QUALITY INFORMATION PACKET
Ann Arbor

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
- Organizational Chart
- Facility Map
- FDA Drug Establishment Current Registration
- Scope of Accreditation to ISO/IEC 17025:2017
- DBA Information

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,

Norman Cyr
Quality Assurance Manager
Element Materials Technology Ann Arbor
4840 Venture Drive
Ann Arbor, MI 48108
(800) 930-5450
ncyr@avomeen.com

GENERAL FACILITY AND QUALITY SYSTEM INFORMATION

General Information	
Company Name	Avomeen Analytical Services
Address of Facility	4840 Venture Dr, Ann Arbor, MI 48108
Phone Number	(800) 930-5450
Website	Avomeen.com
DUNS Number	965534816
Services Provided	Analytical
Number of Permanent Employees	80
Number of Quality Employees	7
Facility Size	27,000 sq ft
FDA FEI Number	3008808597
Expiration Date	Dec 31, 2021
Last FDA Audit	Oct 2018
ISO/IEC 17025:2017 Certificate Number	L21-22
Expiration Date	April 30, 2023
Last ISO Renewal Audit	Dec 2020

Key Personnel Information		
Name	**Title**	**Email**
Mark Harvill	Chief Executive Officer	mharvill@avomeen.com
Andrew Kolbert	President/Chief Technology Officer	andrew@avomeen.com
Carla Totton	Director of Quality & Client Success	ctotton@avomeen.com
Luke Miller	Director of Operations	lmiller@avomeen.com
Ty Tessmer	VP Finance & Administration	ty@avomeen.com
Lori Minnick	HR Manager	lminnick@avomeen.com
Katie Morgan	VP Marketing	kmorgan@avomeen.com

Quality Assurance Information	
Name and Title of QA Manager	Norman Cyr
Telephone Number	(800) 930-5450
Email Address	ncyr@avomeen.com
Reports to	Carla Totton
Number of QA Employees	7
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; see attachment
Are there written job descriptions?	Yes
Do employees have adequate training, experience, and qualifications for their responsibilities?	Yes

Facility Information	
Total size of facility	27,000 sq ft
Area of facility utilized for office space	8,000 sq ft
Area of facility utilized for testing labs	18,900 sq ft
Area of facility utilized for warehouse	N/A
Construction of facility	Single Level
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**
FDA	3008808597	Oct 2018
DEA	RA0521852	Aug 2017
ISO	L21-22	Dec 2020

Quality System Information	
Responsibilities and Authority	
Do you have a quality policy manual?	Yes
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?	varies
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 ADM-0004
Is the test sample log-in procedure computerized?	No
How are test samples stored?	Per ADM-0004
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?	2 Years on-site/Indefinitely off-site

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?	N/A
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	Master Control
Are these computerized systems validated?	Yes; validated to meet requirements of 21 CFR part 11
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 Format	Type
ADM-XXXX	Administration SOP
QLT-XXXX	Quality SOP
POL-XXXX	Policy SOP
INS-XXXX	Instrument
FCT-XXXX	Faculty
LAB-XXXX	Laboratory
MFG-XXXX	Manufacturing

QUALITY SYSTEMS PROCEDURES LIST

SOP Number	Title
ADM-0001	Qualification Protocol Design
ADM-0002	Receiving Product from Couriers
ADM-0003	Checking in Received Packages
ADM-0004	Sample Management
ADM-0005	Shipping
ADM-0006	Method Validation Protocol
ADM-0007	Project Initiation
ADM-0008	Consultants
FCT-0001	"Sanitation, Maintenance, Sewage and Refuse"
FCT-0002	Refrigerator and Freezer Temperature Monitoring
FCT-0003	"ELPRO Monitoring System for Stability Chambers, Refrigerators, Freezers and Manufacturing"
FCT-0004	QC Water System Monitoring
FCT-0005	In-House DI Water System
INS-0001	"Instrument Equipment Qualification, Use, Maintenance and Calibration"
INS-0002	Class II Biological Safety Cabinet Operation and Maintenance
INS-0003	GC Annual Maintenance and Calibration
INS-0004	Anemometer Use for Annual Laboratory Fume Hood Calibrations
INS-0005	GC-MS Annual Maintenance and Qualification
INS-0006	SEM/EDXA
INS-0007	FT-IR
INS-0008	Gas Chromatography (GC-FID)
INS-0009	Gas Chromatography Mass Spectrometry (GC-MS)
INS-0010	AB SCIEX API-3000 LC-MS/MS
INS-0011	Micropipettes and Pipet-Aid
INS-0012	SPEX 6770 Freezer/Mill

