QUALITY INFORMATION PACKET

Element Materials Technology Boston - Acton

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 Boston - Acton, 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,

Jeffrey K. Belitsky
Quality Assurance Manager
Element Materials Technology Acton
33 Nagog Park
Acton, MA 01720
978-393-4100 (Direct)
978-263-2786 (Fax)
jeffrey.belitsky@element.com

GENERAL FACILITY AND QUALITY SYSTEM INFORMATION

General Information	
Company Name	Element Materials Technology Boston - Acton
Address of Facility	33 Nagog Park, Acton, MA 01720
Phone Number	877-287-8738
Website	www.element.com
DUNS Number	829542689
Services Provided	Microbiology testing services, Training & Consulting
Number of Permanent Employees	35
Number of Quality Employees	4
Facility Size	12,049 sq.ft.
FDA FEI Number	1000148174
Expiration Date	December 2021
Last FDA Audit	January 2019
ISO/IEC 17025:2017 Certificate Number	3383.02
Expiration Date	January 2023
Last ISO Renewal Audit	December 2020

Key Personnel Information		
Name	**Title**	**Email**
Joseph Gajewski	Director of Operations	joe.gajewski@element.com
Jeffrey K Belitsky	Quality Assurance Manager	jeffrey.belitsky@element.com
Elaine Cung	Technical Manager	elaine.cung@element.com
Aaron Bisceglia	Technical Project Manager	aaron.bisceglia@element.com
Ryan Burke	Environmental Monitoring Manager	ryan.burke@element.com
Matthew Green	Laboratory Manager	matthew.green@element.com
Stephanie Shepard	Director of Business Development	stephanie.shepard@element.com
Bonnie Sweeney	Accountant	bonnie.sweeney@element.com

Quality Assurance Information	
Name and Title of QA Manager	Jeffrey K. Belitsky, Quality Assurance Manager
Telephone Number	(978) 393-4100
Email Address	jeffrey.belitsky@element.com
Reports to	Katy Kubesh, Quality Director, Life Sciences
Number of QA Employees	4
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	12,049 sq.ft.
Area of facility utilized for office space	7,278 sq.ft.
Area of facility utilized for testing labs	4,210 sq.ft.
Area of facility utilized for warehouse	561 sq. ft.
Construction of facility	Multi-level Building
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
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**
A2LA ISO 17025 Assessment	3383.02	December 2020
U.S. FDA	1000148174	January 2019
A2LA ISO 17025 Assessment	3383.02	December 2020
U.S. FDA	1000148174	May 2014
U.S. FDA	1000148174	November 2011
U.S. FDA	1000148174	January 2008
U.S. FDA	1000148174	August 2005
U.S. FDA	1000148174	April 2003
U.S. FDA	1000148174	June 2001

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?	10-15
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 QC-0007
Is the test sample log-in procedure computerized?	Currently both paper-based and computerized
How are test samples stored?	Per SOP QC-0007
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?	All raw data is stored on-site for a minimum of 3 years, unless otherwise instructed in an established and fully executed Quality Agreement. All data is either stored off site at a secure facility or scanned and stored electronically on a secure server that is fully backed-up in accordance with CORP-IT-0002.

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 INDEX

SOP Number Format	Type of SOP
CORP-IT-XXXX	Corporate IT SOP
P-XXXX	Procedural SOP
QC-XXXX	Quality SOP

