LGGS, INC. / LGGS FLORIDA, INC.

QUALITY MANUAL

3335 E. MIRALOMA AVENUE, # 140
ANAHEIM, CALIFORNIA 92806
PHONE (714) 223-0800 / FAX (714) 223-0801

15370 COUNTY ROAD 565A, SUITE A
GROVELAND, FLORIDA 34736
PHONE (352) 242-0057 / FAX (352) 242-4741

APPROVAL:

5/20/2024

GEORGE SZORENYI, DIRECTOR OF MICROBIOLOGICAL PROGRAMS
QUALITY SYSTEMS MANAGEMENT REPRESENTATIVE

LGGS, INC / LGGS FLORIDA, INC.

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Quality Manual Revision History

Revision no.	Description of Change	Author	Effective Date
0	Initial Release	George Szorenyi	04/01/02
1	Change of format and changes made per TUV recommendation	George Szorenyi	06/07/02
2	Added ISO 13488 in preface section	George Szorenyi	09/10/04
3	Re-write according to ISO 13485:2003	George Szorenyi	09/21/05
4	Changes made per Intertek finding # MA-1 and MA-2	George Szroenyi	10/18/05
5	Add LGGS Florida Organizational Chart	George Szorenyi	02/21/07
6	Identify Site 2 (LGGS Florida) within Scope of QMS; correct Typographical error (page nos.); Update distribution list	George Szorenyi	05/01/07
7	Change of Scope to include exclusions	George Szorenyi	10/19/07
8	Re-write according to ISO 13485-2016	Valerie Salvati	01/25/19
9	Updated sections 7.5.1 through 7.5.9.2 and 8.2.6 to show as excluded and not applicable	George Szorenyi	06/09/2020
10	Update Master Revision List	Valerie Salvati	4/18/2023
11	Added section 4.1.5 Added quality objectives, Risk management Added section 4.2.3 Medical Device File section Changed storage duration	Valerie Salvati	03/01/2024
12	Revised section 4.2.3 Medical Device File to (finding 1443494-6) test report is considered the product not a medical device. Procedures O-SOP-0060, O-SOP-0130, O-SOP-0070 and O-SOP-0075 would be considered the medical device file. Changed storage duration Updated Master Revision List 1.2.2.1 Defined control of production and service provision	George Szorenyi	3/8/2024
13	Added clarification of data analysis to section 8.4	Valerie Salvati	3/20/2024

Note: This Revision Record is a summary of change control only. All obsolete sections of the manual are maintained in the change control log book.

1.0 PREFACE

1.1 General:

This manual defines LGGS, Inc. / LGGS Florida, Inc.'s policies that reflect the requirements of ISO guidelines. Implementation of these policies ensures that we consistently meet the quality and performance requirements of customers in a timely and cost-effective manner.

I personally affirm my commitment to enhancing LGGS, Inc. / LGGS Florida, Inc.'s Quality System through the implementation of ISO 13485:2016. I fully support the provisions of this manual and solicit the active partnership of all LGGS, Inc. / LGGS Florida, Inc. personnel in its implementation throughout the laboratory.

1.2 Application:

1.2.1 Design and development (7.3) are excluded from this Quality Manual for the following reasons:
LGGS, Inc. / LGGS LGGS Florida, Inc. follow industry and regulatory requirements and for this reason; LGGS, Inc. / LGGS Florida Inc. does not design or develop testing methods. Regulatory requirements permit exclusions of design and development controls (see 7.3).

1.2.2 Production and Service Provision (7.5.1 through 7.5.9.2) is excluded from this Quality Manual because this section does not apply to LGGS, Inc. and LGGS Florida, Inc.

1.2.2.1 Control of production and service provision (7.5.1)

- LGGS, Inc / LGGS, Florida's primary deliverable is the comprehensive report issued to customers. In line with our commitment to client confidentiality, we do not retain any customer products due to the destructive nature of our laboratory tests, ensuring that proprietary information is safeguarded while upholding the integrity of our testing procedures.

1.2.2.2 Not applicable: Cleanliness of product (7.5.2)

- LGGS, Inc's product is reports and media no cleaning process is applicable. LGGS, Inc. has a procedure that does apply to cleanroom contamination control (O-SOP-0035)

1.2.2.3 Not applicable: Installation activities (7.5.3)

- There is no installation requirement for test reports generated from testing following ISO and USP guidelines.
- No installation activities are required for media.

1.2.2.4 Not applicable: Servicing activities (7.5.4)

- LGGS, Inc. does not require servicing on the reports generated.
- Media made by LGGS, Inc. manufactured, growth promoted and stored following USP guidelines. No servicing is required.

1.2.2.5 Not applicable: Particular requirements for sterile medical devices (7.5.5)

- LGGS, Inc. does not manufacture a sterile medical device.

1.2.2.6 Not applicable: Particular requirements for validation of processes for sterilization and sterile barrier systems (7.5.7)

- LGGS. Inc. does not have a sterile finished product with sterile barrier system to validate.

1.2.2.7 Not applicable: Particular requirements for implantable medical devices (7.5.9.2)

- LGGS, Inc. does not manufacture implantable medical devices.

