QUALITY INFORMATION PACKET

Element Materials Technology Oakland - Concord

Dear Valued Client,

Due to the large volume of supplier surveys Element Materials Technology receives each year from its Clients and in order to provide you with the most complete information to assist you in your evaluation of Element Materials Technology, this Quality Information Packet has been assembled in the place of completing the questionnaire you have sent. Included in this packet are the following:

- Quality Systems Procedures Index
- Organizational Chart
- Facility Map
- FDA Drug Establishment Current Registration
- Scope of Accreditation to ISO/IEC 17025:2017

Additionally, the following documents can be made available upon request:

- cGMP Equipment List
- Copies of Specific Standard Operating Procedures (SOPs)
- Quality Manual

If there is any additional information you require to complete your evaluation of our facility, please do not hesitate to contact me.

Best Wishes,

Angela Redfield
Director of Quality Assurance
Element Materials Technology Concord
2341 Stanwell Drive
Concord, CA 94520
925.536.1169 (Direct)
angela.redfield@element.com

GENERAL FACILITY AND QUALITY SYSTEM INFORMATION

General Information	
Company Name	Element Materials Technology Oakland – Concord
Address of Facility	2341 Stanwell Drive, Concord, CA 94520
Phone Number	877-287-8738
Website	www.element.com
DUNS Number	792157906
Services Provided	Microbiology, Mycoplasma, Molecular and Virology Testing, Manufacturing & Filling, Environmental Monitoring, Training & Consulting
Number of Permanent Employees	45
Number of Quality Employees	5
Facility Size	10,000 sq.ft.
FDA FEI Number	3006616583
Expiration Date	December 2021
Last FDA Audit	December 2018
ISO/IEC 17025:2017 Certificate Number	3383.01
Expiration Date	December 2022
Last ISO Renewal Audit	August 2020

Key Personnel Information		
Name	**Title**	**Email**
Renee Johnston, B.S. (NCRM)	General Manager	renee.johnston@element.com
Angela Redfield	Director of Quality Assurance	angela.redfield@ element.com
Purag Chuhan	Microbiology Manager	purag.chuhan@ element.com
Sunil Khattar	Director of Virology and Molecular Services	sunil.khattar@ element.com
Daniel Uribe	Analytical Chemistry Manager	daniel.uribe@ element.com
Eric Pierce	Manufacturing Manager	eric.pierce@ element.com
Maria Leone	Environmental Monitoring Lead Technician	Maria.leone@ element.com
Mimi Leong, MBA	Director of Inside Sales	mimi.leong@ element.com
Sanju Sharma, MBA	Director of Business Development	sanju.sharma@ element.com

Quality Assurance Information	
Name and Title of QA Manager	Angela Redfield, Director of Quality Assurance
Telephone Number	925-536-1169
Email Address	angela.redfield@element.com
Reports to	Katy Kubesh, Quality Director – Life Sciences
Number of QA Employees	5
Quality Agreement signed upon request?	Yes
Confidentiality Agreement signed upon request?	Yes
Audit/facility tour available upon request?	Yes

Organizational & Personnel Information	
Is there a formal training program?	Yes
Is training performed and documented when SOP's are created or updated?	Yes
Are changes in ISO 17025, FDA and other regulatory requirements tracked and communicated to employees?	Yes
Are employees provided applicable regulatory training during onboarding and at regular intervals?	Yes
Do employees have adequate training, experience, and qualifications for their responsibilities?	Yes
Are employees tested for proficiency?	Yes
Have any personnel been disbarred by the FDA?	No
Do you have an organizational chart? Can you provide a copy?	Yes, a copy is attached to this document.
Are there written job descriptions?	Yes
Do employees have adequate training, experience, and qualifications for their responsibilities?	Yes

Facility Information	
Total size of facility	Yes
Area of facility utilized for office space	Yes
Area of facility utilized for testing labs	Yes
Area of facility utilized for warehouse	Yes
Construction of facility	Yes
Is there adequate security to assure that there is no entry by unauthorized persons?	Yes
Are there provisions for power backup sources for critical systems if main power should fail?	No
Is there a security system in place and SOP in place and access to the facility controlled at all times?	Yes, a copy is attached to this document.
Is there an appropriate pest control program?	Yes
Is the facility subject to inspections by regulatory authorities?	Yes

Regulatory Information		
Recognized External Authority	**Registration / Certificate Number**	**Date of Inspection**
ISO/IEC / A2LA	3383.01	August 2020
FDA (Routine Inspection)	3006616583	December 2018
ISO/IEC / A2LA	3383.01	September 2018
ISO/IEC / A2LA	3383.01	September 2017
ISO/IEC / A2LA	3383.01	October 2016
ISO/IEC / A2LA	3383.01	November 2015
ISO/IEC / A2LA	3383.01	December 2014
FDA (Routine Inspection)	3006616583	July 2014

Quality System Information	
Responsibilities and Authority	
Do you have a quality policy manual?	Yes; available upon request
Are QA/QC organization's authority and responsibilities clearly defined in writing?	Yes
Is there a mechanism to assure that only current test methods and specifications are in use?	Yes
Are data reviewed and trends monitored? Are adverse trends addressed, and is appropriate management notified?	Yes
Does the QA unit have the authority to halt laboratory, manufacturing, validation and/or calibration testing activities?	Yes
Does QA review all Certificates of Analyses (CofAs) after a thorough review of all associated raw data?	Yes
Complaint Handling	
Is there a formal system to document and review customer complaints?	Yes
Is management made of aware of customer complaints?	Yes
Change Control	
Is there an adequate system, described in an SOP, for controlling changes to methods, documents, and equipment, and requiring evaluation of need for re-qualification or revalidation?	Yes
Is QA involved in the change control process?	Yes
Is there a system in place to assure that changes are approved prior to implementation?	Yes
Audit Programs	
Do you host customer audits?	Yes
If Yes; How many per year?	15-20
Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the quality systems?	Yes
Based on the audit findings and recommendations, are steps taken to correct any areas of noncompliance? Are corrective actions documented? Is their effectiveness verified in subsequent audits?	Yes
If any contractors (e.g., laboratories, off-site storage facilities) are used, are they periodically audited, and their performance monitored?	Yes
Are all suppliers that provide critical materials and/or external calibration services audited/evaluated?	Yes
Test Sample Control	
Is there an SOP for receipt, identification, and storage of incoming test samples?	Yes
How are test samples received?	Per SOP QA-0014, Sample Management and Chain of Custody
Is the test sample log-in procedure computerized?	Currently both paper-based and computerized
How are test samples stored?	Per SOP QA-0014, client specifications, and instruction on the Sample Submission Form submitted by the client.
Is there adequate security for stored test samples?	Yes
Is test sample flow tracked?	Yes
Are test samples reconciled and any discrepancy investigated and reported to the client?	Yes
Is there an SOP controlling retention and/or destruction of excess samples?	Yes