QUALITY SYSTEMS PROCEDURES LIST

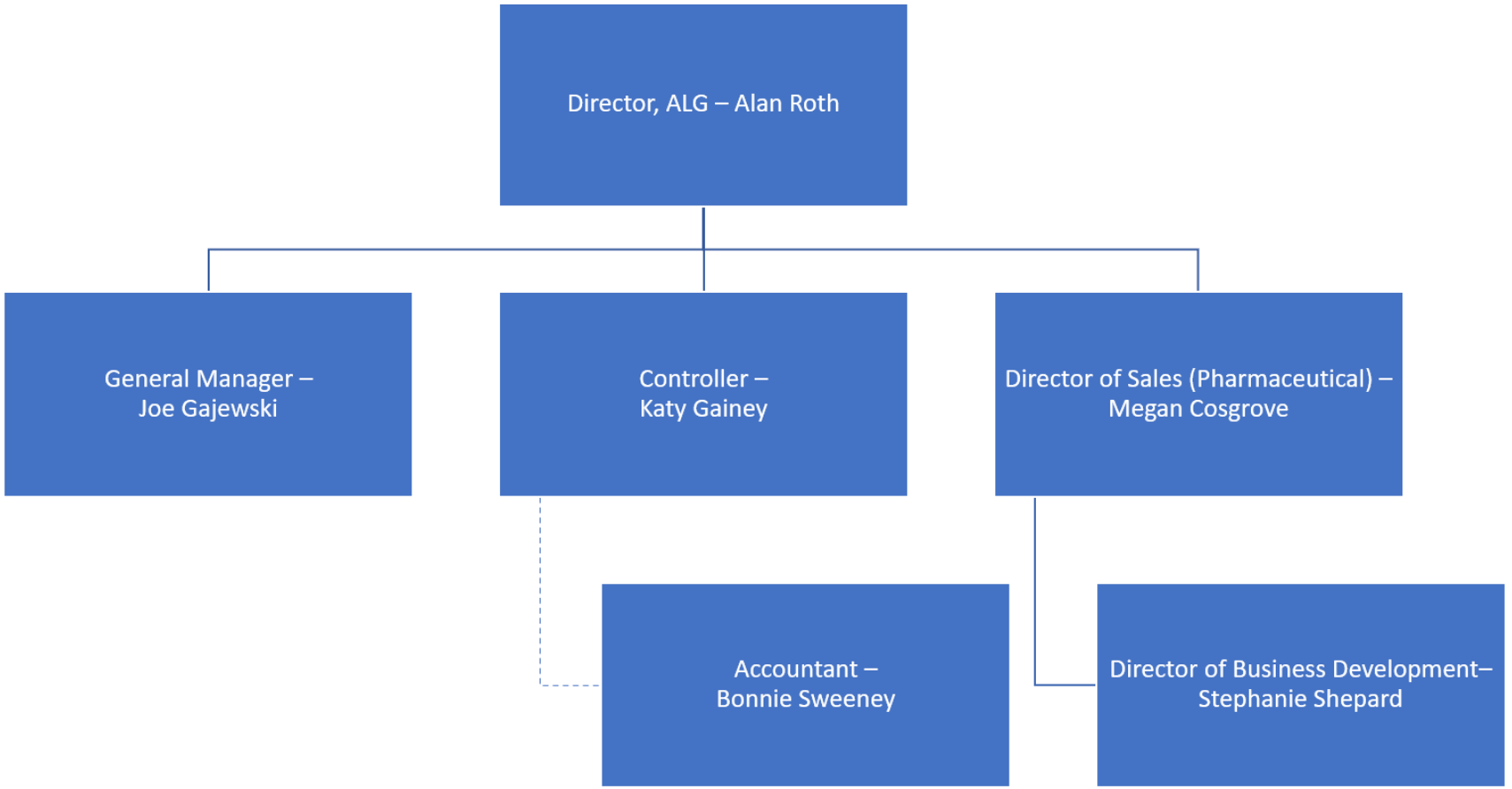
SOP Number	Title
CORP-IT-0001	Electronic Use Signature Policy
CORP-IT-0002	Network Back Up and Disaster Recovery Policy
CORP-IT-0003	Security Management Policy
CORP-IT-0004	Acceptable Use Policy
CORP-IT-0005	Internet Use, Monitoring and Filtering
CORP-IT-0006	Compromised Credentials
CORP-IT-0007	Email Security Training
P-0001	Official Protocol for Total Bacterial Count Procedure
P-0002	Current USP <51> Antimicrobial Effectiveness Testing
P-0003	Protocol for Microbiological Examination of Water Samples
P-0004	USP <71> Sterility Testing of the Finished Product Using Membrane Filtration
P-0005	Sterility Testing Protocol for Biological Indicators
P-0006	USP <71> Sterility Testing of the Finished Product Using Direct Inoculation
P-0007	Procedure for Microbiological Evaluation of Client Environmental Monitoring Plates (Air and Surfaces)
P-0008	Current USP <71> Growth Promotion Test
P-0009	Current USP <71> Method Suitability Test
P-0010	Official Protocol for Bacterial Endotoxin Testing (BET) of Water Samples by Gel Clot Method
P-0011	European Pharmacopeia - Efficacy of Antimicrobial Preservatives in Pharmaceutical Products
P-0012	Minimum Inhibitory Concentration (MIC)
P-0013	Testing of Endotoxin Challenge Vials (for Validation of Depyrogenation Equipment)
P-0014	Antimicrobial Effectiveness Screening Test Current USP <51>
P-0015	PCPC Antimicrobial Effectiveness Testing
P-0016	Procedure for Operation of Millipore Milliflex 100 Water Testing Device