1.2.3 Not Applicable: Monitoring and measurement of Products (8.2.6)

- LGGS has no physical product that is monitorable or measurable.

3/20/2024

George Szoreny – Director of Micro Programs

2.0 QUALITY POLICY

"LGGS, Inc. / LGGS Florida, Inc. is committed to providing the highest quality in microbiological testing services in conformance with applicable regulatory requirements while meeting each customers' service and business objectives."

3.0 KEY DEFINITIONS

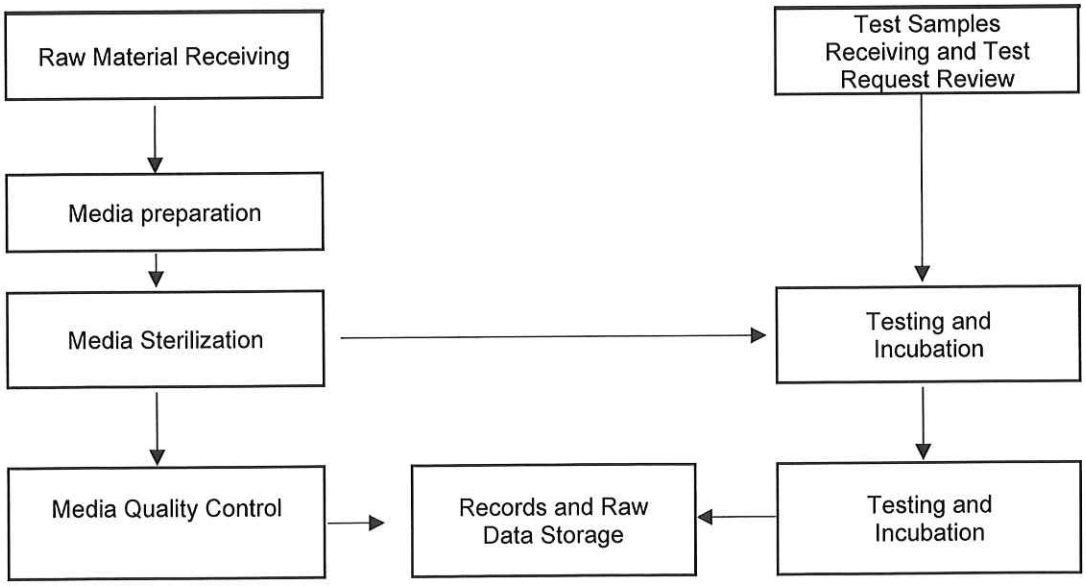
Customer	Any organization or individual that enters into a formal agreement with LGGS, Inc. / LGGS Florida, Inc. for delivery of LGGS, Inc. / LGGS Florida, Inc.'s services.
Quality Policy	Overall intentions and directions of LGGS, Inc. / LGGS Florida, Inc. with regard to quality as formally expressed by executive management.
Quality Record	A subject of records that demonstrates conformance to requirements and the effective operation of the quality system.
Quality System	LGGS, Inc. / LGGS Florida, Inc.'s organizational structure, procedures, processes, and resources needed to implement quality management.
Service	Consulting, physical work, and/or intellectual work.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

4.1.1 LGGS, Inc. / LGGS Florida is a contract microbiological testing laboratory for sterility, bioburden, LAL testing, clean room certification and environmental monitoring for medical device manufacturers. LGGS, Inc. / LGGS Florida, Inc. has prepared and implemented a quality system in compliance with procedures and the stated quality policy. The Quality Manual is maintained and controlled to ensure its adequacy and currency. For the interaction between the processes of the quality management system, see flowchart:

Fig. 1



4.1.2 To ensure activities governed by the Quality System are implemented LGGS, Inc./ LGGS Florida, Inc. shall:

- Determine the processes needed for the quality management system and the applications of these processes throughout the organization.
- Determine the sequence and interaction of these processes.
- Apply a risk-based approach to control appropriate processes.

4.1.3 Each quality management system process, LGGS, Inc./ LGGS Florida, Inc. shall:

- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- Implement actions necessary to achieve and maintain effectiveness of the quality management system processes.
- Monitor, measure, as appropriate, these processes.

4.1.4 Document and maintain records needed to demonstrate conformance. Changes to be made to these processes shall be:

- Evaluated for their impact on the quality management system.
- Evaluated for their impact on the testing produced under this quality management system.
- Controlled in accordance with the requirements of the International Standard and applicable regulatory requirements.

4.1.5 Any outsourced process appropriate controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with clause 7.4. The controls shall include written quality agreements.LGGS Inc. / LGGS Florida Inc. will be notifying the regulatory body if there is any significant change.

4.1.6 If Computer software or application is used in the quality management system, it shall be validated upon use and documented procedures describe the validation process. LGGS, Inc. / LGGS Florida, Inc. procedure O-SOP-0120 defines the procedure for equipment and software validation.