INS-0013	Thermo Finnigan LCQ Deca LC-MS
INS-0014	Standardization and Use of pH meters
INS-0015	Calibration and Use of Dissolution Apparatus in the Analytical Laboratory
INS-0016	"Verifications of Clocks, Timers and Stopwatches"
INS-0017	High Performance Liquid Chromatography (HPLC)
INS-0018	Caron Stability Chamber Series 6000/6500/7000
INS-0019	MCP 100 Polarimeter
INS-0020	Handheld BRIX Refractometer
INS-0021	Viscometer
INS-0022	Karl Fischer Coulometric Titration
INS-0023	Use and Calibration of Balances
INS-0024	Oakton DO 6+ Dissolved Oxygen Meter
INS-0025	Brookhaven Zetasizer
INS-0026	Calibration and Use of Thermometers
INS-0027	Perkin Elmer Lambda 365 Spectrophotometer Calibration and Use
INS-0028	BioTek Epoch Microplate Reader Calibration and Use
INS-0029	TA Instruments Q50 TGA Operation and Semi-Annual Calibration
INS-0030	TA Instruments DSC Q20a
INS-0031	CAP 2000+ Viscometer
INS-0032	Bahnson ES 2000 CDML Photostability Chamber
INS-0033	Sanyo Labo Autoclave Use and Calibration
INS-0034	Seteflash Closed Cup Flash Point Tester
INS-0035	Agilent 7500 CC ICP-MS
INS-0036	Agilent 7500ce Chemstation
INS-0037	Capillary Electrophoresis
INS-0038	LABCONCO Freezone 4.5 Lyophilizer
INS-0039	Franz Vertical Diffusion Cells (VDC)
INS-0040	Conductivity Meter Calibration and Use
INS-0041	"Ci4200 Spectrophotometer Setup, Operation and Calibration"
INS-0042	"ILT2400 Optical ""Light"" Meter Setup, Operations, and Calibration"
INS-0043	SDS-Page with Xcell SureLock Mini-Cell
INS-0044	BioTek FLx800 Multi-Detection Microplate Reader
INS-0045	Waters Acquity UPLC-QTOF LC-MS Instrument
INS-0046	Use of Ovens
INS-0047	Waters Acquity UPLC ◆ QTOF LC-MS Instrument (Xevo G2-S)
INS-0048	Agilent 7800 ICP-MS
INS-0049	Eppendorf Centrifuge 5804R
INS-0050	The Advanced Micro-Osmometer
INS-0051	DIONEX ICS-3000 Ion Chromatography (IC) system
INS-0052	Seivers 900 Total Organic Carbon Analyzer
INS-0053	Benchtop Injection Molder
INS-0054	CETI8 MK3 Smoke Machine
INS-0055	Milestone Microwave
INS-0056	Nanodrop 2000 Spectrophotometer
INS-0057	Using Thermolyne LOCATOR 4 Plus Cryobiological Storage Vessel
INS-0058	HERACELL VIOS 160i CO2 Incubator Operations
INS-0059	Bottle Top Dispenser

