# 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,

Tyran Richards
Quality Manager
Element Materials Technology Concord
2341 Stanwell Drive
Concord, CA 94520
925.270.3800 (Office)
tyran.richards@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, Environmental Monitoring, Analytical Chemistry |
| **Number of Permanent Employees** | 50 |
| **Number of Quality Employees** | 5 |
| **Facility Size** | 10,000 sq.ft. |
| **FDA FEI Number** | 3006616583 |
| **Expiration Date** | December 2024 |
| **Last FDA Audit** | March 2022 |
| **ISO/IEC 17025:2017 Certificate Number** | 3383.01 |
| **Expiration Date** | December 2024 |
| **Last ISO Renewal Audit** | November 2022 |

| Key Personnel Information | | |
|---|---|---|
| **Name** | **Title** | **Email** |
| Renee Johnston, B.S. (NCRM) | General Manager | renee.johnston@element.com |
| Tyran Richards | Quality Manager | tyran.richards@element.com |
| Purag Chuhan | Microbiology Manager | purag.chuhan@ element.com |
| Sunil Khattar | Director of Virology and Molecular Services | sunil.khattar@ element.com |
| Eric Pierce | Program Manager | eric.pierce@ element.com |
| Maria Leone | Environmental Monitoring Supervisor | maria.leone@ element.com |
| Mimi Leong, MBA | Director of Inside Sales | mimi.leong@ element.com |
| Sanju Sharma, MBA | Director of Outside Sales | sanju.sharma@element.com |

| Quality Assurance Information | |
|---|---|
| **Name and Title of QA Manager** | Tyran Richards, Quality Manager |
| **Telephone Number** | 925-536-3786 |
| **Email Address** | Tyran.richards@element.com |
| **Reports to** | Erika Guthrie, 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 SOPs 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** | ~10,000 sq. ft. |
| **Area of facility utilized for office space** | ~2,500 sq. ft. |
| **Area of facility utilized for testing labs** | ~6,000 sq. ft. |
| **Area of facility utilized for warehouse** | ~1,000 sq. ft. |
| **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?** | Yes |
| **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 | November 2022 |
| FDA (Routine Inspection) | 3006616583 | March 2022 |
| ISO/IEC / A2LA | 3383.01 | August 2021 |
| 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 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 (COAs) 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, all original paper records and scans will be kept for NLT 7 years. Clients may choose to have original records returned to them. |

| 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 |
|---|---|
| LS-XXXX | Life Science Business Unit (LSBU) 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 |
| MY-XXXX | Mycoplasma SOP |
| PC-XXXX | PCR SOP |
| QA-XXXX | Quality SOP |
| VA-XXXX | Validation SOP |
| VCS-XXXX | Validation and Calibration SOP |
| VI-XXXX | Virology SOP |

| SOP Number | Title |
|---|---|
| LS-0001 | Computer System Life Cycle Management and 21 CFR 11 Compliance |
| LS-0004 | Electronic Signature Use Policy |
| LS-0005 | Adverse Events |
| LS-0006 | Corrective and Preventive Action Procedure |
| LS-0007 | Internal Audit |
| LS-0008 | Mock Regulatory Inspection Procedure |
| LS-0009 | Out of Specification/Out of Trend (OOS/OOT) Investigations |
| LS-0010 | Inspection Management |
| LS-0012 | Deviation Investigation |
| LS-0014 | Use of DocuSign Part 11 |
| LS-0015 | Data Governance Policy |
| LS-0018 | Quality Risk Management |
| LS-0022 | Network and Back-Up Recovery |
| 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-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-0004 | EP Monograph 0169 - Nitrates in Water for Injection |
| CH-0005 | Appearance of Clear Transparent Liquids |
| CH-0006 | TOC Recovery, Cleaning Verification and Sampling Using Swabs |

