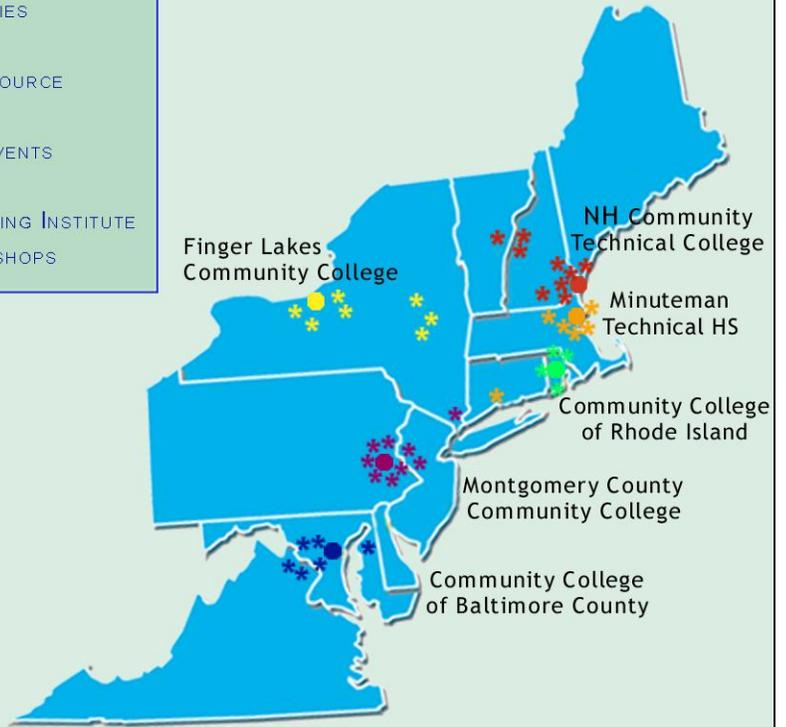




# Northeast Biomanufacturing Center and Collaborative *Biomanufacturing.org*



- ▶ COLLABORATIVE PARTNERS
- ▶ NBC2 COMPANIES
- ▶ LOCAL HUBS
- ▶ EQUIPMENT RESOURCE
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Northeast Biomanufacturing Collaborative [info@biomanufacturing.org](mailto:info@biomanufacturing.org) [NSF Award #0501953](#)

## ***Biopharmaceutical Manufacturing Industry Skill Standards***

## Foreward

In April 1995, the first Bioscience Industry Skill Standards were published by the Education Development Center, Inc.<sup>1</sup> The project, led by Dr. Judith Leff and funded by the U.S. Department of Education, brought employees from pharmaceutical companies, biotechnology companies and clinical laboratories together to describe the skills, knowledge and attributes of their jobs. I was a working member of the project, with an interest in using the skill standards to generate curricula and instructional materials for two courses that were under development in a new Biotechnology program at the New Hampshire Community Technical College (NHCTC) in Portsmouth, New Hampshire. In July 1994, a grant from the National Science Foundation (NSF) from the new Advanced Technological Education (ATE) program provided equipment for the development of two cornerstone courses to the industry in return for the development of protocols to support a course in Discovery Research and Standard Operating Procedures (SOPs) to support a course in Biomanufacturing. Two additional grants from the Alfred P. Sloan Foundation in 1996 and 1997 placed these hands-on modules on the Internet, creating an interactive lab manual for student/world-wide access at <http://biotech.nhctc.edu>. Because of their availability on-line, many instructors utilize these modules to build their own courses, particularly the hands-on SOPs to teach biomanufacturing because instructional materials for biomanufacturing are hard to find.

As students graduated from NHCTC's biotechnology program and went to work, most of them found employment in biomanufacturing because of the many jobs available and the attractive salaries in this field. In the first few years of the program people were employed in the following areas of biomanufacturing: upstream processing, downstream processing, validation, Quality Control biochemistry, Quality Control microbiology, Quality Assurance, process development and environmental health and safety. Later, the Massachusetts Biotechnology Council published a directory of Careers in Biotechnology<sup>2</sup> in which biotechnology jobs were listed with the degrees needed for each job. In that list there were two jobs requiring an Associate degree that did not appear on the list of biomanufacturing jobs taken by NHCTC students. These two jobs are: instrumentation/calibration and facilities technician.

This is the tenth anniversary of NHCTC's Biotechnology program and most of our students continue to favor employment in biomanufacturing. The need for people trained to meet the requirements of a range of biomanufacturing occupations is growing and will continue to grow at an increasingly rapid pace during coming years as more biotechnology companies move into manufacturing. A large portion of these new jobs will be for biomanufacturing technicians. This situation created the opportunity to up-date the bioscience industry skill standards by developing skill standards for ten biomanufacturing jobs. An NSF ATE grant (NSF #0303030) provided the funds to define what work these technicians do in a range of occupations and what knowledge, skills, and behaviors they need to succeed in these jobs.

This book provides the instructor in biomanufacturing the necessary concrete information to construct curriculum, courses and modules and purchase equipment for education and training for ten biomanufacturing jobs. Additional supporting information and documentation for the Biomanufacturing Skill Standards along with downloadable surveys that can be used to validate skills, knowledge and attributes for these ten biomanufacturing jobs in other areas of the country can be found at [www.biomanufacturing.org](http://www.biomanufacturing.org).

Sonia Wallman  
NHCTC  
Portsmouth, New Hampshire  
January 31, 2005

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<sup>1</sup> Education Development Center, Inc. 1995 Gateway to the Future: Skill Standards for the Bioscience Industry for Technical Workers in Pharmaceutical Companies, Biotechnology Companies, and Clinical Laboratories. Education Development Center, Inc. The Institute for Education and Employment

<sup>2</sup> Massachusetts Biotechnology Council 2005 Careers in Biotechnology on-line at <http://www.massbio.org/directory/careers>.

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## **DEVELOPMENT OF THE BIOMANUFACTURING INDUSTRY SKILL STANDARDS**

These standards were developed as part of a project, supported by the National Science Foundation, to provide technical support for the biotechnology industry, education institutions (community colleges and some high schools and 4-year colleges), and other organizations and partnerships in the Northeast region of the United States. The major partners in this project were New Hampshire Community Technical College (NHCTC) and EDC. The development of the standards took place from spring through winter 2004. It began with workshops in the spring, followed by surveys, distributed in the summer and fall. The results of the surveys were analyzed during early winter.

### **Job Analysis Workshops**

The basic information for the standards was obtained in two 2-day workshops, held in May 2004, in which a total of 28 technicians and supervisors representing 10 biomanufacturing occupations participated (see Appendix A). The approach used was a modified DACUM (Designing a Curriculum) process. The participants worked in teams, each representing one occupation, to identify the duty areas (functions), tasks performed, specific competencies required, tools and equipment used, and behavioral traits needed to perform their work. They also identified, for the academic knowledge required, whether the knowledge needed to be only at a basic (B) level (less than six months training and/or experience), intermediate (I) level (less than two years training and/or experience) or advanced (A) level (more than two years training and/or experience), and whether the knowledge needed was conceptual (C) or practical/applied in nature. The participants came from 12 biotechnology companies from five states in the Northeast.

The end products of the workshops were 10 charts, one for each occupation, that included all of the information listed above. All of the completed charts are contained in Appendix A in this booklet.

### **Surveys**

Because the information obtained in the workshops represented only a small sample of people, we needed to obtain a larger sample from a broader number of companies to validate the workshop results. We also wanted to obtain additional information to assist educators in using the standards to develop programs, courses, and curricula.

We reformatted the charts into 10 separate surveys, and e-mailed them to over 170 biomanufacturing technicians, supervisors, and managers in a number of biotechnology companies in the Northeast and Mid-Atlantic regions. We received 57 completed surveys from 15 companies in six Northeast and Mid-Atlantic region states. Respondents were asked to rate the *importance* of each of the competencies on a 4-point scale, and to indicate, for each competency, the *amount of training and/or experience required* to perform at a proficient level. The answers to these questions, which are summarized in Appendix C, provide additional information for people developing programs, courses, and modules.

We analyzed the survey responses and made some revisions to the workshop charts based on those responses. If all or most of the respondents indicated that a particular competency, or occasionally a whole task, ranked very low in importance, we deleted it from the chart. Likewise, if almost no one ranked a particular competency, we concluded that that competency was not performed enough to be included, and we deleted it. We did, however, keep competencies that were ranked by a number of people as needing very little training or experience. These are sometimes important competencies, but usually ones that can be learned very quickly, either as part of an introductory-level course or on the job. The charts in this booklet reflect all of these revisions.

# Biomanufacturing Job Analysis Workshops

## Participants, Their Occupations, and Companies

### Education Development Center, Inc., Newton, Mass., May 6–7, 2004

*Facilitator:* Judith Leff, Education Development Center, Inc.

*Sponsor:* New Hampshire Community Technical College and Education Development Center, Inc.

**Megan Amaral**

Validation Engineer II  
Amgen, Inc., West Greenwich, R.I.

**Rohan Anderson**

Manufacturing Operator  
Biogen Idec Inc., Cambridge, Mass.

**Jim Baillargeon**

Calibration/Instrumentation and Facilities  
Manager  
Dow Pharmaceuticals, Smithfield, R.I.

**William Falk**

Metrology Coordinator  
AstraZeneca Pharmaceuticals,  
Westborough, Mass.

**Lawrence Forman**

Process Development Specialist  
CuraGen Corporation, Branford, Conn.

**Scott Fossier**

Validation Project Manager  
Lonza Biologics, Portsmouth, N.H.

**Erin Giaccone**

Process Development Associate  
Glycofi, Inc., Lebanon, N.H.

**Jon Hardy**

Manufacturing Operator  
Lonza Biologics, Inc., Portsmouth, N.H.

**Scott Kelley**

Manufacturing Operator  
Wyeth Biopharma, Andover, Mass.

**Tony Laccetti**

Process Development Associate  
Biopure Corporation, Cambridge, Mass.

**Angel Mercado**

Manufacturing Operator  
CuraGen Corporation, Branford, Conn.

**Michael Mikolajczak**

Calibration/Instrumentation Supervisor  
Amgen, Inc., West Greenwich, R.I.

**Andrew O'Donnell**

Calibration/Instrumentation Technologist  
Wyeth Biopharma, Andover, Mass.

**Scott Sharland**

Manufacturing Operator  
Amgen, Inc., West Greenwich, R.I.

**Jeffrey Ucran**

Manufacturing Technician  
Wyeth Biopharma, Andover, Mass.

### New Hampshire Community Technical College (NHCTC), Portsmouth, N.H., May 17–18, 2004

*Facilitator:* Judith Leff, Education Development Center, Inc.

*Sponsor:* New Hampshire Community Technical College and Education Development Center, Inc.

**Claire Arsenault**

QC Microbiology Technician  
Wyeth Biopharma, Andover, Mass.

**Richard Austin**

Environmental Health and Safety  
Training Specialist  
Amgen, Inc., West Greenwich, R.I.

**Scott Brouillard**

Facilities/Maintenance Training Specialist  
Amgen, Inc., West Greenwich, R.I.

**Joseph Denton**

QA Documentation Coordinator  
Amgen, Inc., West Greenwich, R.I.

**Kris Evon**

QC Chemistry Technician  
Amgen, Inc., West Greenwich, R.I.

**Judy Franklin**

QC Chemistry Technician  
BioProcessing Inc., Scarborough, Maine

**Josh Getchell**

QC Chemistry Technician  
Lonza Biologics Inc., Portsmouth, N.H.

**Kathleen Lang**

QA Documentation Supervisor  
Genzyme Corporation, Cambridge, Mass.

**Edmond Le Duc**

QC Microbiology Technician  
Wyeth Biopharma, Andover, Mass.

**Jack Shaw**

Environmental Health and Safety  
Specialist  
Stryker Biotech, Lebanon, N.H.

**Donald Taylor**

Facilities Technician  
Stryker Biotech, Lebanon, N.H.

**Scott True**

QC Microbiology Technician  
Lonza Biologics, Portsmouth, N.H.

**Sue Veal**

QA Documentation Manager  
Lonza Biologics, Portsmouth, N.H.