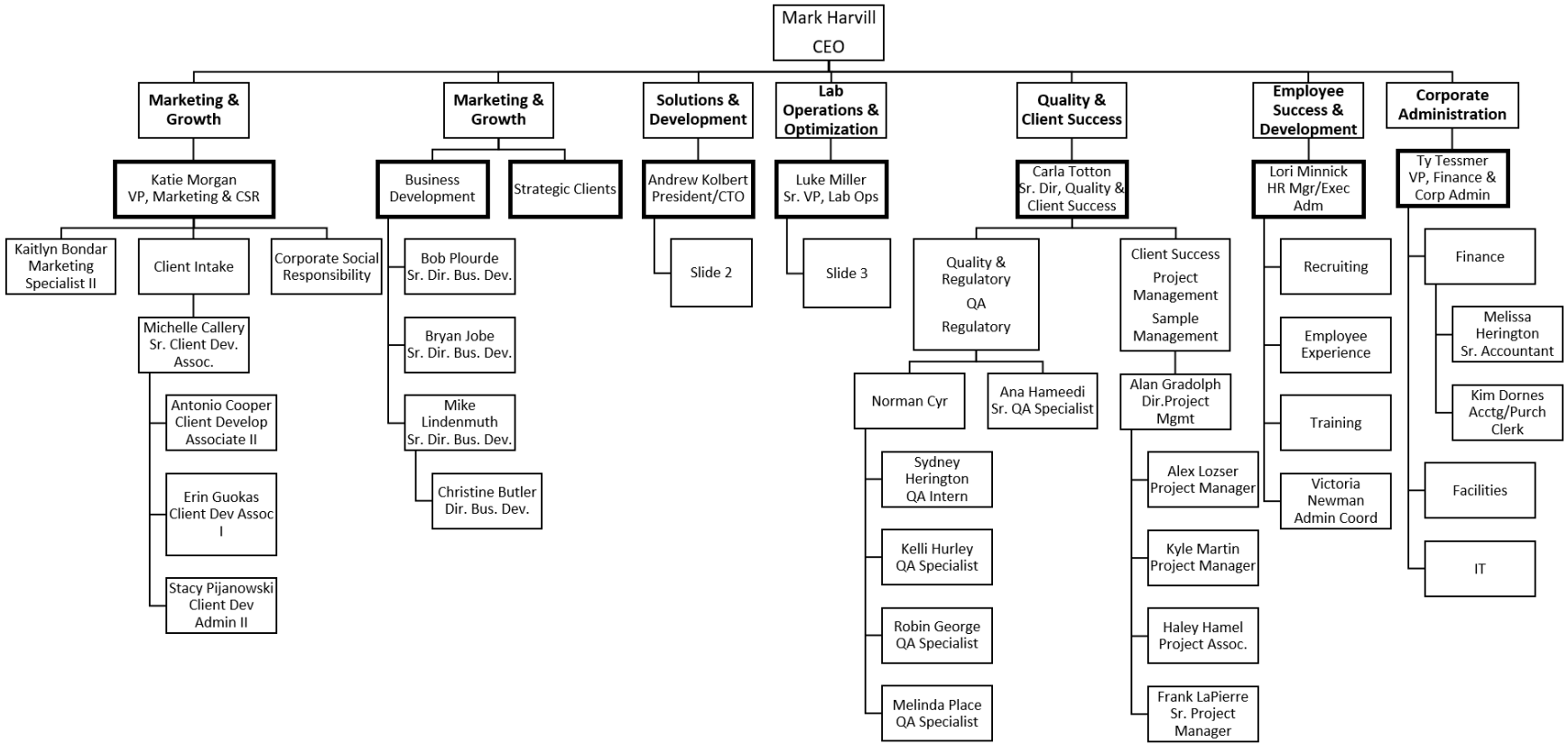
INS-0060	Using BioRad GS-800 Calibrated Imaging Densitometer
INS-0061	Using Countess II Automated Cell Counter
INS-0062	BioTek Synergy H1 Microplate Reader Use
INS-0063	Mettler Toledo EasyPlus Automated Titrator
INS-0064	Abbe Mark II Plus Refractometer
INS-0065	E-Z Press 1&2 Ton & Intrinsic Dissolution Apparatus
INS-0066	Maurice CE-SDS/cIEF
INS-0067	Waters Acquity UPLC and TQD LC-MS Instrument
INS-0068	SM450e Smoke Machine
INS-0069	TruScan RM Handheld Raman Analyzer
INS-0070	Waters Acquity UPLC and Empower Operations
INS-0071	XLW-EC Tensile Tester
INS-0072	GC-MSMS Annual Maintenance and Calibration
INS-0073	QExactive Plus
INS-0074	Gas Chromatography Triple Quad (GC-MSMS)
INS-0075	Instron Electro-Puls
LAB-0001	LabCup
LAB-0002	VWR Inventory Management
LAB-0003	Reagent Inventory
LAB-0004	Handling of Gas Cylinders
LAB-0005	Reference Standards
LAB-0006	Laboratory Labeling
LAB-0007	Peer Review
LAB-0008	Laboratory Cleaning
LAB-0009	"Expiry Dating for Chemicals, Reagents, Solutions, and Solvents"
LAB-0010	Analytical Method Performance
LAB-0011	Instrument Column Use
LAB-0012	Washing Laboratory Glassware
LAB-0013	Conduct of Stability Studies
LAB-0014	Standardization and Use of USP Volumetric Solutions
LAB-0015	Rounding and Significant Figures in Chemical Calculations
LAB-0016	OpenLAB CDS for HPLC and GC
LAB-0017	Use of External Laboratory Vendors
LAB-0018	Decontamination of Hazardous Substances for Disposal
LAB-0019	Cleaning ICP-MS Plastic and Glassware
LAB-0020	Use of Equipment at External Laboratories
LAB-0021	Identification of Unknowns
LAB-0022	Deformulation of Pharmaceutical Products
LAB-0023	Conduct of Extractables and Leachables Studies
LAB-0024	"Handling, Storage and Disposal of Hazardous Waste"
LAB-0025	Method Familiarization of USP Methods
LAB-0026	OpenLAB CDS 2.5
LAB-0027	Laboratory Safety Audits
LAB-0028	Empower CDS for Operation of UPLC Instrumentation
LAB-0029	Creating a Laboratory Notebook
LAB-0030	Basic Lab Skills Proficiency
MFG-0001	Cleaning of Manufacturing Equipment using CIP100 detergent and to test for cleanliness

