QUALITY INFORMATION PACKET

Element Materials Technology Minneapolis - Eagan

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
- Regulatory Overview Document
- Organizational Chart
- Facility Map

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

- 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,

Cody Ganz
Quality Assurance Manager
Element Materials Technology
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121
651.379.5517 (Direct)
651.379.5549 (Fax)
cody.ganz@element.com

GENERAL FACILITY AND QUALITY SYSTEM INFORMATION

General Information	
Company Name	Element Materials Technology Minneapolis - Eagan
Address of Facility	1285 Corporate Center Drive, Suite 110 Eagan MN 55121
Phone Number	877-287-8738
Fax	651-379-5549
Website	www.element.com
Services Provided	Full range of microbiology, virology, analytical chemistry, EPA stability testing
Number of Permanent Employees	~50
Number of Quality Employees	4
Years in Business	30+
Type of Business	Privately Owned
Federal Tax ID	81-3510615

Key Personnel Information		
Name	**Title**	**Email**
Director of Pharma Services	Jihye Jang-Lee	jihye.janglee@element.com
General Manager	Kelleen Lauer	kelleen.lauer@element.com
Quality Assurance Manager	Cody Ganz	cody.ganz@element.com
Technical and Regulatory Manager	Shanen Conway	shanen.conway@element.com
Manager of Study Director Operations	Nicole Felicelli	nicole.felicelli@element.com

Quality Assurance Information	
Name and Title of QA Manager	Cody Ganz, Quality Assurance Manager
Telephone Number	651-379-5517
Email Address	cody.ganz@element.com
Reports to	Kelly Lauer, General Manager Patrick Tierney, Quality Manager II
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 SOPs are created or updated?	Yes
Are changes in EPA, 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

Facility Information	
Total size of facility	35,648 sq. ft.
Area of facility utilized for office space	13,476 sq.ft.
Area of facility utilized for testing labs	19,223 sq.ft.
Area of facility utilized for warehouse	2,949 sq. ft.
Construction of facility	Single story 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 SOPs in place and is 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**
U.S. EPA	Not Applicable	March 2023
U.S. EPA	Not Applicable	December 2019
U.S. FDA	Not Applicable	August 2017
U.S EPA	Not Applicable	September 2016
U.S.D.A	Not Applicable	April 2016
U.S.D.A	Not Applicable	April 2014
U.S. EPA	Not Applicable	September 2013
U.S.D.A	Not Applicable	May 2013
U.S. EPA	Not Applicable	May 2010
U.S. EPA	Not Applicable	December 2006

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
Complaint Handling	
Element Eagan is compliant with U.S. EPA and U.S. FDA GLPs (Good Laboratory Practices). A formal complaint procedure is not required by either of these regulations. However, Element Eagan responds/investigates all client complaints as they are received and when necessary, per internal procedure ALS-0055.	
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?	5-10
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?	Test samples are received in person by receiving personnel.
Is the test sample log-in procedure computerized?	Yes
How are test samples stored?	Test samples are stored in a secured location in appropriate storage conditions as indicated by packaging or client instruction.
Is there adequate security for stored test samples?	Yes
Is test sample flow tracked?	Yes, Test Substance (Sample) Control procedures.
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?	Per SOPs ALS-0035 and ALS-0052

Quality System Information Continued	
Out of Specification Investigation Procedure (OOS)	
The Element Eagan facility is compliant with U.S. EPA and U.S. FDA GLPs (Good Laboratory Practices). A formal Out of Specification procedure is not required by either of these regulations. However, Element Eagan has a laboratory investigation procedure (ALS-0005) in place to investigate and document all unexpected test results.	
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?	Paper records are retained for a minimum of 5 years and electronic records are maintained indefinitely.

Operations Information	
Analytical Control of Supplies	
Are appropriate reference standards used and are they stored in a proper manner to ensure stability?	Yes
Are their expiration dates adequately monitored so they are not used beyond expiration dates?	Yes
If reference standards are not USP, has appropriate characterization (including purity and stability) been performed?	Yes
Are reagents adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?	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
Analytical Testing	
Are there complete written instructions for testing, including methods, equipment, operating parameters, and acceptance specifications?	Yes
Are test methods readily available to the analysts?	Yes
Are test methods followed without approved modification?	No
Is there an SOP describing how numbers are to be rounded?	Yes
Are data and calculations reviewed, verified, and signed by a second person?	Yes
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 smoke 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?	No
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

Operations Information	
Stability Testing	
Are stability testing methods stability-indicating? If so, have they been validated?	Yes, if requested by the Sponsor. Method validation is product-specific, so every individual product should be validated under its own project.
Is stability testing performed in the marketed container/closure systems according to intervals and tests specified in a written stability program?	Yes, if the Sponsor provides us with the product packaged accordingly.
Is stability testing done on time within the specified cycle times appropriate for the test intervals?	Yes
Are stability failures investigated (when unexpected) and appropriately documented?	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 other measuring and testing instruments?	Yes
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
Do SOPs assign responsibilities, include 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, Chromeleon MS Office – Excel
Are these computerized systems validated?	MasterControl and Chromeleon-Yes; systems have been validated to meet requirements of 21 CFR Part 11 and internal standard operating procedures. Excel- all formulas are printed and verified with each use. Also, we have an SOP for validating excel spreadsheets.
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 in regard to potential effects before being instituted and that only authorized personnel can make such changes?	Yes
If necessary, are personnel trained on subsequent 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