## **Companies and Education Institutions Participating in Job Analysis Workshops**

### **Companies**

**Amgen Inc.**  
West Greenwich, RI

**AstraZeneca Pharmaceuticals LP**  
Westborough, MA

**Biogen Idec**  
Cambridge, MA

**Bioprocessing Inc.**  
Scarborough, ME

**Biopure Corporation**  
Cambridge, MA

**CuraGen Corporation**  
Branford, CT

**Dow Pharmaceuticals**  
Smithfield, RI

**Genzyme Corporation**  
Cambridge, MA

**GlycoFi, Inc.**  
Lebanon, NH

**Lonza Biologics Inc.**  
Portsmouth, NH

**Stryker Biotech**  
West Lebanon, NH

**Wyeth BioPharma**  
Andover, MA

### **Education Institutions**

**New Hampshire  
Community Technical College**  
Portsmouth, NH

**Education Development Center, Inc.**  
Newton, MA

**Middlesex Community College**  
Bedford, MA

**Community College of Rhode Island**  
Warwick, RI

## Companies and Education Institutions Participating In Standards Validation Survey

### **Companies**

**Amgen Inc.**  
West Greenwich, RI

**Biogen Idec**  
Cambridge, MA

**Charles River Laboratories**  
Wilmington, MA

**Dow Pharmaceuticals**  
Smithfield, RI

**Genzyme Corporation**  
Cambridge, MA

**Immune Response Corporation**  
King of Prussia, PA

**Nabi Pharmaceuticals**  
Rockville, MD

**Wyeth BioPharma**  
Andover, MA

**AstraZeneca Pharmaceuticals  
LP**  
Westborough, MA

**Centocor, Inc.**  
Malvern, PA

**CuraGen Corporation**  
Branford, CT

**Formatech, Inc.**  
Andover, MA

**GlaxoSmithKline**  
Upper Merion, PA

**Lonza Biologics**  
Portsmouth, NH

**Stryker Biotech**  
West Lebanon, NH

**MdBio**  
Frederick, MD

## **Education Institutions**

**Education Development  
Center, Inc.**  
Newton, MA

**New Hampshire Community  
Technical College**  
Portsmouth, NH

**Middlesex Community  
College**  
Bedford, MA

**Minuteman Technical High  
School**  
Lexington, MA

**Community College of  
Rhode Island**  
Warwick, RI

**Montgomery County  
Community College**  
Blue Bell, PA

**CityLab, Boston University  
Medical School**  
Boston, MA

### **Demographic Summary of Respondents**

#### Size of Company Represented

7% small (1-49 employees)  
11% medium (50-99 employees)  
82% large (100+ employees)

#### Job Category Represented

14% managers  
28% supervisors  
58% technicians

#### Regions Represented by Companies

77% - Northeast state (MA, NH, RI, CT)  
24% - Mid-Atlantic states (MD, PA)

## TRAITS, CHARACTERISTICS, AND BEHAVIORS REQUIRED FOR BIOMANUFACTURING OCCUPATIONS

This list was created by representatives of ten different Biomanufacturing Occupations in 2 Job Analysis Workshops, held in May, 2004. The Workshop Participants agreed that all of these Traits and Behaviors were required for all of the 10 Occupations Analyzed.

Ability to Follow Directions	Intelligence
Ability to Maintain Perspective	Leadership
Ability to be Self Critical	Maturity
Ability to Take Criticism	Mechanical ability
Ability to Handle Stress	Motivation (to do the work)
Ability to Take Initiative	Multi-tasking Ability
Approachability	Persistence
Assertiveness	Physical Energy
Attention to Detail	Preciseness
Common Sense	Problem Solving Ability
Conflict Management/ Resolution Skills	Organizational skills
Consistency	Resiliency
Creativity	Resourcefulness
Curiosity/Ability to Question	Respectfulness
Dedication	Respect for Authority
Dependability	Responsibility
Diversity Understanding	Self-Confidence
Drive/Determination	Self-Control
Endurance	Sense of Humor
Flexibility/Adaptability	Sense of Ownership
Friendliness	Tactfulness
Generosity	Team Player
Honesty	Tenacity
Initiation	Willingness to Learn
Integrity	Work ethic

**Job Functions, Tasks, and Competencies of PROCESS DEVELOPMENT ASSOCIATE**

Evaluates, improves, and assists with scale-up manufacturing processes and technologies in order to improve product yield and reduce overall costs of production.

JOB FUNCTIONS		COMPETENCIES					
<b>1. Manage Raw Materials/ Consumables</b>							
<b>Task A:</b> Maintain order appropriate chemicals and consumables	a Create database for chemicals	b Keep database updated	c Check supplies periodically	d Obtain/order supplies as necessary			
<b>Task B:</b> Identify Materials for Protocols	a Read and follow protocols	b Make list or obtain BOM	c Gather materials order, if necessary				
<b>2. Maintain Lab/Pilot Equipment</b>							
<b>Task A:</b> Replace parts per SOP	a Become familiar with equipment and manuals	b Replace parts periodically as required	c Replace parts according to use				
<b>Task B:</b> Clean and sanitize per SOP/manual	a Document everything	b Gather and prepare reagents/equipment	c Perform cleaning	d Record actions			
<b>Task C:</b> Standardize equipment to specs	a Document everything	b Gather and prepare reagents	c Perform periodic or task-specific standardization	d Record actions			
<b>Task D:</b> Perform routine maintenance	a Develop schedule for equipment maintenance	b Gather tools/materials	c Perform work	d Record actions			
<b>3. Perform Analytical Testing</b>							
<b>Task A:</b> Test water purity	a Collect samples per procedure	b Perform analytical testing; submit to lab	c Record actions				
<b>Task B:</b> Test buffer/media quality	a Check pH	b Check osmolality	c Check conductivity	d Record results			
<b>Task C:</b> Perform product quality assays	a Prepare samples for specific test	b Perform SDS electrophoresis	c Perform HPLC analysis	d Perform ELISA assays	e Perform Isoelectric Focusing electrophoresis	f Perform endotoxin testing	g Perform UV/visible spectroscopy
<b>Task D:</b> Analyze media components	a Analyze amino acids via HPLC	b Analyze trace components (send to outside)	c Check pH/osmolality				
<b>Task E:</b> Perform product concentration assays	a Perform spectroscopy (A280)	b Perform ELISA	c Perform Bradford assay				

JOB FUNCTIONS	COMPETENCIES						
<b>4. Prepare Final Material for Animal Studies</b>							
<b>Task A:</b> Follow protocols to produce upstream intermediate	a Obtain training on procedures	b Prepare fermenters/reagents	c Execute activity	d Harvest cells	e Store intermediate		
<b>Task B:</b> Follow procedures to produce downstream product	a Obtain training on procedures	b Perform chromatography/filtration steps as required by protocol	c Prepare bulk material final formulation				
<b>5. Maintain Cultures/Cell Banks</b>							
<b>Task A:</b> Prepare cell banks per SOP	a Maintain stock culture database	b Maintain storage and control rate freezers	c Grow cell lines	d Centrifuge/resuspend cells	e Add cryoprotectants to cells	f Freeze cells according to procedure.	g Record activities
<b>Task B:</b> Prepare cell cultures per SOP	a Gather materials and shaker equipment	b Use aseptic techniques	c Grow cell lines as needed	d Centrifuge/resuspend cells if required	e Record activities		
<b>6. Prepare Documentation</b>							
<b>Task A:</b> Maintain lab notebook	a Train on notebook procedure	b Use ink for all recording	c Sign and date all recordings	d Record all process-/ product-related activities	e Have entries countersigned		
<b>Task B:</b> Update and revise SOPs as needed	a Perform company change control procedure						
<b>Task C:</b> Write development reports/summaries	a Summarize specific project work findings						
<b>Task D:</b> Maintain training/continuing education documents	a Keep training records in folder for internal review						
<b>7. Prepare Buffers/Media</b>							
<b>Task A:</b> Weigh and dispense reagents	a Perform daily scale calibration check	b Obtain containers for weighing reagents	c Check for proper reagent quality	d Weigh reagents per scale operation procedure			
<b>Task B:</b> Test for buffer/media quality	a Check pH	b Check osmolality	c Check conductivity	d Record results			
<b>Task C:</b> Label and assign lot number and date	a Assign lot number , expiration date and sign label						
<b>Task D:</b> Follow SOP/recipe for specific buffer/media	a Prepare equipment (i.e., tanks, flasks, mixers containers, bags)	b Follow procedure for weighing reagents	c Perform calculation to determine component for the buffers/media	d Filter buffer/media prior to use	e Follow procedure; Adjust pH, if necessary		

JOB FUNCTIONS	COMPETENCIES						
<b>Task E:</b> Dispose of material appropriately	a Check pH	b If pH outside neutral range, dispose of per hazardous waste procedure	c If solution contains hazardous material, dispose of per hazardous waste procedure				
<b>8. Design and/or Implement Experiments</b>							
<b>Task A:</b> Perform literature search	a Review scientific/technical literature prior to designing experiments	b Use Internet/library resources to perform search					
<b>Task B:</b> Consult with colleagues on experimental objectives	a Communicate with peers on ideas for study	b Record suggested ideas					
<b>Task C:</b> Prepare materials and equipment	a Prepare chromatography/filtration equipment for purification required	b Prepare fermentation/cell culture equipment for experiments	c Prepare buffers/media				
<b>Task D:</b> Follow experimental procedures and design	a Record observations in notebook	b Sample at experimental conditions	c Perform appropriate assays				
<b>Task E:</b> Analyze results	a Create Excel spreadsheet	b Plot results in charts and tables	c Record results/formulate conclusions in lab notebook	d Compose report, if required			
<b>9. Write and/or Implement Approved Protocols</b>							
<b>Task A:</b> Develop protocols from prior experiments	a Review prior experiments/data	b Consult with peers/supervisors prior to writing					
<b>Task B:</b> Execute the protocol	a Follow the procedure	b Take samples as needed	c Analyze samples as required; record results	d Record observations			
<b>Task C:</b> Complete protocol documentation	a Ensure all steps are signed and reviewed	b Note deviations and fill out appropriate deviation documentation	c Construct final report and have signed				
<b>Task D:</b> Analyze results	a Create Excel spreadsheet	b Plot results in charts and tables	c Record results/formulate conclusion in lab notebook	d Compose report, if required			

JOB FUNCTIONS	COMPETENCIES						
<b>10. Prepare Experimental Equipment</b>							
<b>Task A:</b> Clean and sterilize per SOPs	a Autoclave as necessary	b Clean process equipment (e.g., chromatography, TFF filters, tanks with chemical cleaners)	c Check pH to determine if cleaning agents have been properly removed prior to use				
<b>Task B:</b> Construct testing equipment as appropriate	a Obtain equipment (e.g., pumps, tubing, filters) Order if necessary	b Confirm integrity of assembled systems	c Build apparatus per experimental design				
<b>Task C:</b> Ensure instruments are calibrated	a Check records for calibration data	b Perform or schedule calibration as required					
<b>11. Ensure Safe Working Environment</b>							
<b>Task A:</b> Obtain training regarding safety	a Schedule training by certified personnel	b Report problems					
<b>Task B:</b> Maintain a safe laboratory	a Housekeeping; put everything in proper place	b Wear PPE as necessary	c Clean up spills according to proper procedure	d Keep a clutter free work area			
<b>Task C:</b> Follow procedures for disposal of hazardous materials	a Bring material to assigned area for disposal	b Report full containers to safety officer for removal					

**Knowledge, Skills, and Equipment  
Process Development Associate**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment	
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Biochemistry and Lab .....B            Biology .....B            Chemistry and Lab .....B            Computer Science.....B            Electronics .....B            Math (Algebra I,II, Statistics) ..... I            Microbiology/Cell Biology and Lab..... I            Organic Chemistry and Lab.....B            Physics and Lab .....B            Principles in Mechanical/                Chemical Engineering .....B            Technical Writing.....B</p>	<p>Aseptic Technique, Biosafety Cabinet, Clean Room            Audit Preparation            Communication            Computer Science            Documentation            Ergonomics            GMPs            Industrial Safety            Mechanical            Organization            Problem Solving            Time Management</p>	<p>Autoclave            Automated cell counters            Balances            Centrifuges            Chromatography            Columns            Clean Steam            Conductivity meter            Controlled Rate            Cryogenic Freezers            Cryogenic Storage            Freezers            Depth Filters            Fermenters            Filtration Hardware            Flow Cytometry            Flow Sensors            Flow Through            Instrumentation            Gel Electrophoresis/            Western Apparatus            Glass Washer            Gradient Makers            Graduated Cylinders/            Volumetric Flasks            Homogenizer            HPLC</p>	<p>Incubators            Laboratory Gases            Laminar Flow Hoods            Microscope/            hemacytometer            Mixers            Osmometer            pH meter            Pipeters            Pipettes            Plate Reader            Pressure Gauges            Pumps            Shakers            Spectrophotometer            Sterile Packaging            Sterilizing Grade Filters            Stir Plates            Tangential Flow Filters            Temperature Monitors            Valves            Water Purification System</p>

**Job Functions, Tasks, and Competencies of VALIDATION SPECIALIST**

Develops, recommends strategies, and designs studies to validate and document effectiveness of systems, equipments, methods, or processes. Conducts processes and qualification programs.