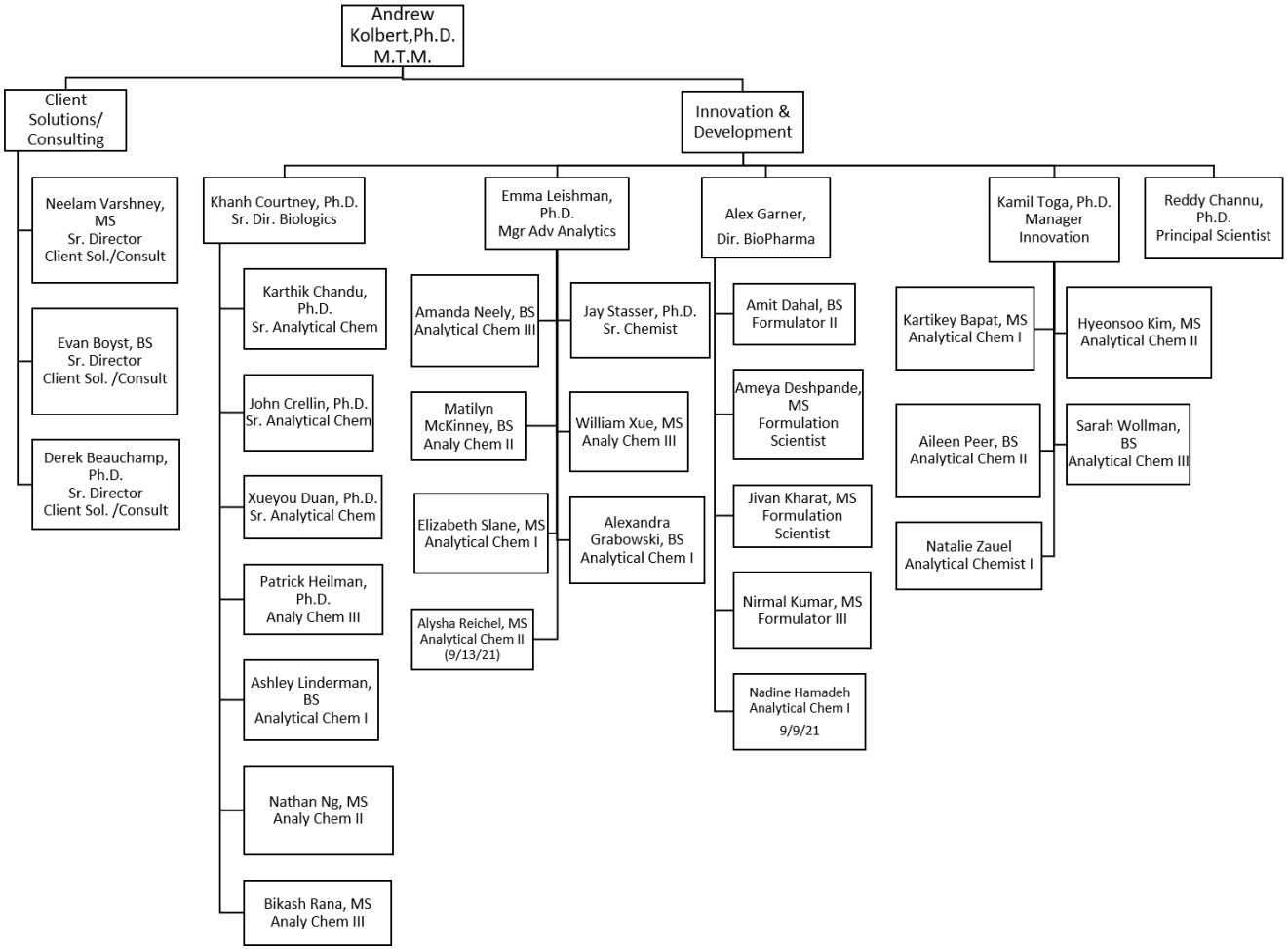
MFG-0002	General GMP guidelines for Clinical Trial Material Manufacturing
MFG-0003	Preparation of Approved Cleaning Solutions
MFG-0004	Procedure for Cleaning of Manufacturing Suite
MFG-0005	Cleaning Procedure Type 1 and Type 2 for Manufacturing Suite and Equipment
MFG-0006	"Maintenance, Use, and Cleaning Logbook (MUCL) Procedure"
MFG-0007	Gowning Procedure for Manufacturing Suite
MFG-0008	Personnel and Material Flow in the Manufacturing suite
MFG-0009	Environmental Monitoring
MFG-0010	"Time, Temperature, Humidity, Differential Pressure Monitoring for Manufacturing Suite"
MFG-0011	Cleaning Procedure for Manufacturing Accessories
MFG-0012	Material Release for CTM Manufacturing
MFG-0013	In-Process and Product Release Specifications For Clinical Trial Material Manufacturing
MFG-0014	"Patterson-Kelley V-Blender Setup, Operation, and Cleaning and Maintenance"
MFG-0015	"Set up, Operation and Cleaning of FitzMill M5A"
MFG-0016	"Set-up, Operation, Cleaning, and Maintenance Procedure for Tube Filling Machine"
MFG-0017	Function and Maintenance of HVAC System in Manufacturing Suite
MFG-0018	Manufacturing Suite and Utilities Layout
MFG-0019	Daily Performance check Operation and Cleaning of Sotax Friabilator
MFG-0020	Operation of Schleuniger 6D Hardness tester
MFG-0021	"Setup Operation, Cleaning and maintenance of O'hara Labcoater"
MFG-0022	Operation and Cleaning of Buchi Spray Dryer B-290
MFG-0023	"Tube Sealer Set-up, Operation, Cleaning and Maintenance"
MFG-0024	General In-Process cleaning
MFG-0025	Labelling Procedure and Control
MFG-0026	"Cap Sealer/Handheld Electronic Induction Sealing Machine Set-up, Operation, Cleaning, Maintenance and Movement"
MFG-0027	Retention of Finished Product
MFG-0028	"Handling, Maintenance and Cleaning of the Sieve Shaker"
MFG-0029	"Handling, Maintenance and Cleaning of VITAMIX 5300"
MFG-0030	"Handling, Maintenance and Cleaning of Sieves"
MFG-0031	"Operation, Cleaning and Maintenance of the Powder Filling Machine"
MFG-0032	"Operation, Cleaning and Maintenance of the Disintegration Tester"
MFG-0033	Set Up and Operation of Tapped Density Tester
MFG-0034	In-Process Inspection of Manufacturing
MFG-0035	"Set up, Operation and Cleaning of Versa Press Tablet Press"
MFG-0036	"Set up, Operation and Cleaning of Rx- 4 Automatic Tablet & Capsule Counter"
MFG-0037	Operation and Cleaning of the Tablet Deduster
MFG-0038	"Set-up, Operation and Cleaning of Unit-Dose Powder Sampler"
MFG-0039	"Daily Performance Check, Operation and Cleaning of Dr Schleuniger Pharmatron FTV-2 Friability Tester"
MFG-0040	Operation and Cleaning of Nilfisk AERO 31 Vacuum Machine
MFG-0041	"Set-up, operation and cleaning of Metal Detector MET30+."
MFG-0042	"Patterson-Kelley Blend Master Lab Blender Set-up, Operation, Cleaning, and Maintenance "
MFG-0043	"Operation, Calibration and Maintenance of Digital Vernier Caliper"
MFG-0044	Operation Maintenance Cleaning and Calibration of Precision Digital Pressure Gauge Model CPG1500

