

ACCURATUS
— LAB SERVICES —
THE ANTIMICROBIAL AUTHORITY

QUALITY MANUAL

This quality policy manual is for the use of Accuratus Lab Services, its Clients, Vendors, and the appropriate Regulatory Agencies. Unauthorized duplication or transfer to others is prohibited.

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Authorization


Authorization Signatures



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Introduction

Quality Manual

This manual defines the Accuratus Lab Services quality system. The manual describes the responsibilities and authority of our Management Team Members and provides an overview of the procedures we use to deliver quality services and meet regulatory requirements. This manual also provides Accuratus Lab Services employees, our Clients, Regulatory Agencies and other interested parties with an overview of the specific controls Accuratus Lab Services uses to assure the highest quality service.

Services and Quality Management System (QMS)

Accuratus Lab Services is a contract testing laboratory that functions as an extension of our Client's quality management systems. Accuratus provides a full range of contract testing services for our Clients:

- Microbiology/Virology Testing Services
- Analytical Testing Services
- Stability Storage and Testing Services

Our Clients are primarily medical device, biotech, and antimicrobial pesticide manufacturers / suppliers. We have developed and implemented a quality management system to enhance our ability to consistently provide testing services that meet Client and regulatory requirements and to achieve Client satisfaction through the effective application of the system. The quality management system also ensures that Accuratus Lab Services avoids involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity.

Company Facility Information

Accuratus Lab Services is a multi-site corporation which provides contract testing services to primarily medical device, biotechnology and antimicrobial industries. Accuratus Lab Services is owned by Ampersand Capital Partners.

Accuratus Lab Services operates a testing facility in Eagan, MN, which is approximately 19,000 sq.ft. and primarily provides EPA GLP (Good Laboratory Practices 40 CFR Part 160) and FDA GLP (Good Laboratory Practices 21 CFR Part 58) testing services, as well as Research and Development and custom antimicrobial product testing services.

Scope of our Quality Management System (QMS)

Accuratus Lab Services has established, documented, and implemented a QMS in accordance with and maintained per the requirements of all applicable regulations and standards. Included within the quality management system are methods and procedures that describe how to maintain the system:

- Identification of processes needed for the quality management system
- Determination of the sequence and interaction of these processes
- Determination of criteria and methods to ensure the effective operation and management of these processes
- Availability of information necessary to support the operation and monitoring of these processes
- Methods to measure, monitor, and analyze these processes
- Implementation of actions necessary to achieve planned results and continual improvement

Regulatory Standards

The quality management system is guided by the following standards:

- FDA 21 CFR Part 58 Good Laboratory Practice For Non Clinical Laboratory Studies
- EPA 40 CFR Part 160 FIFRA Good Laboratory Practice Standards

Quality System Documentation

Accuratus Lab Services' documentation requirements are defined FDA Good Laboratory Practices (GLP) and EPA Good Laboratory Practices standards (GLPs). Accuratus Lab Services maintains documentation that ensures the effective planning, operation and control of processes.

Table 1. Documentation used by Accuratus Lab Services to manage our quality system

Document	Where Document is Applied
Quality manual	Quality management system
Quality procedures	FDA and EPA GLP standard operating procedures
Testing procedures	Testing SOPs, equipment SOPs, and media production
Client procedures	Client specific procedures based on standard testing procedures
References standards	Documents from external origin including but not limited to AAMI, AMSI, USP, ASTM, AOAC, EN etc.
Departmental procedures	Accounting, Sales, Client Relations, Management

Control of Documents

Accuratus Lab Services maintain records that provide evidence of conformity to requirements and of the effective operation of the QMS. Records are kept in hard copy and/or electronic copy in accordance with the record retention policy. Documentation of the type, storage, retention time, and disposition of records are detailed in the facility specific archive SOPs for document control and archiving and assure the following:

- Documents are approved for adequacy and employees are trained prior to issue
- Documents are reviewed and updated as necessary
- Revision history and the current revision status of the documents are identified
- Relevant versions of applicable documents are available at points of use
- Documents remain legible and readily available
- The unintended use of obsolete documents is prevented.
- Documents are retained for a specific period of time

Process Sequence and Interaction

Accuratus Lab Services' quality system has been implemented and is maintained using a process approach to ensure ongoing control and satisfaction to our clients. The process ensures the consideration and importance of:

- Understanding and meeting client requirements
- The need to consider processes in terms of added value
- Obtaining results of process performance and effectiveness
- Continual improvement of processes based on objective measurements
- Ensuring overall client satisfaction

Management Responsibility

Management Commitment

Management at Accuratus Lab Services is committed to the development and implementation of our quality management system and to continually improving its effectiveness by:

- Communicating to the organization the importance of meeting client as well as regulatory requirements
- Establishing the company's quality policy and quality statement
- Ensuring that the company has established quality objectives
- Conducting management reviews
- Ensuring the availability of resources

Quality Policy

Accuratus Lab Services management is dedicated to ensuring that the company's quality policy:

- is appropriate to the business of the organization
- includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system
- provides a framework for establishing and reviewing quality objectives
- is communicated and understood within the organization
- is assessed for continuing suitability

Quality Objectives and Planning

To ensure the goals of our quality policy statement are maintained, Accuratus Lab Services developed company-wide quality objectives and assigned specific people to lead the organization to meet these quality objectives.

The quality objectives—which are measurable and consistent with the quality policy statement—are monitored by senior management and reviewed with the appropriate personnel at staff meetings, management review meetings, and at other times as deemed necessary. Quality objectives start with the quality policy statement and are passed down throughout the company from senior management through all levels of personnel.

Internal Communication

Accuratus Lab Services maintains internal communication through staff meetings, project meetings, company meetings, email, telephone, and memos. Communication is appropriately documented (e.g. meeting minutes or memos) when appropriate and maintained by appropriate personnel.

Responsibility and Authority

Accuratus Lab Services has defined the responsibility and authority for meeting quality objectives within its operations. A detailed description of responsibility is outlined in the job descriptions that have been established for each function. A current organizational chart is maintained at Accuratus Lab Services testing facility.

The Director of Quality Assurance has been appointed as the Management Representative by Executive Management. The Director of Quality Assurance is responsible for quality at Accuratus Lab Services as it relates to GLPs and other applicable Codes of Federal Regulations. The Director of Quality Assurance reports directly to the President and has the responsibility and authority to ensure that quality management system processes are established, implemented, maintained and improved.

The Director of Quality Assurance promotes the awareness of client requirements throughout the organization by means of the "Quality Policy Statement." The Director of Quality Assurance reports to upper management on the process performance in terms of company objectives.

The Director of Operations reports directly to the President and is responsible for continuously improving and measuring quality as it relates to the overall operating activity of the company. The Director of Operations responsibilities include all laboratory and business operations.

Each area Director, Manager, and Supervisor is responsible for continuously improving and measuring quality as it relates to the processes they are responsible for. The scope of their responsibilities have been defined in their job descriptions and are designed to facilitate overall laboratory compliance to applicable GLPs and other applicable Codes of Federal Regulations.

Management Review

Senior Management reviews the quality system at least once per calendar year to ensure its continuing suitability and effectiveness in satisfying the requirements of GLPs and applicable codes of Federal Regulations and Accuratus Lab Services quality policy and objectives. Management review procedures, discussion topics, and reporting are detailed in the Management Review SOP.

Resource Management

Provision of Resources

Accuratus Lab Services has defined the resources needed to implement the QMS and continuously improve the value of the QMS,. Accuratus Lab Services facilities determine and provide resources as required by the QMS. Descriptions of personnel resources are defined in SOPs and/or job descriptions.

As the quality management system continually improves and is revised, the effectiveness of resources is evaluated. Changes are made when necessary in order to reduce process errors and to enhance client satisfaction according to the quality policy.

Competence, Awareness, and Training

Personnel employed by Accuratus Lab Services and whose workmanship affects service quality must be competent on the basis of appropriate education, training, skills and experience.

To ensure the level of competency is maintained, job descriptions have been developed and are used for responsibility delegation, training needs, and performance evaluations. Job descriptions include the job position, responsibility, education, and skills required to perform required functions. Competency of the employee's workmanship is reviewed during the employee performance evaluation.

All employees are trained on the quality systems described in this manual. In addition, employees go through extensive training prior to testing client samples. The training includes a combination of the following, but is not limited to: procedure review, equipment review, test observation, written exams, and a test qualification. Appropriate records of education, training, skills and experience are maintained.