Quality System Information Continued	
Out of Specification Investigation Procedure (OOS)	
Is there an SOP for laboratory investigations of unexpected test results to assure that a uniform procedure is followed to determine why the unexpected result occurred and that corrective actions are implemented when necessary?	Yes
Are clients promptly notified of unexpected and/or out of specification test results?	Yes
Deviation Procedure and Corrective/Preventive Action Procedure (CAPA)	
Is there an SOP for deviations to ensure that a uniform procedure is followed and that the impact is appropriately assessed and documented?	Yes
Is there a formal Corrective Action Preventive Action program?	Yes
Are CAPAs evaluated for efficiency?	Yes
Is there a system in place for continuous improvement and management review?	Yes

Document Control Information	
Standard Operating Procedures (SOPs)	
Are there written SOPs for all areas of the operation?	Yes
Is there an SOP for writing, handling and updating of SOPs? Are SOPs periodically reviewed and updated?	Yes
Is a history of SOP revisions maintained?	Yes
Are current SOPs readily available to employees?	Yes
Is there an adequate system to assure that unneeded or obsolete documents are removed from use?	Yes
Is there an SOP for document control?	Yes
If a client's test procedures or specifications are reformatted, does the client review and approve the reformatted document?	Yes
Are procedural changes approved by QA and controlled to ensure that the most current version of the SOP is in use?	Yes
Testing Records	
Is appropriate information recorded in test records concerning instruments used in tests (ID number, etc.)?	Yes
If chromatograms, charts, spectra are stored separate from other test records, are there adequate cross-references to their locations?	Yes
Are records legible? Are they appropriately signed and dated where required?	Yes
Are there overwrites, whiteouts, or pencil entries in official records?	No
Are changes to data properly initialed, dated, and explained based on an SOP that describes acceptable methods for recording data and correcting errors in official documents?	Yes
Are records reviewed for completeness before filing?	Yes
Is there appropriate security for data and records?	Yes
Are raw data/records retained for an appropriate length of time?	Yes
How long are records retained for?	Per SOP QA-0008, Document and Records Management System. Paper records are retained for NLT 1 year and electronic records are maintained NLT 7 years. Manufacturing Records are retained for at least 1 year after the expiration date of the batch

Operations Information	
Laboratory Cleaning Procedures	
Based on an SOP is the laboratory cleaned and disinfected?	Yes
Is there an adequate procedure for disposal of microbiological waste?	Yes
Are there procedures dictating cross contamination prevention and lab cleaning?	Yes
Laboratory Control of Supplies	
Are reagents and microbiological media adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?	Yes
Is the first in, first out rule enforced for all incoming materials?	Yes
Are all containers of materials or solutions adequately labeled to determine identity, preparer, and dates of preparation and expiration (if applicable)?	Yes
Are preparation records maintained, including manufacturer and lot number, preparer and date?	Yes
Is an expiration date assigned to prepared media and are prepared media stored at manufacturers' recommended storage temperatures?	Yes
Is each lot of biological indicators checked for identity and viability?	Yes
Are positive controls periodically included in autoclave runs?	Yes
Based on an SOP, is there appropriate control and documentation of stock cultures, including storage, propagation, assurance of purity, and traceability?	Yes
Laboratory Testing	
Do personnel eat, drink or some in the laboratory areas?	No
Is environmental monitoring and trending performed on a routine basis?	Yes
Are there complete written instructions for testing, including methods, equipment, operating parameters?	Yes
Are methods validated (when applicable) based on an SOP?	Yes
Are USP methods kept current upon revision?	Yes
Are test methods readily available to the laboratory technicians?	Yes
Are test methods followed without approved modification?	No
Is testing conducted with appropriate technique and in such a manner and place to preclude laboratory contamination of samples?	Yes
Are controls used for testing? Are their results recorded?	Yes
Are data and calculations reviewed, verified and signed by a second person?	Yes

Equipment Information	
Installation and Qualification	
Is there an SOP for qualifying new or significantly changed equipment and instruments?	Yes
Do qualifications of stability chambers, autoclaves, and incubators include temperature distribution studies?	Yes
Is equipment available in sufficient quantity to perform all required testing within required time frames?	Yes
Are there operational SOPs for all equipment and instruments?	Yes
Maintenance and Calibration	
Are there SOPs for inspection and maintenance of equipment and of measuring and testing instruments?	Yes

Equipment Information Continued	
Maintenance and Calibration	
If so, do SOPs assign responsibilities; including schedules; describe methods, equipment, and materials to be used, including calibration over actual range of use and standards traceable to national standards, and include specifications and tolerances; and require maintenance of records?	Yes
Does an SOP specify that equipment cannot be used if it is beyond the calibration due date, and describe actions to be taken if equipment is used that is found to have been beyond the due date or is found to be out of calibration limits?	Yes
Are calibrated instruments labeled with date calibrated and date next calibration is due?	Yes
Is equipment in use observed to be within calibration dating?	Yes
Are periodic verifications performed on analytical balances (using a range of weights) to assure that they remain within calibration in the time between full calibrations?	Yes
Are records maintained for maintenance and calibration operations?	Yes
If so, do SOPs assign responsibilities; including schedules; describe methods, equipment, and materials to be used; and require maintenance of records?	Yes
If instruments malfunction or are determined to be defective, are they immediately taken out of use?	Yes
Are there SOPs for calibration of equipment and instruments?	Yes
Are equipment calibration standards traceable to N.I.S.T or other certification body?	Yes

Computerized Systems Information	
List computerized systems used with regulatory implications	MasterControl
Are these computerized systems validated?	MasterControl -Yes; system have been validated to meet requirements of 21 CFR Part 11 and internal standard operating procedures.
Network Back-up Procedures	
Are suitable backup systems in place, such as copies of programs and files, duplicate tapes, or microfilm?	Yes
Is the network back-up procedure outlined in an SOP?	Yes
Change Control	
Is there a system to control changes to systems and programs?	Yes
Does the system assure that changes receive the proper review and approval with regard to potential effects before being instituted and that only authorized personnel can make such changes?	Yes
If necessary, are personnel trained subsequent to changes?	Yes
Is a record of system and program changes maintained?	Yes
Security	
Is there an appropriate security system to limit access to computerized systems, protect records from tampering, and prevent data alterations?	Yes
If anyone leaves the department or company or otherwise loses authority to access the systems, are there procedures to immediately remove that person's access codes from the system?	Yes