MFG-0045	"Specification, Operation and Maintenance of Traceable Touchless and Contact Tachometer"
MFG-0046	Use of Compressed Air and Nitrogen Cylinders in Clinical Trial Material Manufacturing
MFG-0047	Water Use Requirements Dispensing and Monitoring in Clinical Trial Material Manufacturing
MFG-0048	Silverson High Shear Laboratory Mixer Model AX5
MFG-0049	Water Hose Cleaning and Storage
MFG-0050	General Guidelines for Engineering Batch Manufacturing
MFG-0051	Capsule (Blister Packaging) Sealer Setup Operation Cleaning and Maintenance
MFG-0052	Suppository Molding (Filler) Apparatus Setup Operation Cleaning and Maintenance
MFG-0053	"Setup, Operation and Maintenance of Hot Melt Extruder (HME) Assembly"
MFG-0054	Receiving Disposition and Control of Incoming Raw Materials and Packaging Materials for Manufacturing
MFG-0055	Material and Product Identification Traceability
MFG-0056	Transporting Investigational Product
MFG-0057	"Receiving, Use and Control of Table Press Tooling"
MFG-0058	Evaluation of New Active Pharmaceutical Ingredients (APIs) in Avomeen's Manufacturing Suite
MNL-0002	Chemical Hygiene Plan
MNL-0003	Quality Manual
MNL-0004	Site Master File
POL-0001	Controlled Substances Handling
POL-0002	Safety Policy
POL-0003	Hazardous Waste Disposal
POL-0004	Facility Access and Security Measures
POL-0005	Disaster Policy
POL-0006	Purchasing Policy
POL-0007	Computer Policy
POL-0008	Training Policy
POL-0009	QC Proficiency and Method Uncertainty for ISO Accredited Testing
POL-0010	Pest and Fungus Control
POL-0011	Exposure Control Plan
POL-0012	Master Validation Plan
POL-0013	Quality System Structure
POL-0014	Whistleblower Escalation Policy
POL-0015	Data Integrity
POL-0016	Business Continuity Plan
POL-0017	IT Regulatory Compliance
QLT-0001	Documentation Practices
QLT-0002	Laboratory Investigations
QLT-0003	Deviations
QLT-0004	CAPA (Corrective Action Preventive Action)
QLT-0005	Customer Complaints
QLT-0006	Internal Audit
QLT-0007	Document Control
QLT-0008	Change Control
QLT-0009	Quality System Trending
QLT-0010	Customer Feedback