QUALITY SYSTEMS PROCEDURES LIST

SOP Number	Title
ACS-0001	Overview of Chemistry Techniques
ACS-0002	Common Calculations in Chemistry
ACS-0003	Analytical Chemistry Methods Documentation Control and Records Maintenance in MasterControl
ACS-0004	Labeling and Expiration of Reagents and Solutions in Chemistry
ACS-0005	Analytical Method Validation
ACS-0006	Chemical Characterization and Preliminary Analysis
ACS-0007	Storage Stability
ACS-0008	Extraction Procedures for Towelettes and Aerosol Products for Use in Chemistry Testing
ACS-0009	Empower Chromatography Data Software
ACS-0011	Agilent 6890 Gas Chromatograph (GC)
ACS-0012	Use and Care of HPLC and GC Columns
ACS-0013	Injection Sequence for GC and HPLC Analysis
ACS-0014	Anton Paar DMA 35 Density Meter
ACS-0015	Mettler Toledo Titration Excellence T7 Autotitrator
ACS-0016	Use, Calibration, and Maintenance of Electrodes for the Mettler Toledo Titration Excellence T7 Autotitrator
ACS-0017	Chromeleon Chromatography Software Overview
ACS-0018	Running a Sequence in Chromeleon
ACS-0019	Processing Data in Chromeleon
ACS-0020	Reporting, Reviewing and Audit Trails in Chromeleon
ACS-0021	Agilent High Performance Liquid Chromatograph (HPLC)
ACS-0022	Analytical Chemistry Laboratory Personnel Training, Retraining, and Proficiency Evaluation Procedure
ACS-0025	Corrosion
ACS-0027	Odor
ACS-0029	Oxidation/Reduction: Chemical Incompatibility
ACS-0030	pH Measurement
ACS-0031	Physical State
ACS-0033	Bulk Density of Powders
ACS-0034	Geometric Density of a Solid Test Substance
ALS-0001	Personnel Training, Retraining and Competency Evaluation Procedure
ALS-0002	Training File Contents
ALS-0003	Procedure for Company Organizational Chart, Personnel Job Descriptions and Curriculum Vitaes
ALS-0004	Numbering System for Controlled Documents
ALS-0005	Study Investigation
ALS-0006	Confirmatory Testing Procedures
ALS-0007	Format and Content of Controlled Documents
ALS-0008	Good Documentation Practices
ALS-0010	Corrective Action / Preventive Action System
ALS-0011	Documentation Control and Records Maintenance
ALS-0012	Facility Security and Visitor Identification
ALS-0013	Facility Inspections

SOP Number	Title
ALS-0014	Ishihara's Colour-Blindness Test
ALS-0016	Guidelines for Assay Validation
ALS-0017	Multi-Site Studies
ALS-0018	Labeling of Laboratory Reagents and Solutions
ALS-0019	Measurement Assurance Program
ALS-0020	Statistical Methods
ALS-0021	Reporting Significant Digits and Rounding Numbers
ALS-0022	Safety Training
ALS-0023	Good Laboratory Practice (GLP) Training Program
ALS-0024	Personnel Outline for Nonclinical Studies
ALS-0025	Management and Study Director Responsibilities
ALS-0026	Exact Copies
ALS-0027	Reporting Results for Non-Clinical GLP Studies
ALS-0028	GLP Protocol Requirements
ALS-0029	Deviations and Protocol Amendments
ALS-0030	GLP Final Report Amendments
ALS-0031	Receiving Policies and Procedures
ALS-0032	Archive Procedures for Documentation Records
ALS-0033	Preparing Project Files for Archiving
ALS-0035	Discarding and Returning Substances to Sponsors
ALS-0039	Design, Validation, and Use of Excel Spreadsheets
ALS-0040	Preparation of Electronic Data for Archival
ALS-0041	Maintaining the Master Schedule
ALS-0045	Quality Manual
ALS-0046	Warehouse Management and Purchasing of Supplies
ALS-0047	Use of MFiles Client Document Notification System
ALS-0050	Certificates of Analysis
ALS-0051	Project Folder and Test Substance Accountability Record Generation
ALS-0052	Receipt, Identification and Storage of Test, Control and Reference Substances
ALS-0053	Test Substance Accountability Record Documentation
ALS-0054	Repeat Testing
ALS-0055	Customer Complaints
ALS-0056	Company Policies at Element Eagan
ALS-0057	Proficiency Testing
ALS-0058	Determining Measurement Uncertainty
CEL-0001	Procedure For Splitting and Producing Continuous Cell Lines
CEL-0002	Continuous Cell Line Preservation and Recovery
CGT-0001	AOAC Hard Water Preparation and Determination (CaCO3)
CGT-0002	Preparation of OECD/EN Hard Water
CGT-0003	Sodium Hypochlorite Preparation and Sodium Hypochlorite / Available Chlorine Determination
CGT-0005	Procedure for Monitoring and Documenting Timed Intervals
CGT-0006	Wetness Determination for Towelette Products
CGT-0009	General Laboratory Procedures
CGT-0010	Preparation of Disinfectant for Efficacy Tests
CGT-0011	General Safety Precautions for the Testing Laboratories

