

Competencies Master List	QC CHEM	QC MICRO	MANUF UP	MANUF DOWN	MAINT
Computer Use					
Use word processing software.	x	x	x	x	x
Use spreadsheet software.	x	x	x	x	x
Use process automation software (DCS, PLC, BAS).	x	x	x	x	x
Understand and recognize use of data management software.	x	x	x	x	x
Use computerized management systems (CMMS, LIMS).	x	x	x	x	x
Understand and recognize use of CAD software.					x
Career Skills					
Understand basic project management methodologies.	x	x	x	x	x
Apply professional and technical communication skills.	x	x	x	x	x
Understand basic leadership skills and qualities.	x	x	x	x	x
Set, organize, and adjust workload based on priorities.	x	x	x	x	x
Apply interpersonal communication skills (active listening, oral, written communication).	x	x	x	x	x
Apply customer service skills in working with internal and external partners.	x	x	x	x	x
Critical Thinking					
Critical Thinking Skills					
Apply basic troubleshooting and systematic problem solving skills to work-specific issues.	x	x	x	x	x
Understand methods of investigating the root cause of a production or quality issue.	x	x	x	x	x
Understand basic troubleshooting and problem solving tools and methodologies including FMEA, Fault Tree, Root Cause analysis, SPC.	x	x	x	x	x
Understand CAPA, Six Sigma, and LEAN practices in the biopharmaceutical manufacturing industry.	x	x	x	x	x
Locate and apply information from software user requirements, software specifications, equipment/instrumentation manuals, and other documentation.					x

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Regulatory, Safety, and Environmental Compliance					
Regulatory (cGMP, FDA, etc..)					
Apply and understand batch records and related documentation.	x	x	x	x	x
Understand rationale and methodology for change control when revising documents or procedures.	x	x	x	x	x
Understand SOP writing practices.	x	x	x	x	x
Use of SOPs.	x	x	x	x	x
Understand the consequences of non-compliance.	x	x	x	x	x
Apply GMP documentation practices for recording data including not back dating documents, not forging, proper time/date format, documentation from source, and not falsifying data.	x	x	x	x	x
Ensure that all batch record steps are signed and verified by a present verifier.	x	x	x	x	x
Ensure that most recent version of SOP, batch record, or other document is used.	x	x	x	x	x
Understand working in a GLP environment.	x	x	x	x	x
Knowledge of typical types of documentation related to facilities and equipment. Examples include maintenance logs, calibration certificates, out of tolerance reports, and installation reports.	x	x	x	x	x
Knowledge of electronic documentation (control and data capture storage systems) practices.	x	x	x	x	x
Knowledge of the FDA 6 systems concept.	x	x	x	x	x
Knowledge of use and history of key regulatory guidance documents including 21 CFR Part 11, 210, 211, 600 Subparts A-D, Sterile Drug Products Prod. By Aseptic Proc., FDA Guidance August 2003, EC Guide on Good Mfg. Practice written by the European Commiss	x	x	x	x	x
Knowledge and use of the United States and European Pharmacopoeia.	x	x	x	x	
Knowledge of ISA and BPE standards.			x	x	x
Principles of ISO standards related to maintenance and repair functions			x	x	x

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Regulatory, Safety, and Environmental Compliance (CONTINUED)					
Safety					
Understand and apply basic methods for the safe handling, transport, and storage of biological and chemical materials.	x	x	x	x	x
Understand and apply basic methods for handling hazardous waste.	x	x	x	x	x
Understand and apply Lock-out/Tag-out and line breaking procedures.	x	x	x	x	x
Understand Fall protection (heights).	x	x	x	x	x
Understand and apply Confined space entry methods.	x	x	x	x	x
Understand and use Personal Protective Equipment as required.	x	x	x	x	x
Understand the purpose and procedures associated with Safety audits.	x	x	x	x	x
Understand and apply OSHA regulations.	x	x	x	x	x
Understand basic disinfection and sterilization methods.	x	x	x	x	x
Participate in emergency drills and response teams.	x	x	x	x	x
Identify hazards in the workplace.	x	x	x	x	x
Identify spills/leakages.	x	x	x	x	x
Identify emergency equipment.	x	x	x	x	x
Understand and locate information in an MSDS.	x	x	x	x	x
Understand different biosafety levels.	x	x	x	x	x
Understand rationale behind machine grounding and use of fail-safe devices.	x	x	x	x	x
Environmental					
Understand environmental regulations and plant waste processing systems.	x	x	x	x	x
General Industry Knowledge					
Industry Overview					
Understand the biomanufacturing and pharmaceutical industry, including understanding of the typical product development and manufacturing process, as well as the regulatory environment.	x	x	x	x	x
Appreciate the design and validation of biomanufacturing and/or other types of pharmaceutical manufacturing facilities.			x	x	x
Understand common materials of facility construction Knowledge of principles of adjacency and flow in pharmaceutical operations			x	x	x
Understand and apply principles of adjacency, flow, and product segregation in pharmaceutical operations.			x	x	x
Validation					
Understand principles of validation, commissioning, and qualification.	x	x	x	x	x
Execute IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment	x	x	x	x	x
Understand the principles involved in choosing key process parameters to validate and setting operational specifications.	x	x			
Understand the principles involved in validating new analytical methods					x