SOP Number	Title
P-0017	Official Procedure for Harmonized Bacterial Endotoxin Testing (BET) of Medical Devices and Other Finished Products by Gel Clot Method
P-0018	Current USP <61> and <62> (Ph. Eur. 2.6.12 and 2.6.13) Harmonized Microbial Enumeration and Suitability Test for Specified Microorganism
P-0019	Gram Stain Procedure
P-0020	Protocol for Use of the Vitek 2 Compact Microbial Identification System
P-0021	Procedure for Operation of Millipore Milliflex PLUS Pump Double Head Water Testing Unit
P-0022	Procedure for Microbial Evaluation of Environmental Surfaces Using Swabbing Technique
P-0023	Environmental Monitoring of the Sterility Suite Area Clean Rooms
P-0024	Operation and Maintenance of the Kinetic Endotoxin Testing System
P-0025	Routine Testing, Qualification, and Validation of Endotoxin Samples Using the Kinetic-KQCL and Pyrogent-5000 Methods
P-0026	Procedure for Proper Operation, Calibration and Maintenance of Steritest Symbio Pump
P-0027	Operation, Maintenance and Calibration of the 3300 Series Met One Particle Counter
P-0028	Operation, Maintenance, Calibration and Cleaning of the Air Ideal Microbial Air Sampler (Agar Impaction)
P-0029	Environmental Monitoring for Off-Site Clients
P-0030	Isolation and Identification of Microorganisms
P-0031	Proper Operation, Calibration, Maintenance and Cleaning of AquaLab Series 4TEV Water Activity Meter for Measurement of Water Activity (Aw)
P-0032	Procedure for Requalification of Sterility Suite Cleanrooms
P-0033	Preparation of Bacillus subtilis Spore Suspension for Use in Vancomycin Potency Assay
P-0034	USP <81> Vancomycin Microbial Assay Using Cylinder Plate Method
P-0035	Compressed Air and Gas Testing for Off-Site Clients
P-0036	USP <81> Antibiotics Microbial Assay Using Cylinder Plate Method
P-0037	Operation and Maintenance of the 3400 Series Met One Particle Counter
P-0039	Procedure for Off Site Water Sampling
P-0040	Current USP <60> Microbiological Examination of Nonsterile Products: Tests for Burkholderia cepacia Complex
QC-0001	Procedure for Monitoring Air Quality - Viable and Non-Viable Air Monitoring Laminar Flow Hoods
QC-0002	Monitoring Laminar Flow Hood Surfaces for Viable Counts (Contact Plates)
QC-0003	Preparation, Sterilization and Storage of Microbiological Media
QC-0004	Maintenance of Stock Cultures
QC-0005	Storage, Validation and Use of Biological Indicators
QC-0006	Training Program
QC-0007	Tracking of Laboratory Research Projects and Samples
QC-0008	Procedure for Calibration Check of Pipettes
QC-0009	Procedure for Preparation of a Standard Operating Procedure