Infrastructure

Accuratus Lab Services determines and provides the infrastructure needed to achieve conformity to service requirements. The infrastructure includes, as applicable:

- buildings, workspace and associated utilities
- process equipment (both hardware and software)
- supporting services such as transport or communication
- Analytical Chemistry Laboratory
- Microbiology Laboratory

- Virology Laboratory, including Biosafety Level 3 Laboratory
- Re-usable Device Cleaning Validation Laboratory
- Laboratory Support Area (Media/Glassware Prep)
- Sample Storage Areas

Work Environment

To achieve conformity to service requirements, the organization determines the appropriate means of the work environment for each process based on the nature of the process and key parameters that could be affected by the environment. Work environment criteria is determined, defined, and monitored as part of standard operating procedures.

Project Realization

Planning of Project Realization

This section describes the methods used to plan and develop the process needed for project realization. The responsibility and authority in this area is assigned to the President, COO, all Directors and other Accuratus Lab Services Management Staff. Other individuals may carry out the activities related to this section as designated by the above named individuals.

The methods used for project realization include:

- Quality objectives and requirements for project
- The need to establish processes, documents and provide resources specific to the project
- Required verification, validation, monitoring, inspection and test activities specific to the project and the criteria for product acceptance
- Records required by regulatory standards to provide evidence that the realization processes and resulting project are met.

Client-Related Processes and Review of Requirements Related to the Testing Project

Accuratus Lab Services reviews requirements related to the client's product through our client support and laboratory processes. The Client Relations / Commercial Department with the assistance of laboratory personnel determines if we can meet the client's testing needs. Accuratus Lab Services generates a quotation describing the testing to the client. The Client Relations / Business Development Department discuss applicable lead times and turn around times during this process. Clients send products utilizing the Test Substance Submission Form to document their requests and requirements. In addition, protocols or test request forms are generated by Accuratus Lab Services and approved/signed by the client prior to the initiation of testing. Accuratus Lab Services uses established procedures based on statutory and regulatory references to perform testing. If a client requests custom testing, a protocol will be developed, reviewed, and approved prior to testing. Samples and associated paperwork are inspected and received per applicable SOPs.

Client Communication

Accuratus Lab Services maintains a high level of communication with our clients in terms of obtaining initial testing information, updates of the testing process, final report distribution, notification and

discussion of results. Accuratus Lab Services will cooperate with our clients as it relates to auditing our quality system both onsite and via surveys. Communication with the clients is documented through meeting notes, phone conversation notes, and/or emails.

Accuratus Lab Services maintains external communication through the specific departments. Employees speak with honest dialogue; with the goal to provide continual client satisfaction.

Purchasing

Accuratus Lab Services will ensure that purchased supplies conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased supplies will be dependent upon the effect of the purchased product on subsequent realization of the final testing results.

Production and Service Provision

Accuratus Lab Services Laboratories carries out testing under controlled conditions that include: the use of approved work instructions, the use of suitable equipment/instruments, the monitoring of a suitable work environment, the implementation of monitoring and measurement processes, raw data reviews, draft report reviews, and final report approvals.

Identification/Traceability/Client Property /Preservation of Product

Identification and traceability is maintained throughout the testing process. A unique number is assigned to the product when a product is received for testing. The test/control substance is labeled with the unique number and the number is maintained on all associated test documents throughout testing. The unique number is traceable to the test/control substance name, which used as identification/traceability in the final report. Original documentation is archived by the unique number.

Accuratus Lab Services examines all product packaging for shipping damage and verifies all associated paper work. Clients dictate, via the Test Substance Submission Form, how the product should be stored. Accuratus Lab Services maintains dedicated refrigerators and freezers on emergency backup power to store client product according to specifications. Samples are stored and controlled to achieve traceability, client product care, and preservation of the product.

Control and Monitoring of Measuring Devices

Accuratus Lab Services has developed and implemented an equipment control program that identifies all measuring devices used in laboratory processes. The purpose of the equipment maintenance and calibration program is to provide evidence of conformity and to ensure all equipment is suitable for use during testing. The equipment maintenance and calibration programs are established to meet applicable regulatory compliance and are defined in specific SOPs. Records of calibration and maintenance are maintained.