4.2 Documentation Requirements

4.2.1 General

These documented procedures are controlled and effectively implemented to ensure that LGGS, Inc. / LGGS Florida, Inc. meets customer requirements. The Quality System is defined in the following controlled documents:

Quality System Document Levels

Quality Policy

Document	Purpose
Quality Manual	Quality Policies
SOP Procedure Books	Operating Procedures
Test Specifications	Working Instructions
Quality Records	Objective Evidence of Quality System Maintenance

Procedures that form part of the quality system depend on the complexity of the work, the methods used and the skills and training needed by personnel involved in carrying out the activity. The scope of the documented operational procedures shall be sufficient to define how the requirements for quality are met.

4.2.2 Quality Manual

LGGS, Inc. / LGGS Florida, Inc. has established, documented and maintained this Quality Manual as a statement that our quality management system is compliant with ISO 13485:2016.

4.2.3 Medical Device File

LGGS, Inc. / LGGS Florida, Inc. test report is considered the product not a medical device. Procedure O-SOP-0060 – Procedure for the Report of Test Results is the procedure to outline the method used to develop sponsor reports and revisions to reports, Procedure O-SOP-0130 Client Confidentiality and Proprietary Rights is used to protect the client confidentiality and proprietary rights, Procedure O-SOP-0070 Signature requirements for technical reports and O-SOP-0075 Procedure foe Raw Data Preparation and Storage would be considered the medical device file.

4.2.4. Control of Documents

LGGS, Inc. / LGGS Florida, Inc. ensures that current Quality System documentation and Quality System data are readily available to all QA personnel via a document and data control system. This system ensures that all Quality System documentation and data are reviewed and approved prior to their initial release and any subsequent modifications. Obsolete or invalid Quality System documents and data are destroyed or, if retained, properly marked. It is the responsibility of the laboratory management to identify needed documents to assure execution of stated quality policy objectives. Provisions of control of documents and data on electronic media are not applicable. The authority for review and approval of controlled documents is granted to the Director of Microbiological Programs or the VP/Quality Assurance Microbiology. LGGS, Inc. / LGGS Florida, Inc. procedure O-SOP-0015 details procedure and controls for quality system documentation.

LGGS, Inc. / LGGS Florida, Inc. has written procedures to ensure that documents are reviewed and approved for adequacy by designated individuals prior to use. These procedures include steps to ensure that needed documents are available at all points of use, that obsolete documents are removed from points of use in a timely manner and then retained in change control files. Changes to documents and data are reviewed and approved by the same functionaries that performed the original reviews/approvals. The signatories will have access to pertinent background information when needed upon which to base their review and approval. The nature of document changes is identified in the change control records. A master list documenting revision status of all operational procedures is available.

4.2.5. Control of Records

LGGS, Inc. / LGGS Florida, Inc. maintains all quality records to demonstrate conformance to procedures designed to prevent deterioration or loss and allow rapid retrieval. Quality records are analyzed to provide input to corrective and preventive actions as well as managing and improving the quality management system. Records are collected and filed on a daily basis by customer in order, using the lab number for identification and indexing. The archives facility is under climate control with removal procedures specified within O-SOP-0080. Records are to be stored in designated secure areas or a qualified archival facility for two years after testing is finished. At this time, sponsors of records under review

for destruction shall be notified and given the opportunity to acquire and maintain the data at their facility.

The Quality Assurance Technologist has responsibility of maintaining all quality records. The Management Representative/Quality Assurance Manager and Director of Micro Programs/Senior Technologist have authority to approve and review record storage procedures.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Executive management shall demonstrate its commitment to the development and implementation of the quality management system and maintain its effectiveness by:

- Communicating with LGGS, Inc. / LGGS Florida, Inc. personnel and maintaining awareness of the importance of meeting customer requirements, as well as regulatory and legal requirements.
- Establishing the quality policy.
- Ensuring that the quality objectives are established.
- Conducting management reviews.
- Ensuring the availability of resources.

5.2 Customer Focus

Management ensures that current and future customer requirements and applicable regulatory requirements are understood and consistently met.

5.3 Quality Policy

Top management has established the LGGS, Inc. / LGGS Florida, Inc. quality and ensures that is communicated to all personnel.

5.3.1 Quality Policy:
LGGS Inc./LGGS Florida, Inc. is committed in providing the highest quality in microbiological testing services in conformance with applicable regulatory requirements while meeting each customer's service and business objectives.

5.3.2 Executive management shall ensure that the quality policy is:

- Applicable to the purpose of the organization.
- Includes a commitment to comply with requirements and maintains the effectiveness of the quality management system.
- Provides a framework for establishing and reviewing quality objectives.
- Communicated to and understood by LGGS, Inc. / LGGS Florida, Inc. personnel.
- Reviewed annually during Management Review for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives
Top Management ensures that quality objectives, including those needed to meet customer and regulatory requirements, are established at relevant functions and levels within the organization and are reviewed annually during management review to ensure they are measurable and consistent with the quality policy.