Computerized Systems Information Continued	
Electronic Records	
Is there an SOP or written policy that describes the electronic records retention system that is used?	Yes
Is the system capable of producing accurate and complete copies of records in both paper and electronic formats?	Yes
If a change is made, is the previous information still available?	Yes

QUALITY SYSTEMS PROCEDURES LIST

SOP Number Format	Title
CORP-IT-XXXX	Corporate IT SOP
CC-XXXX	Cell Culture SOP
CH-XXXX	Chemistry SOP
EM-XXXX	Environmental Monitoring SOP
EQ-XXXX	Equipment SOP
GE-XXXX	General SOP
MB-XXXX	Microbiology SOP
MFS-XXXX	Manufacturing Services SOP
MY-XXXX	Mycoplasma SOP
PCR-XXXX	PCR SOP
QA-XXXX	Quality SOP
VA-XXXX	Validation SOP
VCS-XXXX	Validation and Calibration SOP
VI-XXXX	Virology SOP

SOP Number	Title
CORP-IT-0001	Electronic Use Signature Policy
CORP-IT-0002	Network Back Up and Disaster Recovery Policy
CORP-IT-0003	Security Management Policy
CORP-IT-0004	Acceptable Use Policy
CORP-IT-0005	Internet Use, Monitoring and Filtering
CORP-IT-0006	Compromised Credentials
CORP-IT-0007	Email Security Training
CC-0001	Growth and Maintenance of Cell Cultures
CC-0002	Biological Reactivity Tests, In Vitro USP <87> Elution Test
CC-0003	Preparation of Cell Banks
CC-0004	Hybridoma Testing for Sera Products
CC-0005	Beta-Galactosidase Staining of Mammalian Cells
CC-0006	MTT Cytotoxicity Test
CC-0007	Use of the Hemocytometer
CH-0001	The Concentration of Total Organic Carbon in Samples
CH-0002	USP <645> Conductivity/Resistivity Test for Bulk Water
CH-0003	Operation of the Mettler Toledo SevenMulti Meter
CH-0004	EP Monograph 0169 - Nitrates in Water for Injection

SOP Number	Title
CH-0005	Appearance of Clear Transparent Liquids
CH-0006	TOC Recovery, Cleaning Verification and Sampling Using Swabs
CH-0007	Total Dissolved Solids by Mettler Toledo SevenMulti Meter
CH-0008	Refractive Index by Reichert AR200 Digital Refractometer
CH-0009	Water Determination by Coulometric Titration (Karl Fischer) Method
CH-0010	USP-NF Monograph: Nitrogen
CH-0011	Osmolality of Solutions
CH-0012	USP Monograph: Carbon Dioxide
CH-0013	USP Monograph: Oxygen
CH-0014	Storage and Management of Client Stability Samples
CH-0015	Hydrogen Peroxide Concentrate: Identification, Acidity and Assay
CH-0016	USP <197A> Spectrophotometric Identification Tests - IR Absorption by ATR
CH-0017	USP <191> Identification Tests - General
CH-0018	USP <401> Saponification Value of Fats and Fixed Oils
CH-0019	USP < 211> Trace Arsenic in Organic and Inorganic Materials
CH-0020	USP <281> Residue on Ignition/Sulfated Ash
CH-0021	USP <401> Acid Value (Free Fatty Acids) in Fats and Fixed Oils
CH-0022	USP <401> Iodine Value in Fats and Fixed Oils
CH-0023	USP <733> Loss on Ignition
CH-0024	USP <731> Loss on Drying
CH-0025	USP < 841> Specific Gravity of Liquids
CH-0026	EP Monograph 1247: Nitrogen
CH-0027	USP Monograph: Medical Air
CH-0028	Free Chlorine-DPD Method by DR1900 Spectrophotometer
CH-0029	USP <791> pH
CH-0030	Methylene Blue Dye Penetration Analysis by UV-Vis
CH-0031	Titration of Nitric Acid from Passivation Baths
CH-0032	Stability Indication HPLC Method for Papaverine HCl and Phentolamine Mesylate in Bi-Mix and Tri-Mix Formulations
CH-0033	Stability Indication HPLC Method for Alprostadil in Tri-Mix Formulation
CH-0034	Absorbance and Transmission by UV-Vis Spectrophotometer
CH-0036	Water Determination by Volumetric Titration (Karl Fischer)
CH-0037	Operation of Agilent 6890N GC with TCD and 5973N GC-MS
CH-0038	Testing Against the Current USP Individual Monographs
EM-0001	Environmental Monitoring Program of Surfaces, Viable and Non-Viable Particles
EM-0002	Environmental Monitoring of Surfaces
EM-0003	Environmental Monitoring of Viable Particulates using the Air IDEAL Sampler
EM-0004	Water Quality and Sampling of Water Systems
EM-0006	Impurities in Compressed Gas by Drager Detector Tube
EM-0009	Environmental Monitoring of Surfaces Using Swabs
EM-0010	Environmental Monitoring of Particulates for Gas Systems
EM-0011	Certification of Cleanrooms and Associated Controlled Environments

SOP Number	Title
EM-0012	Gas Collection into Gas Sampling Bags
EM-0013	Environmental Monitoring of Particulates Using the Climet CI-1054 and the CI750t Particle Counters
EM-0014	Compressed Gas System Bioburden Testing Using the SMA
EM-0015	Environmental Monitoring of Viable Air Particulates
EM-0016	Environmental Monitoring Using Settling Plates
EM-0017	In-house Environmental Monitoring Excursion
EM-0018	Environmental Monitoring For Sterility Testing in Clean Room 12
EQ-0001	Instrument and Equipment Management Program
EQ-0002	Calibration Program
EQ-0003	GMP Equipment Preventative Maintenance Program
EQ-0004	Change Control and Risk Assessment
EQ-0005	Use and Operation of the CO2 Meter Model Number CM-0010
EQ-0006	General Usage of Liquid N2 Storage Tanks
EQ-0007	Operation, Maintenance and Calibration of the Agilent 6890 GC-TCD
EQ-0008	Equipment Service
EQ-0009	Operation of Balances
EQ-0010	Operation of Fume Hoods
EQ-0011	Operation of Water Baths
EQ-0012	General Use of the Eppendorf 5810R Centrifuge
EQ-0013	Operation and Maintenance of the QAS-70-90-120 Generator
EQ-0014	Use and Installation of Dual Stage Compressed Gas Regulators
EQ-0015	Operation of the Servomax 1175 Paramagnetic Oxygen Analyzer
EQ-0016	Use and Operation of Microscopes
EQ-0017	Operation of the SpectraMax Plus and SpectraMax M2e Microplate Reader and SoftMax Pro Software
EQ-0018	Operation of Laminar Horizontal Flow Clean Bench
EQ-0019	Operation of the Nicolet iS10 FT-IR
EQ-0020	Operation, Maintenance and Calibration of the Beckman DU 640 Spectrophotometer
EQ-0021	Operation and Maintenance of the ABI 7500 Fast RT-PCR System
EQ-0022	Operation of the OMD-580 Portable Oxygen Analyzer
EQ-0023	Operation of the General Eastern Model 500 Electrolytic Hygrometer
EQ-0024	Verification of Tally Counters
EQ-0025	Capillary Column Installation and Maintenance for GC Systems
EQ-0026	Operation and Maintenance of the Biolog Turbidimeter
EQ-0028	Operation and Maintenance of the Sievers M9 TOC Analyzer
EQ-0029	Maintenance of Split/Splitless Inlets
EQ-0030	Operation of the Agilent 1200 HPLC System
EQ-0031	Operation and Maintenance of the HIAC Royco 9703+ Liquid Particle Counting System
EQ-0032	Operation of Fyrite Gas Analyzer
EQ-0033	General Use of the LogTag Temperature Recorder Counting System
EQ-0034	Operation and Maintenance of the Persee T6V Visible Spectrophotometer Counting System