Accuratus has also implemented an equipment validation program that is defined within equipment specific validation procedures. The validation program has been implemented to assure testing equipment is installed, operates, and performs as intended.

Control of Test Methods

Accuratus Lab Services utilizes a variety of test methods for the testing of the products submitted by our clients. Accuratus utilizes current standards and compendial methods to tests client products. Accuratus also develops and transfers test methods based on our clients needs. Protocols are utilized for EPA or FDA GLP testing. The protocol out lines the specific test method to be used and any modifications. Both the Client and the Accuratus Lab Services study director will sign and approve the protocol prior to testing. If changes need to be made to the protocol following the signature and approval process, those changes will be in the form of either a protocol amendment or a protocol deviation. In both cases, the client is notified of any changes needed. For testing that does not require a protocol, the applicable standard operating procedure will be followed that outlines the required method. Changes that are made to standard operating procedures follow the document control process.

Measurement, Analysis and Improvement

Monitoring, Measuring and Analysis

Monitoring, measuring and analysis of processes are conducted to ensure the processes meet expected standards. Where processes are determined to be deficient against standards or quality expectations, recommended improvements are initiated. Several methods are used to monitor processes, which include but are not limited to:

- In process positive and negative control systems
- Temperature monitoring.
- Amended reports
- Laboratory Investigation Reports
- Deviations
- Company goals and objectives
- Budget analysis
- Sales analysis
- Client satisfaction—internal and external
- Corrective and preventive actions

Client Satisfaction

Accuratus Lab Services's Quality Assurance Staff is committed to and is aware of the importance of meeting client as well as statutory and regulatory requirements. To ensure that client requirements are determined and are met with the aim of client satisfaction the following methods are used to measure client satisfaction as applicable to each testing facility:

- Amended report trending
- Testing and Reporting turnaround times
- Internal and External Client Surveys
- Corrective Action and Deviations
- Client Visits/Audit Results

The Management Representative and key staff members report the results of these measurements to senior management as required according to the management review procedures. When determined that client satisfaction has not been achieved, corrective and/or preventive action is initiated through the use of the corrective action system.

Internal/Department Audits

Accuratus Lab Services has established and implemented an internal/department audit program to monitor compliance to the regulations described in the quality manual. Internal audits are conducted on a routine basis. Discrepancies found during the audits are corrected and followed up during subsequent audits. Results of the audits are reviewed with executive management during management review. The Quality Assurance Department maintains audit records.

Laboratory Investigations

Accuratus Lab Services identifies and investigates non-conforming events through multiple systems as applicable to the event including: Laboratory Investigation Reports, Deviations, and Out of Tolerance Reports.

