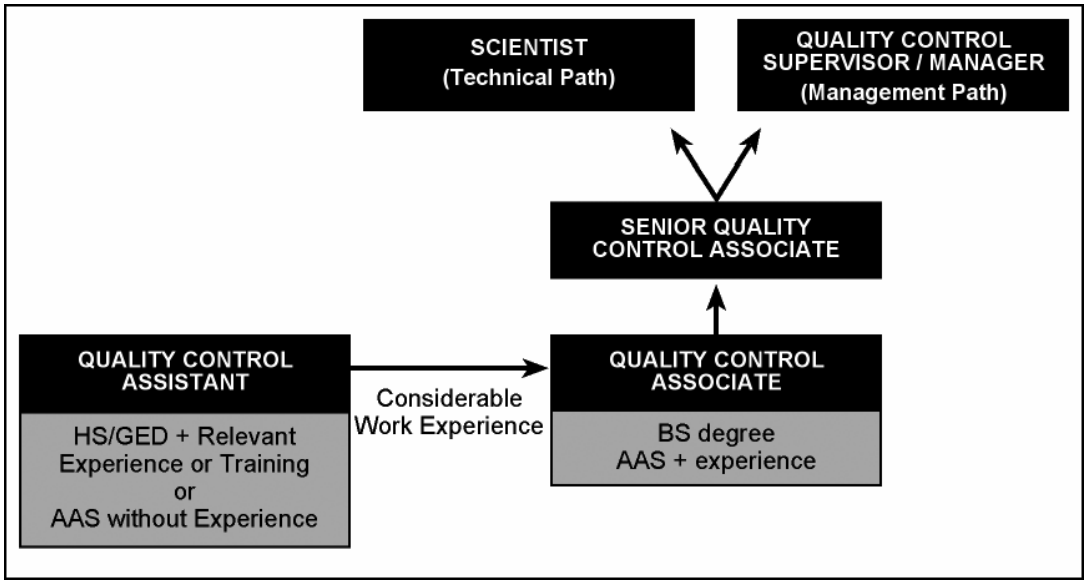
No supervisory or training responsibilities necessary. Works primarily within own unit in laboratory or pilot plant settings.

Associate

No supervisory and training responsibilities at entry-level. Communicates with other areas such as Manufacturing, QA, and Warehouse.

Career Development Paths

In addition to the paths depicted, individuals frequently seek career-advancement opportunities outside of Quality Control (Quality Assurance, Technical Support, Manufacturing, and Process Development). Note that movement into these roles depends on the candidate's education and experience.



Notes:

- **QC Assistant.** Duties may vary from company to company. Promotion from QC Assistant to QC Associate requires appropriate education (AAS) and work experience.
- **Senior Associate:** Additional responsibilities include participation in investigations, coordination of routine lab activities, authorship of SOPs, data review, and training.
- **Supervisor / Manager:** Additional responsibilities include direct oversight of Associates, mentoring new employees, employee performance reviews, managing work and vacation schedules, data review, training, and conducting investigations (i.e., Out-of-Specification results, deviations from procedure, etc.). Skills required include communication & relationships, organization, technical expertise, and problem solving. Typically requires a minimum of a BS degree with 5 years of industry experience.
- **Scientist:** Additional responsibilities include independent technical responsibility for projects, protocol and report authorship, data review, and training. Skills required include advanced technical expertise, and problem solving. Typically requires a minimum of a BS degree with 5 years of industry experience.

Task List

It is important to note that while both assistant and associate-level personnel in quality control may be involved in all of these tasks, their specific roles and responsibilities will differ. For example: A QC Associate may be responsible for performing a product release assay. The QC Assistant may obtain the samples from Production and perform other tasks supporting the QC Associate's duties.

- Performs chemical, microbiological, in-vitro, or in-vivo biological assays and routine analysis in support of pharmaceutical manufacture and clinical trial production. Samples tested typically include:
    - Raw materials
    - In-process intermediates
    - Finished products
    - Stability samples
    - Environmental monitoring samples
    - Process & cleaning validation samples
    - Packaging materials
- Performs or assists in the collection of environmental monitoring samples.
- Follows all standard operating procedures, written test procedures, safety, regulatory requirements, and approved license requirements.
- Analyzes and interprets results and findings from projects, studies, and investigations.
- Participates in the identification, resolution and correction of basic technical issues including:
    - Atypical or out-of-specification (OOS) test results
    - Instrument malfunctions
    - Methodology problems
- Performs mathematical calculations.
- Records observations, generates reports, and maintains accurate records.
- Ensures the accuracy and validity of testing results.
- Prepares media, buffers and reagents.
- Maintains laboratory and work areas in a neat and orderly manner.
- Learns to determine corrective actions and next steps under guidance of supervisor.
- Utilizes Laboratory Information Management Systems.
- Assists in coordinating the testing activities of the group.
- Writes SOPs.
- Conducts training as assigned.
- Conducts sterility and growth promotion testing on finished products.

Quality Control Associate: Job Knowledge and Skills

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
QC Assistant: Depending on the specific nature of the position, ranges from HS/GED plus relevant work experience or training (community college certifications or short courses) to requiring AAS in Scientific Discipline (For example: Industrial Pharmaceutical Technology, Laboratory Technology, Biotechnology, Chemical Technology) with no experience. *QC Associate:* BS in Scientific Discipline (For example: Microbiology, Chemistry, Biochemistry) with no experience. AAS in Scientific Discipline (For example: Industrial Pharmaceutical Technology, Laboratory Technology, Biotechnology, Chemical Technology) plus two years work experience.	

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics are listed in Appendix I.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Essential topics are listed in Appendix I.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, statistics, mathematical modeling, and data analysis.	N/A 1 2 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, networking principles, and use of computerized data management systems (LIMS).	N/A 1 2 3 ☐ Practical / Hands-On Experience
Career Skills: Professional/technical communication skills, interpersonal skills, and organization skills.	N/A 1 2 3 ☐ Practical / Hands-On Experience Note: It is critical that these employees obtain strong interpersonal/technical communication skills in order to know what technical details need to be communicated in regard to a given situation, and how the nature of that communication may change depending on the intended audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A 1 2 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience As QC personnel may spend much of their time in a laboratory environment, a strong working knowledge of laboratory safety is critical. Additionally, as they may routinely enter manufacturing areas, a familiarity with industrial safety is recommended.
Environmental: General understanding of environmental regulations and plant waste processing systems, and specific training in handling laboratory waste.	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience
Know how to access and use regulations from FDA and international agencies including: • United States Pharmacopoeia • European Pharmacopoeia See complete list in Appendix I for other topics.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience Level 2 on indicated items only.
Validation: • General understanding of validation principles • Writing IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment • Writing validation protocols for analytical methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience
Special Topics: • Proficiency in working to GLP standards.	N/A | 1 | 2 | **3** ☒ Practical / Hands-On Experience

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Utility Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Waste collection and processing systems	N/A **1** 2 3 ☐ Practical / Hands-On Experience
Reading P&IDs	N/A 1 2 3 ☐ Practical / Hands-On Experience
Process Equipment:	N/A 1 2 3 ☐ Practical / Hands-On Experience
Process Control:	N/A 1 2 3 ☐ Practical / Hands-On Experience
Aseptic Processing: • Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A 1 **2** 3 ☒ Practical / Hands-On Experience
Special Topics: • Understanding of NIST standards and their application in calibrating analytical instrumentation • Good working knowledge of the ability to calibrate and adjust laboratory equipment	N/A 1 **2** 3 ☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice:	N/A 1 2 3 ☐ Practical / Hands-On Experience
Engineering economics:	N/A 1 2 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Familiarity with select unit operations and processing equipment.	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience Note: QC Associates should be familiar with processes run in the facility where they work in order to understand the nature of in-process samples they analyze.

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques including: • Glassware selection/preparation/use/cleaning • Making solutions/dilutions • Measuring pH/titration; conductivity • Basic equipment calibration • Colorimetric assays (manual and automated) • Microscopy • Culture methods (microbial and mammalian cell) • Sampling technique (as well as labeling/handling/storage of samples) • Adjusting pH • Sterilizing solutions by autoclaving and filtration • Disinfecting surfaces • Aseptic technique	N/A | 1 | 2 | **3** ☒ Practical / Hands-On Experience

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation including: • HPLC • UV/Vis spectrophotometry • Mass spectrometry • Infrared spectrophotometry • NMR spectrometry • Gas chromatography • Refractometry	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience Note: Laboratory technicians should have a broad understanding of all these methods. It is desirable for a student to master at least one common method (HPLC is the most important). Experience preparing samples for use in analytical assays is critical.