SOP Number	Title
CGT-0013	AOAC Disinfectant (Water) for Swimming Pools
CGT-0014	Staining Techniques for Acid Fast Bacilli
CGT-0015	Gram Stain and Colony Morphology Procedure
CGT-0016	Overview of Microbiological Technique
CGT-0017	Available Chlorine in Disinfectants (Germicidal Equivalent Concentration)
CGT-0018	AOAC Bacteriostatic Activity of Laundry Additive Disinfectants
CGT-0019	Standard Test Method for the Evaluation of Laundry Additives as Sanitizers or Disinfectants
CGT-0020	Culture Maintenance Record Keeping Guidelines
CGT-0021	ETest Method for Determining Antimicrobial Susceptibility
CGT-0022	Examination of Penicylinder Carriers
CGT-0023	AOAC Fungicidal Activity of Test Substances
CGT-0024	AOAC Germicidal and Detergent Sanitizing Action of Disinfectants
CGT-0025	Food Contact Sanitizer Test Method for Towelettes
CGT-0026	Efficacy of a Disinfectant or Sanitizer Applied to a Room Via a Fogging, Misting or Vaporizing Device
CGT-0027	AOAC Germicidal Spray Method
CGT-0028	Time Kill Test Method for Antimicrobial Agents
CGT-0029	Residual Self-Sanitizing Efficacy
CGT-0030	Carpet Sanitizer
CGT-0031	Minimum Inhibitory Concentration - MIC Macrodilution Broth Method
CGT-0032	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces
CGT-0033	Pre-Saturated Towelettes for Hard Surface Disinfection
CGT-0034	Sporicidal Activity of Disinfectants
CGT-0035	Malachite Green Staining of Bacterial Endospores
CGT-0036	Preparation of Carriers for Use in Testing
CGT-0037	Quantitative Suspension Method for Determining Tuberculocidal Activity
CGT-0038	AOAC Confirmatory Tuberculocidal Activity Test
CGT-0039	EPA Re-Use Evaluation of a Disinfectant
CGT-0040	Evaluation of Disinfectant Efficacy against a Biofilm - Single Tube Method
CGT-0041	AOAC Use-Dilution Method
CGT-0042	Hard Surface Mildew Fungistatic Test Method
CGT-0043	Fabric Mildew Fungistatic Test Method
CGT-0044	Culture Freezing for European Test Methods
CGT-0045	Culture Maintenance for European Test Methods
CGT-0046	European Suspension Test Methods for Bactericidal, Fungicidal or Yeasticidal Activity
CGT-0047	EN 13697 - European Quantitative Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity
CGT-0048	Kirby-Bauer Method for Determining Bacterial Susceptibility to Antibiotics
CGT-0049	Modified Hodge Test Method for Carbapenemase Detection in Enterobacteriaceae
CGT-0050	Minimum Inhibitory and Minimum Bactericidal Concentration Determination (Microdilution Broth Method)
CGT-0051	Residual Self-Sanitizing Activity (with Exposure and Wear Activity)
CGT-0052	Standard Quantitative Carrier Test Method to Evaluate Germicides
CGT-0053	Production of Clostridium difficile Spores for Efficacy Testing
CGT-0054	Standard Quantitative Disk Carrier Test Method to Evaluate Germicides

SOP Number	Title
CGT-0055	Standard Quantitative Disk Carrier Test Method to Evaluate Germicides Against C. difficile
CGT-0058	Antibacterial Activity Assessment of Textile Materials: Parallel Streak Method (AATCC 147)
CGT-0059	Assessment of Mildew and Rot Resistance of Textile Materials (AATCC 30 Test III)
CGT-0060	Assessment of Antimicrobial Finishes on Textile Materials (AATCC 100)
CGT-0061	Standard Method for Determining Antimicrobial Activity of Antimicrobial Agents (ASTM E2149)
CGT-0062	Standard Method for Determining Antimicrobial Activity in Polymeric or Hydrophobic Materials (ASTM E2180)
CGT-0063	Standard Test Method for Determining Efficacy of Surface-Bound Antimicrobial Agents (JIS Z 2801)
CGT-0064	Disinfectant Qualification Assay for Cleanrooms or Other Manufacturing Facilities
CGT-0065	Purchasing, Receiving, Rehydrating and Freezing Bacterial and Fungal Organisms
CGT-0066	Preparation of Serum Organic Soil Load for the Microbiology Laboratory
CGT-0067	Test Organism Confirmation Procedures
CGT-0068	Solution Preparation for the Microbiology Laboratory
CGT-0069	Antimicrobial Preservative Effectiveness
CGT-0070	Cultivation of Molds for Challenge Testing
CGT-0071	Quality Control of Virucidal Assay
CGT-0072	Documentation of Stock Virus Receipt
CGT-0074	Procedure for the Preparation of Stock Viral Cultures
CGT-0075	Titration of Viruses
CGT-0076	Hemagglutination Assay Procedure
CGT-0077	Viral Isolation - CPE
CGT-0078	Confirmatory Fluorescent Antibody (FA) Test for Viral Identification
CGT-0079	Chlamydia Culture Test Procedure
CGT-0080	Plating Method for Primary Duck Hepatocytes
CGT-0081	Procedure for Counting Cells
CGT-0082	Virucidal Overview
CGT-0083	Preparation of Sephadex Gel and Filtration Columns
CGT-0084	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces - Sephadex Neutralization
CGT-0085	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces-Test for Efficacy Against Human Immunodeficiency Virus Type 1 (HIV-1) - Sephadex Neutralization
CGT-0086	Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces Using Chemical Neutralization
CGT-0087	Virucidal Efficacy Testing of Disinfectants Using a Suspension Assay
CGT-0088	Karber Method of Calculating TCID50 Endpoints
CGT-0089	Reed & Muench Calculation of 50% Endpoint
CGT-0090	Virucidal Efficacy of a Disinfectant Utilizing Duck Hepatitis B Virus
CGT-0091	Virucidal Efficacy Validation of Disinfectants Used to Clean and Disinfect the Exterior Surface of Blood Glucose Meters/Monitors and Lancing Devices Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus
CGT-0092	Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection
CGT-0093	Virucidal Efficacy of a Disinfectant Utilizing Bovine Viral Diarrhea Virus as a Surrogate for Human Hepatitis C Virus