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General Plant Operations					
Plant Utility Systems					
Understand, locate, and use different types of water used in pharmaceutical operations (DI, WFI, USP).	x	x	x	x	
Understand, locate, and use different types of waste collection and processing systems.	x	x	x	x	
Understand and evaluate HVAC room classifications.	x	x	x	x	
Understand, locate, and use different types of air and other process gases used in pharmaceutical operations.			x	x	
Understand the use of chilled water in a process.			x	x	
Understand, prepare, and use CIP solutions.			x	x	
Understand, prepare, and use SIP systems.			x	x	
Understand power distribution schemes and electrical systems.			x	x	
Perform mechanical repairs to plant equipment and utility systems including: pumps, valves, agitators, fans, bearings, couplings, filters, belt drives, mechanical seals, hoists, hydraulics, pneumatics, on-off actuators, diaphragms, filters, fasteners, al			x	x	
Sample equipment and utility fluids.			x	x	x
Process Equipment					
Use data logging devices.	x	x	x	x	
Understand and use different types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing.			x	x	
Understand the characteristics of materials used in pumps, piping, tanks, and valves.			x	x	
Understand the principles of piping and pump sizing.					x
Understand general concepts of pipefitting, fabrication, welding, and passivation as applied in pharmaceutical operations and other principles of sanitary piping installation.					x
Process Control					
Understand and use instrumentation for monitoring common process parameters including flow, level, temperature, pressure, mass, pH, and DO.			x	x	x
Understand the principles and typical role different process automation and control systems (PLC, SCADA and/or DCS) play in the manufacturing process.	x	x	x	x	x
Use a process automation and control system to select and download a method.			x	x	x
Use a process automation and control system to enter process specific parameters			x	x	x
Use a process automation and control system to monitor processes and acknowledge prompts.			x	x	x
Understand the basis for statistical process control and trending analysis.			x	x	x
Understand how to calibrate process instrumentation.			x	x	x

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General Plant Operations (CONTINUED)					
Reading P&IDs					
Understand, define, and identify different equipment, instruments, valves, and utilities symbols typically represented on a P&ID.			x	x	x
Identify system boundaries using a P&ID.			x	x	x
Use a P&ID to verify the location/installation of equipment.					x
Read isometric drawings.					x
Use a P&ID to identify piping use material and specifications.					x
Redline a P&IDs appropriately.					x
Sterilization and Cleaning					
Understand the general principles and types of chemical and physical cleaning, disinfection, and sterilization.	x	x	x	x	x
Understand and explain the rationale for using different cleaning agents.	x	x	x	x	x
Understand and/or apply methods for sterilizing vessels, transfer lines, sample device/ports.	x	x	x	x	x
Understand and/or apply methods for performing CIP operations.	x	x	x	x	x
Understand and/or apply methods for performing SIP operations.	x	x	x	x	x
Explain the types of cleaning equipment used in your area		x	x	x	
List the disinfectant agents & cleaning agents used in your area.		x	x	x	
Identify and explain sterilisation methods used in your area.		x	x	x	
Understand the use of WFI flush monitoring to demonstrate cleaning effectiveness.			x	x	x
Understand steam sterilization theory (Bowie Dick test).			x	x	
Understand the rationale behind clean & sterile holding times.			x	x	
Equipment/System Repair					
Perform mechanical repairs to valves, actuators, agitators, fans, bearings, couplings, belt drives, and mechanical seals.					x
Perform mechanical repairs to hoists, hydraulic and pneumatic equipment					x
Perform mechanical repairs to lectrical and pneumatic control circuits and actuators.					x
Calibration					
Calibrate and adjust all types of control valves, actuators, and positioners			x	x	
Calibrate process instrumentation measuring common parameters including temperature, pressure, flow, level, weight, mass, pH, and DO			x	x	
Calibrate and adjust laboratory equipment.	x	x	x	x	
Understand and use of NIST standards in calibrating analytical instrumentation.	x	x	x	x	