Familiarity with basic analytical methods including:
• Environmental monitoring methods
• Water quality monitoring
• Total organic carbon [TOC] assays
• Endotoxin assays (Kinetic Turbidimetric and Endpoint Chromogenic LAL Assays)
• Bioburden assays
• Growth promotion testing
• Sterility testing
• Dry weight determinations
• Small Molecule Analysis
  • Dissolution assays
  • Friability
  • Flame tests
• Microbial identification methods
• RIA/ELISA assays
• Enzyme assays
• PCR
• Electrophoresis (SDS-PAGE and iso-electric focusing)
• Capillary electrophoresis
• Chromatography (affinity, ion-exchange, HIC, size exclusion, metal chelating)
• Protein quantification assays
• Protein functional assays: e.g. ligand binding
	N/A | 1 | **2** | 3
	☒ Practical / Hands-On Experience
	Note: These technicians should be familiar with all these methods, and will need a high degree of proficiency with the more common ones, depending on the type of production operation they work in.

Special Topics:
• Working knowledge of the principles involved in the validation of new analytical methods
• Process Analytical Technology (PAT)
• Familiar with analytical equipment used in microbiological testing, including:
  • Air sampling equipment
  • Microplate readers (for LAL testing)
	N/A | 1 | **2** | 3
	☐ Practical / Hands-On Experience

Quality Assurance Associate

Job Title

Quality Assurance Associate

General Description

Responsible for ensuring product quality and company compliance with relevant regulations, industry standards, and internal procedures and policies by reviewing and approving GMP documentation supporting operations such as production, quality control, and validation. Document areas include:

- Batch Records
- Laboratory Records
- Change Control
- Deviations, Exceptions, and Out-of-Specification (OOS) results
- Investigations
- Validation and other protocols

Other duties include informing internal and external clients how Quality Assurance works with other departments to ensure quality; performing incoming raw material/consumable inspection; conducting internal and external audits; and providing initial and annual GMP training for new hires, incumbent employees, and contractors.

Qualifications / Requirements

Educational Experience

- Minimum: AAS + two years' experience in pharmaceutical industry (in production, quality control, engineering).
- Preferred: BS degree (science or engineering). Experience in pharmaceutical industry not required but one to two years preferred.

Work Experience

Several years of relevant industry experience in production, quality control, engineering, or other areas is beneficial.

Organizational Responsibilities

Supervisory responsibilities:

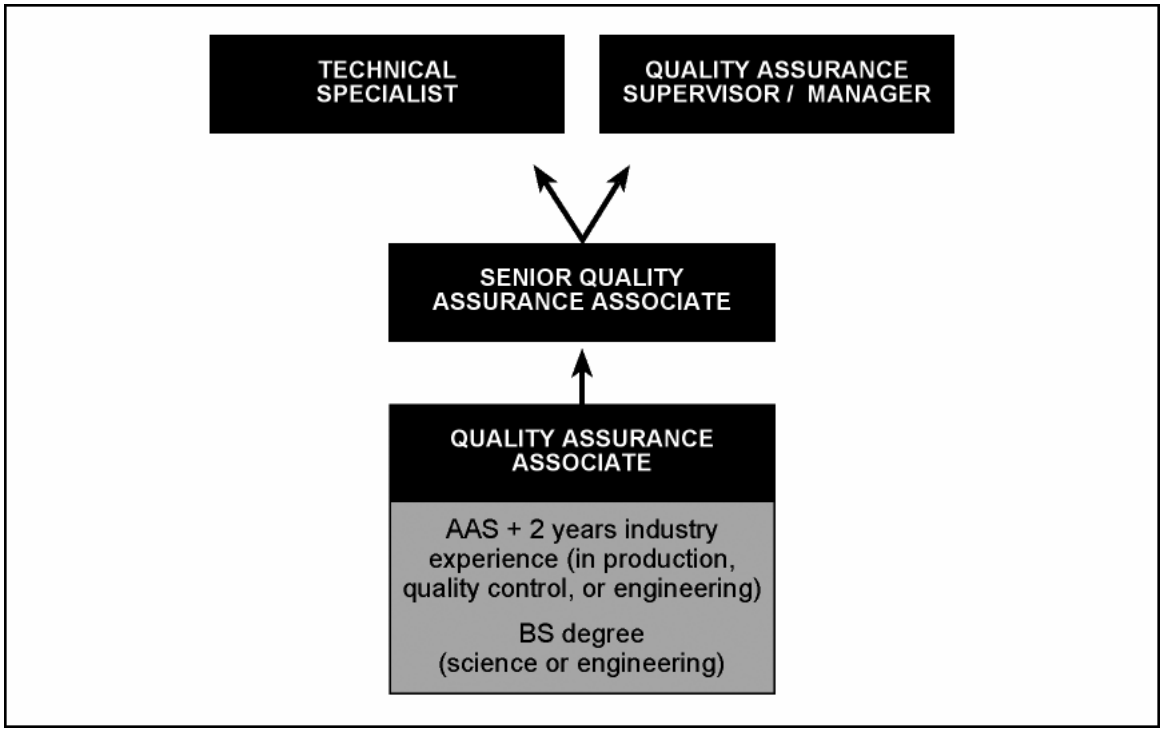
N/A.

Other responsibilities

Incumbents will need to collaborate with multiple internal departments. After training period, has signature/approval authority on certain documents.

Career Development Paths

In addition to the paths depicted, individuals frequently seek career-advancement opportunities outside of Quality Assurance (Business Development, Quality Control, Regulatory Affairs, Technical Support, Manufacturing, and Marketing).



Task List

Introduction

This task list is the product of a discussion with Quality Assurance personnel present at the Model Employee meeting. The purpose of the discussion was to capture the tasks typical of Quality Assurance personnel with respect to broad categories chosen by the industry representatives.

It is important to note that while both entry and senior-level associates may be involved in all of these tasks, their specific roles and responsibilities will differ. Tasks designated with an "s" are typically associated with senior level personnel. Entry-level personnel may assist in these tasks.

Batch record review

- Performs reviews during production runs on the plant floor in order to observe operations including batch record completion.
- Performs review of completed batch records and signs off (approves) if authorized to do so.
- Checks all calculations.
- Checks that in-process product testing parameters are within specified ranges.
- Checks that production equipment operating parameters are within specified ranges.
- Checks that documentation standards are met.
- Identifies deviations, consults with manufacturing personnel, and initiates appropriate actions upon consultation with QA supervisor.
- Confirms that all deviations (open issues) are closed.

Laboratory record review (QC data)

- Performs review of laboratory portions of batch records after assays are completed and signs off (approves) if authorized to do so.
- Performs review of other completed laboratory records (lab notebooks, data forms, LIMS records and signs off (approves) if authorized to do so.
- Checks all calculations.
- Checks that all results are within specified ranges.
- Checks that laboratory equipment operating parameters are within specified ranges.
- Checks that documentation standards are met.
- Identifies deviations, consults with lab personnel, and initiates appropriate actions upon consultation with QA supervisor.

Protocol (Validation and other) Review and Approval [s]

- Reviews and evaluates protocols before execution to ensure format is acceptable, protocol is robust (all necessary tests are included), and acceptance criteria are adequate.
- Reviews final report summary of protocol, data obtained, and conclusions to ensure acceptance criteria were met.
- Reviews data associated with the protocol. May check all calculations.
- Checks that documentation standards are met.
- Identifies deviations, consults with appropriate personnel, and initiates appropriate actions; designs corrective actions.

SOP, Procedures, and Training Materials Review

- Reviews to ensure compliance with regulatory agencies and other company policies. Note: Technical content review is often done by Subject Matter Experts (SME's).
- Reviews training materials inclusive of testing and evaluation methods and/or assessments.
- Ensures documentation standards are met regarding how procedures are written, how data is recorded, and whether the various elements or sections included in a document are adequate.

GMP training [s]

- Designs, reviews, and/or delivers training focused on compliance with cGMPs.
- Provides initial and annual GMP training for new hires, incumbent employees, and contractors.

Stability Testing for Product, Raw Materials, Cell Lines

- Reviews and approves stability studies.
- Follows standard procedure or schedule to determine which lots are going to be chosen for stability testing ("stability lots").
- Determines sampling frequency for testing; establishes specifications for acceptance criteria. [s]
- Reviews stability data.
- Coordinates and monitors sampling processes.
- Notifies regulatory agency of Out-of-Specification (OOS) results [s].