JOB FUNCTIONS	COMPETENCIES							
<b>1. Write Protocols</b>								
<b>Task A:</b> Read P&IDs	a Identify major components	b Identify valve types	c Identify utilities to major components	d Identify instruments	e Identify piping use material and spec	f Identify system boundaries		
<b>Task B:</b> Read and extract information Manuals	a Identify component critical parameters	b Identify corrective/preventative maintenance	c Determine component operation					
<b>Task C:</b> Practice use of equipment/ processes/utilities	a Read and apply pertinent information from system SOPs	b Read and apply information from software specifications	c Read and apply information from process description	d Determine acceptance criteria				
<b>Task D:</b> Read/make use of information from software code specifications	a Read and utilize user requirement specifications	b Read and utilize software design specifications	c Develop traceability matrix	d Develop software life cycle requirements				
<b>Task E:</b> Make use of information from industry standards and regulatory requirements	a Maintain current knowledge on product requirements	b Identify applicable regulations	c Interpret regulations	d Assess regulatory risk				
<b>Task F:</b> Extract information from process requirements	a Work with process development to determine process parameters	b Extract information from validation guidelines	c Identify sources of data collection/information					
<b>2. Execute Protocols</b>								
<b>Task A:</b> Document results	a Learn basic GMP documentation practices	b Apply appropriate units of measure						
<b>Task B:</b> Measure pipe sloping/sizes	a Read isometric drawings	b Read P&IDs						
<b>Task C:</b> Read/walk-down P&IDs	a Identify major components	b Identify valve types	c Identify utilities to major components	d Identify instruments	e Identify piping use material and spec	f Identify system boundaries		

JOB FUNCTIONS	COMPETENCIES							
<b>Task D:</b> Used data loggers to collect temperature data	a Connect wires to data logger	b Calibrate data logger	c Set up and extract information from data logger software	d Place thermocouples	e Use knowledge of steam dynamics to assess impact of TC placement and restriction of steam flow	f Restore equipment to its original state (i.e., leave it how you found it)	g Verify calibration of thermocouples	h Download data from PC or data logger to analyze data
<b>Task E:</b> Collect samples	a Apply proper use of sanitary utility systems	b Apply aseptic techniques for collecting samples	c Use knowledge of proper storage of sample	d Use the proper sample containers for the testing required	e Swab equipment surfaces for residual soiling components	f Use knowledge of environmental impact to samples (i.e., contamination not related to the study)	g Complete paperwork and documentation for submission and testing of samples	h Label containers with appropriate information
<b>Task F:</b> Test software	a Use DCS system	b Use PLC systems	c Use BAS system	d Use databases				
<b>Task G:</b> Perform loop checks	a Check continuity	b Check wire labels	c Check address	d Verify component response				
<b>Task H:</b> Compile data/graphs and spreadsheets	a Apply spreadsheet software knowledge (e.g., max, min, average)	b Calculate conditions for saturated steam	c Generate graphical representation of data (e.g., time vs. temperature)	d Identify data source/location				
<b>Task I:</b> Schedule execution activities	a Apply knowledge of scheduling/project management software	b Make use of time management skills	c Consider impact of other activities on these planned activities	d Communicate change in schedules to stakeholders/equipment owners				
<b>Task J:</b> Prepare for entry into confined spaces	a Obtain confined space entry training and certification	b Complete/obtain approval of entry permit	c Inspect entry equipment (e.g., ropes, fall protection, harness)	d Organize team for entry (e.g., rescue, entrant, attendant)	e Test confined space environment (e.g., air)	f Verify LOTO	g Enter confined space	h Restore confined space
<b>Task K:</b> Comply with LOTO and other safety procedures	a Obtain LOTO training	b Use personal or issued locks and tags	c Follow LOTO procedure for equipment	d Ensure systems are de-energized	e Communicate to individuals when LOTO impacts	f Unlock equipment when work is complete		
<b>Task L:</b> Write summary reports	a Gather and review information, data, and test results	b Apply technical writing skill to summarize data and draw conclusions	c Obtain approvals					

JOB FUNCTIONS	COMPETENCIES								
<b>Task M:</b> Measure temperature, pressure, and humidity	a Use thermometer or thermocouples with data logger	b Use pressure gauge or thermohygrometer	c Use flow meter to check flow rates	d Use boroscope to inspect piping and equipment	e Use particle counters; slit to agar air sampler (viable air sampler)				
<b>Task N:</b> Gown for controlled areas	a Apply basic microbiology knowledge to assure cleanliness	b Apply basic personal hygiene to assure cleanliness	c Apply knowledge of room classifications and how gowning may be different	d Apply knowledge of different areas/products to prevent cross-contamination	e Apply knowledge of equipment/personnel flow and requirements for movement from one area to another				
<b>3. Carry Out Investigation</b>									
<b>Task A:</b> Document failures	a Follow procedure for documenting failure	b Define failure and compare to expected results	c Document chronology of events leading up to the failure	d Document immediate actions taken					
<b>Task B:</b> Identify root cause of failures	a Initiate investigation of failure	b Review supporting data and test results	c Identify all potential causes of the failure	d Document rationale for identified cause of failure					
<b>Task C:</b> Assess product/validation impact	a Repeat validation if no root cause is determined	b Document rationale if no impact to product is determined	c Document justification if validation does not require repeating						
<b>Task D:</b> Resolve failure/identify corrective action	a Obtain approvals of failure documentation	b Coordinate action plan with impacted departments	c Schedule re-qualification activities	d Implement corrective action					
<b>4. Provide Technical Assessment</b>									
<b>Task A:</b> Assess equipment/process changes for validation impact	a Review proposed changes	b Review applicable validation	c Write technical assessment of change and conclude impact						
<b>Task B:</b> Assess deviation/non-conformance for validation impact	a Review deviation	b Review applicable validation	c Write technical assessment of deviation and conclude impact						
<b>Task C:</b> Assess changes to standard operation procedures for validation impact	a Review SOP	b Review applicable validation	c Write technical assessment of document change and conclude impact						

JOB FUNCTIONS	COMPETENCIES							
<b>5. Use PC Skills</b>								
<b>Task A:</b> Perform word processing	a Write protocols using word processing tool	b Write reports using word processing tool	c Write SOP using word processing tools	d Write plans using word processing tools	e Write weekly/monthly status reports using word processing tools			
<b>Task B:</b> Create and use spreadsheets	a Analyze data	b Perform calculations with formulas	c Write macros to facilitate tedious tasks	d Import tables into reports and presentation				
<b>Task C:</b> Create and use charts and graphs	a Analyze data	b Graphically present data	c Import graphs/charts into reports and presentations					
<b>Task D:</b> Maintain database	a Track approval of validation documents	b Track validation of equipment	c Trend deviations	d Generate reports/ queries				
<b>Task E:</b> Use project software	a Identify project tasks	b Identify resources	c Identify task durations	D Track task completion	e Update status of project			
<b>Task F:</b> Use flow charting software	a Create diagram of process flow	b Create sequence of activities	c Create diagram of system boundaries					

**Knowledge, Skills, and Equipment  
Validation Specialist**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Biology .....B            Chemical Engineering .....B            Chemistry .....B            Computer Science .....B            Electronics .....B            Math .....B            Mechanical/Electrical Engineering .....B            Microbiology .....B            Physics .....B            Plumbing (Drawings) .....B            Statistics .....B            Technical Writing .....B</p>	<p>Clean Room            Communication            Computer Applications            Documentation            Ergonomics            GMPs            Handle Audits            Industrial Safety            Mechanical            Organization            Problem Solving            Time Management</p>	<p>Air Monitor (For Vessel Entry)            Air Particle Counter            Air Sampler (For Environmental Sampling)            Biological Indicators            Boroscope            Calculators            Computers            Datalogger (Digistrip, Validator 2000, Temptails)            Digital Protractor            Flow Meters            Multimeter            Personal Protective Equipment (Safety Glasses, Safety Shoes, Gloves, Harness, Fall Protection)            Pressure Gauge            Saturated Steam Tables            Thermocouples            Thermohygrometer            Wet Bulb</p>

**Job Functions, Tasks, and Competencies of MANUFACTURING TECHNICIAN (UPSTREAM)**

Conducts specific manufacturing operations, such as cell culture and growth, fermentation, preparation of media, and buffer components; assists with in-process testing

JOB FUNCTIONS	COMPETENCIES							
<b>1. Perform Cell Culture/Fermentation</b>								
<b>Task A:</b> Establish working cell bank	a Take master cell bank vial out of cryo-unit	b Thaw vial	c Add media to autoclaved spinner flask	d Inoculate spinner flask with contents of vial	e Put spinner flask in incubator	f Scale-up culture to fermentor volume	g Dispense into vials	h Put vials into cryo-unit
<b>Task B:</b> Perform vial thaw	a Take working cell bank vial out of cryo-unit	b Thaw vial	c Add media to autoclaved spinner flask	d Inoculate spinner flask with contents of vial	e Put spinner flask in incubator	f Incubate spinner for desired length of time		
<b>Task C:</b> Perform scale-up ops	a Remove spinner from incubator	b Add media to next larger size spinner flasks	c Aliquot culture from initial spinner into larger spinner flasks	d Incubate larger spinners	e Send used spinner to equipment prep for turnaround			
<b>Task D:</b> Inoculate seed reactor	a Add growth media to sterilized seed reactor	b Connect spinner flask to seed reactor	c Steam feed port of reactor	d Once port has cooled, transfer contents of spinner into seed reactor	e Perform post-steaming of feed port	f Send used spinner to equipment prep for turnaround		
<b>Task E:</b> Inoculate perfusion reactor	a Add media to sterilized perfusion reactor	b Steam transfer line	c Allow transfer line to cool	d Check for positive pressure	e Transfer contents of seed reactor to perfusion reactor	f Perform post-steaming of transfer line		
<b>Task F:</b> Inoculate production reactor	a Add production media to sterilized production reactor	b Steam transfer line	c Allow transfer line to cool	d Check for positive pressure	e Transfer contents of perfusion reactor to production reactor	f Perform post-steaming of transfer line		
<b>Task G:</b> Perform media addition	a Pressure test media filter assembly and transfer line/feed port	b Sterilize filter assembly and transfer line/feed port	c Allow assembly and line to cool	d Add desired media volume to reactor	e Perform post-steaming	f Disassemble filter assembly		
<b>Task H:</b> Monitor culture parameters	a Sample reactor	b Run culture tests to confirm process parameters	c Visually inspect reactor culture	d Check display and trends for proper process parameter	e Adjust set points as necessary to optimize culture			
<b>Task I:</b> Execute sampling	a Prepare sample apparatus	b Aseptically Take sample using appropriate sampling device	c Aliquot required samples	d Label, store, and submit sample	e Make LIMS entries as needed			

JOB FUNCTIONS	COMPETENCIES							
<b>2. Follow Safety Procedures</b>								
<b>Task A:</b> Wear appropriate safety apparatus	a Check MSDS or relevant procedure	b Don appropriate attire	c Follow safety procedures relevant to task					
<b>Task B:</b> Maintain safe working environment	a Assess condition of working area	b Fill out work order for hazardous conditions, if necessary	c Ensure floors are dry	d Reduce clutter in work area	e Be familiar with location of nearest safety station			
<b>Task C:</b> Communicate potential hazards	a Notify supervisor of any near misses	b Verbally communicate to coworkers and oncoming shift the details of potential hazards	c Notify EH&S of potential hazards or near misses					
<b>Task D:</b> Keep safety training up to date	a Check database for your status on a regular basis	b Attend safety trainings and meetings as required	c Complete paperwork for safety trainings					
<b>3. Follow GMPs</b>								
<b>Task A:</b> Maintain training records	a Fill out required documentation as you become proficient	b Sign paperwork to show that you have read and understood SOPs	c Submit paperwork to training department	d Perform any required electronic training				
<b>Task B:</b> Update procedures as required	a Review most current revision to verify accuracy	b Identify any necessary changes	c Fill out change request and revise document	d Submit request for approval	e Sign new revision			
<b>Task C:</b> Follow documented procedures	a Obtain correct procedure and revision for task	b Perform task as written in procedure	c Document in a timely manner as required	d Ensure verifier and documents are present, when required				
<b>Task D:</b> Fill out batch records in a timely manner	a Document and perform tasks in order as specified in batch record	b Ensure verifier is present for tasks requiring a verifier						
<b>Task E:</b> Perform tasks in an ethical manner	a Don't back date	b Don't forge	c Document data directly from source	d Don't falsify data				

JOB FUNCTIONS	COMPETENCIES							
<b>4. Use PC Skills</b>								
<b>Task A:</b> Enter data for process parameters	a Obtain data from batch record	b Enter data into correct database						
<b>Task B:</b> Operate process automation	a Follow procedure	b Select appropriate recipe	c Download recipe	d Enter any specific process parameters required	e Ensure operation runs properly	f Ensure manual configurations are correct	g Acknowledge prompts as needed	
<b>Task C:</b> Fill out work order request	a Obtain work order form	b Fill out required information using appropriate database	c Describe identified problem	d Describe work needed to repair	e Submit request			
<b>Task D:</b> Create/revise procedures	a Obtain document template in Word	b Type up required steps to perform procedure sequentially	c Fill out document revision request form	d Obtain appropriate signatures	e Submit for approval			
<b>5. Perform Sterilization</b>								
<b>Task A:</b> Sterilize vessels and transfer lines	a Ensure pressure test has been performed	b Manipulate valves to specified orientation	c Drain glycol from vessel jacket, if applicable	d Run automated recipe	e Ensure all set points are reached	f Upon completion of sterilization phase, manipulate valves during cool-down as specified	g Document as required	
<b>Task B:</b> Sterilize sample device/port	a Attach sterile sampling device	b Run sterilization per SOP	c Cool per SOP	d Sample from device				
<b>Task C:</b> Autoclave equipment (same procedure for depyrogenation ovens)	a Assemble equipment per procedure	b Load equipment into chamber	c Select appropriate cycle	d Run cycle	e Ensure process parameters are met	f Close valves and unload equipment		
<b>6. Clean Equipment</b>								
<b>Task A:</b> Clean CIP vessels, transfer lines, and filter trains	a Ensure that CIP skid is ready for operation	b Obtain required equipment/cleaning solutions such as hoses ,pump etc	c Set up equipment as required	d Run cleaning operation per SOP	e Disassemble			
<b>Task B:</b> Perform WFI flush of transfer lines	a Set up appropriate valves, hoses, etc.	b Open WFI supply per procedure	c Complete manual manipulations per procedure	d Disassemble				

