



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



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Quality System Information



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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 codes from the system?	Yes



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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	



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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



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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				



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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



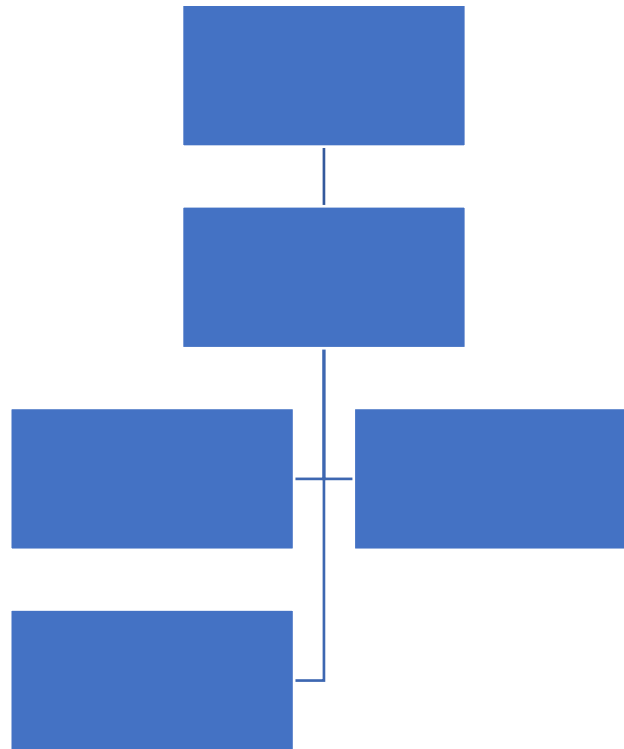
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40 CFR Part 160	21 CFR Part 58	Section	Section Title	Element Eagan SOP	SOP Title
Subpart F -					



Element Eagan Organizational Chart – Business Development

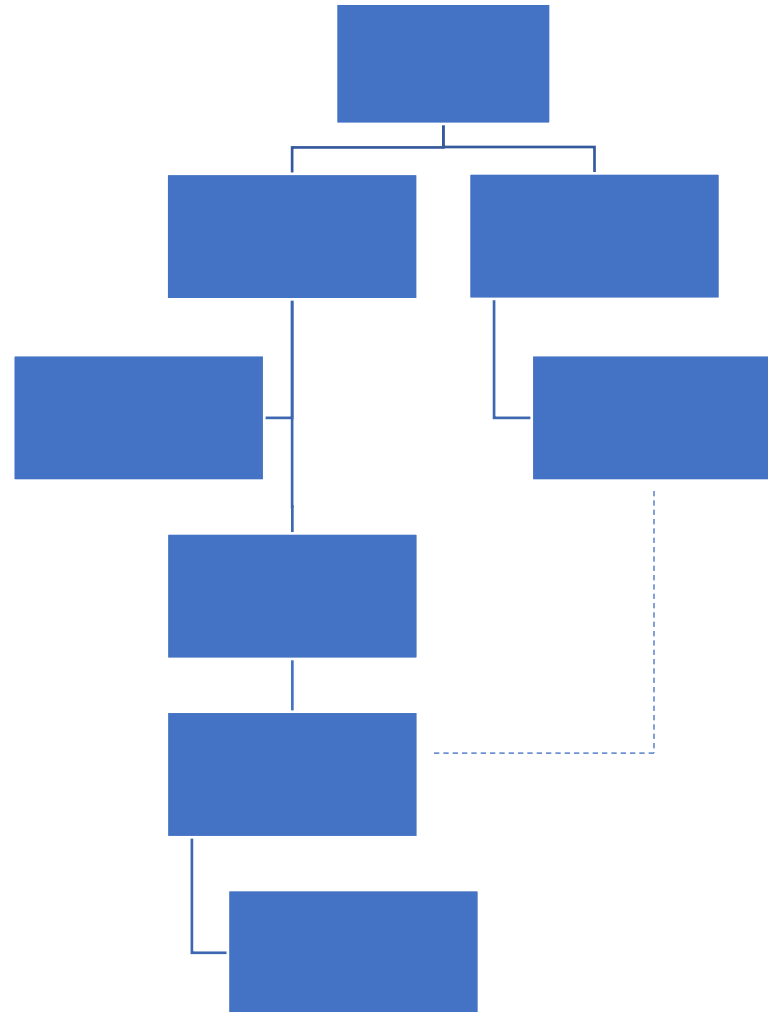




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Element Eagan Organizational Chart - Quality Assurance





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FACILITY MAP

