# Job Functions, Tasks, and Competencies of CHEMISTRY QUALITY CONTROL TECHNICIAN

**Occupational Description:** Performs a variety of inspections, checks, tests, and sampling procedures for the manufacturing process according to standard operating procedures (SOPs). Performs in-process inspection and documents results. Monitors critical equipment and instrumentation. Writes and updates inspection procedures and checklists as necessary. Requires knowledge of current good manufacturing practices (GMPs).

**Term: Competency based (2,000 Minimum Hours)**

**On-The-Job Learning (OJL):** The following competency areas have been identified to lend focus and direction to the professional development of Chemistry QC Technician. The apprentice will attain a basic level of mastery across all competency areas before receiving certification. Basic mastery will be represented by the apprentices being able to articulate their learning with each competency area and demonstrate that they have successfully integrated all the competencies in their work. The order in which the apprentices learn will be determine by the flow of work on-the-job and will not necessarily be in the order listed. Times allotted to these various processes are estimated for the average apprentice to learn each phase of the occupation and demonstrate competency. They are intended only as a guide to indicate the quality of training being provided and the ability of the apprentice to absorb this training in an average amount of time. Due to the competency-based nature of the lab courses approved by the Northeast Biomanufacturing Collaborative up to 1,000 hours of lab time may be included toward completion hours.

| **COMPETENCIES/TASKS** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1. Test Samples** | | | | | | 300-450 hours | Date Exposed | Date Proficient |
| **Task A:** Collect sample | a Identify sample; inspect all sample parameters | b Remove sample with proper technique | c Label sample properly | d Store according to specifications | | | | |
| **Task B:** Determine appropriate testing | a Use familiarity with tests performed in the lab | b Look up in product SOP (Standards Operating Procedure) to determine testing | | | | | | |
| **Task C:** 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 | | |
| **Task D:** Review testing procedures | a Read procedure for clarity | b Acquire all necessary materials and equipment | | | | | | |
| **Task E:** Execute testing | a Set up labeled tubes | b Perform pipetting | c Dilute schemes with many variables | | | | | |
| **Task F:** Analyze data | a Correct and interpret results | b Look for aberrant results | c Determine assay validity | | | | | |
| **Task G:** Evaluate data with regard to specification | a Report results using appropriate medium | b Compare result to acceptance criteria | | | | | | |
| **Task H:** 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 | | | | | |
| **Task I:** Monitor data trending | a Evaluate data with regard to historical results | b Follow applicable procedure for out-of-trend results | | | | | | |

| COMPETENCIES/TASKS | | | | | | | | |
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| **2. Provide Customer Service (Internal)** | | | | | | 100-150 hours | Date Exposed | Date Proficient |
| **Task A:** Consult with appropriate department | a Provide input on scheduling | b Coordinate stat samples | c Give scientific background for situations | | | | | |
| **Task B:** Determine necessary testing | a Determine appropriate department for testing | b Identify correct test to monitor each parameter | | | | | | |
| **Task C:** Report result to appropriate departments | a Communicate results using appropriate system (paper, electronic, verbal) | | | | | | | |
| **Task D:** 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 | | | | | |
| **3. Control Documentation** | | | | | | 200-300 hours | Date Exposed | Date Proficient |
| **Task A:** Write SOPs (Standard Operating Procedures) | a Research procedure or product | b Follow Quality Assurance format for SOPs | c Technically write outline for procedure | d Ensure clarity and readability | | | | |
| **Task B:** Review SOPs (Standard Operating Procedures) | 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 | | | | | |
| **Task C:** Review data | a Review peer assay data for accuracy and GMP compliance | b Archive data in appropriate location | | | | | | |
| **Task D:** Review manufacturing documentation | a Check for accuracy of material content | b Ensure QC (Quality Control) sampling plan is correct | | | | | | |
| **Task E:** 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 | | | | |
| **Task F:** Write technical reports | a Make reports legible and clear | b Follow acceptable SOP for format | c Use appropriate software to defend conclusion | | | | | |
| **Task G:** 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 | | | | |
| **Task H:** Document routine activities | a Record daily calibration/ standardizations | b Record time for applicable cost codes | | | | | | |
| **Task I:** Participate in change control activities | a Give input of process changes | b Perform any changes to document approved system | c Justify changes to QA | | | | | |
| **Task J:** Archive documents/data | a Compile and organize data, assay forms, and other documents | | | | | | | |
| **4. Monitor Environmental Parameters** | | | | | | 160-240 hours | Date Exposed | Date Proficient |
| **Task A:** Monitor water quality | a Perform chemical tests on water samples | b Ensure within specifications for water quality | | | | | | |