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Aseptic Processing					
General Microbiology					
understand what is meant by aseptic technique and the consequences of error.	x	x	x	x	x
Identify and explain behavioural requirements in a controlled environment.	x	x	x	x	x
Transfer equipment and material into area as per procedure.	x	x	x	x	x
Identify areas where human contamination may occur.	x	x	x	x	x
Understand and demonstrate how you would prevent human contamination.	x	x	x	x	x
Understand what is meant by intervention / aseptic manipulation and when it is applied.	x	x	x	x	x
Perform intervention/ aseptic manipulation as per requirements.	x	x	x	x	x
Identify consequences of not behaving appropriately.	x	x	x	x	x
Explain what is meant by a sterile product.	x	x	x	x	
Identify and explain different types of microorganisms and their environments.		x	x	x	
Identify methods of controlling microorganisms.		x	x	x	
Identify and explain area classification and methods of control.		x	x	x	
Identify and briefly explain types of microbial product testing methods.		x	x	x	
Gowning / Cleanroom Work					
Understand and explain the use of personal protective equipment required in working with biohazards.	x	x	x	x	x
Demonstrate proper gowning procedures for cleanroom work.	x	x	x	x	x
Understand and explain basic precautions workers must take to prevent contamination of cleanroom environments and state that worker error is the chief casue of contamination.	x	x	x	x	x
Apply knowledge of basic hygiene and microbiology to ensure cleanliness.	x	x	x	x	x
Understand and define different room classifications.	x	x	x	x	x
Understand the Importance of maintaining positive pressure.	x	x	x	x	x
Identify and explain behavioural requirements in a controlled environment.	x	x	x	x	x
Transfer equipment and material into area as per procedure.	x	x	x	x	x
Identify areas where human contamination may occur.	x	x	x	x	x
Understand and demonstrate how you would prevent human contamination.	x	x	x	x	x
Understand what is meant by intervention / aseptic manipulation and when it is applied.	x	x	x	x	x

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Unit Operations / Manufacturing Methods					
Upstream Bioprocessing (Large-Scale)					
Understand and define different types of growth media.			x		
Prepare growth media for use.			x		
Explain the basics of cell biology (mammalian and bacterial) and the genetic modification processes that enable biopharmaceutical manufacture			x		
Explain the cell culture techniques and processes used to grow cells (mammalian/bacterial) for product manufacture			x		
Understand principles of pasteurization and flow-through sterilization.			x		
Understand the principles of bioreactor/fermenter operation (mammalian and microbial cells).			x		
Inoculate seed reactors, perfusion reactors, and production reactors.			x		
Operate a laboratory-scale bioreactor (mammalian and microbial cells).			x		
Operate a production-scale bioreactor (mammalian and microbial cells).			x		
Understand and explain the principles and techniques involved in operating a production-scale bioreactor.			x		
Understand and explain techniques for harvesting bioreactors.			x		
Understand techniques for preserving and maintaining cultures.			x		
Understand techniques for detecting bioreactor or culture contamination.			x		
Downstream Bioprocessing (Large-Scale)					
Understand and explain techniques for cell disruption (pressure and mechanical lysis).				x	
Perform and demonstrate cell disruption (pressure and mechanical lysis) techniques.				x	
Understand and explain techniques for centrifugation.				x	
Perform and demonstrate centrifugation techniques.				x	
Understand and explain techniques for depth filtration.				x	
Perform and demonstrate depth filtration techniques.				x	
Understand and explain techniques for membrane filtration (micro/ultra/nano/RO/diafiltration).				x	
Perform and demonstrate membrane filtration (micro/ultra/nano/RO/diafiltration) techniques.				x	
Understand and explain different types of chromatography (affinity, ion-exchange, HIC, size-exclusion, metal chelating, measurement of column efficiency)				x	
Understand column packing procedures (assembling column, sanitizing column body, slurry resin, pack resin, and test/prepare for process use).				x	
Demonstrate column packing procedures (assembling column, sanitizing column body, slurry resin, pack resin, and test/prepare for process use).				x	
Understand and explain techniques for precipitation.				x	
Perform and demonstrate precipitation techniques.				x	