QLT-0011	Impact Assessment
QLT-0012	Study Director Roles and Responsibilities
QLT-0013	In-Life Audit
QLT-0014	Master Study List
QLT-0015	QA Project Auditing
QLT-0016	Requirements for the Generation and Review of Certificates of Reports
QLT-0017	QA Responsibilities
QLT-0018	Quality Risk Management Program
QLT-0019	Quality and Vendor Agreements
QLT-0020	Commodity Jurisdiction Classification and Controls (CFIUS Review)
QLT-0021	Monitoring of Quality Data
QLT-0022	Approved Supplier List (ASL) Qualification (Third Party Qualification)
QLT-0023	Regulatory Inspection
QLT-0024	Client Audits
QLT-0025	Writing and Revising Controlled Documents
QLT-0026	Clinical Trial Material (CTM) Batch Review and Release
QLT-0027	Issue and Execution of Batch Manufacturing Records (BMR) for CTM
QLT-0028	Master Control

ORGANIZATIONAL CHART

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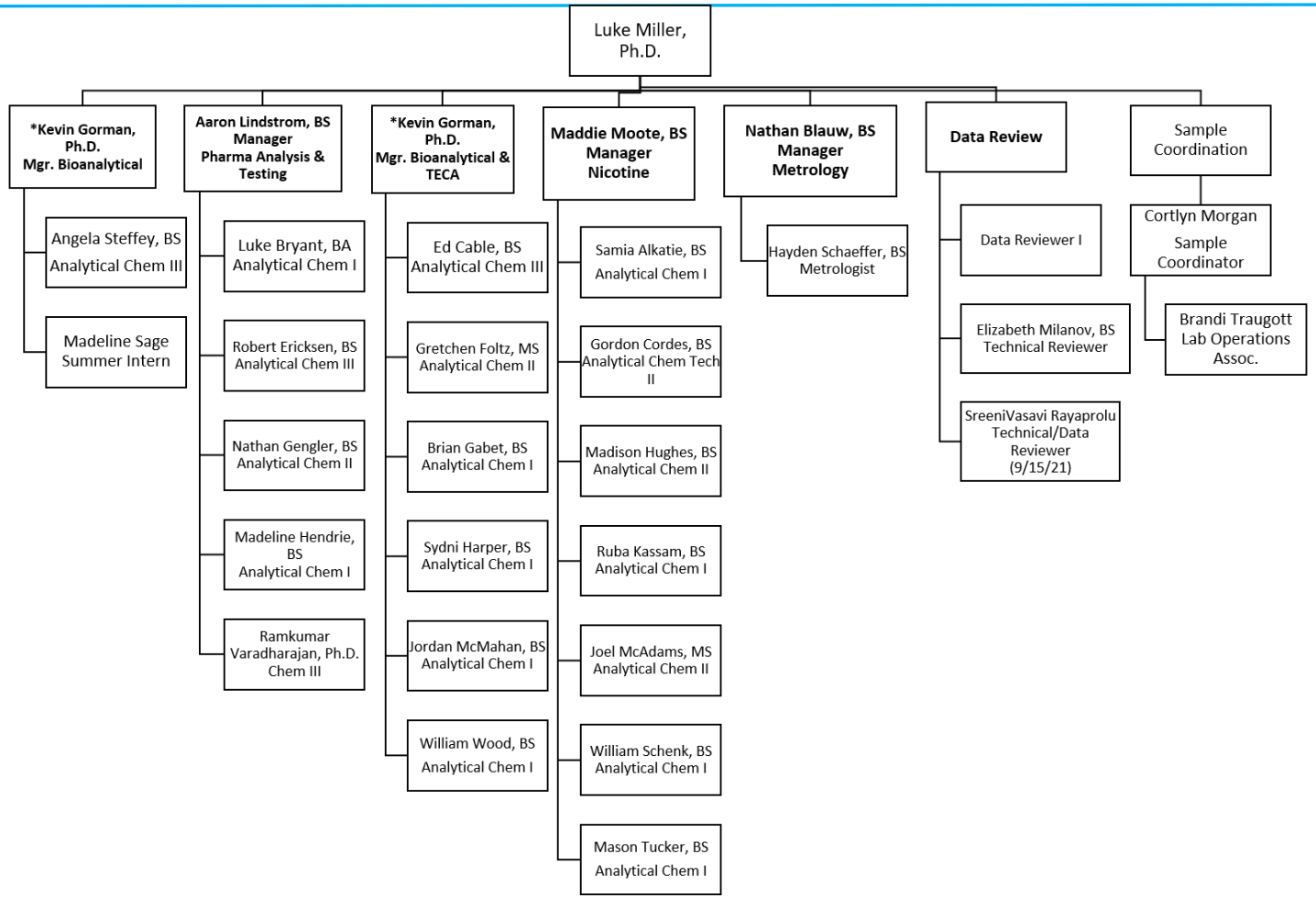
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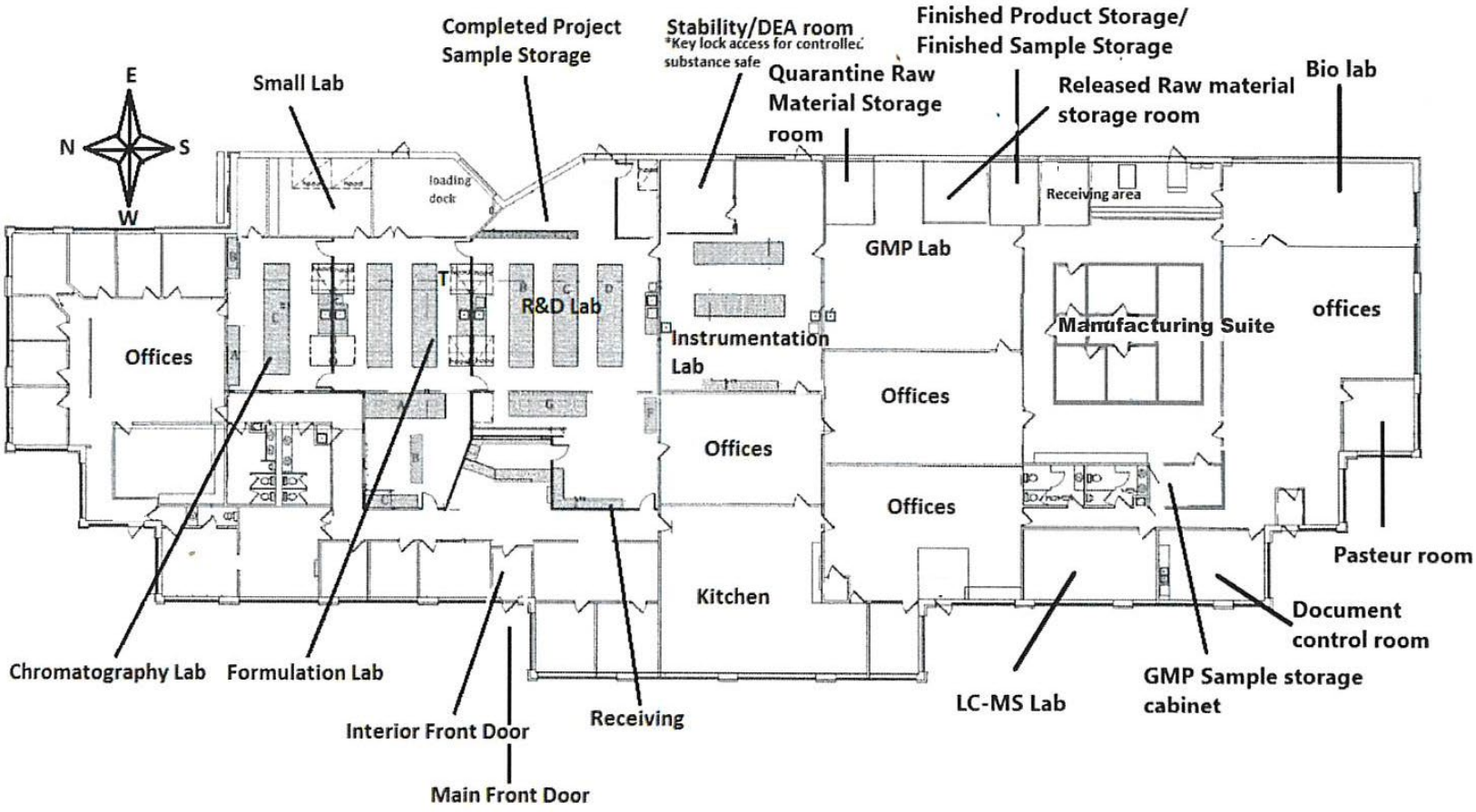
Madison Hughes, BS Analytical Chem II
Ruba Kassam, BS Analytical Chem I
Joel McAdams, MS Analytical Chem II
William Schenk, BS Analytical Chem I
Mason Tucker, BS Analytical Chem I
Nathan Blauw, BS Manager Metrology
Hayden Schaeffer, BS Metrologist
Data Review
Data Reviewer I
Elizabeth Milanov, BS Technical Reviewer
SreeniVasavi Rayaprolu Technical/Data Reviewer (9/15/21)
Sample Coordination
Cortlyn Morgan Sample Coordinator
Brandi Traugott Lab Operations Assoc.