SOP Number	Title
CGT-0094	Virucidal Efficacy of a Laundry Additive
CGT-0095	Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate for Noroviruses
CGT-0096	Virucidal Efficacy of Topical Skin Products Utilizing an Ex-Vivo Skin Model
CGT-0097	Virucidal Efficacy of an Antiviral Treated Face Mask or Fabric
CGT-0098	Virus Propagation in Fertilized Embryonating Chicken Eggs
CGT-0099	Murine Norovirus Plaque Assay
CGT-0100	General Laboratory Procedures for Viruses Requiring Extra Precautions
CGT-0101	BS EN 14476 Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Virucidal Activity in the Medical Area - Test Method and Requirements (Phase 2/Step 1)
CGT-0102	BS EN 14675 Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Virucidal Activity of Chemical Disinfectants and Antiseptics Used in the Veterinary Field - Test Method and Requirements (Phase 2, Step 1)
CGT-0103	Standard Test Method for Determining Antiviral or Antichlamydial Activity and Efficacy of Surface-Bound Antimicrobial Agents (Modification of JIS Z 2801)
CGT-0105	Maintaining Non-Adherent Cell Lines
CGT-0106	Thawing Cells
CGT-0107	Immunofluorescence Antibody (IFA) Assay for Human Immunodeficiency Virus
CGT-0108	Freezing Non-Adherent Cell Suspensions
CGT-0109	Entrance and Exit Procedures for the BSL-3 Laboratory
CGT-0111	Biosafety Level 3 (BSL-3) General Laboratory Procedures
CGT-0120	OECD Production of Clostridium Difficile Spores for Efficacy Testing
CGT-0121	OECD Quantitative Method for Testing Antimicrobial Products Against Spores of Clostridium difficile (ATCC 43598) on Inanimate, Hard, Non-porous Surfaces
CGT-0122	Workflow Process for Laboratory R&D/Method Development Testing
CGT-0123	Quantitative Method for Evaluating Efficacy of Liquid Antimicrobials Against Candida auris (CDC AR-0381) on Hard, Non-Porous Surfaces
CGT-0124	Preparation of Bleach Standard Solutions
CGT-0135	BS EN 16777 Chemical Disinfectants and Antiseptics-Quantitative Mon-Porous Surface Test without Mechanical Action for the Evaluation of Virucidal Activity of Chemical Disinfectants Used in the Medical Area-Test Method and Requirements (Phase 2/Step 2)
CGT-0137	Core Laboratory Personnel Training, Retraining and Proficiency Evaluation Procedure
CGT-0141	ISO 18184 – Determination of Antiviral Activity of Textile Products
CMP-0001	Heat Inactivation of Animal Serums
CMP-0002	Screening of Fetal Bovine Serum
CMP-0003	Quality Control Testing of Cell Culture Media
CMP-0004	Aseptically Produced Media and Reagents
CMP-0005	Preparation of Media and Reagents in the Viral and Cell Culture Laboratories
EQM-0001	Equipment Validation Documentation
EQM-0002	Electronic Digital Caliper Use and Maintenance
EQM-0003	Operation and Cleaning of Centrifuges
EQM-0004	Operation and Maintenance of the Eppendorf Microcentrifuge
EQM-0006	Sunbeam Freightmaster 150 Electronic Scale Calibration Check and General Use
EQM-0007	Storage Stability Chamber Monitoring and Cleaning
EQM-0008	Incubator Monitoring and Cleaning
EQM-0009	Use and Calibration of Gardco Washability and Wear Tester (D10V)

