

QUALITY INFORMATION PACKET

Element Materials Technology Oakland - Concord



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Organizational & Personnel Information

Is there a formal training program?

Is training performed and documented when SOPs





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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



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SOP Number	Title
CH009	Water Determination by Coulometric Titration (Karl Fischer) Method





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



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SOP Number	Title
QA-008	Document and Records Management System
QA-009	Document Control
QA-010	Good Documentation Practices
QA-011	Master Signature Log
QA-012	Issuance, Use and Management of Laboratory Notebooks
QA-013	Logbook Management
QA-014	Sample Management and Chain of Custody
QA-015	Quality Event Investigations
QA-016	Out of Specification/Out of Trend (OOS/OOT) Investigations
QA-017	



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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 Vial Banks
VI-0002	In Vitro Vial Screening Assay for Viable Viruses
VI-0004	Preparation of T75 cm ² Flasks and Six Well Plates for the Vial Screening Assay (VSA)
VI-0005	Screen for Replication Competent Retrovirus (RCR) w/Fea tlfq Hn2 nl



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FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

Drug Name	FDA Establishment Identifier	DIME	Manufacturer	Registration Number	Registration Date

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