SOP Number	Title
EQ-0035	Operation and Maintenance of the BacT/ALERT 3D Dual-T Microbial Detection System Counting System
EQ-0036	Operation of the Countess II FL Automated Cell Counter
EQ-0037	Use of Compressed Gas Cylinders
EQ-0038	Operation and Maintenance for the Consolidated SR Series Sterilizer
EQ-0039	Operation of the Veriteq Temperature Monitoring System
EQ-0040	Operation of Biosafety Cabinets
EQ-0041	Cleaning of Controlled Temperature Environments
EQ-0042	Operation of the Non-Stationary Top Loading Balance EQ ID #103.11
EQ-0043	Operation and Maintenance of the Climet CI-95A
EQ-0044	Operation and Maintenance of the MAS-100 Air Sampler
EQ-0046	Flame Ionization Detector: Operation and Maintenance
EQ-0047	Operation and Maintenance of the GeneAmp PCR System 9700
EQ-0048	Operation of Mettler Toledo DL38 Volumetric Titrator
EQ-0049	Operation and Maintanence of the Ney Vulcan D-130 Muffle Furnace
EQ-0050	Operation and Maintenance of Melting Point Apparatus SMP20
EQ-0053	Operation, Calibration, and Maintenance of the Agilent 8453 UV-Visible Spectrophotometer
EQ-0054	Operation of Pyros Kinetix Flex and ELx808 Instruments with Pryos eXpress Software
EQ-0057	Operation and Maintenance for the Steris Finn-Aqua GLP Sterilizer
GE-0001	ALG-West General Safety Procedure
GE-0002	Cleaning of the Laboratory Areas
GE-0003	Laboratory Reagents Management
GE-0004	Laboratory Standards Management
GE-0005	Laboratory Solutions Management
GE-0006	Sample Transport
GE-0007	Temperature Monitoring
GE-0008	Preparation of Sanitizing Agents
GE-0009	Handling of Chemicals and Chemical Hazardous Waste Management
GE-0010	Handling of Biological Contaminants and Biological Waste Management
GE-0011	Laboratory Workflow
GE-0012	Gowning for Operations in the ISO Classified Areas
GE-0013	General Incubation and Plate Counting Practices
GE-0014	Cleaning and Sanitization of the ISO Controlled Areas
GE-0015	Security at ALG-West
GE-0016	Laboratory Gowning Procedures at ALG-West
GE-0017	Purchasing and Receiving Process at ALG-West
GE-0018	Cleaning of Glassware for Microbiology Assays
GE-0019	Glassware Cleaning for General Analytical Procedures
GE-0020	Estimation of Uncertainty of Measurement
GE-0021	Personnel, Equipment and Material Flow in Clean Room 12 While Performing Sterility Testing
GE-0022	Security Storage and Handling of Controlled Substances at ALG-West