Compliance Inspection / Auditing / Investigation (Internal and External)[s]

- Conducts internal audits. These are systematic evaluations of whether company quality systems are in compliance with regulations and internal procedures are followed, and may include walk-throughs.
    - Creates annual audit schedule.
    - Conducts audits and write observations.
    - Follows up on actions taken.
    - Evaluates effectiveness.
- Conducts external audits. These are systematic evaluation of whether vendor quality systems are in compliance with regulations, vendor's internal procedures are followed, and whether they have adequate quality systems (includes walk-through).
    - Coordinates vendor surveys and conduct audits.
    - Evaluates vendor responses.
    - Recommends vendors for approval.
    - Participates in Material Review Board.
    - Coordinates vendor change notifications.
- Hosts regulatory and client audits.
- Coordinates teams for audits.
- Responds to observations (works with appropriate departments).
- Ensures that actions are taken to address observations.

Facility compliance/environmental regulatory compliance

- Reviews utilities functions/trends.
- Reviews environmental monitoring data and trends.
- Reviews process data/data trending.

Other Tasks

- Follows all change control procedures.[s]
- Inspects incoming raw material/consumables. Tests or ensures testing is performed on incoming raw materials, consumables, etc.
- Reviews documentation associated with new facility commissioning and qualification.[s]
- Performs Annual Product Review.

Quality Assurance Associate: Job Knowledge and Skills

It is important to note that the Quality Assurance department is responsible for ensuring the quality of all company operations. Due to this large scope of responsibility, individuals frequently specialize in a certain area (production, engineering, quality control) based on their individual education and professional experience. As a result, the requisite knowledge for a certain position may be a subset of the information presented in this section.

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
Minimum: AAS + two years' experience in industry (in production, quality control, engineering). Preferred: BS degree (science or engineering).	Note: If coming from a life science background, a "Principles of Engineering" course is desirable, especially one oriented towards pharmaceutical and bioprocess manufacturing operations.

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics are listed in Appendix I.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Essential topics are listed in Appendix I.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, and statistics.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, networking principles, process simulation software, process automation software, and use of computerized data management systems (CMMS, LIMS, etc..).	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Career Skills: Project management, professional/technical communication skills, interpersonal skills, and organization skills.	N/A 1 2 **3** ☐ Practical / Hands-On Experience Note: It is critical that these employees obtain strong interpersonal/technical communication skills in order to know what technical details need to be communicated in regard to a given situation, and how the nature of that communication may change depending on the intended audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A 1 2 3 ☒ Practical / Hands-On Experience As QA personnel are responsible for monitoring the quality of all plant operations, a strong working knowledge of laboratory and industrial safety is critical.
Environmental: General understanding of environmental regulations and plant waste processing systems.	N/A 1 2 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance	N/A 1 2 3 ☐ Practical / Hands-On Experience
Know how to access and use regulations from FDA and international agencies including: • 21 CFR Part 11, 210, 211; 21 CFR Part 600 Subparts A-D • Sterile Drug Products Prod. By Aseptic Proc., FDA Guidance August 2003 • EC Guide on Good Mfg. Practice written by the European Commission • Guide to Inspection of High Purity Water written by FDA • United States Pharmacopoeia • European Pharmacopoeia • ICH Intl Conf on Harmonization (of regulatory requirements) • Health Technical Memorandum 2010 • BS EN 285	N/A 1 2 3 ☐ Practical / Hands-On Experience
Validation: • General understanding of validation principles • Principles and practices of commissioning and qualification • Writing IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment • Writing validation protocols for production processes • Writing validation protocols for analytical methods • Principles governing choice of key process parameters to validate, and setting operational specifications	N/A 1 2 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS (CONTINUED)	LEVEL/COMMENTS
Special Topics: • Proficiency in working to GLP standards • Risk analysis / risk management • Knowledge of GAMP and software validation practices • Electronic documentation (control and data capture storage systems)	N/A 1 **2** 3 ☐ Practical / Hands-On Experience

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Utility Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • Chilled water • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Instrument and process air • Other gases • Electrical systems/power distribution • Waste collection and processing systems	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Reading P&IDs • Working knowledge of symbology • Ability to verify equipment location/installation using P&IDs	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Process Equipment: • Working knowledge of common types of pumps, piping, tanks, valves, and solids handling equipment used in pharmaceutical/bioprocess manufacturing	N/A **1** 2 3 ☐ Practical / Hands-On Experience
Process Control: • Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO • Good operational understanding of process control systems • Statistical process control and trending analysis • Good operational knowledge of the calibration of process instrumentation	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Aseptic Processing: Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A 1 **2** 3 ☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice:	N/A **1** 2 3 ☐ Practical / Hands-On Experience
Engineering economics:	**N/A** 1 2 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Familiarity with select unit operations and processing equipment.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience Note: Generally speaking, it is critical that QA personnel have broad knowledge/familiarity with typical company operations in order to perform job functions and critically evaluate documentation.

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques including: • Glassware selection/preparation/use/cleaning • Making solutions/dilutions • Measuring pH/titration; conductivity • Basic equipment calibration • Colorimetric assays (manual and automated) • Microscopy • Culture methods (microbial and mammalian cell) • Sampling technique (as well as labeling/handling/storage of samples) • Adjusting pH • Sterilizing solutions by autoclaving and filtration • Disinfecting surfaces • Aseptic technique	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience Generally speaking, it is critical that QA personnel have hands-on experience with typical laboratory procedures, tests, and operations in order to perform job functions and critically evaluate documentation.

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation including: • UV/Vis spectrophotometry • HPLC • Infrared spectrophotometry • NMR spectrometry • Mass spectrometry • Gas chromatography • Refractometry	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience Note: A general familiarity with analytical instrumentation is necessary for these employees in order that they may critically evaluate documentation. An understanding of the nature of data obtained and its interpretation is desirable. Some hands-on experience is desirable for pedagogical reasons. PAT will become an increasingly vital topic for these employees.

Familiarity with basic analytical methods including:
• Environmental monitoring methods
• Water quality monitoring
• Total organic carbon [TOC] assays
• Endotoxin assays (Kinetic Turbidimetric and Endpoint Chromogenic LAL Assays)
• Bioburden assays
• Growth promotion testing
• Sterility testing
• Dry weight determinations
• Small Molecule Analysis
  ◦ Dissolution assays
  ◦ Friability
  ◦ Flame tests
• Microbial identification methods
• RIA/ELISA assays
• Enzyme assays
• PCR
• Electrophoresis (SDS-PAGE and iso-electric focusing)
• Capillary electrophoresis
• Chromatography (affinity, ion-exchange, HIC, size exclusion, metal chelating)
• Protein quantification assays
• Protein functional assays: e.g. ligand binding
	N/A | 1 | **2** | 3
	☒ Practical / Hands-On Experience
	Note: A general familiarity with these methods is necessary for employees who review QC laboratory operations in order that they may critically evaluate documentation. An understanding of the nature of data obtained and its interpretation is desirable. Some hands-on experience is desirable for pedagogical reasons.

Special Topics: • Process Analytical Technology (PAT)	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience

Process Development Associate/Scientist

Job Title

Process Development Associate/Scientist

General Description

Responsible for the development, optimization, and transfer of new products and processes from R&D into manufacturing (laboratory-scale through pilot and manufacturing scale). Responsible for designing and/or executing protocols in order to develop new processes, optimize existing manufacturing processes, improve product yield, and reduce manufacturing costs. Researches and implements new methods and technologies to enhance operations. Executes small-to-medium scale production work, which may involve cell culture, fermentation, and purification.

Associate Level

Technical and operational know-how. Responsible for assisting Process Development Scientists in the execution of experiments associated with development, improvement, and scaling-up processes.

Scientist Level

Analytical and problem-solving expertise. Responsible for the design and execution of experiments associated with development, improvement, and scaling-up processes.

Qualifications / Requirements

Associate Level

AAS in scientific discipline (for example: industrial pharmaceutical technology, biotechnology))with 2-5 years industry experience. BS in science or engineering (chemical or bioprocess) preferred.

Scientist Level

MS with 2-5 years industry experience, or PhD in science or engineering (chemical or bioprocess) with no experience.