| COMPETENCIES/TASKS | | | | | | | | |
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| **Task B:** Monitor controlled equipment | a Conduct daily check to ensure equipment operation in spec | b Call for service when necessary | c Troubleshoot when necessary | | | | | |
| **Task C:** Maintain environmental logs | a Check temperature on controlled areas | | | | | | | |
| **5. Obtain and Maintain Permits** | | | | | | 40-60 hours | Date Exposed | Date Proficient |
| **Task A:** 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 | | | | | |
| **6. Educate Employees** | | | | | | 160-240 hours | Date Exposed | Date Proficient |
| **Task A:** Facilitate new employee training | a Coordinate training tasks | b Schedule time for Q&A (Question and Answer) about assay | | | | | | |
| **Task 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 | | | | |
| **Task C:** Train employees in job-specific tasks | a Observe new analyst performing tests | b Review results and procedures | c Give feedback for improvement | | | | | |
| **Task D:** Maintain training records | a Document in compliant manner | b Store records in accessible location | c Know how to document training | | | | | |
| **Task E:** 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" | | | | | | |
| **7. Comply with Regulations** | | | | | | 200-300 hours | Date Exposed | Date Proficient |
| **Task A:** Follow all written procedures exactly | a Follow carefully all controlled documents and procedures | b Recognize that results not valid if established procedure not followed | | | | | | |
| **Task B:** Keep up on industry regulations/literature | a Research better alternative testing methods | | | | | | | |
| **Task C:** Review documentation for regulatory compliance | a Maintain awareness of changes in regulations | | | | | | | |
| **Task D:** 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 | | | | | |
| **8. Provide Technical Support** | | | | | | 200-300 hours | Date Exposed | Date Proficient |
| **Task A:** 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 | | | |

| COMPETENCIES/TASKS | | | | | | | | |
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| **Task 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 | | | | | |
| **Task C:** 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 | | | | | | |
| **Task D:** Troubleshoot at request of customer | a Identify test methods needed to be run | b Investigate any possible root cause of differences | | | | | | |
| **Task E:** Interact with vendors | a Use knowledge/skills to get vendors to work with you | b Accompany vendors while at site | | | | | | |
| **9. Perform and Support Validation** | | | | | | 160-240 hours | Date Exposed | Date Proficient |
| **Task A:** 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 | | | | |
| **Task B:** Execute validation procedures | a Perform needed studies | | | | | | | |
| **Task C:** 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 | | | | | |
| **Task D:** 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 | | | | | |
| **10. Maintain Systems and Equipment** | | | | | | 160-240 hours | Date Exposed | Date Proficient |
| **Task A:** Perform preventive maintenance (PM) | a Create/write PM schedule and protocol | b Order any required parts | c Perform maintenance | d Review peer maintenance | | | | |
| **Task 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 (preventative maintenance) schedule and protocol | f Document that calibration was performed | | |
| **Task C:** Schedule vendor maintenance | a Coordinate with vendor | b Ensure maintenance meets lab schedule | c Review vendor maintenance | d Document that maintenance was performed | | | | |
| **Task D:** Troubleshoot equipment failures | a Identify potential causes for failure | b Determine products/results affected by failure | | | | | | |
| **11. Conform to Health and Safety Procedures** | | | | | | 160-240 hours | Date Exposed | Date Proficient |
| **Task A:** Wear proper personal protective equipment | a Wear gloves, goggles, aprons, and respirator, as needed | | | | | | | |

| COMPETENCIES/TASKS | | | | | | | | |
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| **Task B:** Follow lab safety procedures | a Read and follow approved procedures | b Attend safety orientation | | | | | | |
| **Task C:** 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 | | | | | | |
| **Task D:** Maintain familiarity with MSDSs (Material Safety Data Sheet) | a Know where MSDSs are located | b Be familiar with chemical labels | | | | | | |
| **Task E:** Use hoods where appropriate | a Practice proper use of chemicals and procedures | b Perform all reactions that emit fumes in the hood | | | | | | |
| **Task F:** 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 | | | | | |
| **Task G:** Complete accident reports at time of occurrence | a Follow safety guidelines and procedures | b Report all incidents to supervisor and on official form immediately | | | | | | |
| **12. Comply with Environmental Regulations** | | | | | | 80-120 hours | Date Exposed | Date Proficient |
| **Task A:** 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 (Environment, Health and Safety) | c Dispose of materials in properly labeled containers | | | | | |
| **13. Manage People** | | | | | | 80-120 hours | Date Exposed | Date Proficient |
| **Task A:** 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 | | | | |
| **Task 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 | | | | |
| **Task C:** Perform peer/management period reviews | a Perform period reviews | b Follow procedures for adequate/ approved documentation | | | | | | |
| **Task D:** Participate in recruitment process | a Identify resources needed within the lab | | | | | | | |
| **Task E:** 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 | | | | |
| **Total OJL (On the Job Learning) Hours** | | | | | | | | **2,000 -3,000 hours** |