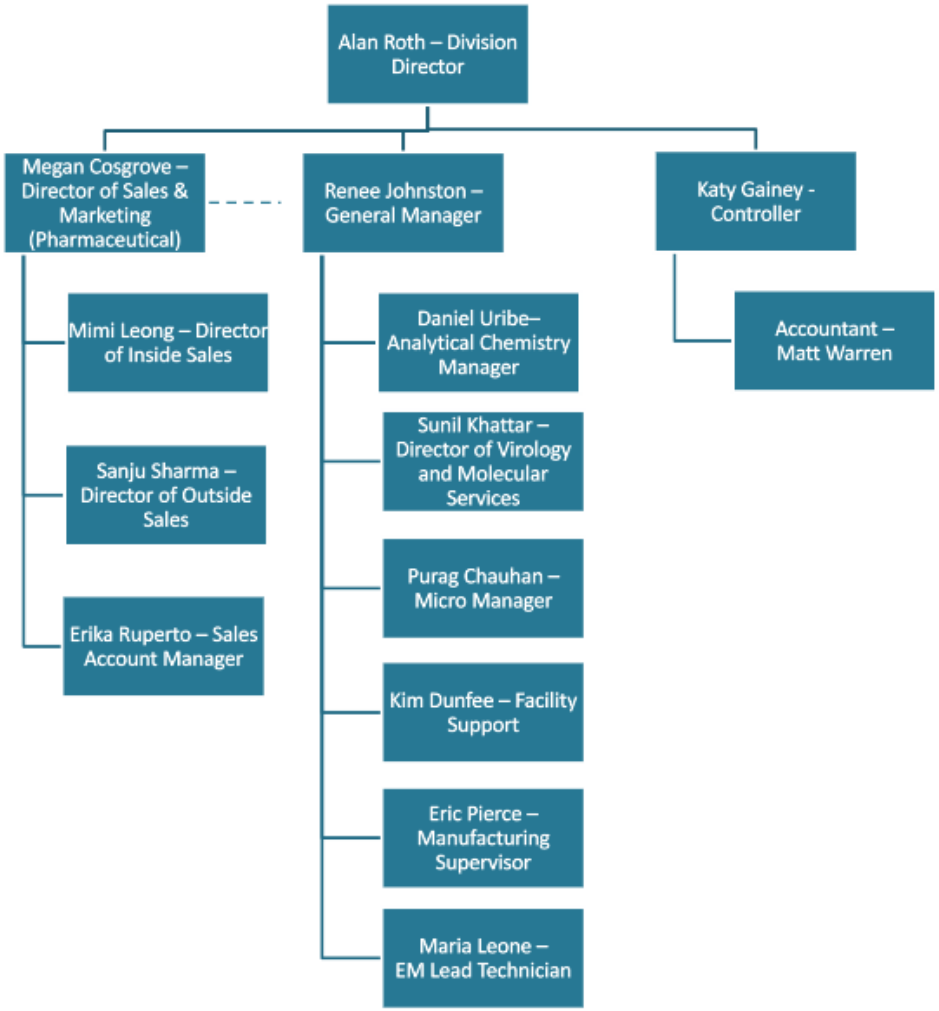
SOP Number	Title
MB-0001	Growth Promotion and Quality Testing of Environmental and Microbiological Media
MB-0002	Stock Culture Master Bank and Suspension Preparation
MB-0003	Water Microbial Load Testing by Membrane Filtration Method
MB-0004	Microbial Identification
MB-0006	USP <61> Microbiological Examination of Nonsterile Product Microbial Enumeration Test
MB-0007	Microbiological Examination of Nonsterile Products: Microbial Enumeration Method Suitability
MB-0008	Preparation of Microbiological Media and Diluents
MB-0009	USP <85> Bacterial Endotoxin Test
MB-0010	Aseptic Technique Training
MB-0011	Pipetting and Dilution Qualification
MB-0012	Microbiological Examination of Nonsterile Products: Suitability Test for Specified Microorganisms
MB-0013	USP <62> Microbiological Examination of Nonsterile Products: Test for Specified Microorganisms
MB-0014	Preparation and Extraction of Medical Device/ Solid Material samples for Endotoxin Test
MB-0015	Total Coliform Membrane Filtration Method
MB-0016	USP <71> Sterility Testing by Direct Inoculation
MB-0017	Bacteriostasis and Fungistasis Test for USP <71> Sterility Testing by Direct Inoculation Method
MB-0018	Microbial Immersion Challenge Test
MB-0019	Analysis by BioLog Omnilog Microbial ID System
MB-0020	Incubation of Client Microbiological Media Samples
MB-0021	LAL Endotoxin Testing Using the Kinetic Chromogenic Method
MB-0022	General Handling of Biological Indicators
MB-0023	Preparation and Testing of Endotoxin Challenge Containers or Items
MB-0024	USP and EP Antimicrobial Preservative Effectiveness Test
MB-0025	Non-Compendial Product Microbial Load Testing by Membrane Filtration Method
MB-0026	Detection of Phage Through the Use of Phage-Susceptible E. Coli Bacterial Lawn
MB-0027	Incubation and Inspection of Media Filled Containers
MB-0028	USP <71> Sterility Testing by Membrane Filtration
MB-0029	Bacteriostasis and Fungistasis Test for Sterility Testing by Membrane Filtration
MB-0030	Culture Viability, Plasmid Retention and Purity Testing for Bacterial Cell Banks
MB-0031	Determination of Organism Concentration Based on OD
MB-0032	Non-Compendial Product Microbial Load Testing by Spread Plate Method
MB-0033	Antibiotic Sensitivity Testing by Kirby Bauer Antibiotic Disc Diffusion Test Method
MB-0034	Processing of Mold Isolates with the BioLog MicroStation / MicroLog System
MB-0035	Particulate Matter in Injections by Light Obscuration Method 1
MB-0037	Rapid Sterility Testing by BacT/ALERT 3D Dual-T Microbial Detection System
MB-0038	Bacteriostasis and Fungistasis Method Suitability Test for BactT/ALERT 3D
MB-0039	Selectable Marker Retention Analysis of Escherichia coli Cell Bank
MB-0040	Viability Determination via the Most Probable Number Method
MB-0041	USP <85> Endotoxin Tests using Pyros Kinetix Flex – Turbidimetric Method

SOP Number	Title
MB-0042	USP <85> Endotoxin Inhibition/Enhancement and Validation using Pyros Kinetix Flex – Turbidimetric Method
MB-0043	USP <85> Endotoxin Tests using Pyros Kinetix Flex – Chromogenic Method
MB-0044	USP <85> Endotoxin Inhibition/Enhancement and Validation using Pyros Kinetix Flex – Chromogenic Method
MB-0045	USP <60> Microbiological Examination of Nonsterile Products: Test for Burkholderia Cepacia
MB-0046	USP <60> Microbiological Examination of Nonsterile Products: Suitability Test for Burkholderia Cepacia
MFS-0001	Aseptic Practices in the Aseptic Manufacturing Areas
MFS-0002	Aseptic Manufacturing Area Monitoring Program
MFS-0003	Personnel, Equipment and Material Flow in the ISO Controlled Manufacturing Areas
MFS-0004	Materials Program for Manufacturing Areas
MFS-0005	Storage and Transportation of Finished Products
MFS-0006	Release of Manufacturing Finished Products
MFS-0007	ISO Controlled Area Monitoring Program for Manufacturing
MFS-0008	Inventory and Management of Client Manufactured Cell Banks
MFS-0009	Line Inspection for Manufacturing Operations
MFS-0010	Environmental Monitoring in the Aseptic Areas During Filling Operations
MFS-0011	Media Fill Program
MFS-0012	Cleaning and Disinfection of Miscellaneous Clean Room Materials
MFS-0013	Preventive Maintenance of Classified Areas
MFS-0014	Batch Production Record Preparation, Issuance and Tracking
MFS-0016	Preparation of Finished Product Specifications
MFS-0017	Manufacturing Supplier Program
MFS-0018	Preparation of Raw Material Specifications
MY-0001	Growth Promotion and Sterility Test of Mycoplasma Media
MY-0002	Mycoplasma Stock Culture, Master Bank, and Suspension Preparation
MY-0003	Preparation of Mycoplasma Media
MY-0004	Mycoplasma Detection by Points to Consider (Direct Method)
MY-0005	Detection of Mycoplasma in Cell Cultures by Fluorescence Methods
MY-0006	Suitability Testing (Mycoplasmastasis) for Detection by Points to Consider (Direct Method)
MY-0007	Mycoplasma Detection by USP and EP Culture Method
MY-0008	Mycoplasma Detection using MycoSeq Mycoplasma RT-PCR Detection Kit from ABI
MY-0009	Staining of Mycoplasma Colonies on Agar Plates
PC-0001	Mycoplasma Testing by Touch Down PCR
PC-0003	Agarose Gel Electrophoresis
PC-0004	DNA Purification using QIAamp DNA Mini Kit for PCR Applications
PC-0005	Detection of Murine Leukemia Virus (MuLV) by Real Time Quantitative Polymerase Chain Reaction (RT-qPCR)
PC-0006	Viral DNA or RNA Purification Using QIAamp Viral RNA Mini Kit
PC-0007	Sample Preparation Using the PrepSEQ Nucleic Acid Extraction Kit
PC-0008	Producing a Standard Curve for Real-Time PCR Assay Validation on the Applied Biosystems 7500 Fast
PC-0009	Receipt and Dilution of Primers