| SOP Number | Title |
|---|---|
| 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-0017 | USP <191> Identification Tests - General |
| CH-0020 | USP <281> Residue on Ignition/Sulfated Ash |
| 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-0029 | USP <791> pH |
| CH-0030 | Methylene Blue Dye Penetration Analysis by UV-Vis |
| 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 |
| CH-0039 | Particulate Matter in Injections by Light Ob |
| EM-0001 | Environmental Monitoring Program of Surfaces, Viable and Non-Viable Particles |
| EM-0002 | Environmental Monitoring of Surfaces |
| 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-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 |
| EM-0019 | In House Environmental Monitoring Program for ISO Classified Areas |
| EQ-0001 | Instrument and Equipment Management Program |
| EQ-0002 | Calibration Program |
| EQ-0003 | GMP Equipment Preventative Maintenance Program |
| 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-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 |

| SOP Number | Title |
|---|---|
| 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-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-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 |
| 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-0048 | Operation of Mettler Toledo DL38 Volumetric Titrator |
| EQ-0049 | Operation and Maintenance of the Ney Vulcan D-130 Muffle Furnace |
| EQ-0050 | Operation and Maintenance of Melting Point Apparatus SMP20 |
| EQ-0054 | Operation of Pyros Kinetix Flex and ELx808 Instruments with Pryos eXpress Software |
| EQ-0057 | Operation and Maintenance for the Steris Finn-Aqua Sterilizer |
| EQ-0058 | Operation of the Mettler Toledo SevenMulti Meter |
| EQ-0059 | Operation of the Advanced Instruments Micro Osmometer Model 3320 |
| EQ-0060 | Operation and Maintenance of the Millipore Milli-Q® HX 7080 Water Purification System |
| EQ-0061 | Operation and Maintenance of Zeiss Axio Vert.A1 FL-LED Microscope with Axiocam 705 Camera and Carl Zeiss ZEN Pro Software version 3.3 |
| EQ-0063 | Operation and Maintenance of the SAS Super 180 |
| EQ-0064 | Operation and Maintenance of the HVAC System |
| GE-0001 | 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 |