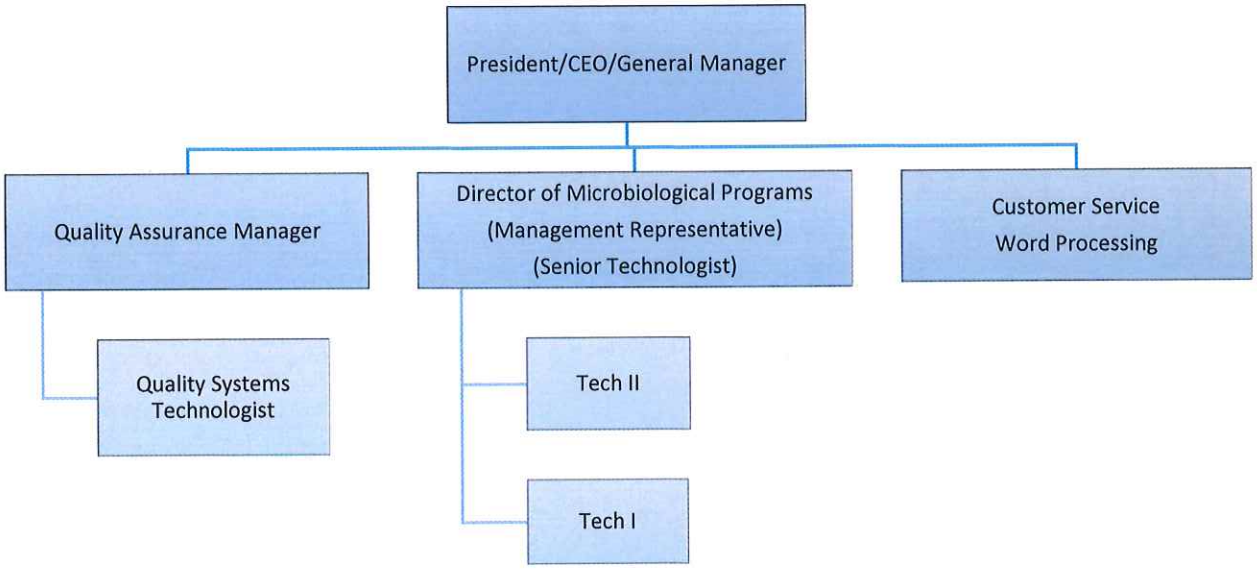
5.4.2. Quality Management System Planning
Top Management ensures quality planning is carried out in order to meet the requirements as well as quality objectives. The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Executive management has the authority to direct organizational structure. Each employee has the responsibility to execute assigned job and organizational responsibilities. The responsibility, authority and interrelation of personnel who manage, perform and verify work affecting quality shall be documented and defined within organization charts and job descriptions. (See Fig. 1, Fig. 2 and O-SOP-0095)

