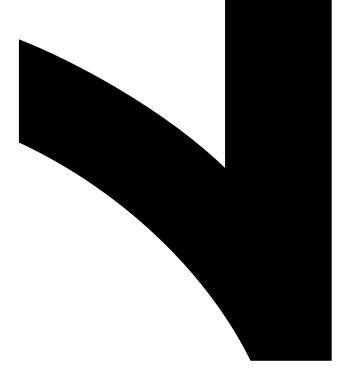




Organizational & Personnel Information

Is there a formal training program?

Is training performed and documented when SOPs











Element Materials Technology Oakland - Concord

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



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	Title

Water Determination by Coulometric Titration (Karl Fischer) Method CHOOD





SOP			
Number	Title		
CE-0009	Handling of Chemicals and Chemical Hazardous Waste Management		
GE-0010	Handling of Biological Contaminants and Biological Waste Management		
GE-0011	LaboratoryWorkflow		
GE-0012	Gowring for Operations in the ISO Classified Areas		
GE-0013	General Incubation and Plate Counting Practices		
GE-0014	Clearing and Saritization of the ISO Controlled Areas		
GE-0015	Securityat Element - Concord		
GE-0016	Laboratory Govring Procedures at Element - Concord		
GE-0017	Purchasing and Receiving Process at Element - Concord		
GE-0018	Clearing of Glassware for Mordbiology Assays		
GE-0019	Glassware Cleaning for General Analytical Procedures		
GE-0020	Estimation of Uncertainty of Measurement		
GE-0021	Personnel, Equipment and Material Flowin 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		
MB0002	StockCulture Master Bankand Suspension Preparation		
MB 000B	Water Microbial Load Testing by Membrane Filtration Method		
MB 0004	Madial Identification		
MB 0006	USP < 61> Marchiological Examination of Nonsterile Product Marchial Enumeration Test		
MB 0007	Microbiólogical Examinítion of Nonsterille Préducts: Microbial Enumeration Method Suitability		
MB 0008	Preparation of Microbiological Media and Diluents		
MB-0010	Aseptic Technique Training		
MB-0011	Pipetting and Dilution Qualification		
MB 601D	Microbiological Examination of Nonsterile Products: Suitability Test for Specified		
	Macagarisms		
MB 0013	USP < 62> Microbiological Examination of Nonsterile Products: Test for Specified		
	Macagarisms		
MB 0014	Preparation and Extraction of Medical Device/Solid Material samples for Endotoxin Test		
MB 0015	Total Coliform Ventuane Filtration Method		
MB 0016	USP < 71> Sterility Testing by Direct Inoculation		

MB



SOP Number	Title
Q4000B	DocumentantlRecords Management System
Q4-0009	DocumentControl
Q4-0010	GoodDocumentationPractices
Q4-0011	Master Signature Log
Q4-0012	Issuance, Use and Management of Laboratory Notebooks
Q4-0013	LogbookManagement
Q4-0014	Sample Management and Chain of Custody
Q4-0015	Quality Event Investigations
Q4-0016	Out of Specification Out of Tiend (OOS/OOI) Investigations
QA-0017	



SOP	Title
Number	
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
VF0001	Preparation of Viral Barks
MOOS	In Vitro Viral Screening Assay for Viable Viruses
VI-0004	Preparation of T75 cm2 Flashs and Six Well Plates for the Viral Screening Assay (VSA)
VI-0005	Scientian Replication Competent Retrovirus (RCR) vFeat[fq lin2 nl



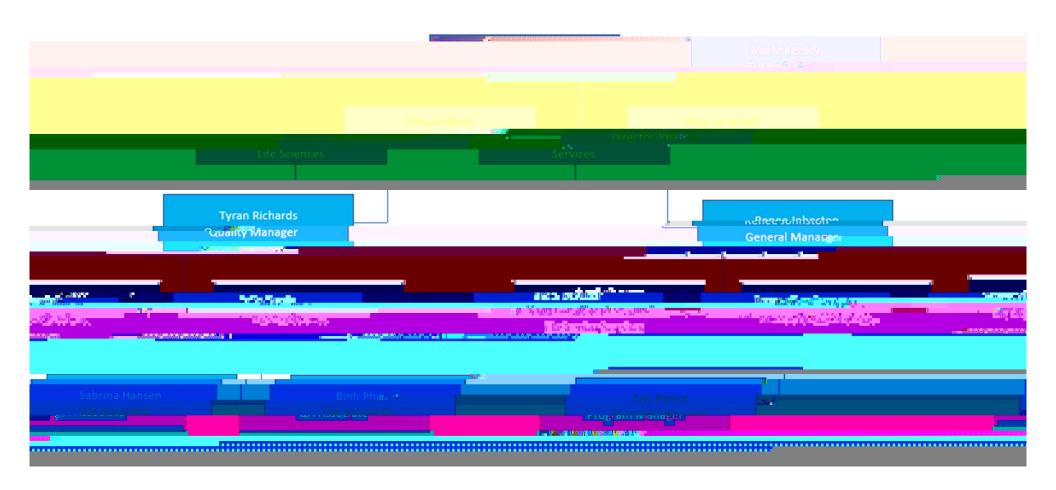
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ORGANIZATIONAL CHART





ORGANIZATIONAL CHART







FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