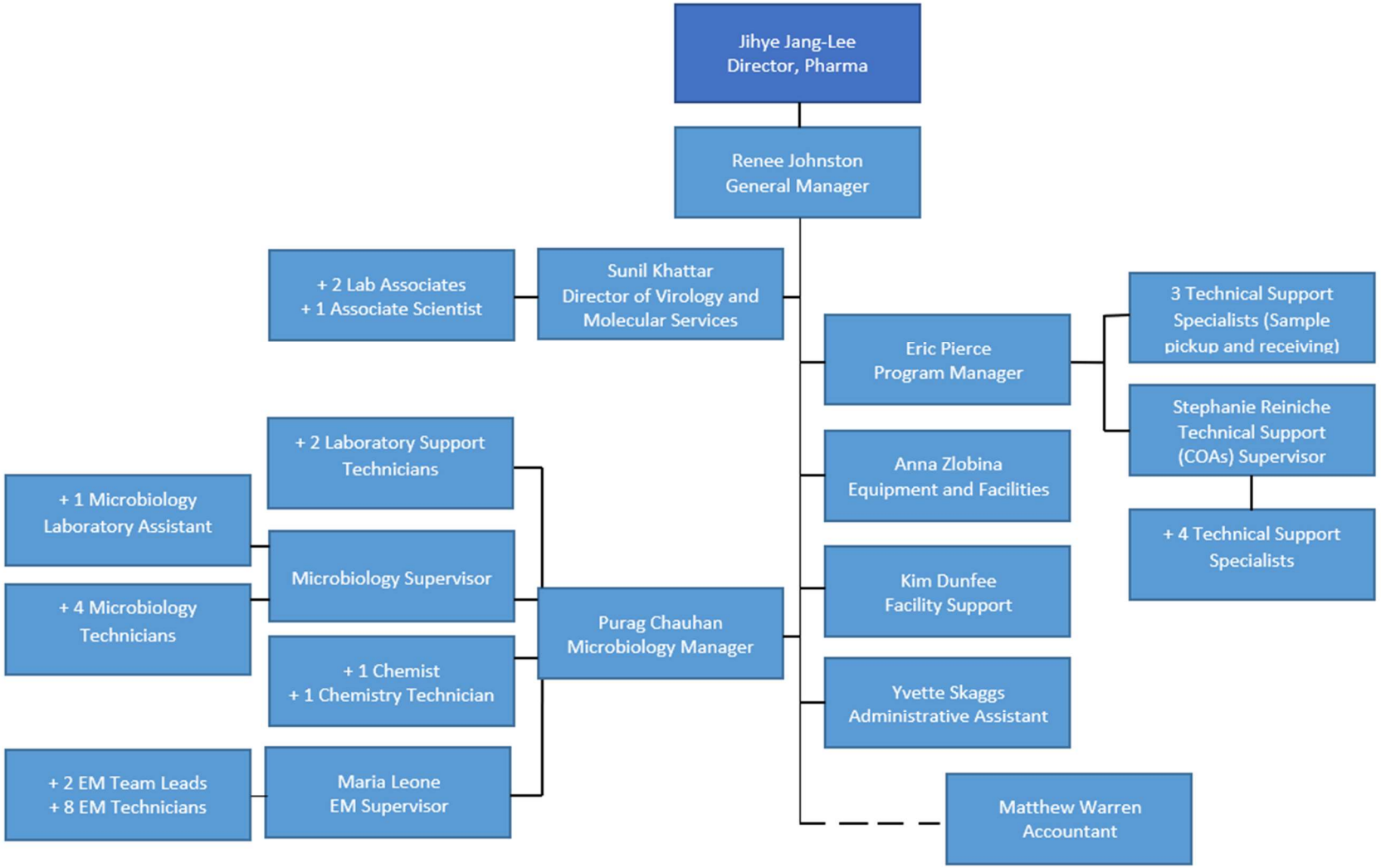
| SOP Number | Title |
|---|---|
| GE-0009 | Handling of Chemicals and Chemical Hazardous Waste Management |
| GE-0010 | Handling of Biological Contaminants and Biological Waste Management |
| GE-0011 | Laboratory Workflow |
| GE-0012 | Gowning for Operations in the ISO Classified Areas |
| GE-0013 | General Incubation and Plate Counting Practices |
| GE-0014 | Cleaning and Sanitization of the ISO Controlled Areas |
| GE-0015 | Security at Element - Concord |
| GE-0016 | Laboratory Gowning Procedures at Element - Concord |
| GE-0017 | Purchasing and Receiving Process at Element - Concord |
| 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 |
| GE-0023 | Air Visualization of ISO Classified Areas |
| GE-0024 | Documents Review |
| GE-0026 | Management of Client Storage Material |
| GE-0027 | Transportation of Finished Products Stored at Element-Concord |
| GE-0028 | Clean Room Materials Management |
| GE-0029 | Issuance of Codes to Access Clean Room |
| 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-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-0020 | Incubation of Client Microbiological Media Samples |
| 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-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-0032 | Non-Compendial Product Microbial Load Testing by Spread Plate Method |
| 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 |

| SOP Number | Title |
|---|---|
| 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 |
| 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 |
| 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-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-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 Homogeneity Check Based on 260 nm Absorbance UV Spectrophotometry |
| PC-0017 | Detection of DNase and RNase 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 |
| PC-0022 | Plasmid DNA Extraction using the QIAGEN Plasmid Mini Assay Kit |
| PC-0023 | A280 Analysis of Protein Concentration Using a Spectrophotometer |
| 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-0007 | Preparation of Client Protocols |