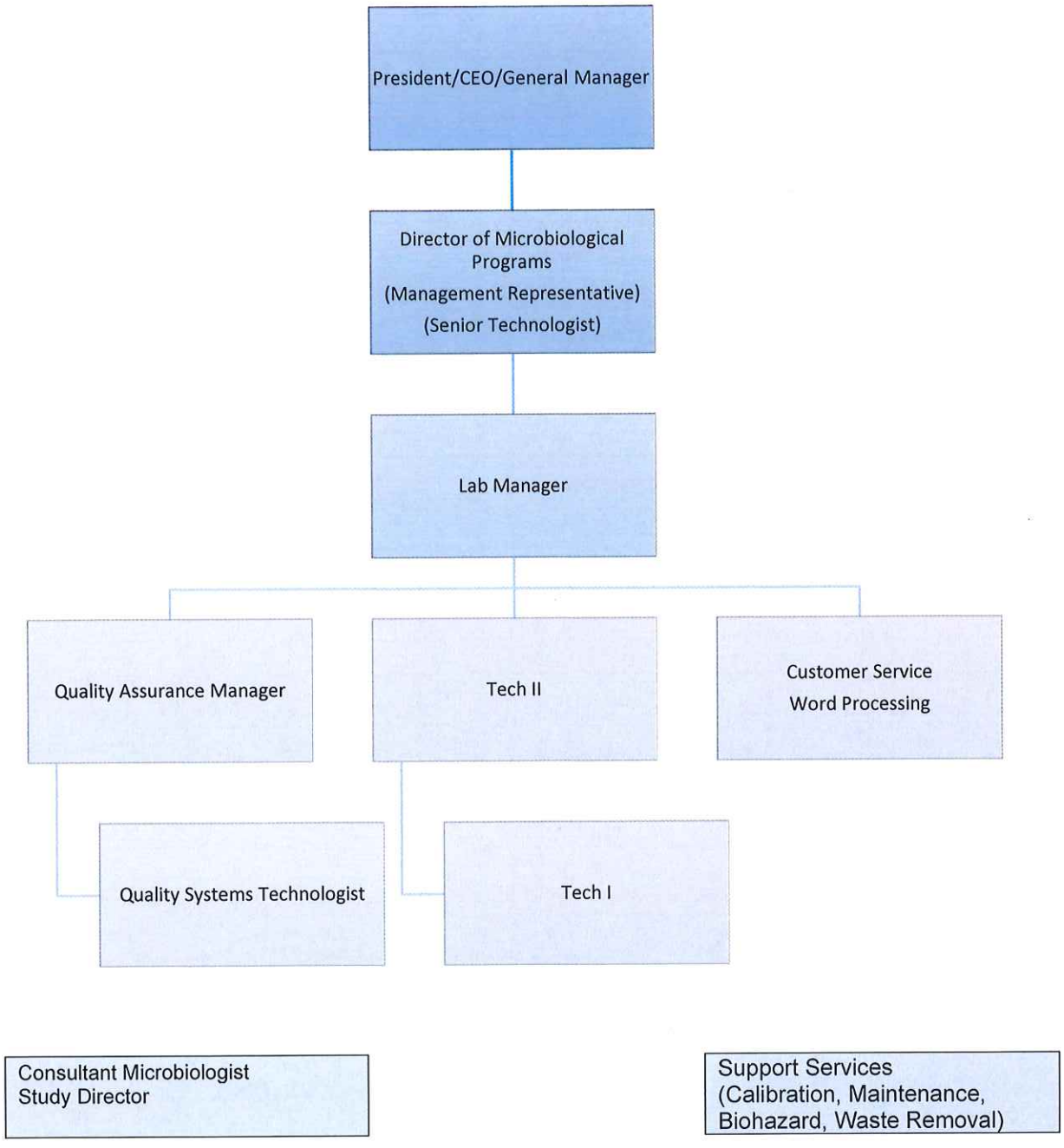
Fig. 1
LGGS, INC.
ORGANIZATIONAL CHART



Consultant Microbiologist
Study Director

Support Services
(Calibration, Maintenance,
Biohazard, Waste Removal)

Fig. 2
LGGS FLORIDA, INC.
ORGANIZATIONAL CHART



5.5.2 Management Representative

Executive management has appointed the Director of Microbiological Programs as the management representative. The representative shall provide the executive management with reports of quality system suitability and effectiveness.

The Quality System Management Representative shall:

- Document and maintain the LGGS, Inc. / LGGS Florida, Inc. Quality Policy.
- Ensure that the Quality System is established, implemented, and maintained in accordance with LGGS, Inc. / LGGS Florida, Inc.'s Quality Manual.
- Coordinate and chair the Quality Management Review meetings to determine if the performance of the Quality System is suitable, adequate and effective in meeting the goals and objectives of LGGS, Inc. / LGGS Florida, Inc.'s Quality Policy and the Quality System.

5.5.3 Internal Communication

Appropriate communication from management will be extended to all employees regarding the importance and effectiveness of the quality management system. This will take place in the form of a summary memo from the management review and distributed to all employees. Memo and summary page will be posted for employees and retained in the management review file.

5.6 Management Review

5.6.1 General

Quality Management Review meetings shall be held at least once a year during the first quarter. This review includes assessing opportunities for improvement and the need for changes to the quality management system including quality policy and quality objectives, and changes in applicable regulatory requirements.

The following employees shall be in attendance:

- President/CEO/General Manager
- Director of Microbiological Programs
- Quality Assurance Manager/Lab Manager

Conclusions (Minutes and Agenda) are recorded and maintained following LGGS, Inc. / LGGS Florida, Inc. procedure O-SOP-0080 procedure for storing and laboratory quality records.

5.6.2 Review Input

Quality Management Review meetings agendas shall include reports in the following areas:

- Open action items from previous Quality Management Review meetings.
- Results of quality audits including customer, registrar and internal audits.
- Changes that could affect the quality system.
- Customer satisfaction, including complaints.
- Status of corrective and preventive action.
- Review of organizational structure, the quality of actual service in relation to quality objectives, preventative action, corrective action, nonconformities, audit finding from the outside auditor and determine potentially necessary updates of the quality system due to new technology, quality concepts or other conditions.
- Discussion on the suitability, adequacy and effectiveness of the LGGS, Inc. / LGGS Florida, Inc. Quality Management System in meeting the Quality Policy and its objectives.
- Opportunities for improvement.
- New or revised regulatory requirements.
- Risk Management

5.6.3 Review Output

Minutes of the Quality Management Review meetings are prepared, distributed and the status of assigned action is tracked. A Quality Record containing Quality Management Review documents and minutes will be generated and managed by the Management Representative. Quality Records will be kept in archive room.

LGGS, Inc. / LGGS Florida, Inc. will identify and document appropriate actions to be taken regarding the following issues:

- Improvement on the stability, adequacy and effectiveness of the quality management system and its processes
- Improvement of products/procedures related to customer requirements
- Changes needed to respond to applicable new or revised regulatory requirements.
- Resource needs
- A memo of the management review will be posted in order to communicate the effectiveness of the quality management system to the employees on an annual basis.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resource

LGGS, Inc. / LGGS Florida, Inc. has established an organizational structure and defined individual job descriptions to meet laboratory functional needs. Executive management maintains final authority over allocation of resources. The VP/Quality Assurance Manager and Quality Systems Technologist are responsible for verification of training documentation. The Quality Systems Technologist performs laboratory verifications and initial quality audits while having no direct responsibility for the conduct of the tests under verification review. Executive management review laboratory resource requirements during management reviews conducted once per year.