JOB FUNCTIONS	COMPETENCIES							
<b>Task C:</b> Clean COP equipment (or sonicator)	a Prepare solution in COP tank	b Place equipment into bath	c Soak for specified time	d Rinse with WFI				
<b>Task D:</b> Wash glassware equipment	a Prepare glasswasher	b Load equipment into glasswasher	c Run appropriate cycle	d Remove equipment and allow to dry	e Prepare or wrap equipment			
<b>Task E:</b> Perform scheduled sanitizations of hoods	a Prepare disinfectant	b Wipe down equipment surfaces starting from cleanest to dirtiest	c Wipe down surfaces with water	d Wipe down surfaces with IPA				
<b>7. Prepare Buffers and Medias</b>								
<b>Task A:</b> Weigh components	a Calibrate scale	b Obtain raw material	c Tare container	d Place raw material in container to specified weight	e Close container			
<b>Task B:</b> Dispense components	a Move materials to appropriate storage area	b Perform inventory transaction for movement	c Record on batch record	d Place batch record with materials				
<b>Task C:</b> Prepare batch	a Ensure systems have been sterilized and prepared as necessary	b Obtain raw materials	c Charge batch vessel with WFI	d Add specified raw materials	e Mix for specified time	f Filter and transfer to storage vessel	g Store at specified temperate and assign expiration date	
<b>8. Perform Testing</b>								
<b>Task A:</b> Test integrity of filters	a Wet filters	b Set up and attach tester	c Execute test	d Check for passing results				
<b>Task B:</b> Perform pressure test	a Set-up equipment	b Pressurize equipment to desired pressure	c Check for leaks	d Monitor pressure loss for specified time	e Ensure that passing criteria are met	f Release pressure		
<b>Task C:</b> Use testing probes	a Obtain probes	b Prepare probes for use	c Standardize probes per procedure					
<b>Task D:</b> Perform in-process testing	a Obtain sample	b Aliquot sample as required	c Run sample on applicable meters	d Record results				
<b>Task E:</b> Perform cell counting	a Obtain sample and hemacytometer	b Dilute sample in trypan blue	c Vortex sample	d Pipette sample onto hemacytometer	e Count cells under microscope			
<b>9. Perform Recovery/ Filtration</b>								
<b>Task A:</b> Run TFF skid	a Buffer flush/equilibration	b Download appropriate recipe	c Initiate operation per procedure	d Monitor trans-membrane pressure	e Sample as necessary			

JOB FUNCTIONS	COMPETENCIES							
<b>Task B:</b> Perform depth filtration	a Ensure filters have been steamed and are ready for processing	b Charge solution to filters	c Bleed filters	d Monitor filtration				
<b>Task C:</b> Perform centrifugation	a Set up centrifuge	b Get bowl up to speed	c Start feeding product	d Monitor centrifuge	e Adjust dislodge			
<b>Task D:</b> Run homogenizer	a Set-up homogenizer	b Start feeding	c Apply pressure to pistons	d Run 2 to 3 feeds	e Monitor operation			
<b>10. Maintain Communication</b>								
<b>Task A:</b> Deliver shift change update	a Compose shift change update	b Pass update on to Supervisor	c Pass update onto oncoming shift					
<b>Task B:</b> Contact appropriate groups for specific needs	a Determine needs	b Contact appropriate groups for specific needs						

**Knowledge, Skills, and Equipment  
Manufacturing Technician (Upstream)**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Biology .....B            Chemistry.....B            Computer Sciences.....B            Math.....B            Microbiology .....B            Plumbing.....B            Technical Writing .....B</p>	<p>Cleanroom Experience            Communication            Computer Applications            Documentation            Ergonomics            GMPs            Handle Audits            Industrial Safety            Mechanical            Organization            Problem-Solving            Time Management</p>	<p>Autoclaves            Bio-Safety Cabinet And Laminar Flow Hood            Blood Gas Analyzer            Centrifuge            Chart Recorders            CIP Skids            Computers            Conductivity Meter            Filter Integrity Tester            Filtration Devices            Gas Cylinders            Hemocytometer Or Automated Cell Counter            Homogenizer            Incubators            Liquid Nitrogen Containers            Microscope            Osmometer            Peristaltic Pumps And Other Pumps            Ph And DO Probes            Ph Meter            Pipettes            Pressure Gauges            Regulators            Rupture Discs            Scales And Balances            Shakers And Rockers            Spectrophotometer            Steam Traps            Stir Plates            Valves And Piping            Water Baths</p>

**Job Functions, Tasks, and Competencies of MANUFACTURING TECHNICIAN (DOWNSTREAM)**

Conducts specific manufacturing operations, such as CIP/SIP of equipment, column chromatography, ultrafiltration, diafiltration, protein purification operations, monitoring control devices

JOB FUNCTIONS		COMPETENCIES						
<b>1. Adhere to GMPs</b>								
<b>Task A:</b> Gown personnel	a Enter gown room	b Don gowning materials in correct order per SOP						
<b>Task B:</b> Follow procedures	a Train on SOP	b Use procedures to do tasks	c Record and report all deviations from normal processing					
<b>Task C:</b> Train personnel	a Find qualified trainer	b Identify deficient area for training	c Conduct training	d Assess trainee	e Document training procedure or task			
<b>Task D:</b> Complete batch documentation	a Perform task per procedure	b Document appropriately into batch document	c Verify independently that task was done accurately	d Record and capture events accurately and clearly	e Document events in real time			
<b>Task E:</b> Review batch documentation	a Obtain completed documentation	b Verify that all entries are accurate	c Sign document as completed	d Distribute to Quality Assurance				
<b>Task F:</b> Label and apply status to equipment and materials	a Obtain labels	b Identify status	c Record accurately	d Attach to equipment				
<b>Task G:</b> Maintain open lines of communication	a Exchange information efficiently about status of work day	b Organize tasks assigned	c Complete task in framework of a team	d Comprehend assigned tasks	e Respect authority	f Voice concerns to upper management	g Plan between functional departments	h Use communication tools effectively (e-mail/voicemail)
<b>Task H:</b> Maintain safe working environment	a Use PPE	b Follow appropriate safety procedures	c Review MSDS guidelines as necessary	d Clean spills in real time	e Dispose of waste properly	f Report all incidents to safety department	g Adhere to alarms	
<b>2. Prepare Solutions</b>								
<b>Task A:</b> Weigh raw materials	a Obtain raw material required	b Verify from label that material is released for use	c Standardize balance	d Determine amount of raw material needed from batch documentation	e Dispense in appropriate environment	f Formulate solution by mixing dispensed materials		

JOB FUNCTIONS	COMPETENCIES							
<b>Task B:</b> Filter solutions	a Use appropriate filter	b Filter into appropriate vessel						
<b>Task C:</b> Sample and test solution	a Remove in-process assays	b Ensure for passing results prior to transfer						
<b>Task D:</b> Transfer solution to use point	a Identify receiving area	b Transfer under appropriate conditions						
<b>3. Clean Environment and Equipment</b>								
<b>Task A:</b> Clean environment	a Use appropriate agent	b Use correct amounts of cleaning agent						
<b>Task B:</b> Perform clean in place	a Obtain SOP	b Set manual valves	c Download automated sequence	d Monitor sequence in process	e Close clean system			
<b>Task C:</b> Perform steam in place	a Obtain SOP	b Set manual valves	c Download automated sequence	d Pressure test Vessel	e Steam system at appropriate temperature	f Cool to room temp with air pressure	g Shut down system	
<b>Task D:</b> Autoclave materials	a Clean material	b Wrap material	c Load autoclave	d Ensure for passing run				
<b>Task E:</b> Depyrogenate material	a Clean material	b Wrap material	c Load Depyro	d Ensure for passing run				
<b>Task F:</b> Wash glassware and small equipment	a Soak equipment	b Rinse equipment	c Dry equipment	d Label equipment	e Store equipment			
<b>4. Pack Columns</b>								
<b>Task A:</b> Assemble column body	a Obtain and soak new frits and O-rings	b Install frits and O-rings to flow adapters						
<b>Task B:</b> Sanitize column body	a Soak column body in caustic	b Rinse column until cleaning solution removed						
<b>Task C:</b> Slurry resin	a Add slurry buffer to desired ratio	b Shake vigorously	c Pour into column body					
<b>Task D:</b> Pack resin to specifications	a Flow buffer to specification	b Remove air	c Lower top flow adapter to resin surface	d Measure bed height	e Calculate column volume			
<b>Task E:</b> Prepare column for process use	a Test column for efficiency	b Calculate HETP and asymmetry	c Clean resin for preparation for use	d Sample prepared column as required				

JOB FUNCTIONS	COMPETENCIES							
<b>5. Perform Protein Purification</b>								
<b>Task A:</b> Receive product from upstream processing	a Initiate transfer sequence	b Mix product	c Sample product	d Prepare tanks and equipment for process steps	e Sample and test product			
<b>Task B:</b> Perform chromatography steps	a Clean column with appropriate buffer	b Equilibrate column with appropriate buffer	c Load column with product	d Elute product from column	e Regenerate column			
<b>Task C:</b> Filter product as necessary	a Pressurize holding tank	b Assemble filter train	c Bleed air from filter	d Monitor transfer	e Integrity test filter once transfer complete			
<b>Task D:</b> Perform UF/DF and viral removal steps	a Assemble filters into UF skids	b Clean skid	c Integrity test filters	d Concentrate product	e Exchange buffer	f Integrity test filters	g Insert filter into house	h Run test program
<b>Task E:</b> Bulk fill purified product	a Sterilize final product containers	b Clean room and BSC/LFA	c Pool final product into final containers	d Integrity test filter	e Transfer for further processing			
<b>Task F:</b> Troubleshoot process	a Respond to alarms	b Identify abnormal conditions	c Communicate instances of abnormality to subject matter experts	d Use data management systems to identify trends				
<b>Task G:</b> Sample and manage process testing	a Remove volume needed for test from vessel	b Standardize test equipment	c Aliquot sample to appropriate containers	d Prepare solutions as necessary for particular test	e Analyze results	f Deliver sample for testing or to appropriate location	g Record results	h Discard unused sample quantity
<b>Task H:</b> Operate and use control systems	a Operate methods for chroma-tography steps	b Download CIP/SIP sequences	c Run data systems for batch reporting	d Use IT platforms required for business systems	e Operate quality systems (LIMS, change control)			

**Knowledge, Skills, and Equipment  
Manufacturing Technician (Downstream)**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Biochemistry ..... B            Chemistry ..... B            Computer Science ..... I            Electronics ..... B            Math ..... B            Mechanical Engineering ..... I            Microbiology ..... B            Plumbing ..... I            Technical Writing ..... I</p>	<p>Clean Room Experience            Communication            Computer Applications            Documentation            Ergonomics            GMP            Handle Audit            Industrial Safety            Mechanical            Organizational            Problem Solving            Time Management</p>	<p>Chromatography Skid            Clamps            Columns            Conductivity Meters            Flexhoses            Flowmeter            Gaskets            Integrity Testers            Peristaltic Pumps            pH Meters            Pressure Gauges            Process Tanks            Scales            UF Skid            UV Spectrophotometer</p>

**Job Functions, Tasks, and Competencies of INSTRUMENTATION/CALIBRATION TECHNICIAN**

Maintains, calibrates, tests, troubleshoots, and repairs circuits, components, analytical equipment, and instrumentation. Performs validation studies. Requests purchase of components.

JOB FUNCTIONS	COMPETENCIES							
<b>1. Perform Calibration</b>								
<b>Task A:</b> Schedule instrument calibration with end use	a Use PC skills to generate calibration work order	b Use communication skills to schedule calibration activity with end users						
<b>Task B:</b> Read SOP	a Read and use SOPs	b Apply concepts to work process						
<b>Task C:</b> Gather necessary tools	a Use standards and required equipment	b Demonstrate appropriate mechanical aptitude when using tools	c Follow safety procedures and regulations when working					
<b>Task D:</b> Note as-found conditions of instrument to be calibrated	a Use documentation skills to record how the instrument is installed	b Use appropriate tools to remove the instrument to be calibrated						
<b>Task E:</b> Perform calibration	a Use mechanical skills to attach and operate calibration reference standard equipment	b Use electrical skills when attaching related electrical calibration reference standard equipment	c Use analytical skills to evaluate data from calibration reference standard equipment and compare it to instrument being calibrated	d Work safely; follow safety procedures and regulations when working	e Perform math/calculations comparison to determine the error of the instrument being calibrated from the reference standard equipment	f Use scientific calculator to perform calculations and comparisons	g Practice fundamentals of temperature, pressure, flow, weight, speed, time, pH, and/or resistivity/conductivity	h Practice measured values and units/conversions
<b>Task F:</b> Document and notify appropriate people of the results	a Use PC skills to notify appropriate persons	b Use documentation skills to document completion of calibration						

JOB FUNCTIONS	COMPETENCIES							
<b>Task G:</b> Return to as-found condition	a Use appropriate tools to return instrument to original state	b Use mechanical aptitude to attach and return instrument to original state	c Work safely; follow safety procedures and regulations when working					
<b>Task H:</b> Review documentation	a Demonstrate math skills to verify math calculations performed during calibration	b Use standard documentation process						
<b>Task I:</b> Enter findings in database; update and retrieve data from database	a Use PC skills to enter data							
<b>2. Perform Documentation</b>								
<b>Task A:</b> Generate calibration report	a Use PC skills to generate report (e.g., Blue Mountain, Maximo, Datastream)	b Use appropriate documentation skills						
<b>Task B:</b> Document as-found data	a Use PC skills to generate report (e.g., Blue Mountain, Maximo, Datastream)	b Use appropriate documentation skills						
<b>Task C:</b> Document as-left data	a Use PC skills to generate report (e.g., Blue Mountain, Maximo, Datastream)	b Use appropriate documentation skills						
<b>Task D:</b> Label instrument when complete	a Use appropriate documentation skills							
<b>Task E:</b> Document change or out-of-tolerance condition	a Use appropriate documentation skills							