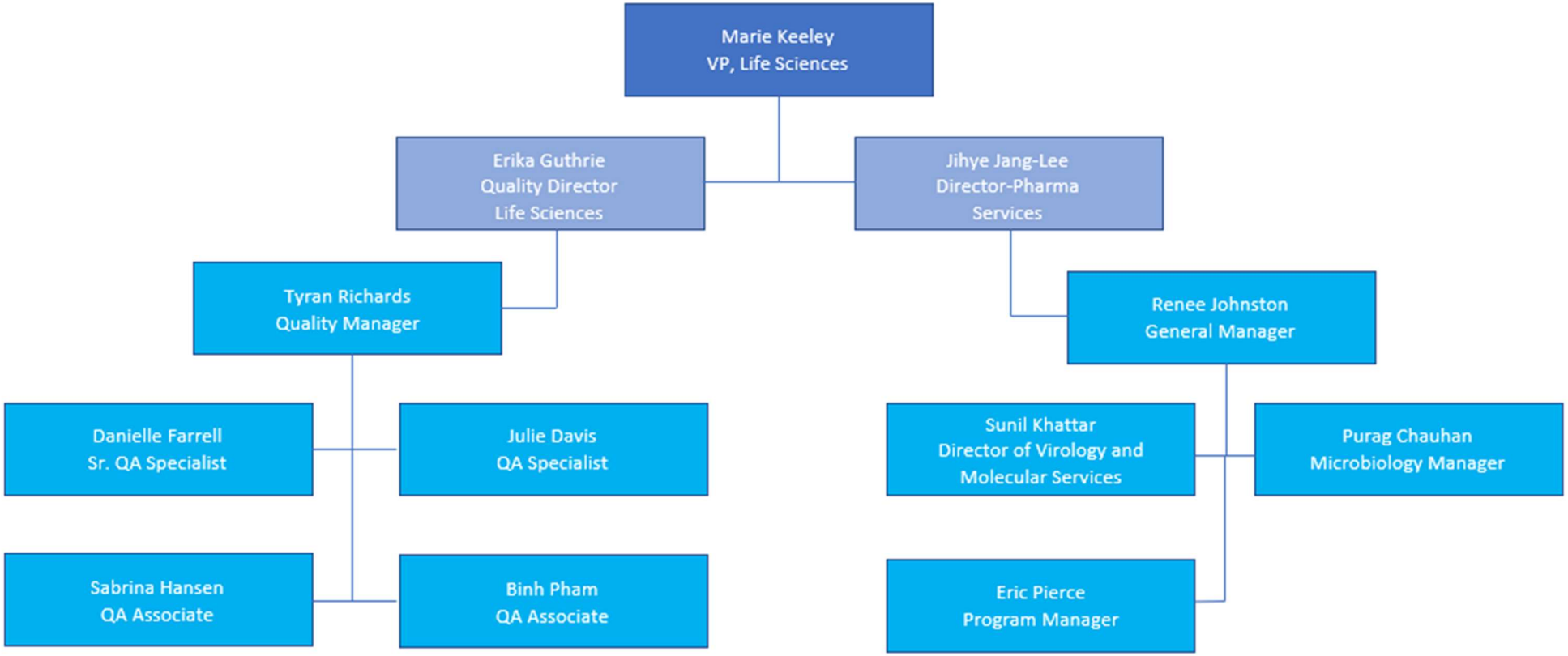
| SOP Number | Title |
|---|---|
| QA-0008 | Document and Records Management System |
| QA-0009 | Document Control |
| QA-0010 | Good Documentation Practices |
| QA-0011 | Master Signature Log |
| QA-0012 | Issuance, Use and Management of Laboratory Notebooks |
| QA-0013 | Logbook Management |
| QA-0014 | Sample Management and Chain of Custody |
| QA-0015 | Quality Event Investigations |
| QA-0016 | Out of Specification/Out of Trend (OOS/OOT) Investigations |
| QA-0017 | Corrective and Preventive Action (CAPA) and Issue Reviews |
| QA-0018 | Quality Auditing Procedure |
| QA-0019 | Supplier Management Program |
| QA-0020 | Performing External Physical Audits |
| QA-0021 | Training for GMP 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 |
| QA-0030 | Proficiency Testing Plan |
| QA-0031 | Preparation of Internal Proficiency Testing Samples |
| QA-0032 | Data Integrity |
| QA-0034 | Risk Management |
| QA-0036 | Change Control Management |
| QA-0037 | Signature Use Policy |
| QA-0038 | Root Cause Determination |
| QA-0039 | Preparation of Client Methods |
| 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 |

| SOP Number | Title |
|---|---|
| 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-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 |