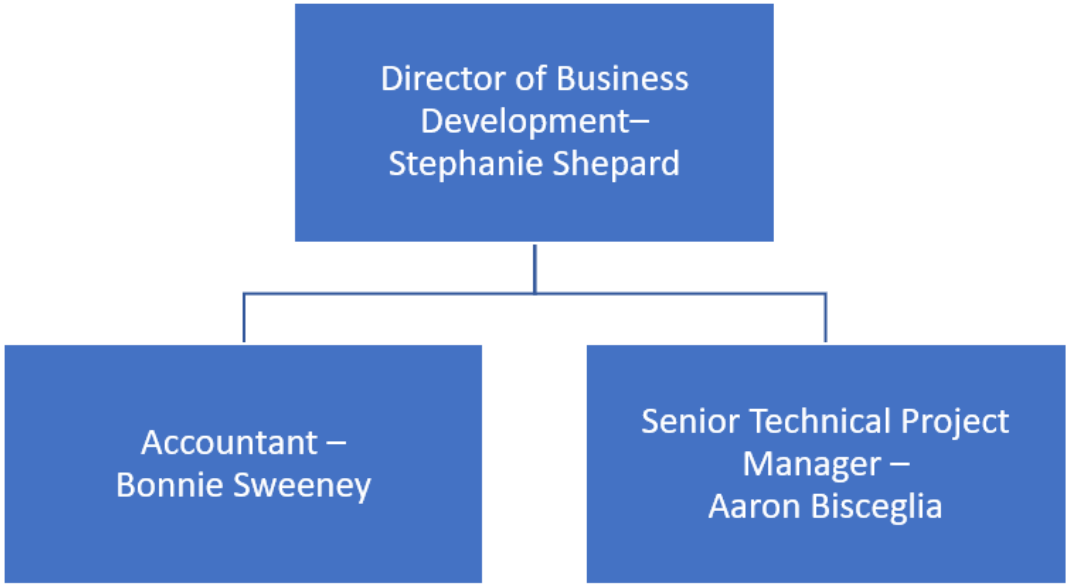
SOP Number	Title
QC-0010	Monitoring and Maintaining Required Temperature Ranges for Laboratory Incubators, Refrigerators, and Freezers
QC-0011	Proper Methodology of Recording Laboratory Test Data
QC-0012	Equipment Maintenance and Calibration
QC-0013	Protocol for Document Change Control and Validated Systems Change Control
QC-0014	Procedure for the Control of Raw Material
QC-0015	Procedure for Archiving Records
QC-0016	Protocol for Incubator, Refrigerator, and Freezer Validation
QC-0017	Standard Operating Procedure for Investigating Out of Specification Results
QC-0018	Procedure for Cleaning Glassware
QC-0019	Procedure for General Laboratory Cleaning
QC-0020	"In-House" Calibration Check of the Ohaus Balance
QC-0021	Standard Operating Procedure for Qualification of Vendors (Vendor Audit)
QC-0022	Quality Audit Procedure
QC-0023	Company Procedure to Resolve Customer Complaints to Element Materials Technology Acton
QC-0024	Power Outage Procedure for Laboratory Testing and Equipment
QC-0025	Pest Control
QC-0026	Quality Audit Procedure by Outside Clients
QC-0027	Protocol for Transporting Samples
QC-0028	Protocol for Training of 3rd Party On-Site Vendors
QC-0029	Accident Reports and Investigation
QC-0030	Guideline for Handling and Disposal of Hazardous Materials in the Laboratory
QC-0031	Procedure for Calibration of the Mettler Toledo Precision Balance
QC-0032	Growth Promotion of Microbiological Media
QC-0033	Procedure for Qualification/Validation of Vitek 2 Compact Microbial Identification System
QC-0034	Proper Use, Handling, Service of Advantage Plus Series Autoclave (Steam Sterilizer)
QC-0035	Validation Qualification Protocol for Consolidated Steam Sterilizer ST-2
QC-0036	Annual Re-Validation Protocol for Consolidated Steam Sterilizer ST-2
QC-0037	Procedure for Aseptic Technique
QC-0038	Procedure for Calibration of the Weight-Measurement Function and Verification of Pump Functions for Milliflex PLUS Pump
QC-0039	Procedure for Proper Operation and Disinfection of Surface Air System (SAS) Super 180 Microbial Air Sampler, and DUO SAS Super 360 Microbial Air Sampler
QC-0040	Procedure for Proper Operation and Maintenance of Elix Essential 5 (UV) Reverse Osmosis (RO)/Electrical Deionization (EDI) Water System
QC-0041	Procedure for Proper Operation and Maintenance of APC ErgoTouch Pro 2 Airborne Particle Counter
QC-0042	Procedure for Operation of pH 510 pH/mV/Temperature Bench Meter
QC-0043	Corrective Action and Preventative Action Procedure
QC-0044	Security at Element Materials Technology Acton
QC-0045	Test Report Generation and Review