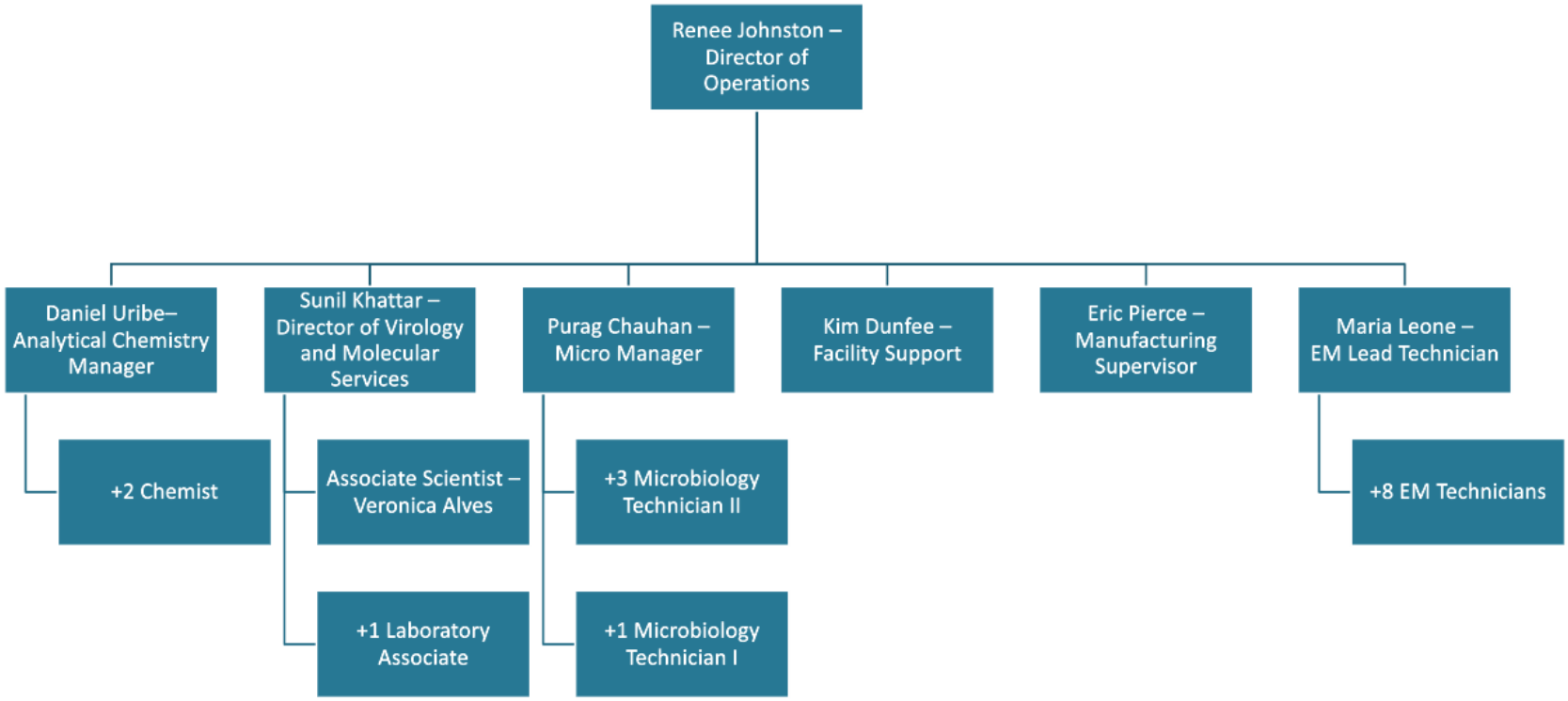
SOP Number	Title
PC-0010	Residual CHO DNA resDNASEQ Quantitative Assay Kit
PC-0011	Detection of Minute Virus of Mouse by RT-PCR Using the ABI 7500 Fast
PC-0012	Diagnostic Restriction Endonuclease Digest of Plasmid DNA
PC-0013	Nucleic Acid Analysis by Agarose Gel Electrophoresis
PC-0014	Nucleic Acid Concentration and Purity Based on 260/280 Absorbance UV Spectrophotometry
PC-0015	Protein Quantification by Micro BCA Assay
PC-0016	Nucleic Acid Concentration and Homogenaity Check Based on 260 nm Absorbance UV Spectrophotometry
PC-0017	Detection of DNase and RNase Activity
PC-0018	Fluorescence Based Detection of Protease Activity
PC-0019	PCR Amplification of Products Prepared from Genomic DNA
PC-0020	Detection of Protease Activity Using the Protease Fluorescent Detection Kit
PC-0021	Protein Quantitation using Thermo Fisher Micro BCA Protein Assay Kit
QA-0001	Quality Manual
QA-0002	Responsibilities of the Quality Assurance Unit
QA-0003	Preparation of Standard Operating Procedures (SOPs)
QA-0004	Preparation of Certificates of Analysis and Distribution of Confidential Information
QA-0005	Policy for Using the A2LA Accredited Symbol
QA-0006	GLP Program for Nonclinical Laboratory Studies
QA-0007	Preparation of Client Protocols
QA-0008	Document and Records Management System
QA-0009	Document Control
QA-0010	Good Documentation Practices
QA-0011	Master Signature Log
QA-0012	Issuance, Use and Management of Laboratory Notebooks
QA-0013	Logbook Management
QA-0014	Sample Management and Chain of Custody
QA-0015	Deviations and Investigations
QA-0016	Suspected Test Failures and Invalid Tests
QA-0017	Corrective Action and Preventive Action (CAPA)
QA-0018	Quality Auditing Procedure
QA-0019	Supplier Management Program
QA-0020	Performing External Physical Audits
QA-0021	Training for GMP/GLP Operations
QA-0022	Quality System Review
QA-0023	Server Backup and Disaster Recovery
QA-0024	Pest Control
QA-0025	Requirements for Reporting Calculations in Raw Data
QA-0026	Identifying, Handling and Trending Customer Complaints
QA-0027	Customer Surveys
QA-0028	Management Review
QA-0029	Contract Review