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Laboratory Work					
Basic Laboratory Techniques					
Obtain and/or sample materials with an understanding of methods and environments.	x	x	x	x	
Understand and apply basic material handling, storage, and monitoring techniques.	x	x	x	x	
Sterilize solutions by autoclaving and filtration.	x	x	x	x	
Measure weights and volumes accurately.	x	x	x	x	
Select, use, prepare, and clean basic laboratory glassware and other containers.	x	x	x	x	
Use a laboratory-scale autoclave.	x	x	x	x	
Understand and apply basic disinfection techniques.	x	x	x	x	
Prepare basic solutions and dilution.	x	x	x	x	
Prepare buffers.	x	x	x	x	
Filter solutions.	x	x	x	x	
Understand and apply pH adjustment techniques.	x	x	x	x	
Understand basic physical chemistry, theory, safety, use of radioactive material (14C, 32P).	x	x	x	x	
Use a laboratory-scale water bath.	x	x			
Use glassware washers.	x	x			
Use depyrogenation oven.	x	x			
Understand, use, and apply aseptic laboratory techniques.	x	x			
Use a pipette.	x	x			
Perform basic laboratory tests including conductivity and UV/VIS.	x	x			
Prepare reference standards.	x	x			
Understand, use, and apply standard curves.	x	x			
Laminar Flow Hoods					
Understand the principles and purpose of biological safety cabinets (VLAFC) usage.	x	x	x	x	
Identify activities in your work environment, which are performed within a biological safety cabinet (VLAFC).		x	x	x	
Set up and use biological safety cabinet (VLAFC) as per procedure.		x	x	x	
Explain biological safety cabinet (VLAFC) cleaning requirements.		x	x	x	
Refrigerator/Incubator					
Understand the principles and purpose of refrigerator / incubator usage.	x	x	x	x	
Identify the location and temperature ranges of the refrigerators/ incubators in your laboratory.	x	x	x	x	
Understand the requirement for refrigerator / incubator calibration checks	x	x	x	x	
Perform equipment calibration checks as per procedure	x	x	x	x	
Set Up and use refrigerator / incubator as per procedure.	x	x	x	x	
Explain refrigerator / incubator cleaning requirements.	x	x	x	x	

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Laboratory Work (CONTINUED)					
Chromatography (Lab Scale)					
Understand principles, types, and applications of laboratory-scale chromatography.	x	x		x	
Prepare and pack chromatography column.	x	x		x	
Test chromatography column.	x	x		x	
Collect and pool fractions.	x	x		x	
Cell Culture/ Fermentation (Lab Scale)					
Inoculate cultures into vials and spinner flasks.		x	x		
Identify the different parts/components of a bioreactor.		x	x		
Assemble and prepare a laboratory-scale bioreactor for use.		x	x		
Basic Microbiological Techniques.					
Understand the principles and purpose of streaking out plates.		x			
Identify hazards and risks in preparation of the area and equipment		x			
Prepare area and equipment as per procedure.		x			
Streak plates as per procedure.		x			
Post streaking, ensure plates are labelled appropriately and processed as per procedure (if applicable).		x			
Identify common problems experienced during streaking of plates.		x			
Perform techniques for colony isolation.		x			
Perform techniques for staining cells.		x			
Microscopy					
Understand the principles behind different microscopy techniques (SEM, AFM, TEM, fluorescence, and immunohistochemistry).	x	x	x	x	
Perform and use SEM techniques.	x		x	x	
Perform and use AFM techniques.	x	x	x	x	
Perform and use TEM techniques.	x	x	x	x	

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Laboratory Work (CONTINUED)					
Environmental and Process Monitoring					
Understand principles behind use environmental monitoring of air (total air/ viable air) and surfaces.	x	x	x	x	
Perform water quality monitoring and chemical testing of steam and cooling water systems.	x	x	x	x	
Perform sterility testing, total organic carbon [TOC] assays, bioburden assays, and growth promotion testing.	x	x	x	x	
Perform microbial identification methods and virus testing.	x	x	x	x	
Perform endotoxin assays (Kinetic Turbidimetric and Endpoint Chromogenic LAL Assays).	x	x	x	x	
Use remote environmental monitoring systems.		x			
Use touch plates.		x			
Use microplate readers		x			
Sample total air / viable air particulates.		x			
Sample surfaces.		x			
Instrumentation					
Utilize analytical instrumentation, including: NMR spectrometry, mass spectrometry, gas chromatography, UV/Vis spectrophotometry, infrared spectrophotometry.	x	x	x	x	
Utilize process analytical technology (PAT) to monitor processes.	x	x	x	x	
Utilize predictive technologies (vibration analysis, laser alignment)					x
Biochemical assays					
Perform immunoassays (ELISA, RIA, and Western blots).	x	x			
Perform PCR.	x	x			
Perform HPLC and conventional chromatography, including metal chelate and other affinity separations as well as ion-exchange, hydrophobic interaction, and size exclusion chromatography.	x	x			
Perform electrophoresis (SDS-PAGE and iso-electric focusing, as well as capillary electrophoresis).	x	x			
Perform protein functional assays, including enzyme assays; and protein quantification assays, including BCA and Biuret.	x	x			
Perform FACS (fluorescence activated cell sorting). Use a fluorescence laminator.	x	x			
Analyze and interpret data from biochemical assays.	x	x			
Other analytical work					
Perform manual and automated colorimetric assays and titrations.	x	x			
Perform tests for measuring pH, conductivity, ionic strength, and heat sensitivity.	x	x			
Use a refractometer.	x	x			
Characterize products by performing dry weight determinations, stability testing, dissolution assays and friability assays.	x	x			
Perform inorganic chemical analyses.	x	x			
Perform flame tests.	x	x			