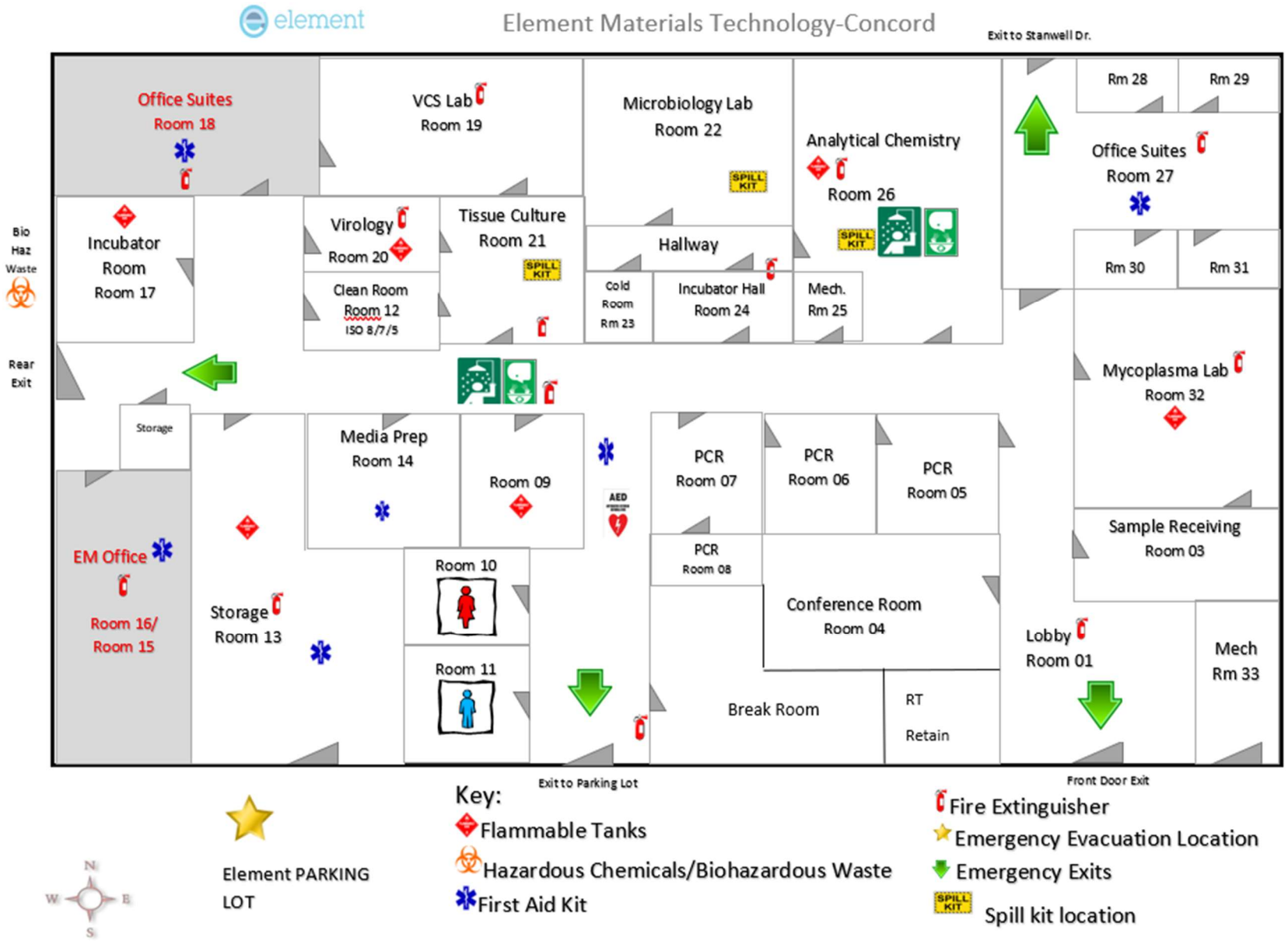
## ORGANIZATIONAL CHART



## ORGANIZATIONAL CHART



## FACILITY MAP



## FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Registration Expiration Date |
|---|---|---|---|---|---|
| Element Materials Technology Oakland - Concord Inc. | 3006616583 | 792157906 | ANALYSIS | 2341 Stanwell Drive, Concord, California (CA) 94520, United States (USA) | 12/31/2024 |