6.2 Human Resources

6.2.1 General

LGGS, Inc. / LGGS Florida, Inc. has established an organizational structure and defined individual job descriptions to meet laboratory functional needs.

6.2.2 Competence, Awareness and Training

LGGS, Inc. / LGGS Florida, Inc. maintains a staff with sufficient background and training to meet stated quality policy objectives. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. An ongoing training program is in place which includes: GMP orientation – review and signing of the quality policy – SOP reading assignments each quarter and documented "on the job" training. Appropriate records of training shall be maintained. Qualifications and records of consultants utilized are also a part of the laboratory training records. Responsibility for personnel training is granted to designated trainers and supervisors in the laboratory. Executive management holds authority for providing sufficient personnel.

6.3 Infrastructure

Procedures included as SOP's have been prepared and reviewed to assure conformance to applicable guidelines. Test specifications, which provide product specific instructions are prepared and jointly approved by laboratory management and the customer. These process control procedures ensure that testing conforms to quality policy objectives. Processing deficiencies may become apparent only after the product is in use. The process shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that requirements are met. Where applicable, qualifications and operations, equipment and personnel are specified and records maintained. LGGS, Inc. / LGGS Florida, Inc. does not utilize computer software for process control.

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

LGGS, Inc. / LGGS Florida, Inc. minimizes the risk of damage to or deterioration of materials and products by handling, storing, packaging, preserving, and delivering materials and products in accordance with standard operating procedures, unless special requirements are identified.

Responsibility for proper handling procedures are applicable to all personnel at appropriate function.

6.4.2 Contamination Control

LGGS, Inc. / LGGS Florida, Inc. shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel or product.

7.0 PRODUCT REALIZATION

7.1 Planning the Product Realization

To ensure that quality requirements are met, LGGS, Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures for following inspections and test activities in order to verify that the specific requirements for the product have been identified, performed and documented prior to dispatch of test results. To reduce risk of accidents and expenditures arising from them to a minimum, a risk management procedure is established based on current addition of ISO 14971 guidelines, current revisions of USP and additional AAMI / ISO guidelines.

7.2 Customer-Related Process

7.2.1 Determination of requirements related to the product

LGGS, Inc. / LGGS Florida, Inc. shall utilize test request forms completed by customer as a contract for each service requested. The test request forms shall be reviewed upon receipt to verify that test requirements are defined and any differences or problems are resolved and documented by amendment to the test request at that time. Test requests and changes to the test request form shall not be received by verbal means. Applicable regulatory requirements, trained personnel for testing to be performed and any additional requirements shall be determined. LGGS, Inc. / LGGS Florida, Inc. procedure O-SOP-0100 defines the procedure for customer complaints and feedback.

7.2.2 Review of requirements related to the product

A review of the requirements related to the product are conducted prior to executing the agreements with the customer. This review shall ensure that:

- Product requirements are defined and documented.
- Any contract requirements differing from those previously expressed are resolved.
- Applicable regulatory requirements are met.
- Any personnel training needed to ensure specified performance is identified and documented.
- Ensure that the ability to meet the defined requirements are met.

Record of the results of the review and any actions from the review shall be maintained.

7.2.3 Communication

LGGS, Inc. / LGGS Florida, Inc. will communicate with customers in the most effective way regarding all inquiries.

7.3 Design and Development

Not applicable, LGGS, Inc. /LGGS Florida, Inc. does not design testing methods. Testing is performed by following industry and regulatory guidelines.

7.4 Purchasing

7.4.1 Purchasing Process

All supplies purchased by LGGS, Inc. / LGGS Florida, Inc. are finished products that are used following manufacturer's directives. Purchasing control procedures have been established to ensure that purchased product conforms to specified purchasing information. Evaluation and selection of suppliers criteria shall be based on the supplier's ability to provide product that meets the requirements of the organization. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the evaluations and any necessary actions that arise from the evaluation shall be maintained. A list of approved suppliers will be maintained.

7.4.2 Purchasing Information

LGGS, Inc. / LGGS Florida, Inc. shall describe or reference the product to be purchased including as appropriate:

- Product specifications
- Requirements for product acceptance, procedures, processes and equipment
- Requirements for qualification of supplier personnel
- Quality management systems

7.4.3 Verification of Purchased Product

LGGS, Inc. / LGGS Florida, Inc. shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on supplier evaluation results and the risks associated with the purchased product. Any changes to the purchased product the organization will evaluate and determine if these changes affect the final test results.

When LGGS, Inc. / LGGS Florida, Inc. or its customers intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained.

7.5 Production and Service Provision

This section is excluded since production and service provisions do not apply to LGGS, Inc and LGGS Florida, Inc.

7.6 Control of Monitoring and Measuring Devices

LGGS Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures to control, calibrate and maintain monitoring and measuring devices.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENTS

8.1 General

LGGS, Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring and test equipment.