SOP Number	Title
QC-0046	Procedure for Gowning Before Entering the Sterility Suite Clean Room Area
QC-0047	Cleaning and Disinfection Procedure for the Sterility Suite
QC-0048	Procedure for Proper Operation and Care of LXeC Dishwasher
QC-0049	Protocol for Glassware Cleaning Validation
QC-0050	Operation of the Mfiles Data Management System
QC-0051	Exposure Plan for Bloodborne Pathogens
QC-0052	Procedure for Proper Operation and Maintenance of Beckman Coulter HHPC Airborne Particulate Counter
QC-0053	Procedure for Operation of FiveEasy Plus FP20 pH/mV Bench Meter
QC-0054	Procedure for Proper Operation and Care of VWR Laboratory Glassware Washer
QC-0055	Deviations
QC-0056	Determination of Measurement Uncertainty
QC-0057	Proficiency Testing
QC-0058	Disaster Recovery Plan
QC-0059	Operation and Maintenance of the Peni Cylinder Dispenser
QC-0060	Operation and Maintenance of Trinity V3 AutoAssay Software - Antibiotic Potency Zone Reading
QC-0061	Proper Use, Handling, Service of Steris Amsco Lab 250LS Steam Sterilizer (Autoclave)
QC-0062	Validation Qualification Protocol for Steris Amsco 250LS Steam Sterilizer ST-3
QC-0063	Equipment Validation Plan
QC-0064	Annual Re-Validation Protocol for Steris Amsco 250LS Steam Sterilizer
QC-0065	Quality Manual for Element Materials Technology Acton