SOP Number	Title
QA-0030	Proficiency Testing Plan
QA-0031	Preparation of Internal Proficiency Testing Samples
QA-0032	Data Integrity
QA-0033	Quality Plan (QP) Preparation
VA-0001	Equipment Qualification Group B
VA-0002	Preparation of Equipment Qualification Documents
VA-0003	Method Validations & Document Preparation
VA-0004	Validation and Qualification Master Plan
VA-0005	Equipment Qualification Group C
VA-0006	USP <1226> Verification of Suitability for Compendial Analytical Procedures
VCS-0001	General Calibration procedure
VCS-0002	Calibration of Viable Air Samplers
VCS-0003	Operation of Valsuite Software
VCS-0004	Calibration of Environmentally Controlled Chambers
VCS-0005	Calibration of Thermometers and Temperature Logging Devices
VCS-0006	Calibration of Centrifuges
VCS-0007	Calibration of Gas Flow Rotameters
VCS-0008	Calibration of Timers and Stopwatches
VCS-0009	Calibration of Balances
VCS-0011	Calibration of Pressure Gauges
VCS-0012	Certification of Fume Hoods
VCS-0013	Calibration of Mechanical Pipettes Using Calibry
VCS-0014	Calibration of Veriteq Loggers
VCS-0015	Generating Certificates for In-House Calibration
VCS-0016	Decontamination of Biological Safety Cabinets
VCS-0017	Calibration of ABI 7500 Fast Real-Time PCR System
VCS-0018	Class II Biosafety Cabinets (BSCs) Certification Reference
VCS-0019	Calibration of the Gene Amp® 9700 Thermal Cycler
VI-0001	Preparation of Viral Banks
VI-0002	In-Vitro Viral Screening Assay for Viable Viruses
VI-0003	Detection of Bovine Viruses
VI-0004	Preparation of T75 cm2 Flasks and Six Well Plates for the Viral Screening Assay (VSA)
VI-0005	Screen for Replication Competent Retrovirus (RCR) with Mus Dunni Enrichment
VI-0006	Calculating TCID50 with Spearman Karber Excel Spreadsheet
VI-0008	Purification of Virus Using the Sartorius VivaFlow Apparatus