SOP Number	Title
EQM-0010	Fyrite % CO2 Level Determination in Incubators
EQM-0011	Humidity Chamber Operation and Maintenance
EQM-0012	Hygrometer Use and Maintenance
EQM-0013	Microscope Use & Maintenance
EQM-0014	Use and Calibration of Pipettors
EQM-0015	Use and Calibration of Repeat Pipettors
EQM-0016	pH Meter Operation and Calibration Procedure
EQM-0017	Operation of the Masterflex® l/P® Precision Brushless Drive, Model 77410-10, and Easy-Load® Pump Head
EQM-0018	Ultrasonic Cleaner Monitoring
EQM-0019	Refrigerator and Freezer Monitoring and Cleaning
EQM-0020	Use and Calibration of Touch Tachometers
EQM-0021	Use and Maintenance of Stereoscopes
EQM-0022	Water Bath Monitoring and Cleaning
EQM-0023	Decontaminating/Cleaning Reagent Preparation and Work Area Decontamination Documentation
EQM-0024	Liquid Nitrogen Tank Maintenance
EQM-0025	Anaerobic/Microaerophilic Gas Generating Systems
EQM-0026	Shaker Monitoring and Cleaning
EQM-0027	Wrist Action Shaker Use and Monitoring
EQM-0028	Maintaining Chart Recorders
EQM-0030	Biological Safety Cabinet Monitoring, Maintenance and Certification
EQM-0031	Fume Hood Operation and Certification
EQM-0032	Room Temperature Monitoring
EQM-0033	Use of the Beckman Du Series 500 (Du 520) Spectrophotometer
EQM-0034	Use and Calibration of Laboratory Thermometers
EQM-0035	Use and Calibration of Timers
EQM-0036	Vacuum Pump Operation/Maintenance
EQM-0037	Use and Calibration of the Digital Barometer Module
EQM-0038	Lyon Electric Profi I Egg Incubator Operation and Maintenance
EQM-0039	Documenting Equipment Monitoring
EQM-0040	AND GX-6100 Balance Calibration Check and General Use
EQM-0041	Documentation of Equipment Cleaning, Maintenance, and Repair
EQM-0043	Compulab 3 Modular Dispensing System Operation and Maintenance
EQM-0044	Use of the Traceable® Dual-Display Light Meter
EQM-0045	Ohaus CS200 Scale Calibration and General Use
EQM-0046	Soxhlet Condenser Apparatus Operation and Maintenance
EQM-0049	Preparation of CDC Biofilm Reactor
EQM-0050	Use, Maintenance and Calibration of the Mettler Toledo AB104 Scale
EQM-0051	Use, Maintenance and Calibration of the Mettler Toledo XP205 Delta Range Analytical Balance
EQM-0053	Use, Maintenance and Calibration of the Spectronic 20 Genesys Spectrophotometer
EQM-0056	Use, Maintenance and Calibration of the Denver Instruments APX-323 Balance
EQM-0057	Use of the Testing Room for Laboratory Studies
EQM-0058	Laminar Flow Hood Operation
EQM-0069	Operation of the Millipore Synergy Water Purification System

SOP Number	Title
EQM-0070	Use and Calibration of Manual Burets
EQM-0072	VWR Forced Air Oven Models 89511-410 Operation and Maintenance
EQM-0073	Labconco Scrubair Pipette Washer/Dryer Operation and Maintenance
EQM-0077	Use, Calibration, and Maintenance of Digital Burettes
EQM-0078	Use, Calibration, and Maintenance of Sartorius Picus NxT Electronic Pipettes
EQM-0079	Use, Maintenance, and Calibration of the Mettler Toledo XSR205DU Analytical Balance
EQM-0080	Mettler Toledo MS-TS Precision Balance Use, Maintenance and Calibration
EQM-0082	Peak Scientific Air Compressors and Gas Generators
EQM-0083	Air Ion Counter AIC2 Operation and Maintenance
EQM-0084	Collision Nebulizer Operation and Maintenance
EQM-0085	BioSpot-VIVAS 310 Bioaerosol Sampler Operation and Maintenance
EQM-0086	SKC Biosampler Bioaerosol Collection Device Operation and Maintenance
EQM-0087	Particles Plus 7301-AQM Air Quality Monitor Operation and Maintenance
EQM-0088	Airwash PRO HEPA Air Filtration System Operation and Maintenance
EQM-0089	CURIS Fogger Operation and Maintenance
EQM-0090	SKC Field Rotameter Operation and Maintenance
EQM-0091	PortaSens III Portable Gas Leak Detector Model D16
EQM-0092	Brinsea Ova-Easy Advance Series II Cabinet Incubator and Humidity Pump Operation and Maintenance
EQM-0102	Use, Maintenance, and Calibration of the Ohaus EX6202 Balance
EQM-0103	Use of the VWR M4 UV/Vis Spectrophotometer
FAC-0001	Facility Pest Control
FAC-0002	Generac Generator Operational Checks and Preventative Maintenance
FAC-0003	LockOut/TagOut Procedure
FAC-0004	Refrigerator, Freezer and Ultra Low Freezer Preventative Maintenance
FAC-0005	Air Handling, Air Conditioning & Exhaust Fan Preventative Maintenance
FAC-0006	High Pressure Boiler, Autoclave and Dishwasher Preventative Maintenance
FAC-0007	Carbon Dioxide System Monitoring and Maintenance
FAC-0008	Walk-In Refrigerator Preventative Maintenance
FAC-0009	Incubator Preventative Maintenance
FAC-0010	Sanitization of the Deionized Water System
FAC-0011	Routine Water Sampling for the Deionized Water System
FAC-0012	Environmental Chamber and Humidity Chamber Preventative Maintenance
FAC-0013	Preventative Maintenance Documentation
FAC-0014	Biosafety Level 3 Laboratory Annual Preventative Maintenance
IT-0005	Procedures for Archiving Electronic Data
IT-0011	Administration of the Chromeleon Chromatography Data System Software
LS-0001	Computer System Life Cycle Management and 21 CFR Part 11 Compliance
LS-0002	Master Validation Plan
LS-0003	Change Control Procedures for Validated Software Systems
LS-0004	Electronic Signature Use Policy
LS-0007	Internal Audit
LS-0022	Network Backup and Recovery
MPR-0001	Media Production Laboratory Cleaning and Maintenance
MPR-0002	Chemical and Media Receiving, Storage and Stocking