JOB FUNCTIONS		COMPETENCIES						
<b>Task F:</b> Review document	a Demonstrate math skills to verify math calculations performed during calibration	b Use standard documentation skills						
<b>3. Troubleshoot Instrument Failure</b>								
<b>Task A:</b> Obtain work order from end user or work-group coordinator	a Complete work order according to procedures							
<b>Task B:</b> Schedule work for troubleshooting instrument that failed	a Use PC skills	b Use communication skills	c Use mechanical and technical skills required for general troubleshooting					
<b>Task C:</b> Gather tools	a Collect necessary tools and reference standard equipment	b Demonstrate mechanical aptitude	c Work safely; follow safety procedures and regulations when working					
<b>Task D:</b> Repair, replace, and/or purchase a new instrument to replace the failed instrument	a Use mechanical aptitudes to adjust or determine appropriate replacement instrument	b Use electrical skills when attaching related electrical meters and/or calibration reference standard equipment	c Use analytical skills to evaluate data from the calibration reference standard equipment and compare it to the instrument being calibrated	d Work safely; follow safety procedures and regulations when working	e Perform math/calculations/comparison to determine the error of the instrument being calibrated from the reference standard equipment	f Practice fundamentals of temperature, pressure, flow, weight, speed, time, pH, and/or resistance/conductivity.	g Practice measured values and units/conversions	
<b>Task E:</b> Log and close out	a Use PC skills to generate report (e.g., Blue Mountain, Maximo, Datastream)	b Perform required documentation to enter work performed in appropriate work order						
<b>Task F:</b> Return to owner	a Use communication skills to notify end user of work completion	b Use PC skills to notify end user and/or others of work completion and results						

JOB FUNCTIONS	COMPETENCIES							
<b>4. Coordinate Calibration Activities</b>								
<b>Task A:</b> Schedule instruments to be calibrated by the time they become due	a Use communication skills to schedule instrument and equipment that may be interrupted due to calibration	b Demonstrate consistent required times associated with calibrations						
<b>Task B:</b> Notify end user prior to performing instrument calibration	b Communicate information to others							
<b>Task C:</b> Notify end user after calibration completion	a Use PC skills to notify end user to completed calibration	b Communicate information to others						
<b>Task D:</b> Notify user of non-conformance and/or out-of-tolerance	a Use standard procedures for notification							
<b>Task E:</b> Communicate within work group about completed calibration to avoid duplicating work	a Use communication skills to notify others within work group	b Cross off instruments that have been completed to notify others within work group						
<b>5. Use Computer for Various Technical Work</b>								
<b>Task A:</b> Write/revise documents	a Use MS Word	b Use MS Excel	c Use MS Access					
<b>Task B:</b> Program parameters	a Use Programmable Logic Controller programming software	b Use Operator Interface Terminal and/or Human Machine Interface programming software	c Use BMS (building management system)	d Use Distributed Control Systems	e Use HART or equivalent protocol for programming instruments			
<b>Task C:</b> Use company/proprietary software packages	a Use new software	b Use general PC database skills						
<b>6. Understand cGMPs</b>								
<b>Task A:</b> Practice good documentation	a Use appropriate documentation skills							

JOB FUNCTIONS	COMPETENCIES							
<b>Task B:</b> Attend training to support cGMPs	a Use PC skills to attend online training courses	b Use documentation skills to record training completed	c Use communication skills to notify others within work group of training completed					

**Knowledge, Skills, and Equipment  
Instrumentation/Calibration Technician**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Algebra 1 &amp; 2 .....B            Chemistry .....B            Computer Science            (Automation and            Programming).....I            English .....B            Physics .....B</p>	<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Basic Electricity and Electronics .....I            Basic Plumbing and Piping .....I            Computer Applications .....A            GMP .....A            Technical Writing .....A</p> <p><b>Calibration/Instrumentation Specific Training</b></p> <ul style="list-style-type: none"> <li>• Analytical (pH, Conductivity and Resistivity, DO2, TOC)</li> <li>• Control Valves</li> <li>• Flow Liquid and Mass Flow</li> <li>• Level (Transmitters, Load Cells, Differential, Radar, Sonar, Float Type, Capacitance)</li> <li>• Limit Switches</li> <li>• Pressure Calibration (Transmitters, Switches, Gauges, Differential, Vacuum, I/P)</li> <li>• Profibus/Fieldbus (Digital Technology)</li> <li>• Rotational (Pumps, Motors, VFD, Agitators)</li> <li>• RS LOGIX</li> <li>• Temperature (Thermocouples, RTD's, BiMetallic Thermometers, Glass Thermometers, Transmitters, Chambers)</li> <li>• Time (Timers, Stopwatches)</li> <li>• Weight/Mass (Balances And Scales)</li> </ul>	<p><b>Calibration Standards Traceable to NIST (Pressure/Temperature Flow)</b></p> <p>Amp Meters            Decade Box            Fluke Multimeters            Fluke Process Calibrators            Frequency Generator            Hart Communicators (Smart Communications)            Soldering Equipment/Materials</p>

**Job Functions, Tasks, and Competencies of CHEMISTRY QC TECHNICIAN**

Tests samples for internal and external customers; analyzes, communicates results; reviews, validates, troubleshoots procedures; monitors environment, equipment, instrumentation

JOB FUNCTIONS	COMPETENCIES					
<b>1. Test Samples</b>						
<b>Task A:</b> Collect sample	a Identify sample; inspect all sample parameters	b Remove sample with proper technique	c Label sample properly	d Store according to specifications		
<b>Task B:</b> Determine appropriate testing	a Use familiarity with tests performed in the lab	b Look up in product SOP to determine testing				
<b>Task C:</b> Prepare reagents	a Use balance	b Use pH meter	c Fill out appropriate paperwork	d Use conductivity meter	e Use filter/degas	f Review post-preparation
<b>Task D:</b> Review testing procedures	a Read procedure for clarity	b Acquire all necessary materials and equipment				
<b>Task E:</b> Execute testing	a Set up labeled tubes	b Perform pipetting	c Dilute schemes with many variables			
<b>Task F:</b> Analyze data	a Correct and interpret results	b Look for aberrant results	c Determine assay validity			
<b>Task G:</b> Evaluate data with regard to specification	a Report results using appropriate medium	b Compare result to acceptance criteria				
<b>Task H:</b> Accept or reject data	a If reject, follow applicable procedure	b Initiate deviation/out-of-specification/discrepancy report	c If accept, follow procedure to hand off results to next group			
<b>Task I:</b> Monitor data trending	a Evaluate data with regard to historical results	b Follow applicable procedure for out-of-trend results				
<b>2. Provide Customer Service (Internal)</b>						
<b>Task A:</b> Consult with appropriate department	a Provide input on scheduling	b Coordinate stat samples	c Give scientific background for situations			
<b>Task B:</b> Determine necessary testing	a Determine appropriate department for testing	b Identify correct test to monitor each parameter				
<b>Task C:</b> Report result to appropriate departments	a Communicate results using appropriate system (paper, electronic, verbal)					
<b>Task D:</b> Troubleshoot aberrant results or parameters	a Discuss which tests to run to eliminate causes	b Review data to identify cause	c Define corrective actions/preventive actions			

JOB FUNCTIONS	COMPETENCIES					
<b>3. Control Documentation</b>						
<b>Task A:</b> Write SOPs	a Research procedure or product	b Follow QA format for SOPs	c Technically write outline for procedure	d Ensure clarity and readability		
<b>Task B:</b> Review SOPs	a Conduct peer/ department review using knowledge of SOPs	b Check for SOP clarity and conciseness	c Ensure responsibilities can be met by department receiving SOPs			
<b>Task C:</b> Review data	a Review peer assay data for accuracy and GMP compliance	b Archive data in appropriate location				
<b>Task D:</b> Review manufacturing documentation	a Check for accuracy of material content	b Ensure QC sampling plan is correct				
<b>Task E:</b> Capture investigations/ deviations	a Know how to technically write investigation/ deviation	b Generate data in report format	c Fill out all appropriate forms	d Execute corrective action/preventive action		
<b>Task F:</b> Write technical reports	a Make reports legible and clear	b Follow acceptable SOP for format	c Use appropriate software to defend conclusion			
<b>Task G:</b> Maintain notebooks/ logbooks	a Complete daily entries in GMP manner properly	b Review peer notebooks	c Compile and archive periodically	d Document maintenance and out of service		
<b>Task H:</b> Document routine activities	a Record daily calibration/ standardizations	b Record time for applicable cost codes				
<b>Task I:</b> Participate in change control activities	a Give input of process changes	b Perform any changes to document approved system	c Justify changes to QA			
<b>Task J:</b> Archive documents/data	a Compile and organize data, assay forms, and other documents					
<b>4. Monitor Environmental Parameters</b>						
<b>Task A:</b> Monitor water quality	a Perform chemical tests on water samples	b Ensure within specifications for water quality				
<b>Task B:</b> Monitor controlled equipment	a Conduct daily check to ensure equipment operation in spec	b Call for service when necessary	c Troubleshoot when necessary			
<b>Task C:</b> Maintain environmental logs	a Check temperature on controlled areas					

JOB FUNCTIONS	COMPETENCIES					
<b>5. Obtain and Maintain Permits</b>						
<b>Task A:</b> Maintain awareness of permits of controlled substances	a Identify controlled substances in lab	b Educate yourself on rules of necessary permits	c Document necessary information			
<b>6. Educate Employees</b>						
<b>Task A:</b> Facilitate new employee training	a Coordinate training tasks	b Schedule time for Q&A about assay				
<b>Task B:</b> Follow approved curriculum for training	a Ensure new employees attend all required trainings	b Review new employee curriculum for additions or omissions	c Customize for specific employee based on skills and background	d Identify needed assays for highest priority training		
<b>Task C:</b> Train employees in job-specific tasks	a Observe new analyst performing tests	b Review results and procedures	c Give feedback for improvement			
<b>Task D:</b> Maintain training records	a Document in compliant manner	b Store records in accessible location	c Know how to document training			
<b>Task E:</b> Identify additional training needs (e.g., outside resources)	a Supplement training with seminars/courses provided by experts	b Use internal employees, vendors, institutions, and consulting firms as “experts”				
<b>7. Comply with Regulations</b>						
<b>Task A:</b> Follow all written procedures exactly	a Follow carefully all controlled documents and procedures	b Recognize that results not valid if established procedure not followed				
<b>Task B:</b> Keep up on industry regulations/literature	a Research better alternative testing methods					
<b>Task C:</b> Review documentation for regulatory compliance	a Maintain awareness of changes in regulations					
<b>Task D:</b> Participate in regulatory audits	a Use of both internal and external audits	b Ensure compliance on all procedures	c Answer questions concisely, without extraneous information			
<b>8. Provide Technical Support</b>						
<b>Task A:</b> Transfer new technology/assays	a Perform initial correlation studies to determine acceptable parameters	b Work with customers to validate new process/assays	c Troubleshoot in instances where there is non-comparability	d Identify approved alternative vendors	e Document protocol and final report	
<b>Task B:</b> Instruct an optimum use (product, instrumentation, systems)	a Identify customer requirements	b Explain uses of product or instrumentation to meet needs	c Ensure explanation is adequate to meet needs through communication			

JOB FUNCTIONS		COMPETENCIES				
<b>Task C:</b> Provide technical training to customer (internal and external)	a Give appropriate trainings to meet customer needs	b Provide trainings that encompass scientific theory, history, and background				
<b>Task D:</b> Troubleshoot at request of customer	a Identify test methods needed to be run	b Investigate any possible root cause of differences				
<b>Task E:</b> Interact with vendors	a Use knowledge/skills to get vendors to work with you	b Accompany vendors while at site				
<b>9. Perform and Support Validation</b>						
<b>Task A:</b> Develop validation procedures	a Identify necessary parameters to measure	b Identify acceptance criteria for parameters	c Write protocol and validation plan	d Obtain needed approval for validation plan		
<b>Task B:</b> Execute validation procedures	a Perform needed studies					
<b>Task C:</b> Defend validation results	a Write validation report	b Capture and explain any discrepancies to validation plan	c Obtain necessary approval for validation report to implement change			
<b>Task D:</b> Test manufacturing validation samples	a Support manufacturing validation efforts through testing	b Perform any test requested by manufacturing regularly run by the lab (sterility, pH, protein concentration)	c Develop or purchase other tests at the request of manufacturing not currently supported			
<b>10. Maintain Systems and Equipment</b>						
<b>Task A:</b> Perform preventive maintenance (PM)	a Create/write PM schedule and protocol	b Order any required parts	c Perform maintenance	d Review peer maintenance		
<b>Task B:</b> Perform instrument calibrations	a Create/write calibration schedule and protocol	b Perform calibration	c Use document results	d Generate out-of-tolerance/ discrepancy when necessary	e Obtain review of calibration; create/write PM schedule and protocol	f Document that calibration was performed
<b>Task C:</b> Schedule vendor maintenance	a Coordinate with vendor	b Ensure maintenance meets lab schedule	c Review vendor maintenance	d Document that maintenance was performed		
<b>Task D:</b> Troubleshoot equipment failures	a Identify potential causes for failure	b Determine products/results affected by failure				