- Calibration records identify all equipment, ID numbers, locations, frequency of checks, check methods, acceptance criteria and actions to be taken when results are unsatisfactory.
- Records of all calibrations are maintained and available when required by customers for verification. Once calibrated a calibration sticker is affixed to each instrument, and results are reviewed following SOP directive. If equipment is to be found out of calibration, validity of previous measurements is reviewed.
- Calibrations are conducted by certified calibration companies using NIST traceable standards and suitable environmental conditions as well as internally by LGGS Inc. / LGGS Florida, Inc.. Test facilities and equipment are handled by designated individuals in a manner, which ensures the accuracy and fitness for use are maintained.
- Adjustment logs are utilized to ensure that no adjustments that would invalidate calibration settings are performed.

8.2 Monitoring and Measurement

8.2.1 Feedback

Customer feedback is established in the current revision of O-SOP-100 – Handling of Customer Complaints.

8.2.4 Internal Audit

LGGS, Inc. / LGGS Florida, Inc. conduct internal quality audits at planned intervals to measure the effectiveness of the Quality Management System, provide objective evidence that adequate controls are in place and assure that the procedures provide quality test results.

- Ensuring that timely corrective action is taken on nonconformances found during an internal audit
- Verifying the implementation and effectiveness of corrective action and documenting as a Quality Record
- Quality audits covering testing are conducted on a bi-annual schedule
- Quality audits covering the quality system and quality procedures are conducted and scheduled no less than once per year

8.2.5 Monitoring and Measurement of Processes

LGGS Inc. / LGGS Florida Inc. performs monitoring and, where applicable, measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, procedure following O-SOP-0020 will be implemented and documented to correct nonconformity.

8.2.6 Monitoring and Measurement of Product

This section is excluded since LGGS, Inc. has no physical product that is monitorable and measurable.

8.3 Control of nonconforming product

8.3.4 General

LGGS, Inc. / LGGS Florida, Inc. will implement documented procedures to prevent the unintended use, installation, or delivery of nonconforming products. These procedures provide for the identification, documentation, evaluation, segregation (when practical), disposition, and appropriate notification of the occurrence of non-conformances.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any action taken, including the evaluation, any investigations and the rational for decisions shall be maintained.

Note: Due to the nature of laboratory tests, reworking or scrapping of test results is not applicable. All results would be reported to the customer with a statement of nonconformity or deviation.

8.4 Analysis of data

LGGS, Inc. / LGGS Florida, Inc. determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the Quality Management System can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction/feedback.
- Conformance to product requirements.
- Characteristics and trends to processes and product, including opportunities for improvement.
- Suppliers
- Audits
- Service report, as appropriate.

Data collected for analysis includes:

- Results from customer complaints/feedback. (O-SOP-0100 Customer Complaints/Feedback)
- Results from monthly operations report (False Positive Report) and internal audits. (O-SOP-0105 Quality Audits)
- Results from cleanroom environmental monitoring. (M-SOP-0100 Environmental Monitoring of Laboratory Cleanroom)
- Non-conformance reports. (O-SOP-0020 Document Nonconformity)
- Approved supplier list, Supplier self-assessment, and Biannual critical vendor review.

The results of data analysis are depicted within appropriate trend charts whenever possible and distributed to members of Top Management during the annual Management Review If the analysis of data shows that the quality management system is not suitable, adequate, or effective, LGGS, Inc./ LGGS Florida, Inc. shall use this analysis as input for improvement as required.

8.5 Improvement

8.5.1 General

LGGS, Inc. / LGGS Florida, Inc. continually improves the effectiveness of the Quality Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Preventive and corrective action is taken to eliminate potential or existing nonconformance to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered to eliminate or minimize the impact on safety, performance, dependability, processing cost, quality-related cost, and customer satisfaction.

Note: Implementation of advisory notices are not applicable. LGGS Inc./ LGGS Florida, Inc. is a contract testing laboratory. We do not issue advisory notices. This would be the responsibility of the customer.

8.5.2 Corrective Action

LGGS, Inc. / LGGS Florida, Inc. will take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions will be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. Records of the results of any investigations will be maintained.

Corrective action procedure O-SOP-0025 defines requirements for:

- Reviewing nonconformities (including customer complaints).
- Determining the cause of nonconformities.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation.
- Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
- Reviewing the effectiveness of the corrective action taken.

8.5.3 Prevention Action

LGGS, Inc. / LGGS Florida, Inc. determined from the action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. Records of the results of any investigations will be maintained.

Preventive action procedure defines requirements for:

- Determining potential nonconformities and their causes.
- Evaluating the need for action to prevent occurrence of nonconformities;
- Planning and documenting action needed and implementation of such action, including, as appropriate, updating documentation;
- Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- Reviewing the effectiveness of the preventive action taken, as appropriate.