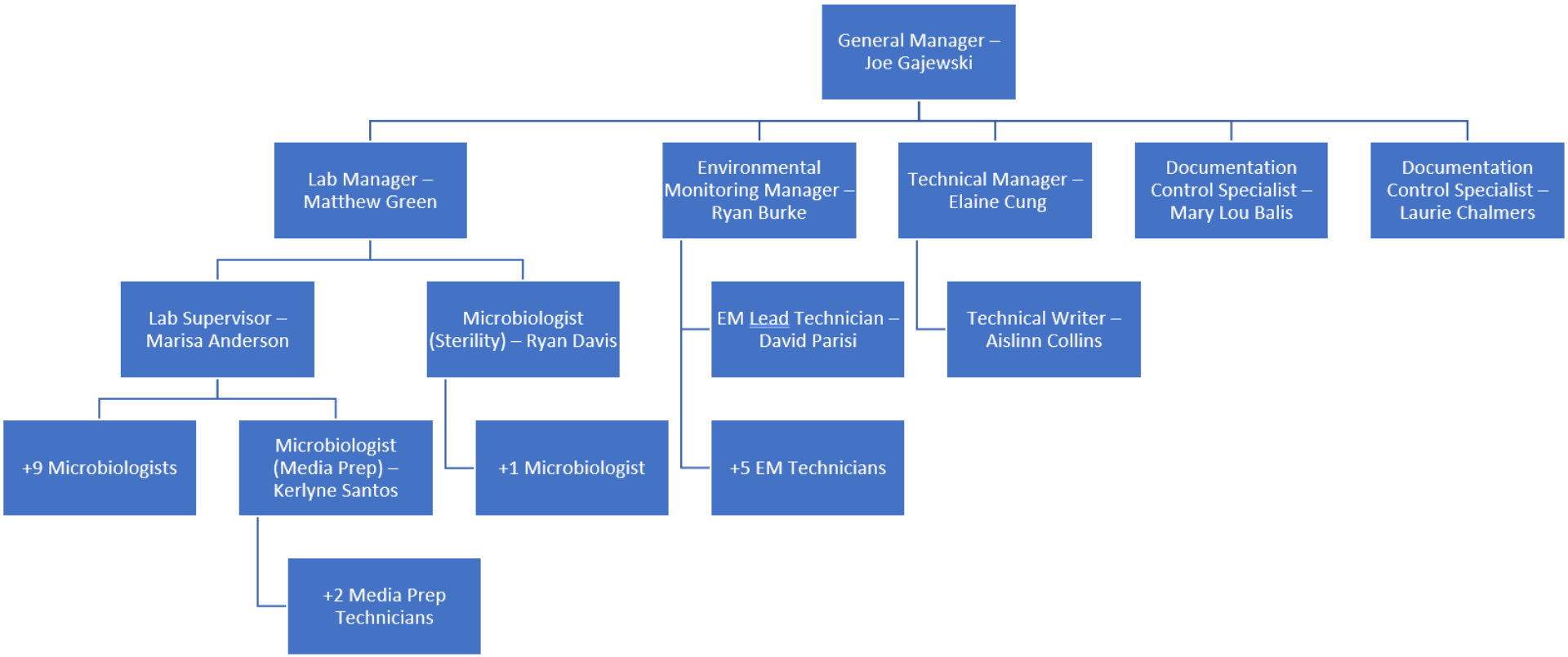
ORGANIZATIONAL CHART



ORGANIZATIONAL CHART



ORGANIZATIONAL CHART

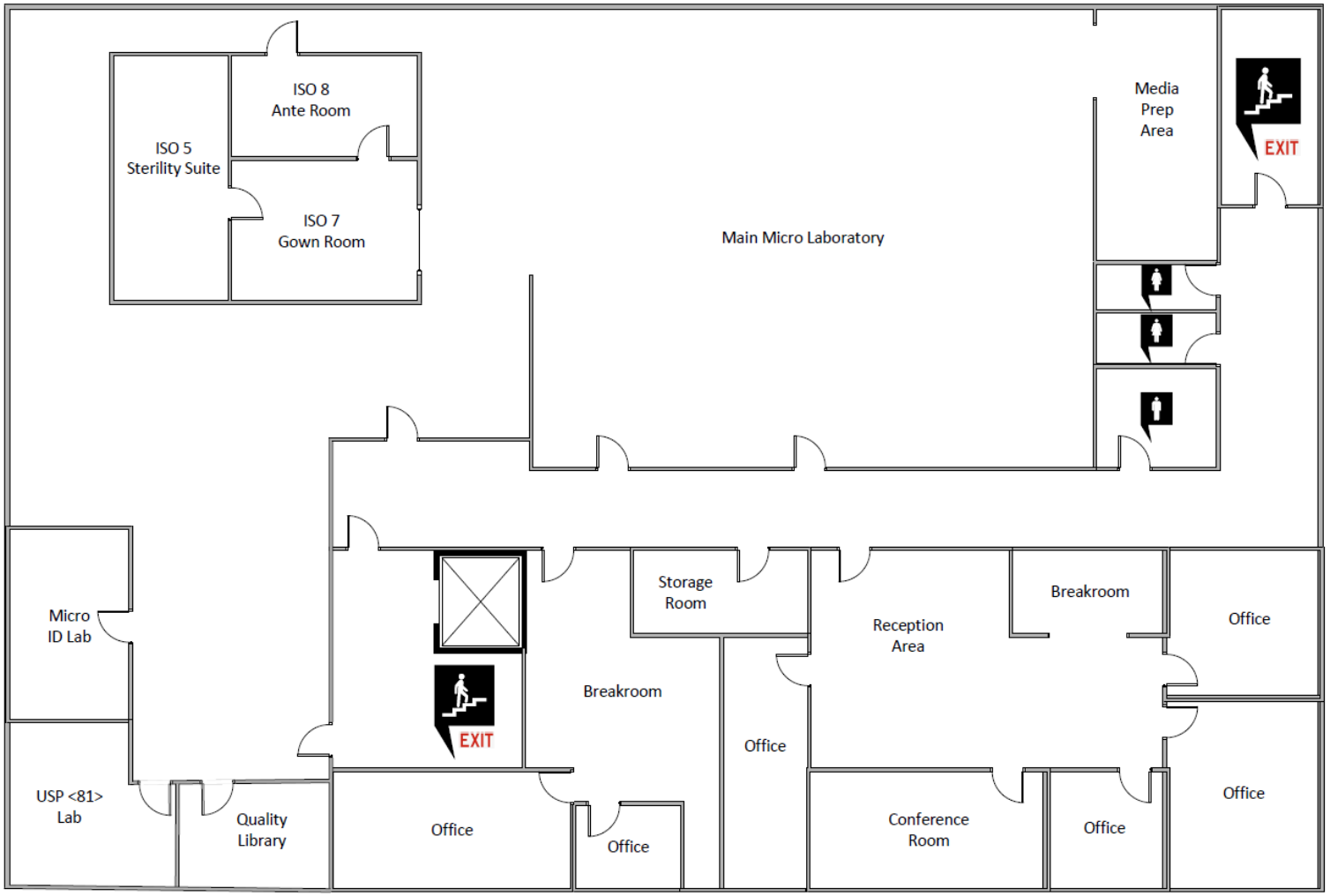


ORGANIZATIONAL CHART

FACILITY MAP – First Floor

Total Sq. Footage = 4,000 sq.ft.

FACILITY MAP – Third Floor



Total Laboratory Sq. Footage = 4,266 sq.ft.
Total Admin Sq. Footage = 3,778 sq.ft.
Total Sq. Footage = 4, 000 sq.ft.

FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Microbiology Research Associates, Inc	1000148174	829452689	ANALYSIS;	33 Nagog Park, Acton, Massachusetts (MA) 01720, United States (USA)	12/31/2021

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY BOSTON – ACTON INC.
33 Nagog Park
Acton, MA 01720
Mr. Jeffrey K. Belitsky Phone: 978-393-4100
Jeffrey.Belitsky@analyticallabgroup.com

BIOLOGICAL

Valid To: January 31, 2023 Certificate Number: 3383.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on injectable, topical, and oral pharmaceuticals, raw materials, personal care products, cosmetics, medical devices, water, biological indicators, and controlled environments:

Test:	Test Method(s):	Internal Method(s):
Antimicrobial Effectiveness Testing	USP <51>; CTFA M-3 and M-4	P-0002, P-0014, P-0015
Biological Indicators BI Population Verification	USP <55>	QC-0005
Endotoxin Testing	USP <85>	P-0010, P-0013, P-0017, P-0025
Environmental Evaluation of Clean Rooms[1]	USP <1116>, <797>	P-0007, P-0029
Microbial Examination of Nonsterile Products: Microbial Enumeration Tests and Tests for Specified Microorganism	USP <61>, <62>	P-0018
Microbiological Examination of Non-Sterile Products: Tests for Burkholderia cepacia Complex	USP<60>	P-0040
Sterility Testing	USP <71>; ASNI/AAMI ISO 11137	P-0004, P-0006, P-0009
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> Water for Pharmaceutical Methods	P-0003

[1] This laboratory meets A2LA R104- *General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for this test.

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

Accredited Laboratory

A2LA has accredited

Element Materials Technology Boston – Acton Inc.

Acton, MA

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 2nd day of February 2021.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3383.02
Valid to January 31, 2023
Revised June 1, 2021

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