SOP Number	Title
MPR-0003	Quality Control Testing Media and Reagents
MPR-0004	Preparation of Labels for Media and Reagents
MPR-0005	Preparation of Media and Reagents in the Media Production Laboratory
MPR-0006	Media Plates, Slants, Bottle and Flask Production
QAU-0001	Internal Audit Procedure
QAU-0002	Quality Assurance Review of Controlled Documents
QAU-0003	Monitoring Subcontractors for GLP Compliance
QAU-0004	Quality Assurance Unit (QAU) Responsibilities for Non-Clinical Studies
QAU-0005	Performance of Critical Phase Inspections
QAU-0006	Quality Assurance Report Audit Instructions for Non-Clinical GLP Studies
QAU-0007	Multi-Site Studies: Test Site Quality Assurance Unit (QAU) Responsibilities
QAU-0008	Management Review
QAU-0009	Qualification of Vendors
SAF-0001	Emergency Procedures
SAF-0003	General Safety
SAF-0004	Exposure Plan for Bloodborne and Other Pathogens
SAF-0005	Exposure Control Plan for Chemicals
SAF-0006	Waste Management
SAF-0008	Employee Right to Know
STE-0001	Preparation of Items for Sterilization
STE-0002	Dishwashing of Laboratory Items
STE-0003	Labconco SteamScrubber Dishwasher Operation and Maintenance
STE-0004	Operation of the Autoclaves
STE-0005	VWR International Horizontal Air Flow Oven, Model 1675 Operation and Cleaning
STE-0006	Sterilization Lab Process Flow

REGULATORY OVERVIEW DOCUMENT

Element Eagan provides antimicrobial and biocide testing services through a comprehensive range of microbiology, virology and analytical chemistry tests. In doing so, we comply with the following regulations:

EPA
40 CFR Part 160 — Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Good Laboratory Practice Standards

FDA
21 CFR Part 58 — Good Laboratory Practice for Nonclinical Laboratory Studies

On the following page, you will find a Compliance Outline that summarizes how Element Eagan complies with the regulations stated above.

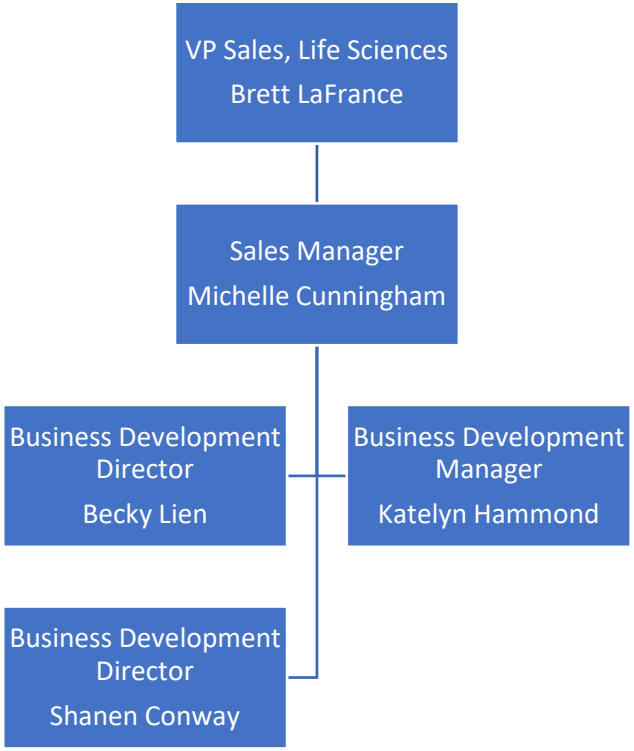
ELEMENT EAGAN COMPLIANCE OUTLINE

40 CFR Part 160	21 CFR Part 58	Section	Section Title	Element Eagan SOP	SOP Title
Subpart A - General Provisions					
160.1	58.1		Scope		
160.1	58.1		Applicability to studies performed under grants and contracts	ALS-0028	GLP Protocol Requirements
160.3	58.3		Definitions		
160.12			Statement of compliance or non-compliance	Compliance Statement is included with each GLP Report	
160.15	58.15		Inspection of a testing facility	ALS-0013	Facility Inspections
160.17			Effects of non-compliance		
Subpart B - Organization and Personnel					
160.29	58.29	(a)-(f)	Personnel	ALS-0024	Personnel Outline for Non-Clinical Studies
160.29	58.29	(a)	Personnel	ALS-0001	Personnel Training, Retraining and Competency Evaluation Procedure
160.29	58.29	(b)	Personnel	ALS-0023	Good Laboratory Practice (GLP) Training Program
160.29	58.29	(b)	Personnel	ALS-0002	Training File Contents
160.29	58.29	(b)	Personnel	ALS-0003	Procedure for Company Organizational Chart, Personnel Job Descriptions and CVs
160.29	58.29	(d), (e), (f)	Personnel	CGT-0011	General Safety Precautions for the Testing Laboratories
160.29	58.29	(d), (e), (f)	Personnel	ALS-0022	Safety Training
160.31	58.31	(a)-(c), (e)-(g)	Testing Facility Management	ALS-0025	Management and Study Director Responsibilities
160.33	58.33	(a)-(f)	Study Director	ALS-0025	Management and Study Director Responsibilities
160.35	58.35	(a), (b)(1)-(7)	Quality Assurance Unit	QAU-0004	Quality Assurance Unit (QAU) Responsibilities for Non-Clinical GLP Studies
160.35	58.35	(c),(d)	Quality Assurance Unit	QAU-0006	Quality Assurance Audit Instructions for Non-Clinical GLP Studies