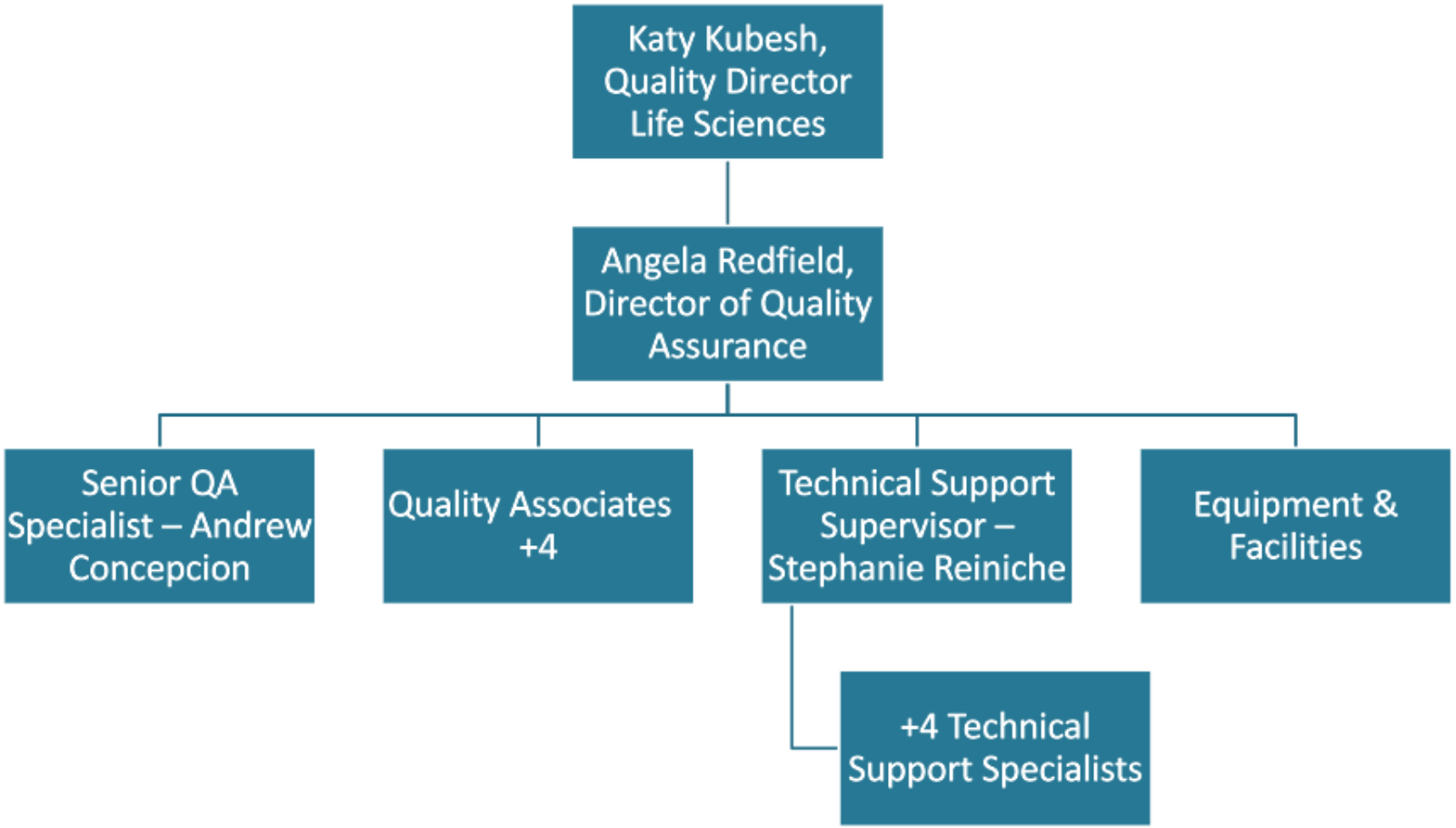
ORGANIZATIONAL CHART



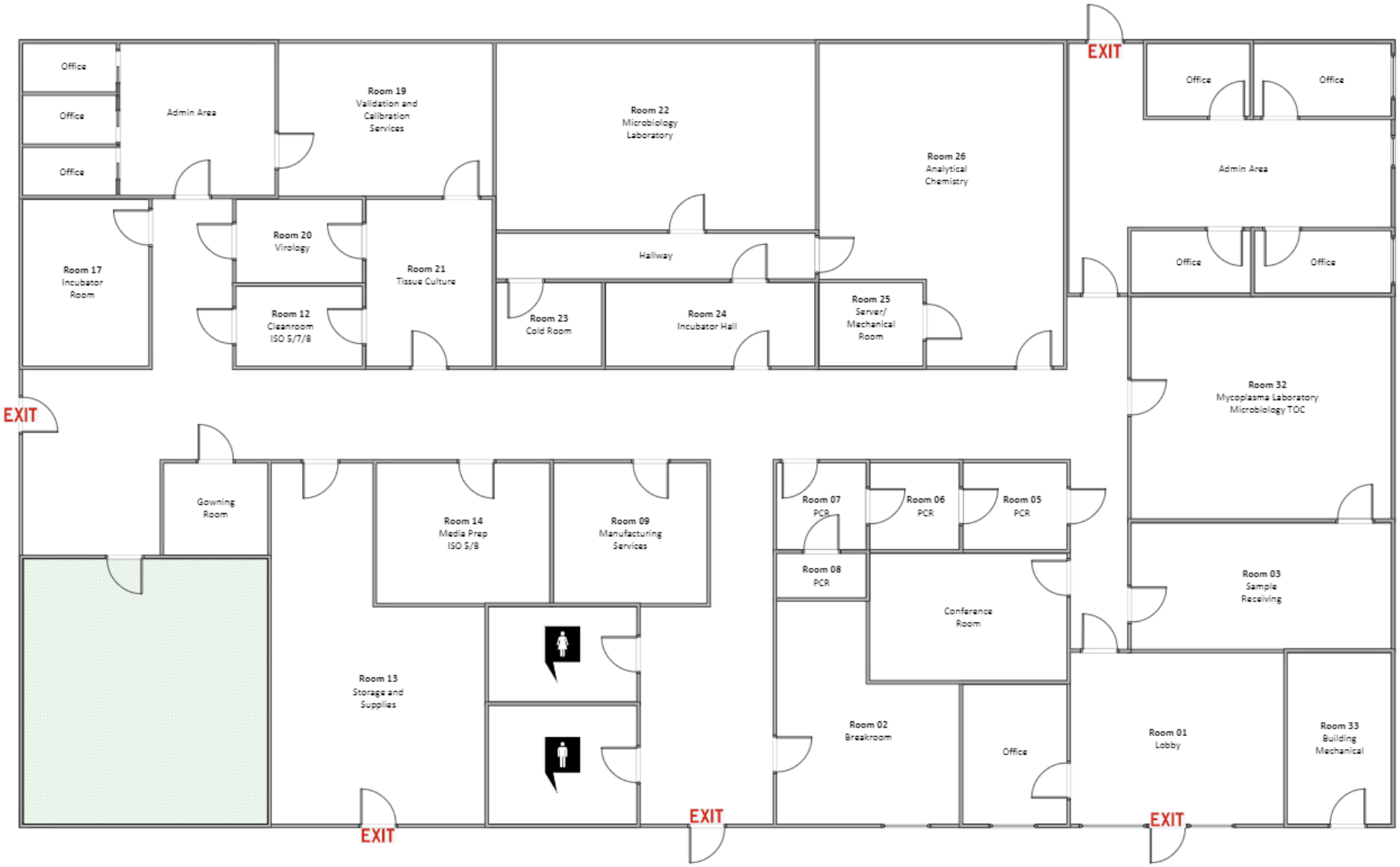
ORGANIZATIONAL CHART



ORGANIZATIONAL CHART



FACILITY MAP



FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Microbiology & Quality Associates, Inc.	3006616583	792157906	ANALYSIS;	2341 Stanwell Drive, Concord, California (CA) 94520, United States (USA)	12/31/2021

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY
2341 Stanwell Dr.
Concord, CA 94520
Renee Johnston Phone: (925) 536-1168
renee.johnston@analyticallabgroup.com

BIOLOGICAL

Valid To: December 31, 2022 Certificate Number: 3383.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on pharmaceuticals, biotech products, drug products, food products, controlled environments, water, environmental samples, and medical devices:

Test(s)	Reference Method(s)	SOP(s)
Antimicrobial Effectiveness Test	USP <51> EP XVIC CTFA M3, M6	MB-0024
Bacterial Endotoxin Test	USP <85>	MB-0009 MB-0014 MB-0021 MB-0041 MB-0042 MB-0043 MB-0044
Biological Indicators	USP <55>	MB-0022
*Compressed Gas Sampling and Testing	USP <797> USP <1116> ISO 8573	EM-0006 EM-0010 EM-0012 EM-0014
Cytotoxicity and Biological Reactivity	ISO 10993-5 USP <87>	CC-0002 CC-0006
Detection of Mycoplasma and Virus by PCR	EU 2.6.7 In-House	PC-0001 PC-0003 PC-0005 PC-0006 PC-0007 PC-0011 MY-0008
Detection of Virus in Test Articles	9 CFR 113.46; 9 CFR 113.47; 9 CFR 113.53; 21CFR 210, 211 FDA Points to	VI-0002

Test(s)	Reference Method(s)	SOP(s)
	Consider in Characterization of Cell Lines Used to Produce Biologicals (1993) USP <1050> USP <1237>	
*Environmental Monitoring Testing	USP <797> USP <1116> ISO 14644-1 ISO 14644-2	EM-0002 EM-0003 EM-0005 EM-0007 EM-0009 EM-0011 EM-0013 EM-0015 MB-0020 MB-0027
Growth Promotion and Sterility Testing of Microbiological Media	USP <61> USP <62> USP <71> USP <2021>	MB-0001
Microbial Identification	USP <1113>	MB-0004 MB-0019 MB-0034
Microbiological Examination of Non-Sterile Products: Pour Plate, Spread Plate, Membrane Filtration Methods and Microbial Enumeration Method Suitability	USP <61> USP <2021> ANSI/AAMI ISO 11737-1, -2	MB-0006 MB-0007 MB-0025 MB-0032
Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms for: *Escherichia coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus, Clostridia, Candida Albicans,* and *Burkholderia cepacia*	USP <60> USP <62>	MB-0012 MB-0013 MB-0045 MB-0046
Mycoplasma Detection by Direct and Indirect Methods	USP <63> USP <1211> EP 7th ED 2.6.7 FDA Points to Consider in Characterization of Cell Lines Used to Produce Biologicals (1993)	MY-0001 MY-0003 MY-0004 MY-0005 MY-0006 MY-0007
*Sampling of Water Systems	USP <1116>	EM-0004
Sterility Test	USP <71> ANSI/AAMI ISO 11137-1, -2, -3	MB-0016 MB-0017 MB-0028 MB-0029

Test(s)	Reference Method(s)	SOP(s)
		MB-0037 MB-0038
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> Standard Methods for the Examination of Water and Wastewater 9222 EPA Method 1604	MB-0003 MB-0015

CHEMICAL

Test	Reference Method(s)	SOP
Conductivity Test	USP <645>	CH-0002
Nitrogen Purity Assay	USP-NF Monograph – Nitrogen EP Monograph 1247	CH-0010
Total Organic Carbon	USP <643>	CH-0001

* This laboratory meets *A2LA R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for these tests.

Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY

Concord, CA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 28th day of September 2020.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3383.01
Valid to December 31, 2022
Revised June 17, 2021

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.