FACILITY MAP



Total Laboratory Sq. Footage = 18,900 sq ft
Total Admin Sq. Footage = 8,000 sq ft
Total Sq. Footage = 27,000 sq ft

FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Avomeen Analytical Services	3008808597	965534816	ANALYSIS;	4840 Venture Dr., Ann Arbor, Michigan (MI) 48108, United States (USA)	12/31/2022

PERRY JOHNSON LABORATORY ACCREDITATION,INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

Avomeen, LLC

4840 Venture Drive, Ann Arbor, MI 48108

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system
(as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

Chemical Testing

(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

ilac-MRA

PJLA

For PJLA:

Initial Accreditation Date: Issue Date: Expiration Date:

April 2, 2019 January 18, 2021 April 30, 2023

Tracy Szerszen President

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

Accreditation No: Certificate No:

78365 L21-22

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlabs.com

Certificate of Accreditation: Supplement

Avomeen, LLC
4840 Venture Drive, Ann Arbor, MI 48108 Contact
Name: Carla Totton Phone: 800-930-5450

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Chemical [F]	Pharmaceuticals, Cosmetics, Liquids, Solids, Glass, Plastics	Volatile and Semi-volatile Organic Compounds	GC-FID[2] AMR 404.00	GC-FID LOD: 0.000 05 % (0.5 ppm) LOQ: 0.000 1 % (1 ppm) Range: 0.000 1 % to 98 % 1 ppm to 980 000 ppm
		Chemical Makeup	GC-MS AMR 403.00 FTIR[2] AMR 350.002	Qualitative
		Compound Identification and Quantification	HPLC AMR 401.00	0.5 ppm to 100% LOD: 0.2 ppm LOQ: 0.5 ppm

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer [F] would mean that the laboratory performs this testing at its fixed location.

2. Accreditation is granted through technology based flexible scope criteria. Additional methods other than listed above may fall under the accreditation of the laboratory. A complete listing of method capabilities can be derived from the laboratory upon request.

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Issue: 01/2021 This supplement is in conjunction with certificate #L21-22 Page 2 of 2

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QUALITY INFORMATION PACKET

Ann Arbor