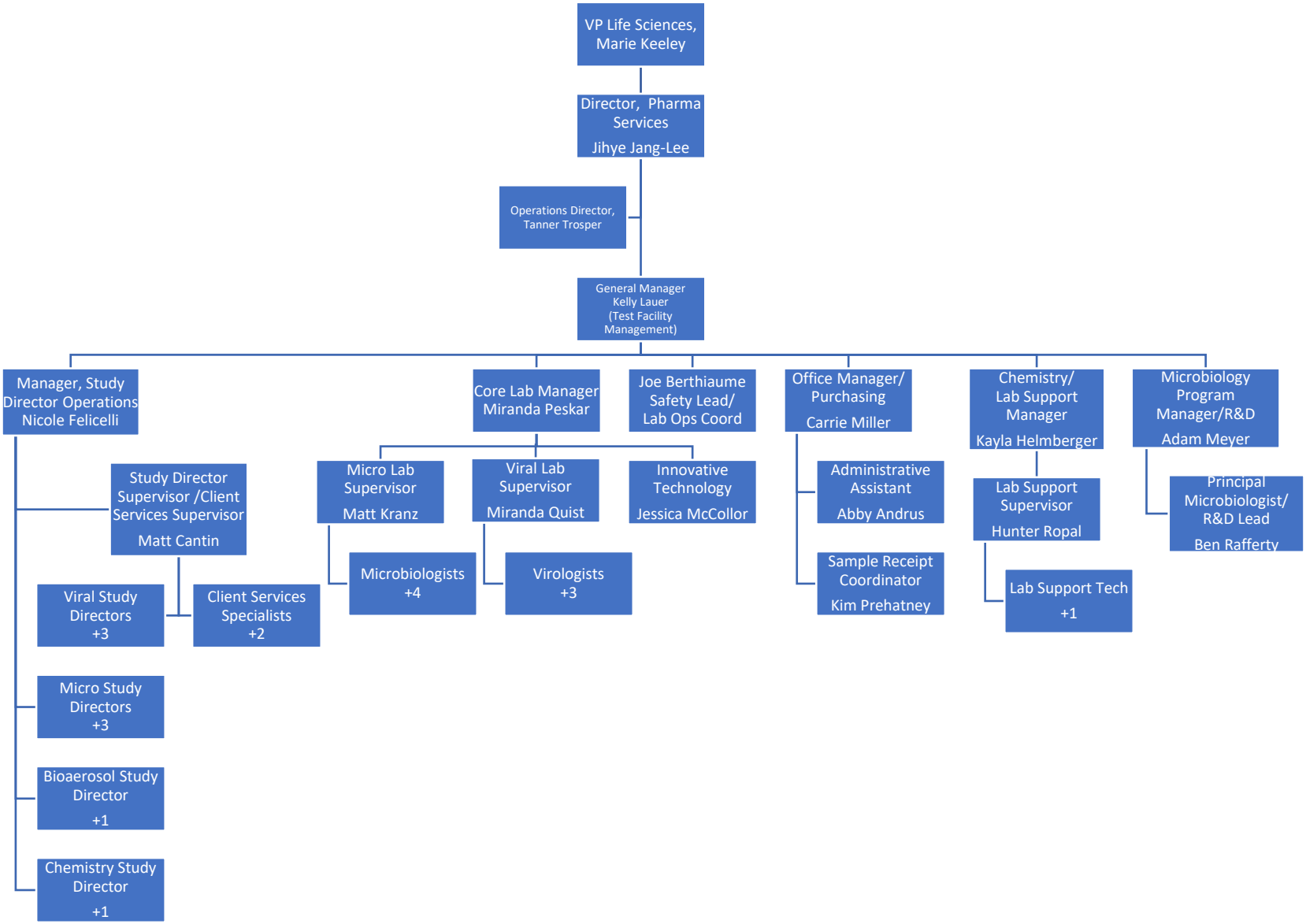
40 CFR Part 160	21 CFR Part 58	Section	Section Title	Element Eagan SOP	SOP Title
Subpart C - Facilities					
160.90	58.90		Animal and other test system care	FAC-0001	Facility Pest Control
160.41	58.41		General	ALS-0012	Facility Security and Visitor Identification
160.43	58.43		Test system care facilities	CGT-0009	General Laboratory Procedures
160.45	58.45		Test system supply facilities	ALS-0031	Receiving Policies and Procedures
160.47	58.47		Facilities for handling test, control and reference substances	ALS-0052	Receipt, Identification and Storage of Test, Control and Reference Substances
160.49	58.49		Laboratory operation areas		Element Eagan has separate areas for microbiology, virology, media preparation and analytical chemistry.
160.51	58.51		Specimen and data storage facilities	ALS-0032	Archive Procedures for Documentation Records
Subpart D - Equipment					
160.61	58.61		Equipment Design	ALS-0019	Measurement Assurance Program
160.63	58.63		Maintenance and calibration of equipment	ALS-0019	Measurement Assurance Program
Subpart E - Testing Facilities Operation					
160.81	58.81	(a)-(d)	Standard operating procedures	ALS-0011	Documentation Control and Records Maintenance
160.81	58.81		Standard operating procedures	ALS-0007	Format and Content of Controlled Documents
160.81	58.81		Standard operating procedures	ALS-0004	Numbering System for Controlled Documents
160.83	58.83		Standard operating procedures	ALS-0018	Labeling of Laboratory reagents and Solutions
160.90	58.90	(a)-(c)	Reagents and solutions	CGT-0020	Culture Maintenance Record Keeping Guidelines
160.90	58.90		Animal and other test system care	CGT-0074	Procedure for the Preparation of Stock Viral Cultures
160.90	58.90		Animal and other test system care	CGT-0065	Purchasing, Receiving, Rehydrating and Freezing Bacterial and Fungal Organisms
160.90	58.90		Animal and other test system care	CGT-0072	Documentation of Stock Virus Receipt
160.90	58.90		Animal and other test system care	CGT-0009	General Laboratory Procedures
160.90	58.90		Animal and other test system care	CGT-0067	Test Organism Confirmation Procedure
160.90	58.90		Animal and other test system care	CGT-0071	Quality Control of Virucidal Assay