Organizational Responsibilities

Associate Level

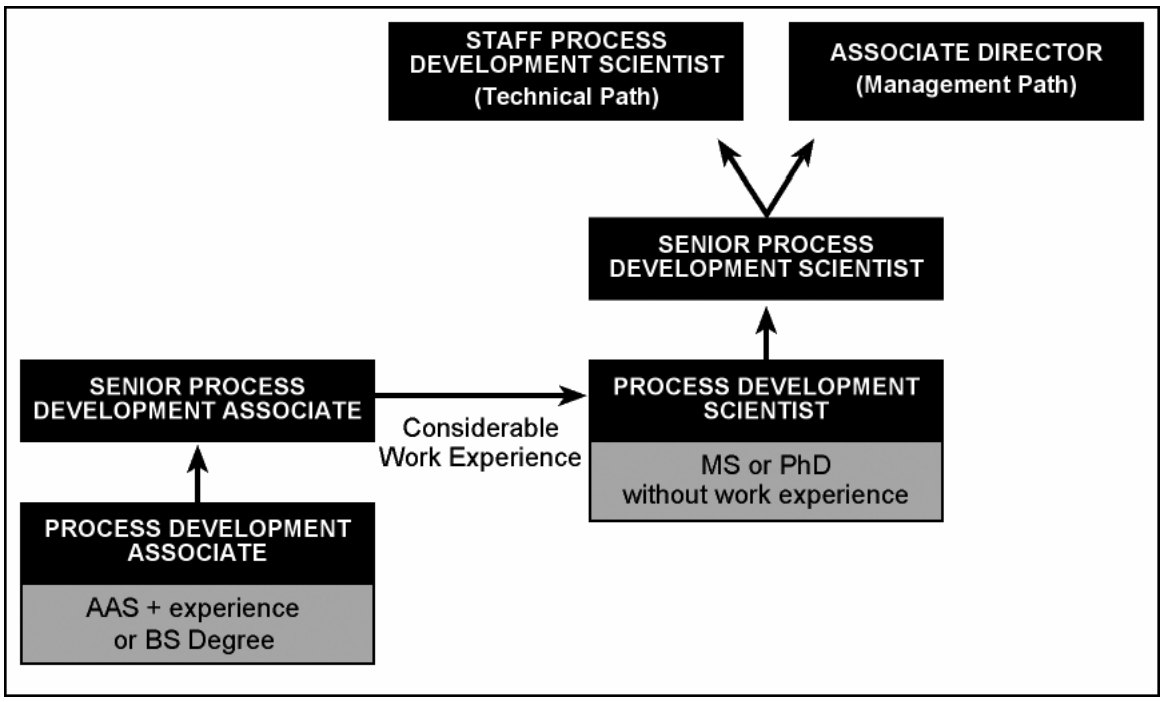
No supervisory or training responsibilities at entry-level. At higher levels, may have some management responsibilities. Works primarily within own unit in laboratory or pilot plant settings.

Scientist Level

Some supervisory and training responsibilities at entry-level. May have project management responsibilities. Communicates with other company personnel.

Career Development Paths

This flowchart depicts a typical career path for both Process Development Associates and Process Development Scientists. In addition to the paths depicted, individuals frequently seek career-advancement opportunities outside of Process Development (Quality Assurance, Quality Control, Technical Support, and Manufacturing, and Marketing).



Task List

Introduction

This task list is the product of a discussion with Process Development personnel present at two Model Employee meetings. The purpose of the discussion was to capture tasks common to all Process Development personnel. It is important to note that while both associates and scientists may be involved in all of these tasks, their specific roles and responsibilities will differ. Typically:

- **Scientists** have responsibility for planning and executing the overall task, analyzing and interpreting any data obtained, as well as communicating project status with individuals outside of the department.
- **Associates** perform supervised work to assist Scientists in the execution of these tasks.

Development of processes to manufacture new products

- Performs activities related to the scale up of cell culture or fermentation processes from flasks or roller bottles to bioreactors.
- Optimizes feed, DO levels, and mixing for bioreactor operation.
- Develops and scales-up purification protocols for proteins expressed in insect, mammalian, fungal, or bacterial cells. Example: For product recovery step, compare dead end filtration with tangential flow filtration and/or centrifugation with respect to product yield and stability.
- Develops or selects methodology and standard operating parameters for in-process analysis.
- Develops formulation/lyophilization/storage protocols for products.
- Executes accelerated stability protocols.
- Executes process validation and/or equipment qualification procedures.
- Executes production runs to develop clinical trial materials.

Process transfer

- Assists in development of validation procedures for production processes.
- Identifies critical process parameters for validation.
- Sets critical operating ranges for key process parameters (analyzes results from practice runs to set these values; executes production runs to demonstrate consistency with which critical parameters are within set range.)
- Performs statistical analyses to determine/define consistency from one batch to another.
- Executes protocols to validate critical procedures, processes, and control points. Example: Execute a CIP protocol and demonstrate that it works.
- Works with production personnel to implement new processes.
- Trains manufacturing personnel on new equipment and processes.
- Writes batch records to support new processes.

Process support / optimization/ trouble-shooting

- Develops and executes experiments and protocols in order to:
    - Assess productivity.
    - Identify sources of process variability.
    - Identify and resolve issues with materials, processes, or equipment.
- Performs change-out procedures.
- Assists with maintenance of production equipment.
- Participates in diagnosing/troubleshooting problems.
- Makes adjustments to bring operations into standard operating range.

General

- Records data.
- Analyzes data and interpret results.
- Prepares technical reports, summaries, protocols and quantitative analyses.
- Assists in the preparation of regulatory filings.
- Exercises technical discretion (appropriate to level of responsibility) in the design, execution and interpretation of experiments.
- Performs literature searches.
- Performs all work according to cGMP and cGLP standards as required.
- Maintains laboratory equipment. Makes reagents and prepare test samples. Maintains inventory of materials.
- Observes appropriate safety practices and documents those as required. Attends regular safety training.
- Keeps accurate records according to regulatory requirements. Maintains laboratory notebooks in accordance with company policy and legal requirements. Works with electronic data management systems.
- Counts cells.
- Assembles bench and pilot-scale bioreactors.

Process Development Associate: Job Knowledge and Skills

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
Associate Level AAS with 2-5 years industry experience required. BS in science or engineering (chemical or bioprocess) preferred. No prior experience required. *Scientist Level* MS with 2-5 years industry experience. PhD in science or engineering (chemical or bioprocess). No prior experience required.	Engineers need a basic knowledge of cellular metabolism and factors affecting protein structure/stability. Scientists need a basic acquaintance of engineering design principles.

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics are listed in Appendix I.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Essential topics are listed in Appendix I.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, statistics, calculus (differential equations), mathematical modeling, and data analysis.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Computer Usage: Word processing, spreadsheets, networking principles, familiarity with CAD, process simulation software, process automation software, and use of computerized management systems (CMMS, LIMS, etc.).	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Career Skills: Professional/technical communication skills, interpersonal skills, and organization skills.	N/A 1 2 **3** ☐ Practical / Hands-On Experience Note: It is critical that these employees obtain strong interpersonal/technical communication skills in order to know what technical details need to be communicated in regard to a given situation, and how the nature of that communication may change depending on the intended audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A 1 **2** 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Lock-out/Tag-out procedures • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience As Process Development personnel routinely operate in both laboratory and manufacturing (pilot and production scale) environments, a strong working knowledge of laboratory and industrial safety is critical.
Environmental: General understanding of environmental regulations and plant waste processing systems.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience
Know how to access and use regulations from FDA and international agencies. See Appendix I for complete list.	**N/A** | 1 | 2 | 3 ☐ Practical / Hands-On Experience
Validation: • General understanding of validation principles • Principles and practices of commissioning and qualification • Writing IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment • Writing validation protocols for production processes • Writing validation protocols for analytical methods • Principles governing choice of key process parameters to validate, and setting operational specifications	N/A | 1 | 2 | **3** ☐ Practical / Hands-On Experience
Special Topics: • Proficiency in working to GLP standards	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Utility Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • Chilled water • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Instrument and process air • Other gases • Electrical systems/power distribution • Waste collection and processing systems	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Reading P&IDs • Working knowledge of symbology • Ability to verify equipment location/installation using P&IDs • Ability to redline P&IDs appropriately	N/A 1 **2** 3 ☒ Practical / Hands-On Experience
Process Equipment: • Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing • Principles of piping and pump sizing • Characteristics of materials used in pumps, piping, tanks, and valves	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Process Control: • Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO. • Good operational understanding of process control systems • Statistical process control and trending analysis • Good operational knowledge of the calibration of process instrumentation	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Aseptic Processing: Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A **1** 2 3 ☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice: • Knowledge of scale-up issues in typical processes run in pharmaceutical/biopharmaceutical facilities and how to resolve such issues • Experimental design • Practical experience in designing and running a process, especially fermentation, cell culture, or downstream processing equipment	N/A 1 **2** 3 ☒ Practical / Hands-On Experience
Engineering economics: • Calculating equipment, process, and/or project costs. • Enterprise resources planning and tracking	N/A 1 **2** 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Familiarity with select unit operations and processing equipment including: • Batch and/or continuous chemical reaction operations • Distillation/stripping • Growth media prep • Bioreactor operation (mammalian and microbial cells) • Cell disruption (pressure and mechanical lysis) • Centrifugation • Depth filtration • Membrane filtration (micro/ultra/nano/RO/diafiltration) • Chromatography (affinity, ion-exchange, HIC, size-exclusion, metal chelating) • Liquid-liquid extraction • Precipitation • Crystallization • Lyophilization • Granulation • Pasteurization/flow-through sterilization • Immobilized enzyme technology • Solid dosage forms preparation • Formulation of aerosols and injectibles • Filling / sterile filling operations • Isolation / barrier technology	N/A | 1 | 2 | **3** ☒ Practical / Hands-On Experience Note: Process Development personnel should have thorough knowledge of operations they will work with in a particular company.