JOB FUNCTIONS	COMPETENCIES					
<b>11. Conform to Health and Safety Procedures</b>						
<b>Task A:</b> Wear proper personal protective equipment	a Wear gloves, goggles, aprons, and respirator, as needed					
<b>Task B:</b> Follow lab safety procedures	a Read and follow approved procedures	b Attend safety orientation				
<b>Task C:</b> Maintain awareness of correct ergonomic positions and activities	a Maintain awareness of repetitive motion problems, especially pipetting	b Avoid standing at hood for long periods of time				
<b>Task D:</b> Maintain familiarity with MSDSs	a Know where MSDSs are located	b Be familiar with chemical labels				
<b>Task E:</b> Use hoods where appropriate	a Practice proper use of chemicals and procedures	b Perform all reactions that emit fumes in the hood				
<b>Task F:</b> Dispose of sharps properly	a Know that sharps are to be discarded in appropriate container	Dispose of broken glass in appropriate container	c Ensure correct labeling on all waste containers			
<b>Task G:</b> Complete accident reports at time of occurrence	a Follow safety guidelines and procedures	b Report all incidents to supervisor and on official form immediately				
<b>12. Comply with Environmental Regulations</b>						
<b>Task A:</b> Dispose of hazardous and chemical waste properly	a Identify hazardous materials within lab	b Maintain familiarity with disposal regulations and guidelines set forth by EHS	c Dispose of materials in properly labeled containers			
<b>13. Manage People</b>						
<b>Task A:</b> Determine employee development plan	a Assess employee's current abilities and skills	b Identify future goals through discussions	c Put into place proper training and opportunities to achieve goals	d Periodically review development plan		
<b>Task B:</b> Monitor employee work load and stress level	a Regularly assess employee stress and workload, and communicate to team	b Ensure work is spread correctly across lab	c Promote teamwork through action and leadership	d Be aware of activities and logistics involved in assays/data analysis/review		
<b>Task C:</b> Perform peer/management period reviews	a Perform period reviews	b Follow procedures for adequate/ approved documentation				
<b>Task D:</b> Participate in recruitment process	a Identify resources needed within the lab					

JOB FUNCTIONS	COMPETENCIES					
<b>Task E:</b> Develop positive staff morale	a Demonstrate leadership and interaction; encourage positive morale	b Remedy problems as they occur	c Use effective communication skills, identifying specific personal issues	d Work to reduce office gossip/unprofessional behavior		

**Knowledge, Skills, and Equipment  
Chemistry QC Technician**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment	
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Algebra ..... B            Biology ..... B            Business Management              (Basics; Budget; Cost-Benefit              Analysis Economics) ..... I            Computer Skills and            English ..... A            Logic/Critical Thinking/Cause              Analysis ..... B            Microcomputer Applications              (MS Office) ..... I            Regulatory Affairs ..... B            Social Science (Ethics, Psychology,              Sociology) ..... I            Statistics ..... B            Technical Writing ..... B</p>	<p>Aseptic Technique (Gowning; Laminar Flow Hoods; BSCs)            Corrective and Preventive Action            GMPs            Office Equipment Operation            Plant or Material Flow (Dirty/Clean)            Technical Reading and Writing            Time Management</p>	<p>AIEF            Analytical/Guard Columns            Autoclave            Autotitrator            Balance            Centrifuge            Coagulation Analyzer            Concentrators            Conductivity Meter            Degasser            Densitometer            De-salting Columns            Dialysis Cassettes/Tubes            Electrochemical Detectors            FTIR            Fume Hood            Gamma Counter            GC            Gel Dry System            Turbidity Meter            Gel Power Packs            Glucose/Glutamine Meter            Heat Block            Hot Stir Plate            HPLC            Hydrometer            IEF            IEP Tanks            Immunodiffusion Plates            Immunodiffusion Viewer            Incubator            Ion Chromatography            Mass Spec</p>	<p>NIR            NMR            Nutrient Meter (dO, NH<sub>3</sub>,            dCO)            Osmometer            Ph Meter            Pipettors            Plate Reader            Plate Shaker            Plate Washer            Plate Washer For Beads            Printers            Purification Fraction            Collector            Refrigerator/Freezer            SDS-Page (Poured And Pre            Cast)            Shaker/Incubator            Sparge System            Spectrophoter            Test Tube Racks            Vacuum Centrifuge            Vacuum Pump            Volumetric Pipettes And            Flasks            Vortexer            Water Bath            Wrenches</p>

**Job Functions, Tasks, and Competencies of MICROBIOLOGY QC TECHNICIAN**

Performs routine microbiological testing of raw materials, in-process samples, and finished products. Monitors manufacturing areas, equipment, and processes. Calibrates and maintains equipment.

JOB FUNCTIONS		COMPETENCIES				
<b>1. Perform Testing</b>						
<b>Task A:</b> Monitor environmental conditions	a Sample total air particulates	b Sample viable air particulates	c Test surface cleanliness			
<b>Task B:</b> Identify microbial growth	a Isolate colonies	b Perform staining techniques (e.g., Gram stain)	c Perform biochemical tests (e.g., Catalase test)	d Utilize identification systems (e.g., Midi, Vitek)	e Use selective media	
<b>Task C:</b> Test for endotoxin (e.g., water, in-process, final product)	a Use gel clot or kinetic method	b Use endotoxin detection systems (e.g., Endoscan)				
<b>Task D:</b> Test for bioburden (e.g., water, in-process, final product)	a Use spread plates	b Use membrane filtration (i.e., Nalgene filters or Milliflex system)	c Use pour plates			
<b>Task E:</b> Test with biological indicators	a Use ampoules	b Use spore strips				
<b>Task F:</b> Test for quality of media/reagents	a Perform growth promotion	b Perform population recovery testing				
<b>Task G:</b> Perform basic microbiology lab techniques	a Streak/isolate on media	b Use pipettes	c Perform aseptically	d Conduct reagent preparation		
<b>Task H:</b> Monitor personnel	a Use touch plates	b Use surface sampling plates (e.g., RODAC plates)				
<b>Task I:</b> Transfer methods/technologies	a Transfer customer methods/ technologies	b Transfer developed technologies across company sites				
<b>Task J:</b> Review data	a Ensure compliance with SOPs	b Verify calculations	c Search for and fix errors			
<b>2. Provide Customer Service</b>						
<b>Task A:</b> Work with internal customers	a Coordinate sampling with other departments	b Communicate results and information to departments				
<b>Task B:</b> Work with external customers	a Communicate with vendors	b Communicate with contract manufacturing sites/personnel				
<b>3. Conduct Documentation</b>						
<b>Task A:</b> Author documents	a Develop methods/forms	b Write SOPs				
<b>Task B:</b> Control documents	a Track/ reconcile assay data sheets	b Track official copies of SOPs/ forms				

JOB FUNCTIONS		COMPETENCIES				
<b>Task C:</b> Maintain training records	a Read and understand current SOPs					
<b>Task D:</b> Check for cGMP compliance	a Enter data accurately on paperwork and in computer	b Use control data sheets	c Record appropriate reference numbers in log book	d Review data	e Acquire and become familiar with the Code of Federal Regulations (CFR) and other regulatory information	
<b>Task E:</b> Conduct electronic documentation	a Enter assay data into computer database (i.e., LIMS)	b Maintain list of samples to verify test completion and to track samples received	c Generate periodic reports according to department needs (i.e., quarterly reports)			
<b>4. Manage Information</b>						
<b>Task A:</b> Obtain/report data	a Accurately record assay raw data on paperwork; enter data in computer	b Prepare environmental action/excursion follow-up reports				
<b>Task B:</b> Trend/benchmark data	a Analyze data from testing results	b Prepare reports of data (e.g., trend reports, quarterly identification reports)				
<b>Task C:</b> Review data	a Review report	b Search for trends				
<b>5. Conduct Training</b>						
<b>Task A:</b> Train people to follow SOPs	a Instruct people to read procedure documentation	b Instruct people to observe procedure	c Observe people performing procedure	d Make sure people can perform the procedure independently		
<b>Task B:</b> Train people on in-house protocols	a Use aseptic techniques	b Use gowning techniques				
<b>6. Provide Technical Support</b>						
<b>Task A:</b> Assist with process investigations	a Track information or locate information	b Write memos or technical information bulletins				
<b>7. Perform/ Support Validation</b>						
<b>Task A:</b> Validate methods	a Write instrument qualifications or performance qualifications	b Perform assays for qualification				
<b>Task B:</b> Validate equipment	a Write instrument qualifications or performance qualifications	b Perform assays for qualifications				
<b>8. Conduct Maintenance</b>						
<b>Task A:</b> Troubleshoot instruments	a Perform routine maintenance	b Perform corrective maintenance	c Maintain maintenance records			

JOB FUNCTIONS	COMPETENCIES					
<b>Task B:</b> Monitor equipment performance	a Monitor temperature charts daily	b Conduct environmental monitoring of lab BSCs				
<b>Task C:</b> Maintain laboratory space	a Wrap/prepare items for autoclaving	b Check expiration dates of reagents, media, equipment calibration dates	c Perform routine cleaning (i.e., BSC, incubator, bench tops)	d Order reagents/media (i.e., inventory control)		
<b>9. Follow Health/ Safety Procedures</b>						
<b>Task A:</b> Dispose of waste	a Dispose of biohazardous wastes according to protocol	b Dispose of sharps according to protocols				
<b>Task B:</b> Use routine lab safety precautions	a Wear safety glasses	b Wear lab coat properly (e.g., buttoned)	c Read MSDS reports for lab chemicals, etc.	d Wear long pants	e Tie back long hair	f Follow lab safety protocols

**Knowledge, Skills, and Equipment  
Microbiology QC Technician**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Algebra .....</p> <p>Biochemistry .....</p> <p>Biology .....</p> <p>Cell And Molecular Biology .....</p> <p>Chemistry .....</p> <p>Computer Skills/Microcomputer Applications (MS Office) .....</p> <p>Diagnostic Microbiology .....</p> <p>English.....</p> <p>Immunology .....</p> <p>Logic/Critical Thinking/Cause Analysis.....</p> <p>Microbiology .....</p> <p>Regulatory Affairs .....</p> <p>Social Science (Ethics, Psychology, Sociology) .....</p> <p>Statistics .....</p> <p>Technical Writing .....</p> <p>Virology .....</p>	<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Aseptic Technique (Gowning; Laminar Flow Hoods; BSCs).....</p> <p>Autoclave Theory/Practice.....</p> <p>Chemical Handling.....</p> <p>Corrective and Preventive Action .....</p> <p>GLPs .....</p> <p>GMPs .....</p> <p>Instrumentation (Process Controls and Calibration).....</p> <p>Pharmaceutical Grade Waters (WFI; Water Pre-Treatment; Reverse Osmosis, DI).....</p> <p>Plant or Material Flow (Dirty/Clean) .....</p> <p>Technical Reading and Writing.....</p> <p>Time Management .....</p>	<p>Anaerobic Chamber</p> <p>Autoclave</p> <p>Biology</p> <p>BSCs</p> <p>Centrifuges</p> <p>Colorimeters</p> <p>Fluorescent Microscope</p> <p>Freezers</p> <p>Fume hood</p> <p>Heating Blocks</p> <p>ID Systems: Vitek, API, MIDI</p> <p>Incubators</p> <p>Kinetic-chromatogenic Plate Reader For Endotoxin Testing</p> <p>Label maker</p> <p>Leader 50 (for Mycoplasma Detection)</p> <p>LIMS</p> <p>Manual and Electronic Pipettes</p> <p>Media</p> <p>Microscopes</p> <p>MicroStar</p> <p>Milliflex Bioburden System</p> <p>Pipet Aids</p> <p>Plate readers</p> <p>Refrigerators</p> <p>Scan RDI</p> <p>Total Particulate Monitors (Met One, CliMet, )</p> <p>Viable Particulate Monitors (RCS, RCS Plus, M-Air-T)</p> <p>Vortexes</p> <p>Water Baths</p>

**Job Functions, Tasks, and Competencies of ENVIRONMENTAL HEALTH AND SAFETY TECHNICIAN**

Monitors water and air; calibrates and maintains scientific monitoring equipment and performs routine analysis of all environmental and monitoring systems; processes permits