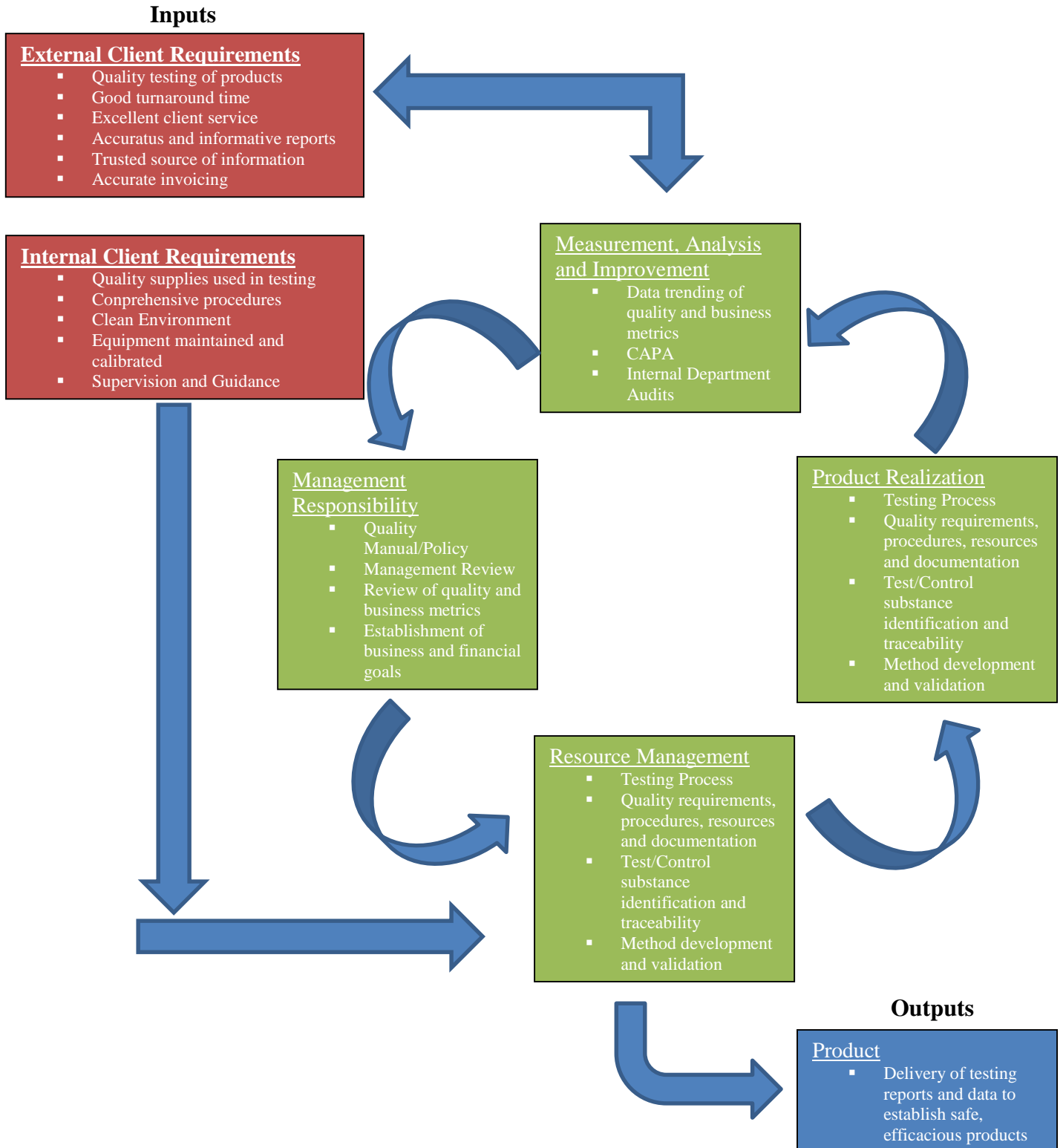
Corrective and Preventive Action (CAPA)

Accuratus Lab Services has developed and implemented a corrective and preventive action program to continuously improve the quality of testing services. The systems that feed into the corrective and preventive program include (but are not limited to) the following: client audits, out of specification results, equipment failures, deviations, management reviews, process measurement trends, and complaints. The corrective/preventive actions, person responsible, expected completion date, completion date, and references to documented evidence are specified on CAPA forms. Documentation is maintained and trended by the Quality Assurance Department.

Continuous Improvement Process

Accuratus is committed to the continuous improvement of the quality management system. The continuous improvement diagram that is included in this manual illustrates the process Accuratus Lab Services uses to drive continuous improvement.

Continual Improvement Process



Quality Policy Statement

This following is our quality policy statement as developed by the Accuratus Lab Services management team and supported by Senior Management of Accuratus Lab Services:

Accuratus Lab Services provides the highest quality antimicrobial and biocide testing services which is essential to our success of improving global public health and generating value for our customers. Each employee strives to maintain the highest standards in meeting customer requirements as well as statutory and legal requirements.

Mission/Vision Statement

It is Accuratus Lab Services mission to be the premier provider of microbiology, virology and analytical chemistry testing services necessary to support product development and regulatory compliance requirements for the Antimicrobial, Pharmaceutical and Medical Device industries.

Our vision is to take an aggressive stance in our commercial markets to grow top-line revenue, while focusing on continuous improvement in our business process to make our operations more efficient. We will maintain our commitment to the superior science our clients value, while performing our work at the highest level of quality, which they expect.

Alan Roth
General Manager/CFO – Accuratus Lab Services

Revision History

Revision	Description
001	New Quality Policy Manual - This quality manual has been established due to the combination of ATS Labs and MicroTest Labs to form Accuratus Lab Services.
002	Entire document revised to reflect only Accuratus Lab Services, Eagan MN.