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques including: • Glassware selection/preparation/use/cleaning • Making solutions/dilutions • Adjusting/Measuring pH/titration; conductivity • Basic equipment calibration • Colorimetric assays (manual and automated) • Microscopy • Culture methods (microbial and mammalian cell) • Sampling technique (as well as labeling/handling/storage of samples) • Sterilizing solutions by autoclaving and filtration • Disinfecting surfaces • Aseptic technique	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation including: • HPLC • UV/Vis spectrophotometry • Mass spectrometry • Infrared spectrophotometry • NMR spectrometry • Gas chromatography • Refractometry	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience Note: Hands-on proficiency with more commonly applied ones at laboratory scale; and increasingly in the future, familiarity with application of selected methods to automated in-process analysis of product streams.

Familiarity with basic analytical methods including:
• Environmental monitoring methods
• Water quality monitoring
• Total organic carbon [TOC] assays
• Endotoxin assays
• Bioburden assays
• Growth promotion testing
• Sterility testing
• Dry weight determinations
• Small Molecule Analysis
  • Dissolution assays
  • Friability
  • Flame tests
• Microbial identification methods
• RIA/ELISA assays
• Enzyme assays
• PCR
• Electrophoresis (SDS-PAGE and iso-electric focusing)
• Capillary electrophoresis
• Chromatography (affinity, ion-exchange, HIC, size exclusion, metal chelating)
• Protein quantification assays
• Protein functional assays: e.g. ligand binding
	N/A | 1 | 2 | 3
	☒ Practical / Hands-On Experience
	Note: Process Development personnel should have familiarity with the following methods; and hands-on proficiency with many, depending on the product/process.

Special Topics: • Working knowledge of the principles involved in the validation of new analytical methods • Process Analytical Technology (PAT)	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience

Process Engineer

Job Title

Process Engineer

General Description

Participate in the design, installation, start-up, operation, maintenance, or ongoing improvement of biomanufacturing and pharmaceutical manufacturing processes and facilities. Entry-level engineers in this position would initially assist in, and with increasing experience would assume increasing responsibility for, functions such as the following:

- Develop Functional Requirement Specifications (FRS) from design P&IDs for new processes;
- Design, specification, and procurement of equipment;
- Technical transfer of processes from development into commercial scale production;
- Training of production personnel associated with new process transfer;
- Collaboration with manufacturing support groups in the planning, reviewing, performance, and scheduling of activities related to start up of new processes.
- Support equipment installation, start-up, and validation activities.

Qualifications / Requirements

Educational Experience

- BS (usual) or MS degree (for some positions) in Biochemical, Bioprocess, Chemical, or Mechanical Engineering.
- BS or MS degree in Food Science (curriculum emphasizing Food Engineering, not Nutrition)

Work Experience

None required. Co-ops and/or internships are beneficial.

Organizational Responsibilities

Supervisory Responsibilities

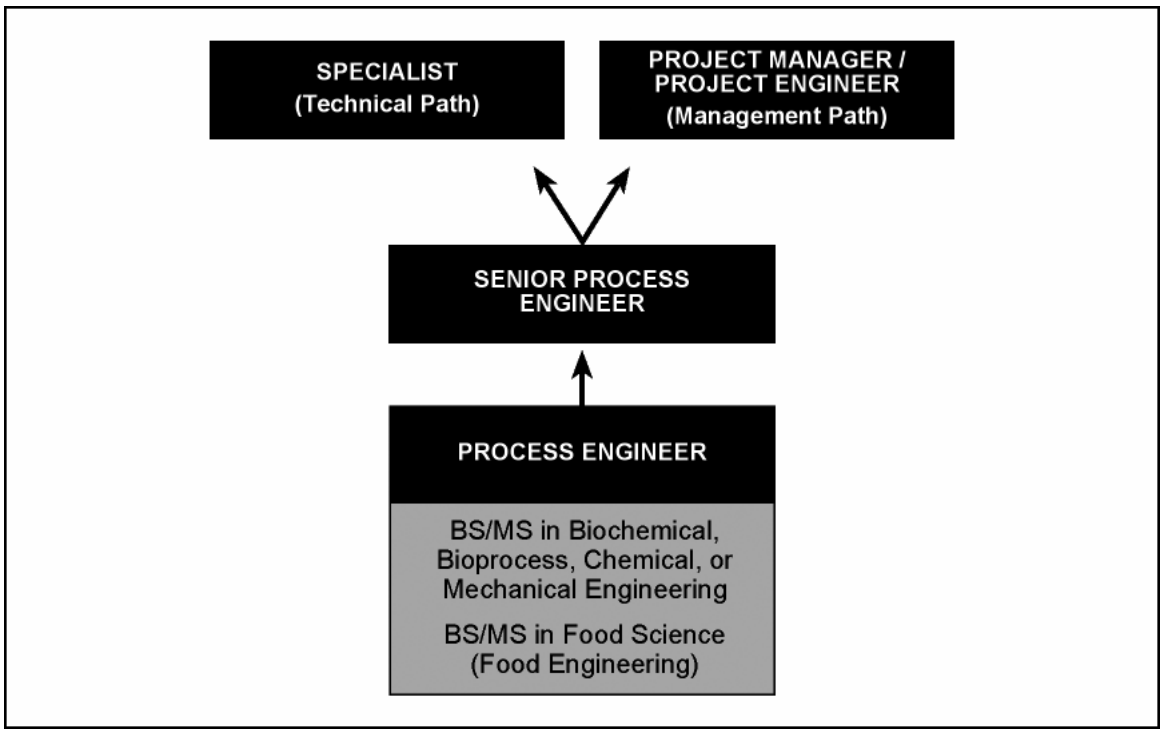
Supervisory and training responsibilities are minimal at entry level but increase with increasing experience on the job.

Other Responsibilities

While typically a first shift job, process engineers should be ready to be on-call during second and third shift. Incumbents will need to collaborate with multiple internal departments.

Career Development Paths

Generally speaking, process engineers in both consulting firms and manufacturing companies choose either a path of technical specialization (left) or a managerial path (right) as they progress in their career. In both cases, engineers also move out of engineering into other careers areas such as consulting, quality assurance, marketing, sales, and business development.



Task List

Introduction

This task list is the product of a discussion with Process Engineers at a Model Employee meeting. The purpose of the discussion was to capture tasks typical of Process Engineers at all levels. It is important to note that while both entry and senior-level engineers may be involved in all of these tasks, their specific roles and responsibilities will differ. Typically:

- **Senior Level** have responsibility for planning and executing the overall task, as well as leading cross-functional teams and communicating project status with individuals outside of the department.
- **Entry Level** engineers perform supervised work to assist senior personnel in the execution of these tasks.