40 CFR Part 160	21 CFR Part 58	Section	Section Title	Element Eagan SOP	SOP Title
Subpart F - Test and Control Articles					
160.105	58.105		Test and control article characterization	ALS-0028	GLP Protocol requirement
160.107	58.107	(a)-(d)	Test and control article handling	ALS-0052 and ALS-0053	Receipt, Identification and Storage of Test, Control and Reference Substances Test Substance Accountability Record Documentation
160.113	58.113		Mixtures of articles with carriers	CGT-0009	General Laboratory Procedures
Subpart G - Protocol for and conduct of a non-clinical laboratory study					
160.120	58.120	(a)-(b)	Protocol	ALS-0028	GLP Protocol requirement
160.120	58.120	(b)	Protocol	ALS-0029	Deviations and Protocol Amendments
160.130	58.130	(e)	Conduct of a nonclinical laboratory study	ALS-0008	Good Documentation Practices
160.130	58.130	(c)	Conduct of a nonclinical laboratory study	CGT-0009	General Laboratory Procedures
160.135			Physical and chemical characterization studies		Physical and chemical characterization studies are run under GLP protocols & systems
Subpart J - Records and Reports					
160.185	58.185	(a)-(b)	Reporting of nonclinical laboratory study results	ALS-0027	GLP Final Reports
160.185	58.185	(c)	Reporting of nonclinical laboratory study results	ALS-0030	GLP Final Report Amendments
160.190	58.190	(a)-(e)	Retention of records	ALS-0032	Archive Procedures for Documentation Records
160.190	58.190		Retention of records	ALS-0033	Preparing Project Files for Archiving
160.195		(a)-(i)	Storage and retrieval of records and data	ALS-0032	Archive Procedures for Documentation Records

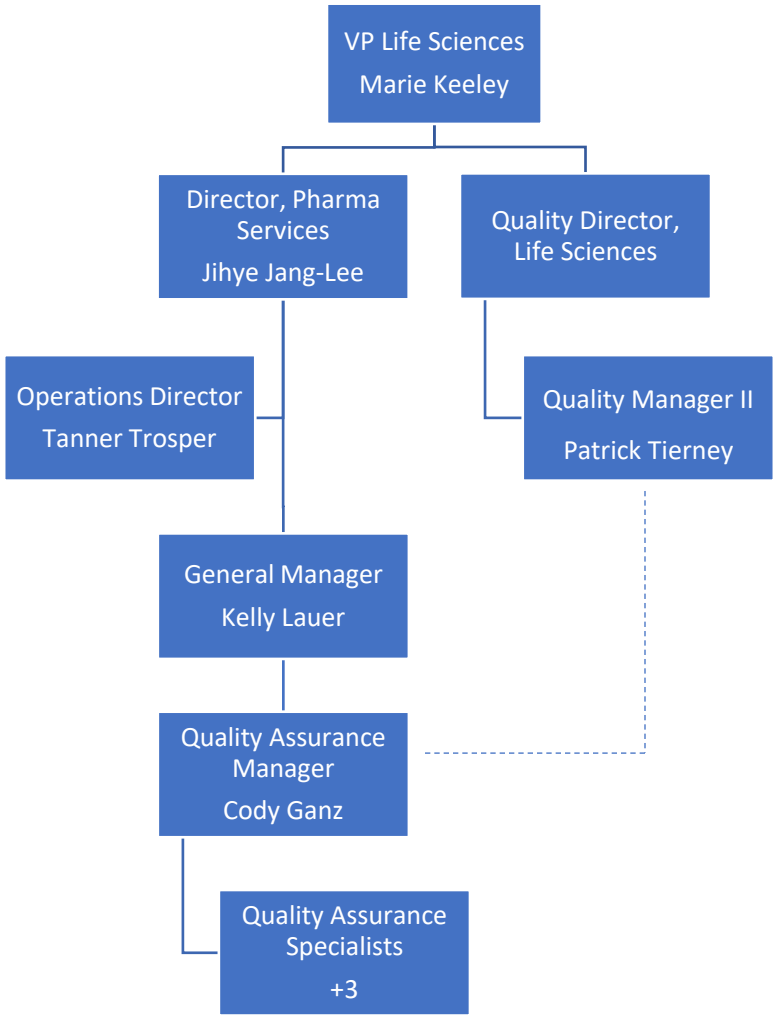
Element Eagan Organizational Chart – Business Development



Element Eagan Organizational Chart – Operations



Element Eagan Organizational Chart – Quality Assurance



FACILITY MAP