JOB FUNCTIONS	COMPETENCIES				
<b>1. Pursue Professional Credentials</b>					
<b>Task A:</b> Maintain certifications	a Maintain OSHA site emergency operations standard (HazWoper)	b Use first aid/AED (automatic external defibrillator)/CPR	c Maintain OSHA-related professional organization certifications		
<b>Task B:</b> Comply with pertinent regulations	a Comply with OSHA	b Comply with EPA/FDA	c Comply with state/local regulations	d Comply with NFPA (National Fire Protection Association)	e Comply with ATF (Bureau of Alcohol, Tobacco, and Firearms) regulations
<b>Task C:</b> Attend job-related industry events and professional development courses	a Attend ASSE (American Society of Safety Engineers) events	b Attend ASIH (American Society of Industrial Hygienists) events	c Keep updated about other professional organizations	d Make use of adult learning and teaching skills	
<b>Task D:</b> Be proficient with pertinent software programs	a Use MS Word	b Use MS Powerpoint	c Use MS Excel	d Use MS Access	e Use MS Projects
<b>2. Maintain Documentation</b>					
<b>Task A:</b> Maintain records (e.g., pest control, wastewater, waste manifests, air, SPCC, RCRA, safety-OSHA)	a Apply knowledge of MS Excel and MS Access	b Apply knowledge of regulatory requirements for specific records	c Use filing techniques	d Use technical writing skills	
<b>Task B:</b> Collect data (e.g., pest control, wastewater, waste manifests, air, SPCC, RCRA, safety-OSHA)	a Apply knowledge of MS Excel and MS Access	b Apply knowledge of regulatory requirements for specific records	c Use filing techniques	d Use technical writing skills	
<b>Task C:</b> Track data (e.g., pest control, wastewater, waste manifests, air, SPCC, RCRA, safety-OSHA)	a Apply knowledge of MS Excel and MS Access	b Apply knowledge of regulatory requirements for specific records	c Use filing techniques	d Use technical writing skills	
<b>Task D:</b> Prepare and maintain SOPs	a Make use of technical writing skills	b Use MS Word	c Use subject knowledge		
<b>3. Train Personnel</b>					
<b>Task A:</b> Conduct new hire orientation	a Teach new employees the community right-to-know standard	b Teach how to use personal protection equipment (PPE) requirements	c Explain the specifics of the site emergency action plan		
<b>Task B:</b> Provide safety training (according to 29 CFR 1910)	a Apply knowledge of 29 CFR 1910 (OSHA)	b Use adult learning and teaching skills	c Train people on site emergency action plans		
<b>Task C:</b> Provide environmental training	a Provide knowledge of hazardous waste classifications, labeling, and waste streams (RCRA)	b Provide knowledge of medical waste (e.g., handling, storage, transportation, disposal, classification)	c Provide knowledge of SCCP (spill control contingency plan) (e.g., storm water control)		
<b>Task D:</b> Conduct contractor safety training	a Provide knowledge of OSHA construction safety regulations				

JOB FUNCTIONS	COMPETENCIES				
<b>Task E:</b> Provide health training	a Provide knowledge of back safety, lifting, and back mechanics	b Provide knowledge of ergonomics	c Provide knowledge of industrial hygiene	d Provide knowledge of respiratory protection	
<b>4. Comply with regulations</b>					
<b>Task A:</b> Create plans (i.e., be able to use pertinent regulations)	a Use knowledge of pertinent regulations	b Use technical writing skills	c Use MS Word/MS Excel		
<b>Task B:</b> Maintain permits and plans (e.g., air, water, waste)	a Prepare periodic reports as required by regulations or circumstances	b Use negotiating skills	c Use technical writing skills	d Use MS Word/MS Excel	
<b>5. Provide Technical/Customer Support</b>					
<b>Task A:</b> Conduct job hazard assessment (JHA)	a Use knowledge of safety committees, cultures, and theories	b Use technical writing skills	c Use communication skills	d Use diplomacy skills	e Use safety equipment according to function and purpose
<b>Task B:</b> Perform environmental health and safety audits	a Use appropriate auditing techniques	b Use technical writing skills	c Communicate information to appropriate people	d Use diplomacy skills when communicating to people	
<b>6. Address Health Issues in Workplace</b>					
<b>Task A:</b> Conduct industrial hygiene monitoring	a Use knowledge of monitoring equipment	b Apply knowledge of methods of collection and proper medium to use for collection	c Use knowledge of indoor air quality standards	d Use knowledge of Material Safety Data Sheets (MSDS)	e Make use of American Conference of Governmental Industrial Hygienists (ACGIH) standards
<b>Task B:</b> Maintain auditory protection program	a Use knowledge of equipment	b Use knowledge of auditory functions			
<b>Task C:</b> Maintain respiratory program	a Use knowledge of equipment	b Use knowledge of respiratory functions	c Apply knowledge of fit testing		
<b>Task D:</b> Maintain first aid team	a Maintain basic first aid certification	b Maintain CPR certification	c Maintain automatic external defibrillator certification		
<b>7. Address Safety Issues in Workplace</b>					
<b>Task A:</b> Investigate accidents; use investigative skills	a Interview parties, access damage, secure scene, take samples, and reconstruct incident	b Apply methods of critical thinking	c Conduct a root-cause analysis	d Determine corrective/preventive action	
<b>Task B:</b> Provide safety training	a Hold workshops for personnel	b Provide literature about safety issues			
<b>Task C:</b> Coordinate worker compensation issues	a Communicate specific required knowledge to workers				
<b>8. Manage Information</b>					
<b>Task A:</b> Provide reports and feedback	a Use knowledge of statistical methods	b Use technical writing skills	c Use MS Word/MS Excel/MS Powerpoint	d Use public speaking skills to provide information	

**Knowledge, Skills, and Equipment  
Environmental Health and Safety Technician**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Algebra.....I Anatomy and Physiology .....B Biology.....B Business Management (Basics; Budget; Cost-Benefit Analysis Economics) .....B Chemistry .....I Computer Skills and Microcomputer Applications (MS Office) .....I Earth Sciences .....B Engineering (Environmental) .....B English.....I Environmental Law .....I Environmental Science.....A Health Science/Industrial Hygiene .....A Logic/Critical Thinking/Cause Analysis .....B Microbiology .....B Organic Chemistry .....B Physics.....B Regulatory Affairs .....A Social Science (Ethics, Psychology, Sociology) .....B Statistics .....I Technical Writing.....A Toxicology .....B</p>	<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p>Aseptic Technique (Gowning; Laminar Flow Hoods; BSCs) .....B Boilers.....B Chemical Handling.....A Corrective and Preventive Action .....A Electricity/Electronics .....B Fall Prevention (Heights) .....A GMPs .....B HVAC .....B Lock-Out/Tag-Out (LOTO) .....A Mobile Elevated Work Platforms .....A Office Equipment Operation .....B Plant or Material Flow (Dirty/Clean) .....B Powered Industrial Vehicles.....A Pressure Safety (Increasingly Important) .....A Pumps.....B Risk Assessment .....A Technical Reading and Writing.....A Time Management .....B Waste Water Treatment.....A</p>	<p>Industrial Hygiene Monitoring Equipment Four-Gas Monitor Audiometer Safety Shower Test Equipment Fall Protection Equipment Safety Glasses/Goggles Chemical Apron Sleeve Protectors Face Shield Respirator Steel Toe Shoes Hard Hats Hearing Protection Hand Truck pH meters Conductivity Meters Medical Oxygen AEDs Drum Dolly ISCO Sampler Air Emission Monitoring Equipment Confined Space Rescue Equipment SCBA Spill response Equipment Fire Extinguishers HVAC Vacs (Explosion Proof) Drum Pumps Fire Suppression/Alarm Systems</p>

**Job Functions, Tasks, and Competencies of QA DOCUMENTATION COORDINATOR**

Provides administrative support related to documentation systems. Audits all documentation manuals to assure accuracy, timelines, availability. Maintains and archives all master documents.

JOB FUNCTIONS	COMPETENCIES							
<b>1. Provide Customer Services</b>								
<b>Task A:</b> Evaluate others' priorities and rank their urgency	a Display understanding of deadlines and other priorities	b Use planning skills (e.g., scheduling)	c Use time management skills	d Use task analysis skills to determine priorities	e Learn about company culture, objectives, goals, structure in order to understand big picture	f Manage projects to meet deadlines	g Use communication skills	h Be realistic about what you can achieve
<b>Task B:</b> Troubleshoot/negotiate	a Define issues clearly to your clients and your manager	b Demonstrate familiarity with issues	c Dig for facts to understand full picture and respond correctly	d Use diplomacy/people skills	e Learn about company culture, objectives, goals, structure; understand big picture			
<b>Task C:</b> Train customers	a Teach classes (e.g., revisions of SOPs)	b Provide one-on-one training	c Develop lesson plans (write materials, create presentations)	d Record that training was done	e Assess training; modify if necessary; provide retraining			
<b>Task D:</b> Provide technical support	a Respond to questions	b Provide knowledge on system subject	c Use database skills					
<b>Task E:</b> Provide electronic copies of SOPs	a Provide customers with e-copies	b Use knowledge of system to meet needs						
<b>Task F:</b> Provide weekly list of document changes	a Implement knowledge of system/subject matter, etc.	b Use task management skills	c Use e-mail system					
<b>Task G:</b> Maintain smooth interdepartmental relationships	a Use people skills	b Attend meetings with customers						
<b>Task H:</b> Communicate department's policies, schedules, and priorities to other departments	a Acquire and develop speaking skills	b Demonstrate knowledge of system/subject matter, etc.	c Communicate departmental philosophy					

JOB FUNCTIONS	COMPETENCIES							
<b>2. Manage Documentation/ Information and Records</b>								
<b>Task A:</b> Process documents	a Use computer skills	b Be able to proofread/edit documents, using common proofreading marks	c Pay attention to detail	d Manage work flow	e Communicate with change agents/ approvers, etc.	f Know and follow deadlines		
<b>Task B:</b> Archive, retrieve, determine retention, authorize destruction of records	a Follow procedures/policies	b Maintain orderly system	c Meet and understand deadlines					
<b>Task C:</b> Control official documentation	a Follow SOPs	b Train new administrators/users	c Know about, follow company culture, goals, structure in order to understand big picture	d Learn and use database/computer skills	e Learn and use audit skills/knowledge to audit documents			
<b>Task D:</b> Issue and review batch records	a Pay attention to detail (such as math calculations, all blocks filled in)	b Proofread documents	c Learn and use math skills (sig figs, etc.) to verify calculations, formulas, etc.	d Read documentation and attend training to understand process	e Use time management skills	f Display flexibility in responding to shifting work loads		
<b>Task E:</b> Review incoming materials for accuracy and compliance	a Learn and understand other departments' procedures, as well as own	Pay attention to detail	c Follow procedures/policies	d Use judgment skills to ensure proper attachments, signatures, etc., are there				
<b>Task F:</b> Create and maintain official document books; provide training copies of documents; conduct periodic reviews	a Use database skills	b Follow SOP for creating and maintaining document books	c Negotiate delivery, creation, content	d Provide customer service				
<b>Task G:</b> Issue part numbers; create packet for materials management	a Follow SOP procedures for creating part numbers	b Practice organization skills	c Present packets to reviewers and approvers					
<b>Task H:</b> Facilitate document approvals	a Guide work flow by negotiating timelines	b Maintain awareness of deadlines	c Exercise understanding of approval process					
<b>Task I:</b> Enter data into databases and spreadsheets for tracking/trending purposes	a Use database skills to enter data to create reports (e.g., Excel)	b Use computer skills to retrieve data and monitor trends	c Follow procedures					

JOB FUNCTIONS	COMPETENCIES							
<b>Task J:</b> Order supplies and maintain inventories	a Develop familiarity with system used to order supplies	b Monitor/participate in budgeting (some general accounting)	c Maintain inventory	d Anticipate need/demand	e Follow up with vendor			
<b>3. Train New Employees, Outside Vendors, Incumbent Workers, Temporary Workers</b>								
<b>Task A:</b> Train customers	a Develop a lesson plan	b Provide one-on-one training	c Record training					
<b>Task B:</b> Train employees and staff	a Train to use new software	b Educate staff about other departments' systems	c Train and mentor new colleagues	d Educate and train superiors	e Use presentation skills to train new employees			
<b>Task C:</b> Train staff on GMPs	a Develop a strong subject-matter knowledge	b Attend and actively participate in outside courses on GMPs	c Pursue continued education	d Learn how to translate GMPs to practical applications				
<b>4. Comply with Regulations</b>								
<b>Task A:</b> Maintain device master files	a Use database skills to enter/retrieve data	b Know and use both documenting and manufacturing process	c Develop interdepartmental relationships					
<b>Task B:</b> Write policies/procedures in accordance with regulations	a Maintain knowledge of regulations (read, review, comprehend)	b Use writing skills	c Use computer skills	d Use industry standards				
<b>Task C:</b> Perform and support internal audits	a Pay attention to detail	b Use communication skills	c Use diplomacy when dealing with people being audited	d Train in audit techniques	e Create and maintain spreadsheets	f Maintain files	g Understand and follow procedures/policies	
<b>Task D:</b> Review and approve nonconformance reports	a Pay attention to detail	b Know company's processes	c Know and follow regulations	d Use computer skills				
<b>Task E:</b> Support regulatory affairs	a Use spreadsheet database skills	b Maintain files	c Analyze data	d Provide customer service	e Use knowledge of regulations			
<b>Task F:</b> Keep current training record files	a Attend training	b Follow regulations/procedures/policies	c Be attentive to QA documentation revisions to keep training records current					
<b>Task G:</b> Adhere to SOPs	a Follow SOPs for various procedures							

JOB FUNCTIONS	COMPETENCIES							
<b>5. Provide Technical Support to Internal Customers</b>								
<b>Task A:</b> Process documents	a Use office equipment and systems	b Use databases	c Manage work flow					
<b>Task B:</b> Use and provide metrics	a Use and improve database skills	b Use data analysis skills	c Determine purpose of metrics					
<b>Task C:</b> Maintain systems (user accounts, passwords, back-ups)	a Maintain knowledge of systems	b Follow SOPs	c Interact with help desk	d Know and use software changes (upgrades, etc.)	e Demonstrate communication skills	f Know and use regulations		
<b>Task D:</b> Train on QA doc tools (templates, forms, etc.)	a Use word processing skills	b Know and use systems						
<b>Task E:</b> Translate documents and process changes	a Acquire foreign language skills or use computer translation system	b Use work processing skills						
<b>Task F:</b> Provide style guides	a Know and use English style and usage							
<b>6. Manage People</b>								
<b>Task A:</b> Implement HR policies	a Maintain knowledge of HR policies	b Maintain knowledge of HR resources (e.g., templates, forms, trainings, etc.)	c Maintain knowledge of big picture (i.e., know what's coming/future corporate goals)	d Maintain awareness of corporate philosophy	e Approve timesheets, vacation requests, medical leaves; make use of HR resources	f Conduct performance reviews; motivate employees to develop careers	g Know labor laws	
<b>Task B:</b> Manage daily activities	a Establish work goals	b Demonstrate leadership skills	c Communicate with and know your staff	d Assess skill sets (e.g., future project, new position, etc.)	e Give and receive constructive feedback	f Encourage development of staff skills	g Motivate employees	h Set example of work ethic for staff
<b>Task C:</b> Resolve disputes	a Use conflict management skills	b Practice diplomacy	c Be assertive	d Respond to problems immediately				
<b>Task D:</b> Promote career development; mentor staff	a Maintain knowledge of career options	b Utilize HR resources	c Provide career development skills to employees					