Design

- Advises on commitment of resources (cost and schedule).
- Designs and develops sequence, layout, and arrangement of operations necessary for a project (new process, process scale-up, or revision to existing process). All designs are created with a number of factors in mind, including:
    - Incorporate GMP principles.
    - Develop everything so that it is feasible, robust, and within budget.
    - Design for waste management minimization.
- Creates blueprints, P&IDs, and process flow diagrams.
- Simulates process operations on computer.
- Calculates material/energy balances.
- Designs, specifies, and procures equipment as well as investigating alternative equipment configuration of existing equipment.
- Develops Functional Requirement Specifications (FRS) from design P&IDs for new processes.
- Develops user requirements for new processes.
- Develops CIP or SIP protocols for new processes.
- Scales up the process to pilot and manufacturing scale.
- Conducts safety or HAZOP (hazard and operability) reviews of a process in order to identify potential hazards and operability problems caused by deviations from the design intent of both new and existing process plants.

Installation

- Manages installation, validation, and start-up activities.
- Writes and submits change control documents.
- Assists in developing and executing Commissioning/Qualification/and Validation protocols for new equipment. Typical protocols include:
    - Factory acceptance test (FAT) procedures
    - Validation master plan
    - System-commissioning protocols
    - Validation protocols
    - Installation qualification (IQ)
    - TOP (Turn Over Package) documentation
    - Operation qualification (OQ)
    - Performance qualification (PQ)
- Determines and orders raw materials for commissioning and validation. Identifies alternate vendors/suppliers.
- Writes operation qualification and process qualification test plans.
- Performs dry runs of automation sequences (Site Acceptance Testing or SAT).
- Performs equipment qualification protocols including automation control.
- Writes SOPs for equipment operation.
- Walks down P&IDs and isometric drawings for installation verification and drawing accuracy.
- Develops batch records.
- Develops preventive maintenance (PM) and calibration schedules.
- Creates and revises construction punch lists.
- Signs-off and accepts facility and equipment.
- Performs start-up training on equipment.
- Determines spare parts requirements.

Operation

- Collaborates with manufacturing support groups such as Operations, Validation, Engineering/Facilities Engineering Services, and Instrumentation/Calibration Services in the planning, reviewing, performance, and scheduling of activities related to start up of new processes and support of existing processes.
- Supports and defines PVRs (Process Validation Runs).
- Investigates process, equipment, and automation deviations (ongoing troubleshooting).
- Performs process improvement functions including:
    - bottleneck analysis
    - activities to improve robustness
    - technology transfer from process development
- Performs activities related to process control such as data trending, maintenance and automation changes, and control scheme updates, and monitors product quality (e.g. particle-size distribution of a granulated product).
- Performs activities related to change control such as identifying potential change, design and pre-approval of changes, implementation, required regulatory submissions, validation, and ROI analysis.
- Performs activities related to shutdown (and subsequent startup).
- Assists in emergency maintenance and monitors frequent/repeat maintenance repairs.
- Designs experiments to optimize and improve the process.
- Performs environmental, health, and safety support activities by acting as a technical resource and investigating incidents.

General

- Manages and/or supports cross-functional teams.
- Writes proposals, reports, and regulatory submission packages for projects.
- Determines solutions to technical problems.
- Secures and protects intellectual property.
- Writes and revises SOPs, batch records, preventive maintenance procedures, and P&IDs.
- Trains production personnel associated with new processes and/or new or revised equipment.
- Supports budget preparation.
- Designs, leads, and supports equipment and automation changes.

Process Engineer: Job Knowledge and Skills

DEGREE/CERTIFICATION REQUIREMENT	COMMENTS
BS/MS in Chemical, Biochemical, Bioprocess, or Mechanical Engineering *BS/MS in Food Science* *Essential Engineering topics:* Mass/energy balances, transport phenomena involving mass, momentum, and energy, chemical reaction kinetics, reactor design, process control, and materials science	Note: Food Science curricula that emphasize engineering principles would be good preparation.

GENERAL PREPARATION	LEVEL/COMMENTS
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics are listed in Appendix I.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience
Chemistry: General, Organic, and Analytical Chemistry. Essential topics are listed in Appendix I.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience
Mathematics: Applied math, algebra, statistics, calculus (differential equations), mathematical modeling, and data analysis.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience Note: Calculus is not used much in practical applications, but is part of degree programs.
Computer Usage: Word processing, spreadsheets, networking principles, familiarity with CAD, process simulation software, process automation software, and use of computerized management systems.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience Note: Candidates should be "power users" of spreadsheets, especially calculation functions.
Career Skills: Project management, professional/technical communication skills, leadership skills, priority management skills, interpersonal skills, and organization skills.	N/A | 1 | 2 | **3** ☐ Practical / Hands-On Experience Note: It is critical that these employees obtain strong technical communication skills in order to know what technical details need to be communicated, and how the nature of that communication may change depending on audience.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

COMPLIANCE: SAFETY AND ENVIRONMENTAL	LEVEL/COMMENTS
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Lock-out/Tag-out procedures • Fall protection • Confined space entry • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods	N/A | 1 | **2** | 3 ☒ Practical / Hands-On Experience As Process Engineers are responsible for designing or modifying facilities as well as inspecting facilities and supervising operations, a strong working knowledge of industrial safety is critical.
Environmental: General understanding of environmental regulations and plant waste processing systems.	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience

REGULATORY COMPLIANCE: FDA REQUIREMENTS	LEVEL/COMMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing / Understanding and working from SOPs • Consequences of non-compliance	N/A | 1 | **2** | 3 ☐ Practical / Hands-On Experience
Know how to access and use regulations from FDA and international agencies including: • 21 CFR Part 11, 210, 211, 21 CFR Part 600 Subparts A-D • Sterile Drug Products Prod. By Aseptic Proc., FDA Guidance August 2003 • EC Guide on Good Mfg. Practice written by the European Commission • Guide to Inspection of High Purity Water written by FDA • United States Pharmacopoeia / European Pharmacopoeia • ICH Intl Conf on Harmonization (of regulatory requirements) • Health Technical Memorandum 2010 • BS EN 285	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience
Validation: • General understanding of validation principles • Principles and practices of commissioning and qualification • Writing IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment • Writing validation protocols for production processes • Principles governing choice of key process parameters to validate, and setting operational specifications	N/A | 1 | 2 | **3** ☐ Practical / Hands-On Experience
Special Topics: • Knowledge of GAMP and software validation practices • Knowledge of ISA and BPE standards.	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience

GENERAL PLANT OPERATIONS	LEVEL/COMMENTS
Plant Utility Systems: Understanding of functions of typical plant utility systems including: • Water--types typically used in pharmaceutical operations: DI, WFI, USP • Chilled water • CIP solutions • Steam and clean steam; SIP systems • HVAC (particle counts, classifications) • Instrument and process air • Other gases • Electrical systems/power distribution • Waste collection and processing systems	N/A 1 **2** 3 ☐ Practical / Hands-On Experience
Reading P&IDs • Working knowledge of symbology • Ability to verify equipment location/installation using P&IDs • Ability to redline P&IDs appropriately	N/A 1 2 **3** ☐ Practical / Hands-On Experience
Process Equipment: • Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing • Principles of piping and pump sizing • Characteristics of materials used in pumps, piping, tanks, and valves • Pipefitting: Fabrication, welding, and passivation; especially as the latter two methods are applied in pharmaceutical operations; other principles of sanitary piping installation	N/A 1 **2** 3 ☒ Practical / Hands-On Experience
Process Control: • Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO • Good operational understanding of process control systems • Statistical process control and trending analysis • Good operational knowledge of the calibration of process instrumentation	N/A 1 **2** 3 ☒ Practical / Hands-On Experience
Aseptic Processing: • Basic principles of cleanroom work, laminar flow hoods, and gowning procedures	N/A **1** 2 3 ☐ Practical / Hands-On Experience
Special Topics: • Troubleshooting principles applicable to instrumentation and control system hardware	N/A 1 **2** 3 ☒ Practical / Hands-On Experience

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP	LEVEL/COMMENTS
Design principles and practice: • Knowledge of and experience in design and validation of biomanufacturing and/or other types of pharmaceutical manufacturing facilities • Knowledge of scale-up issues in typical processes run in these types of facilities and how to resolve such issues • Experimental design • Working knowledge of common materials of facility construction • Practical experience in designing and running a process, especially fermentation, cell culture, or downstream processing equipment • Thorough understanding of principles of and ability to develop quantitative specifications for design of reactors and other equipment • Knowledge of principles of adjacency and flow in pharmaceutical operations	N/A | 1 | 2 | 3 ☒ Practical / Hands-On Experience
Engineering economics: • Calculating equipment, process, and/or project costs. • Enterprise resources planning and tracking	N/A | 1 | 2 | 3 ☐ Practical / Hands-On Experience

UNIT OPERATIONS AND MANUFACTURING METHODS	LEVEL/COMMENTS
Familiarity with select unit operations and processing equipment including: • Batch and/or continuous chemical reaction operations • Distillation/stripping • Growth media prep • Bioreactor operation (mammalian and microbial cells) • Cell disruption (pressure and mechanical lysis) • Centrifugation • Depth filtration • Membrane filtration (micro/ultra/nano/RO/diafiltration) • Chromatography (affinity, ion-exchange, HIC, size-exclusion, metal chelating) • Liquid-liquid extraction • Precipitation • Crystallization • Lyophilization • Granulation • Pasteurization/flow-through sterilization • Immobilized enzyme technology • Solid dosage forms preparation • Formulation of aerosols and injectibles • Filling / sterile filling operations • Isolation / barrier technology	N/A | 1 | 2 | 3 ☐ Practical / Hands-On Experience Note: Candidates need understanding of the common kinds of operations, including principles and types of equipment used.

