

<h1>Quality Control Technician (Microbiology)</h1>	
REF	Key Functions & Tasks (Quality Control Microbiology Technician)
1	Work in compliance with EH&S.
1.a	Wear appropriate personal protective equipment.
1.b	Work in controlled environments.
1.c	Participate in emergency drills and emergency response teams.
1.d	Use routine lab safety procedures, identify unsafe conditions, and take corrective action.
1.e	Appropriately and safely access production and laboratory equipment.
1.f	Handle, label, and dispose of hazardous / biohazard materials.
1.g	Access and utilize MSDS.
1.h	Perform permitting procedures.
1.i	Carries out operations with attention to OSHA and EPA regulations, and other applicable state and federal regulations.
1.j	Participate in all company safety training and audits as required.
1.k	Assists with waste treatment operations.
1.l	Dispose of wastes .
1.m	Follows SOPs, written test procedures, safety, regulatory requirements, and approved license requirements.
1.n	Use hoods where appropriate.
1.o	Dispose of sharps properly.
2	Work in compliance with cGMPs.
2.a	Follow SOPs for all operations.
2.b	Records laboratory data and completes lab records as required.
2.c	Maintain equipment and instrument logbooks.
2.d	Control and receipt of raw materials.
2.e	Maintain training documentation.
2.f	Maintain equipment and methods in a validated state.
2.g	Working in controlled/classified areas (gowning, aseptic technique).
2.h	Ensure appropriate flow of personnel, equipment, and materials.
2.i	Change control for process, equipment, and documentation.
2.j	Label and apply status to equipment and materials.
2.k	Identify and report exception events and CAPA.
2.l	Review data.
2.m	Participate in change control activities.
2.n	Archive documentation/data.
3	Clean and maintain production areas.
3.a	Housekeeping / pest control.
3.b	Sanitize and clean of controlled spaces.
3.c	Preparation of cleaning materials and solutions
3.d	Document cleaning.
4	Maintain effective communication.
4.a	Maintain security and confidentiality.
4.b	Respond appropriately to internal auditors and external inspectors.
4.c	Assist in writing, reviewing, and commenting on technical documents.
4.d	Consult appropriately with internal customers.
4.e	Report result to appropriate departments.
4.f	Interact with vendors.

REF	Key Functions & Tasks (Quality Control Microbiology Technician)
5	Receive and/or collect samples.
5.a	Receive/collect samples (stability, in-process, water, raw materials, final product, environment, validation) per batch records or plans.
5.b	Monitor controlled equipment.
5.c	Maintain equipment logs.
5.d	Label samples appropriately.
5.e	Record sample collection and distribution (storage and chain of custody).
6	Laboratory Work.
6.a	Prepare reagents.
6.b	Prepare samples.
6.c	Review testing procedures
6.d	Execute testing.
6.e	Perform mathematical and statistical calculations as appropriate.
6.f	Evaluate data with regard to specification.
6.g	Perform scheduled sanitizations of hoods.
6.h	Prepare and standardize probes and ancillary instruments.
6.i	Visually inspect equipment.
6.j	Maintain equipment logs and status tags.
6.k	Complete, review and approve equipment process records.
7	Perform Microbiological Testing and Culturing.
7.a	Take environmental monitoring samples from production areas and personnel.
7.b	Perform microbial identification.
7.c	Test for mycoplasma and virus.
7.d	Test for endotoxin/pyrogen using LAL (e.g., water, in-process, final product)
7.e	Test for bioburden (e.g., water, in-process, final product)
7.f	Test sterilization cycles with biological indicators.
7.g	Test for quality of media/reagents using growth promotion tests.
7.h	Conducts sterility testing on in-process materials and finished products.
7.i	Qualify sanitizing agents and disinfectants.
7.j	Maintain reference cultures.
8	Managing Information
8.a	Support data trending activities.
8.b	Utilize Laboratory Information Management Systems (LIMS)
8.c	Records observations, generates reports, and maintains accurate records
9	Provide Technical and/or Validation Support
9.a	Troubleshoots basic technical issues and investigations of OOS results, instrument malfunctions, and methodology problems.
9.b	Assist in executing validation procedures
10	Maintain laboratory systems and equipment
10.a	Perform preventive maintenance (PM).
10.b	Standardize laboratory instrumentation.
10.c	Identify and assist in troubleshooting instrument and equipment failures.