JOB FUNCTIONS	COMPETENCIES							
<b>Task E:</b> Counsel employees	a Use communication skills	b Use listening skills	c Have patience	d Be able to tolerate different behavioral styles				
<b>7. Manage Project</b>								
<b>Task A:</b> Plan priorities and events (e.g., define, measure, analyze)	a Use organizational skills	b Demonstrate communication skills	c Follow through to realize goals	d Apply knowledge of big picture	e Interact with other departments	f Practice leadership skills	g Apply knowledge of personal styles/ behaviors/skills of the group	h Follow timelines and meet deadlines
<b>Task B:</b> Troubleshoot problems in work	a Use negotiation skills	b Use prioritization skills	c Be assertive	d Be creative	e Use problem solving, critical thinking, etc.	f Be flexible		
<b>8. Observe Safety Standards</b>								
<b>Task A:</b> Prepare workers' compensation incident reports	a Prepare reports using knowledge of requirements							
<b>9. Maintain Own Professional Development</b>								
<b>Task A:</b> Keep up credentials	a Maintain understanding of industry standards	b Attend classes that support your professional development	c Keep updated on literature	d Complete paperwork for credentials, etc.				
<b>Task B:</b> Read industry literature	a Obtain literature	b Relate literature to your work						
<b>Task C:</b> Learn new systems	a Attend development courses	b Be able to budget as needed	c Work on cross-functional teams	d Maintain understanding of industry norms	e Train others on new systems			
<b>Task D:</b> Develop leadership skills	a Attend courses	b Use presentational skills	c Practice leadership skills					
<b>Task E:</b> Develop time management skills	a Attend development courses	b Practice time management skills	c Learn from others (or trial and error)					

**Knowledge, Skills, and Equipment  
QA Documentation Coordinator**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Algebra.....B            Biology.....B            Business Management              (Basics; Budget; Cost-Benefit              Analysis Economics) .....I            Computer Skills and              Microcomputer              Applications (MS Office) .....A            English            Logic/Critical Thinking/              Cause Analysis .....B            Regulatory Affairs .....B            Social Science (Ethics,              Psychology, Sociology) .....I            Statistics .....B            Technical Writing.....B</p>	<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required:</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Aseptic Technique (Gowning;              Laminar Flow Hoods; BSCs) ..... B            Corrective and Preventive              Action..... B            GMPs ..... B            Office Equipment Operation ..... I            Plant or Material Flow              (Dirty/Clean) ..... B            Technical Reading and              Writing ..... B            Time Management ..... I</p>	<p>Archiving Boxes            Archiving Equipments (Microfilming Cameras, Readers, CDs,              etc.)            Binders            Binding Machine            Computer            Copier            Copy Paper            Copy Stamps, Date Stamps, etc            Database Software (Access, Filemaker Pro, Oracle)            Excel            Fax Machine            File Cabinets (Fire Proof)            Files &amp; Folders            Hanging Folders            Label Maker            Labels            LCD Projector            Master Paper            Materials Management Software            Ms Word            Overhead Projector            Powerpoint            Printer            Project            Proprietary Software (Document Management Software)            Scanner            Shredders            Staple Removers            Three Hole Punch            Tools            Visio</p>

**Job Functions, Tasks, and Competencies of FACILITIES TECHNICIAN**

Performs daily monitoring, repair, and preventive maintenance activities on critical systems and equipment; troubleshoots, installs, evaluates, and modernizes new and existing systems.

JOB FUNCTIONS	COMPETENCIES				
<b>1. Conduct Testing</b>					
<b>Task A:</b> Test boiler water	a Test for pH	b Conduct testing	c Test for phosphate	d Know how to test sulfite	
<b>Task B:</b> Test vessels and systems for leaks	a Test for pressure	b Conduct hydro test			
<b>Task C:</b> Test conductivity of RO water (pharmaceutical waters)	a Test pharmaceutical waters	b Sample pharmaceutical waters			
<b>Task D:</b> Test system alarms	a Test reverse osmosis alarm system	b Provide water for injection alarm testing	c Test boiler alarm	d Maintain knowledge of waste treatment alarms	e Maintain knowledge of Biokill alarm testing
<b>Task E:</b> Test filter integrity	a Pre-test filters	b Post-test filters			
<b>Task F:</b> Test component functionality	a Perform static and dynamic tests of pumps, agitators, seals, motors, flow control valves, etc.				
<b>2. Provide Customer Service</b>					
<b>Task A:</b> Fulfill work order requests	a Receive work order	b Prioritize and schedule work	c Perform the requested work	d Follow up on the work you performed	
<b>3. Perform Documentation</b>					
<b>Task A:</b> Perform daily equipment readings	a Conduct readings of air compressors and air dryers	b Monitor boiler readings	c Take water treatment readings	d Build management system readings and alarms	
<b>Task B:</b> Develop, review, revise and update of SOPs	a Review SOPs	b Revise SOPs	c Perform all work according to SOPs and cGMPs.		
<b>Task C:</b> Use GMPs when working with all documentation	a Ensure operational log paperwork, daily log files, and work order documentation is completed with accurate information				
<b>4. Obtain and Maintain Permits</b>					
<b>Task A:</b> Obtain hot work permits	a Perform a work assessment	b Obtain required approvals			
<b>Task B:</b> Obtain confined entry permits	a Perform a work assessment	b Perform air sampling	c Obtain required approvals		
<b>Task C:</b> Obtain excavation permits	a Perform a work assessment	b Obtain required approvals			
<b>5. Provide Training for Employees</b>					
<b>Task A:</b> Provide and support peer training	a Facilitate job shadowing for new hires	b Facilitate job shadowing or training of processes on new equipment			

JOB FUNCTIONS	COMPETENCIES				
<b>6. Comply with Regulations</b>					
<b>Task A:</b> Observe and comply with CFR (Code of Federal Regulations)	a Learn which federal regulations apply to your job, tasks, and industry	b Perform all jobs according to applicable federal regulations			
<b>Task B:</b> Observe and comply with cGMPs	a Learn the cGMPs that apply to your job, tasks, or industry	b Perform all tasks according to cGMPs			
<b>Task C:</b> Observe and follow all applicable SOPs	a Follow all pertinent SOPs (may be more than one SOP per task)				
<b>7. Provide Technical Support</b>					
<b>Task A:</b> Assist in cause analysis	a Perform root cause analysis	b Gather and compile information	c Perform failure analysis	d Troubleshoot miscellaneous equipment and systems	
<b>Task B:</b> Support plant engineering on projects	a Help start-up of new equipment	b Evaluate new processes and equipment	c Fabricate and install new systems and equipment		
<b>8. Perform/ Support Validation</b>					
<b>Task A:</b> Assist with the development and lead in the execution of validation documents for mechanical equipment	a Assist with start-up of new equipment to ensure it meets all mechanical design specifications				
<b>9. Perform Systems and Equipment Maintenance</b>					
<b>Task A:</b> Perform root analysis of utility, process and HVAC related equipment/ systems	a Use critical-thinking, brainstorming, and cause-analysis methods	b Use CMMS (computerized maintenance management systems)			
<b>Task B:</b> Perform preventive and corrective maintenance on process systems	a Use reliability-centered maintenance	b Adhere to SOPs and cGMPs.	c Use CMMS (computerized maintenance management systems)		
<b>Task C:</b> Perform Preventive and Corrective maintenance of utility systems	a Use reliability-centered maintenance	b Follow SOPs and cGMPs	c Use CMMS (computerized maintenance management systems)		
<b>Task D:</b> Perform component-level repairs, rebuilds, and maintenance	a Use OEM (original equipment manufacturer) manuals	b Use of reliability-centered maintenance practices	c Follow SOPs and cGMPs	d Use CMMS (computerized maintenance management systems)	
<b>Task E:</b> Maintain a working spare parts inventory	a Use OEM (original equipment manufacturer) manuals	b Use CMMS (computerized maintenance management systems)	c Contact and interact with approved vendors	d Track and order spare parts and components	
<b>Task F:</b> Interpret and review utility, process system/equipment, plumbing, ductwork, architectural and HVAC P&IDs (piping and instrumentation diagrams)	a Read and comprehend system schematics	b Review and change P&IDs or system schematics			
<b>Task G:</b> Evaluate and optimize systems and components	a Offer ideas for system improvements				

JOB FUNCTIONS	COMPETENCIES				
<b>10. Comply with Environmental Regulations</b>					
<b>Task A:</b> Comply with EPA rules and regulations when disposing of waste products	a Dispose of waste oils and refrigerants	b Dispose of hazardous wastes			
<b>11. Maintain Safety of Systems</b>					
<b>Task A:</b> Monitor and maintain confined space entries	a Obtain required permits and authorization	b Perform required air monitoring	c Follow company specific procedures		
<b>Task B:</b> Perform hot work procedures	a Gather required equipment	b Obtain required permits and authorization	c Follow company-specific procedures		
<b>Task C:</b> Conduct Lockout Tagout	a Obtain required permits and authorization	b Lock out and tag out all potential energies	c Fill out forms and file according to procedures		
<b>Task D:</b> Perform continual housekeeping	a Maintain an orderly and clean working area				
<b>12. Manage People</b>					
<b>Task A:</b> Communicate with peers	a Effectively communicate ideas through verbal and written forms				
<b>Task B:</b> Interact with peers	a Interact constructively with peers and teams				
<b>Task C:</b> Collaborate with peers and vendors	a Collaborate and coordinate with outside vendors				
<b>13. Manage Information</b>					
<b>Task A:</b> Write SOPs	a Write clear and concise technical documents using technical writing skills.				
<b>Task B:</b> Make logbook entries	a Make all needed entries in logbooks				
<b>Task C:</b> Share information	a Communicate job-related information with peers and other shifts using e-mail, logbooks, etc.				
<b>Task D:</b> Obtain information required to perform work	a Find any needed information that would be helpful with cause analysis and troubleshooting	b Find information needed to order replacement components and parts			

**Knowledge, Skills, and Equipment  
Facilities Technician**

Academic Knowledge	Technical Knowledge/Skills	Tools/Equipment
<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required</b> C – Conceptual P – Practical/Applied</p> <p align="right"><b>Level</b></p> <p>Algebra.....B            Biology.....B            Chemistry.....B            Computer Skills and .....                microcomputer                Applications (MS Office) .....I                Regulatory Affairs .....I            English.....I            Environmental Science.....B            Health Science/                Industrial Hygiene .....B            Logic/Critical                Thinking/Cause                Analysis.....A            Microbiology.....B            Physics.....B            Social Science                (Ethics, Psychology,                Sociology) .....B            Statistics.....B            Technical Mathematics.....I            Technical Writing.....I</p>	<p><b>Key to Knowledge/Skill Level Required:</b> B – Basic I – Intermediate A – Advanced</p> <p><b>Key to Type of Knowledge/Skill Required</b> C – Conceptual P – Practical/Applied</p> <p>Aseptic Technique (Gowning;                Laminar Flow Hoods; BSCs) ..... A            Autoclave Theory/Practice.....I            Boilers.....A            Chemical Handling.....B            CIP; SIP .....I            Clean Steam Generators .....A            Depyrogenation.....I            Electricity/Electronics .....I            Fall Prevention (Heights) .....A            GMPs .....I            Hydraulics .....A            Instrumentation (Process                Controls and Calibration) .....I            Lock-Out/Tag-Out (LOTO) .....A            Lyophilization .....B            Mobile Elevated Work Platforms.....A            Office Equipment Operation .....I            Pharmaceutical Grade Waters                (WFI; Water Pre- Treatment; Reverse                Osmosis, DI) .....A            Plant or Material Flow                (Dirty/Clean) .....A            Pneumatics .....A            Powered Industrial Vehicles.....A            Pumps.....A            Sanitization .....I            Technical Reading and Writing.....I            Valves (Check Valves; Flow                Control Valves, etc.).....A            Waste Water Treatment.....A</p>	<p>Arbor Presses            Bearing Heaters            Bore Scope            Chemical Test Kits            Chlorine Test Kit            Conductivity Meters            Confined Space Entry/Retrieval Equipment            Fall Arrest Equipment            Flow Gauges            Gasket Cutters            Gear Pullers            Hand Tools            Hoists            Hydraulic Presses            Laser Aligners            Levels            Micrometers            Multimeters            Ph Meters            Pipe Threading Equipment            Power Tools            Precision Measuring Equipment            Pressure Gauges            Profilometers            Pyrometer            Silt Density Index            Thermo Graphic Cameras            Torches            Vacuum/Pressure Pumps            Vibration Analyzers            Water Softener Test Kit            Welding Equipment</p>