BASIC LABORATORY WORK	LEVEL/COMMENTS
Familiarity with basic laboratory techniques. See complete list of basic lab techniques in Appendix I.	N/A | **1** | 2 | 3 ☒ Practical / Hands-On Experience Note: Candidates would probably pick up sufficient basic proficiency in biology and chemistry courses that form part of engineering degree programs.

ANALYTICAL INSTRUMENTATION AND METHODS	LEVEL/COMMENTS
Familiarity with analytical instrumentation. Candidates need a general understanding of common methods including those most used now and those which are the most likely to be applied in-line in PAT systems. These include UV/Vis spectrophotometry, HPLC and mass spectrometry. They should be familiar with the kinds of data from common analytical methods and what these data indicate about process operations.	N/A | **1** | 2 | 3 ☐ Practical / Hands-On Experience
Familiarity with basic analytical methods. Engineers need to understand the importance of controlling quality in processes. They should be familiar with the kinds of data from common analytical methods and what these data indicate about process operations. Good examples would include: • Water quality assays • TOC and endotoxin assays • Conductivity • Friability • Protein function assays	N/A | **1** | 2 | 3 ☒ Practical / Hands-On Experience

Appendix I: Knowledge and Skill Master List

The following pages provide a master list of all knowledge and skill items listed in the job descriptions. Selected topics of particular importance to specific positions are listed in the individual Job Descriptions.

GENERAL PREPARATION
Biology: Microbiology, Cell Biology, and Biochemistry. Essential topics include prokaryotic and eukaryotic cell culture and metabolism, molecular biology, Prokaryotic and eukaryotic metabolism and cell culture methods, properties and characterization of biological molecules, protein structure, analytical methods and separation technologies for proteins, gene expression, basics of recombinant strain construction, and environmental monitoring and microbial identification.
Chemistry: General, Organic, and Analytical Chemistry. Learning objectives are to recognize and understand characteristics of all chemicals and biochemicals involved in typical processes, understand chemical reaction kinetics, and acquire proficiency in analytical methods.
Mathematics: Applied math, algebra, statistics, calculus (differential equations), mathematical modeling, and data analysis.
Computer Usage: Word processing, spreadsheets, networking principles, familiarity with CAD, process simulation software, process automation software, and use of computerized management systems (CMMS, LIMS, etc.).
Career Skills: Project management, professional/technical communication skills, leadership skills, priority management skills, interpersonal skills, and organization skills.
Industry Overview: Familiarity with the biomanufacturing and pharmaceutical industry including the typical development/manufacturing process, and regulatory environment.

COMPLIANCE: SAFETY AND ENVIRONMENTAL
Safety: General understanding of industrial safety practices and regulations, in particular such topics as: • Safe handling, transport, and storage of biological and chemical materials • Handling hazardous waste • Lock-out/Tag-out procedures • Fall protection • Confined space entry • Personal protective equipment • Safety audits: purpose and procedures • OSHA regulations • Disinfection and sterilization methods
Environmental: General understanding of environmental regulations and plant waste processing systems.

REGULATORY COMPLIANCE: FDA REQUIREMENTS
General understanding of GMP principles, procedures, and vocabulary including: • Batch record content • Documentation (basic data recording practices) • Change control • Deviation control • SOP writing • Understanding and working from SOPs • Consequences of non-compliance
Know how to access and use regulations from FDA and international agencies including: • 21 CFR Part 11, 210, 211 • 21 CFR Part 600 Subparts A-D • Sterile Drug Products Prod. By Aseptic Proc., FDA Guidance August 2003 • EC Guide on Good Mfg. Practice written by the European Commission • Guide to Inspection of High Purity Water written by FDA • United States Pharmacopoeia • European Pharmacopoeia • ICH Intl Conf on Harmonization (of regulatory requirements) • Health Technical Memorandum 2010 • BS EN 285
Validation: • General understanding of validation principles • Principles and practices of commissioning and qualification • Writing IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment • Writing validation protocols for production processes • Writing validation protocols for analytical methods • Principles governing choice of key process parameters to validate, and setting operational specifications

Special Topics:
• Principles of ISO standards related to maintenance and repair functions
• Proficiency in working to GLP standards
• Knowledge of typical types of documentation related to facilities and equipment. Examples include:
  • Maintenance logs
  • Calibration certificates
  • Out of tolerance reports
  • Installation reports
• Knowledge of GAMP and software validation practices
• Electronic documentation (control and data capture storage systems)
• Knowledge of ISA and BPE standards.

GENERAL PLANT OPERATIONS

Plant Utility Systems: Understanding of functions of typical plant utility systems including:

- Water--types typically used in pharmaceutical operations: DI, WFI, USP
- Chilled water
- CIP solutions
- Steam and clean steam; SIP systems
- HVAC (particle counts, classifications)
- Instrument and process air
- Other gases
- Electrical systems/power distribution
- Waste collection and processing systems

Reading P&IDs

- Working knowledge of symbology
- Ability to verify equipment location/installation using P&IDs
- Ability to redline P&IDs appropriately

Process Equipment:

- Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing
- Principles of piping and pump sizing
- Characteristics of materials used in pumps, piping, tanks, and valves
- Pipefitting: Fabrication, welding, and passivation; especially as the latter two methods are applied in pharmaceutical operations; other principles of sanitary piping installation

Process Control:

- Good operational understanding of instrumentation for monitoring common process parameters: flow, level, temperature, pressure, mass, pH, DO
- Good operational understanding of process control systems
- Statistical process control and trending analysis
- Good operational knowledge of the calibration of process instrumentation

Aseptic Processing:

Basic principles of cleanroom work, laminar flow hoods, and gowning procedures

Special Topics:

- Chemical testing of steam and cooling water systems
- Repair and maintenance of equipment and systems listed above or their components, including:
  - Valves, actuators, agitators, fans, bearings, couplings, belt drives, and mechanical seals
  - Hoists, hydraulic and pneumatic equipment
  - Electrical and pneumatic control circuits and actuators
- Calibration:
  - Good working knowledge of and ability to calibrate and adjust all types of control valves, actuators, and positioners
  - Good working knowledge of and ability to calibrate process instrumentation measuring common parameters including temperature, pressure, flow, level, weight, mass, pH, and DO
  - Understanding of NIST standards and their application in calibrating analytical instrumentation
  - Troubleshooting principles applicable to instrumentation and control system hardware
  - Good working knowledge of the ability to calibrate and adjust laboratory equipment
- Troubleshooting principles applicable to instrumentation and control system hardware

PROCESS, EQUIPMENT, AND/OR FACILITY DESIGN AND SCALE-UP

Design principles and practice:

- Knowledge of and experience in design and validation of biomanufacturing and/or other types of pharmaceutical manufacturing facilities
- Knowledge of scale-up issues in typical processes run in these types of facilities and how to resolve such issues
- Experimental design
- Working knowledge of common materials of facility construction
- Practical experience in designing and running a process, especially fermentation, cell culture, or downstream processing equipment
- Thorough understanding of principles of and ability to develop quantitative specifications for design of reactors and other equipment
- Knowledge of principles of adjacency and flow in pharmaceutical operations

Engineering economics:

- Calculating equipment, process, and/or project costs.
- Enterprise resources planning and tracking

UNIT OPERATIONS AND MANUFACTURING METHODS

Familiarity with select unit operations and processing equipment including:

- Batch and/or continuous chemical reaction operations
- Distillation/stripping
- Growth media prep
- Bioreactor operation (mammalian and microbial cells)
- Cell disruption (pressure and mechanical lysis)
- Centrifugation
- Depth filtration
- Membrane filtration (micro/ultra/nano/RO/diafiltration)
- Chromatography (affinity, ion-exchange, HIC, size-exclusion, metal chelating)
- Liquid-liquid extraction
- Precipitation
- Crystallization
- Lyophilization
- Granulation
- Pasteurization/flow-through sterilization
- Immobilized enzyme technology
- Solid dosage forms preparation
- Formulation of aerosols and injectibles
- Filling / sterile filling operations
- Isolation / barrier technology

BASIC LABORATORY WORK
Familiarity with basic laboratory techniques including: • Glassware selection/preparation/use/cleaning • Making solutions/dilutions • Measuring pH/titration; conductivity • Basic equipment calibration • Colorimetric assays (manual and automated) • Microscopy • Culture methods (microbial and mammalian cell) • Sampling technique (as well as labeling/handling/storage of samples) • Adjusting pH • Sterilizing solutions by autoclaving and filtration • Disinfecting surfaces • Aseptic technique

ANALYTICAL INSTRUMENTATION AND METHODS

Familiarity with analytical instrumentation including:

- UV/Vis spectrophotometry
- HPLC
- Infrared spectrophotometry
- NMR spectrometry
- Mass spectrometry
- Gas chromatography
- Refractometry

Familiarity with basic analytical methods including:

- Environmental monitoring methods
- Water quality monitoring
- Total organic carbon [TOC] assays
- Endotoxin assays (Kinetic Turbidimetric and Endpoint Chromogenic LAL Assays)
- Bioburden assays
- Growth promotion testing
- Sterility testing
- Dry weight determinations
- Small Molecule Analysis
    - Dissolution assays
    - Friability
    - Flame tests
- Microbial identification methods
- RIA/ELISA assays
- Enzyme assays
- PCR
- Electrophoresis (SDS-PAGE and iso-electric focusing)
- Capillary electrophoresis
- Chromatography (affinity, ion-exchange, HIC, size exclusion, metal chelating)
- Protein quantification assays
- Protein functional assays: e.g. ligand binding

Special Topics:

- Process Analytical Technology (PAT)
- Working knowledge of the principles involved in the validation of new analytical methods
- Chemical testing of steam and cooling water systems
- Predictive technologies (vibration analysis, laser alignment)
- Familiar with analytical equipment used in microbiological testing, including:
    - Air sampling equipment
    - Microplate readers

Appendix I: Knowledge and Skill Master List

Appendix II: Industrial Curriculum Committee Members

Allsbury, Kris
BioNetwork Coordinator
North Carolina Community College System

Balchunas, John
Workforce Training Manager
North Carolina Biotechnology Center

Culp, Chris
Manufacturing Manager
Wyeth Vaccines

Finnigan, Jay
Vice President
Noverant

Harewood, Ken
Director, BBRI
North Carolina Central University

Hess, Mike
Staff Engineer, Recovery
Novozymes

Kelly, Timothy
Director, Quality Control
Diosynth RTP, Inc.

Kennedy, Kathleen
VP, Education and Training
North Carolina Biotechnology Center

Kilpatrick, Peter
Director, BTEC
North Carolina State University

Matthews, Martha
Manager, Technical Training
Biogen IDEC, Inc.

Pidgeon, Charles
Interim Director, BRITE
North Carolina Central University

Price, Hal
President/CEO
Price Consulting

Roganti, Frank
Principal Scientist
Novo Nordisk Pharmaceutical Industries

Seymour, Susan
Director, BioNetwork
North Carolina Community College System

Steele, Donna
Performance Development Manager
Bayer Biologicals

Appendix II: Industrial Curriculum Committee Members

Appendix III: Focus Group Meeting Participants

We are indebted to the many employees of North Carolina biopharmaceutical and pharmaceutical manufacturing facilities and educators who participated as advisors in this study. Participants in all the focus group meetings convened for this research, and other contributors to Model Employee Job Descriptions, are listed below:

Allsbury, Kris
BioNetwork Coordinator
North Carolina Community College System

Balchunas, John
Workforce Training Manager
North Carolina Biotechnology Center

Black, Amy
Sr. Administrative Assistant
North Carolina Biotechnology Center

Bushey, Dean
New Business Ventures- BioScience
Bayer CropScience

Butler, Severin
Sr. Manufacturing Engineer
Biogen-Idec

Carson, Sue
Academic Coordinator
North Carolina State University

Chisnell, John
Assistant Director, Biotechnology Administration
North Carolina State University

Clendenen, Jerry
Lead Instructor, Electronics
Central Carolina Community College

Culp, Chris
Manufacturing Manager
Wyeth Vaccines

Cummings, Marisa
QA Specialist III
Wyeth Vaccines

Daubert, Chris
Associate Director, BTEC
North Carolina State University

Dawson, Ray
Engineering Trainer
Wyeth Vaccines

D'haene, Dorie
Sr. Scientist
GlaxoSmithKline

Dumers, David
QA Compliance Specialist
Wyeth Vaccines

Easterly, Mary Chris
QA Manager
Diosynth-RTP Inc.

Fehr, Stefan
Technical Trainer, Performance Development
Bayer

Harewood, Ken
Director, BBRI
North Carolina Central University

Hess, Mike
Staff Engineer, Recovery
Novozymes

Hinton, Clif
Industrial Pharmaceutical Technology
Wake Technical Community College

Jessee, Rick
Maintenance Director
Diosynth-RTP Inc.

Kaufman, Allan
Sr. Manager, Bioanalytical
Biogen Idec

Kennedy, Kathleen
VP, Education and Training
North Carolina Biotechnology Center

Appendix III: Focus Group Meeting Participants

Lee, Kathy
Vice President, Quality and Regulatory
KBI BioPharma, Inc.

Lekwauwa, Aju
Forsyth Technical
Community College

Lewis, John
Process Discipline Leader
O'Neal, Inc.

Lineberger, Mark
Metrology Department
Novo Nordisk Pharmaceuticals

Lorenc, Andrew
Manufacturing Engineer
Biolex

Lympany, Steve
Department Chair, Engineering Technologies
Central Carolina Community College

Madan, Jay
Chromatography Specialist
Millipore Corporation

McGhinnis, Jason
Operational Analyst
Merck Manufacturing

Mehltretter, Scott
Sr. Assoc., Manufacturing Sciences
Biogen-Idec

Morgan, Joe
QA Supervisor
Diosynth-RTP

Odum, Jeff
Associate of CRB
CRB Consulting Engineers, Inc.

Ownby, David
Associate Director, Purification
Diosynth RTP

Pidgeon, Charles
Director, BRIITE
North Carolina Central University

Price, Hal
President/CEO
Price Consulting

Read, Russ
Exec. Director, National Center for Biotechnology Workforce
Forsyth Technical Community College

Reikowsky, Fred
Maintenance Manager
Novozymes

Robbins, Renee
QA Associate I
Biogen Idec

Rocque, Warren
Manager, Gene Expression
GlaxoSmithKline

Runyon, Greg
Sr. Scientist, Purification Process Development
Diosynth-RTP Inc.

Shepard, Scot
Director, Cell Culture/Fermentation Proc. Dev.
Diosynth-RTP Inc.

Steele, Donna
Performance Development Manager
Bayer Biologicals

Telez, Marcelo
Director of Applications
NCSRT

Winston, Hubert
Executive Assistant Director, BTEC
North Carolina State University

Yarley, David
Bioprocess Engineer

Yates, Mark
Sr. Technical Services Scientist
Wyeth Vaccines

Appendix IV: Feedback Form

In order to encourage feedback that will clarify, expand upon, and further develop the findings presented in this report, the ICC determined that this publication should be a "living document," with an established mechanism for collecting feedback from readers.

Please use the feedback form on the following page to send us your comments for consideration in future editions of this publication.

Appendix IV: Feedback Form

The Model Employee Feedback Form

Please use this form to submit feedback so that we may further clarify, expand upon, and develop the information presented in this publication. Completed forms and/or comments may be submitted by:

- **US Mail:** North Carolina Biotechnology Center
  Education and Training Program
  15 T.W. Alexander Drive
  Research Triangle Park, NC 27709
- **Fax:** 919.549.9710
- **Email:** john_balchunas@ncbiotech.org
- **WWW:** www.ncbiotech.org/education/modelemployee.cfm

Name: _____

Title: _____

Company/Organization: _____

Phone: _____

Email _____

COMMENTS