# Knowledge, Skills, and Equipment

## Chemistry QC Technician

### Academic Knowledge

**Key to Knowledge/Skill Level Required:**
B – Basic I – Intermediate A – Advanced

**Key to Type of Knowledge/Skill Required:**
C – Conceptual P – Practical/Applied

| | Level | Type |
|---|---|---|
| Algebra | B | C |
| Biology | B | C |
| Business Management (Basics; Budget; Cost-Benefit Analysis Economics) | I | P |
| Computer Skills and English | A | P |
| Logic/Critical Thinking/Cause Analysis | B | C |
| Microcomputer Applications (MS Office) | I | P |
| Regulatory Affairs | B | C |
| Social Science (Ethics, Psychology, Sociology) | I | P |
| Statistics | B | C |
| Technical Writing | B | P |

### Technical Knowledge/Skills

Aseptic Technique (Gowning; Laminar Flow Hoods; Biological Safety Cabinets BSCs)
Corrective and Preventive Action
GMPs (Good Manufacturing Practices)
Office Equipment Operation
Plant or Material Flow (Dirty/Clean)
Technical Reading and Writing
Time Management

### Tools/Equipment

AIEF Automated Isoelectric Focusing
Analytical/Guard Columns
Autoclave
Autotitrator
Balance
Centrifuge
Coagulation Analyzer
Concentrators
Conductivity Meter
Degasser
Densitometer
De-salting Columns
Dialysis Cassettes/Tubes
Electrochemical Detectors
FTIR Fourier Transform Infrared (spectroscopy)
Fume Hood
Gamma Counter
GC Gas Chromotagraphy
Gel Dry System
Turbidity Meter
Gel Power Packs
Glucose/Glutamine Meter
Heat Block
Hot Stir Plate
HPLC High Pressure Liquid Chromatography
Hydrometer
IEF Isoelectric Focusing
IEP Tanks
Immunodiffusion Plates
Immunodiffusion Viewer
Incubator
NIR Near Infra Red
NMR Nuclear Magnetic Resonance
Nutrient Meter (dO, NH3, dCO)
Osmometer
Ph Meter
Pipettors
Plate Reader
Plate Shaker
Plate Washer
Plate Washer For Beads
Printers
Purification Fraction Collector
Refrigerator/Freezer
SDS-Page Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis (Poured And Pre Cast)
Shaker/Incubator
Sparge System
Spectrophoter
Test Tube Racks
Vacuum Centrifuge
Vacuum Pump
Volumetric Pipettes And Flasks
Vortexer
Water Bath
Wrenches

| | | |
|---|---|---|
| | | Ion Chromatography<br>Mass Spec |

| Chemistry Quality Control Technician | | | | |
|---|---|---|---|---|
| **RELATED TECHNICAL INSTRUCTION OUTLINE** | | | | |
| **Course** | **Course Credit** | | | **Related Technical Instruction** |
| **Semester/ Course Name** | **Lecture Academic Credit Hours** | **Lab Academic Credit Hours** | **Total Academic Credit** | **Related Theory Instruction Hours** |
| First Year (Fall) | | | | (413) |
| General Biology I | 3 | 3 | 4 | 40+***80****=120 |
| Introduction to Computers | 2 | 2 | 3 | 27+***53***=80 |
| General Chemistry | 3 | 3 | 4 | 40+***80***=120 |
| College Composition | 4 | 0 | 4 | 53 |
| Intermediate Algebra | 3 | 0 | 3 | 40 |
| First Year (Spring) | | | | (400) |
| General Biology II | 3 | 3 | 4 | 40+***80***=120 |
| Microbiology | 3 | 3 | 4 | 40+***80***=120 |
| General Chemistry II | 3 | 3 | 4 | 40+***80***=120 |
| Writing Technical Documents | 3 | 0 | 3 | 40 |
| Social Science Elective | 3 | 0 | 3 | 40 |
| Second Year (Fall) | | | | (467) |
| Biotech Experience I: Discovery Research 2 | 2 | 9 | 6 | 27+***240***=267 |
| Organic Chemistry | 3 | 3 | 4 | 40+***80***=120 |
| Ethics (or Bioethics) Foreign | 3 | 0 | 3 | 40 |
| Language/Humanities/Fine | 3 | 0 | 3 | 40 |

| | | | | |
|---|---|---|---|---|
| Arts Elective | | | | |
| Second Year (Spring) | | | | (467) |
| Biotechnology Explorations | 2 | 0 | | 27 |
| Biotech II: Bio-Manufacturing | 2 | 9 | 6 | 27+***240***=267 |
| Probability and Statistics | 4 | 0 | 4 | 53 |
| Technical Elective | 3 | 3 | 4 | 40+***80***=120 |
| **Total Hours** | | | | **1747** |
| NOTE: 1000 lab hours may be counted towards the OJL**.** | | | | |

*lab hours are in bold & italics