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY OAKLAND – CONCORD INC.
2341 Stanwell Dr.
Concord, CA 94520
Ms. Tyran Richards Phone: 925 536-3786
tyran.richards@element.com

BIOLOGICAL

Valid To: December 31, 2024 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 | Reference Method(s) | SOP(s) |
|---|---|---|
| Antimicrobial Effectiveness Test | USP <51> | MB-0024 |
| Bacterial Endotoxin Test | USP <85> | MB-0041<br>MB-0042<br>MB-0043<br>MB-0044 |
| Biological Indicators | USP <55> | MB-0022 |
| *Compressed Gas Sampling and Testing | USP <797><br>USP <1116><br>ISO 8573 | EM-0006<br>EM-0010<br>EM-0012<br>EM-0014 |
| Cytotoxicity and Biological Reactivity | ISO 10993-5<br>USP <87> | CC-0002<br>CC-0006 |
| Detection of Mycoplasma and Virus by PCR | EU 2.6.7 | PC-0001<br>PC-0003<br>PC-0005<br>PC-0006<br>PC-0007<br>PC-0011<br>MY-0008 |
| Detection of Virus in Test Articles | USP <1050><br>USP <1237> | VI-0002 |
| *Environmental Monitoring Testing | USP <797><br>USP <1116><br>ISO 14644-1<br>ISO 14644-2 | EM-0002<br>EM-0003<br>EM-0009<br>EM-0011<br>EM-0013<br>EM-0015 |
| Incubation of Media | USP <797><br>USP <1116><br>ISO 14644<br>ISO 13408 | MB-0020<br>MB-0027 |



5202 Presidents Court, Suite 220 | Frederick, MD 21703-8398 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

| Test(s) | Reference Method(s) | SOP(s) |
|---|---|---|
| Growth Promotion and Sterility Testing of Microbiological Media | USP <61><br>USP <62><br>USP <71><br>USP <2021> | MB-0001 |
| Microbial Identification | USP <1113> | MB-0004 |
| Microbiological Examination of Non-Sterile Products: Pour Plate, Spread Plate, Membrane Filtration Methods and Microbial Enumeration Method Suitability | USP <61><br>USP <2021><br>ISO 11737 | MB-0006<br>MB-0007<br>MB-0025<br>MB-0032 |
| Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms for: *Escherichia coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus, Clostridia, Candida Albicans, Burkholderia cepacia* | USP <60><br>USP <62> | MB-0012<br>MB-0013<br>MB-0045<br>MB-0046 |
| Mycoplasma Detection by Direct and Indirect Methods | USP <63><br>EP 2.6.7 | MY-0001<br>MY-0003<br>MY-0004<br>MY-0005<br>MY-0006<br>MY-0007 |
| *Sampling of Water Systems | USP <1116> | EM-0004 |
| Sterility Test | USP <71> | MB-0016<br>MB-0017<br>MB-0028<br>MB-0029<br>MB-0037<br>MB-0038 |
| Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test | USP <1231><br>EPA 1604 | MB-0003<br>MB-0015 |

CHEMICAL

| Test | Reference Method(s) | SOP |
|---|---|---|
| Conductivity Test | USP <645> | CH-0002 |
| Nitrogen Purity Assay | USP-NF Nitrogen<br>EP 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.

(A2LA Cert. No. 3383.01) 12/28/2022

# Accredited Laboratory

A2LA has accredited

## ELEMENT MATERIALS TECHNOLOGY OAKLAND – CONCORD INC.

*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 December, 2022.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3383.01
Valid to December 31, 2024

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