Appendix A

Master List of QMS Documents

LGGS Inc./ LGGS Florida, Inc Microbiology/ Laboratory Operational Procedures

SOP Number	Standard Operating Procedures (SOP)	Date	Revision
O-SOP-0001	General Quality Policy Statement	02/29/24	003
O-SOP-0005	SOP Preparation and Data Entry Control	01/25/19	002
O-SOP-0010	Change Control	01/25/19	002
O-SOP-0015	Document Control	09/30/21	013
O-SOP-0020	Document Nonconformity	01/08/19	004
O-SOP-0025	Corrective/ Preventive Actions	06/02/20	006
O-SOP-0030	Deviations from Protocol, Procedure or Specification	01/25/19	001
O-SOP-0035	Contamination Control	09/21/22	004
O-SOP-0040	Calibration of Laboratory Equipment	08/03/23	005
O-SOP-0045	Laboratory Equipment Maintenance	08/03/23	005
O-SOP-0050	Test Design Control	01/25/19	001
O-SOP-0055	Receipt of Test Samples & Test Request Review	01/25/19	005
O-SOP-0060	Report of Test Results	09/04/19	002
O-SOP-0065	Fax Transmittal of Test Results	01/25/19	001
O-SOP-0070	Signature Requirements	01/25/19	003
O-SOP-0075	Raw Data Preparation & Storage	03/8/24	003
O-SOP-0080	Storage of Laboratory Quality Records	03/8/24	004
O-SOP-0085	Purchasing Control	02/28/24	012
O-SOP-0090	Procedure for Creating Customer Related Documentation	01/25/19	001
O-SOP-0095	Personnel Training	02/29/24	009
O-SOP-0100	Customer Complaints/ Customer Feedback	02/28/24	004
O-SOP-0105	Quality Audits	09/30/21	006
O-SOP-0110	Risk Management	01/25/19	002
O-SOP-0115	Procedure for Management Review	02/29/24	002
O-SOP-0120	Procedure for Equipment/ Software Validation	01/25/19	000
O-SOP-0125	Procedure for Inter-laboratory Proficiency Review	01/25/19	001
O-SOP-0130	Client Confidentiality and Proprietary Rights	01/25/19	000

SOP Number	Standard Operating Procedures (SOP)	Date	Revision
M-SOP-0001	(GLP) Good Laboratory Practices Study Procedure	01/25/19	001
M-SOP-0005	Handling Procedure	01/25/19	003
M-SOP-0010	Storage Procedure	01/25/19	002
M-SOP-0015	Labeling & Storage of Laboratory Media and Reagents	01/25/19	002
M-SOP-0020	Stock Culture Maintenance	01/25/19	002
M-SOP-0025	Preparation of Phosphate Buffered Water (PBW)	11/03/23	004
M-SOP-0030	Preparation of Soybean Casein Digest Agar (SCDA)	01/25/19	001
M-SOP-0035	Preparation of Soybean Casein Digest Broth (SCDB) & Fluid Thioglycollate Medium (FTM)	09/02/21	002
M-SOP-0040	Procedure for Preparation and Growth Promotion Testing of General Purpose Nutrient Medium	11/03/23	003
M-SOP-0050	Loading, Operation and Maintenance of Autoclave	01/25/19	003
M-SOP-0055	Calibration and use of Ph Meters	01/25/19	001
M-SOP-0060	Removal of Biohazard Waste Materials	01/25/19	003
M-SOP-0061	Procedure of Microbial Limits Preparatory Testing	01/25/19	005
M-SOP-0062	Procedure of Microbial Limits Testing	01/25/19	004
M-SOP-0063	Procedure for Gowning and Working in the General Laboratory Area and Hoods	01/25/19	001
M-SOP-0064	Procedure for Cleaning of the General Laboratory Area and Hoods	01/25/19	001
M-SOP-0065	Bioburden Testing	01/25/19	003
M-SOP-0070	Standard Plate Count	01/25/19	002
M-SOP-0075	Modified Spore Strips and Inoculated Products	01/25/19	003
M-SOP-0080	Total Plate Count of Spore Strips Suspensions	01/25/19	003
M-SOP-0085	Gowning and Entry into Sterile Test Suite	01/25/19	002
M-SOP-0090	Sterility Test Facility Control	01/25/19	002
M-SOP-0095	Cleaning and Sanitation/Disinfection of Sterility Test Cleanroom	01/25/19	002
M-SOP-0100	Environmental Monitoring of Laboratory Cleanroom	01/25/19	004
M-SOP-0105	Use of Incubators for Sterility Testing	01/25/19	005
M-SOP-0110	Sterility Testing – Spore Strips and Inoculated Products	01/25/19	002
M-SOP-0115	Sterility Testing by Immersion Method	01/25/19	002
M-SOP-0120	Sterility Testing by the Membrane Filtration Method	01/25/19	002
M-SOP-0125	Sterility Testing by the In Situ Method	01/25/19	001
M-SOP-0130	Procedure for Method Suitability Test (B/F)	01/25/19	003

M-SOP-0135	Interpretation of Sterility Test Results	01/25/19	001
M-SOP-0140	Gram Stain Determination	01/25/19	001
M-SOP-0145	Spore Stain Determination	01/25/19	001
M-SOP-0150	Samples for Organism Identification	02/04/20	003
M-SOP-0155	Cleanroom Contamination Control Practices	01/25/19	001
M-SOP-0160	Cleanroom Facility Microbial Monitoring	01/25/19	003
M-SOP-0161	Procedure for Cleanroom Particulate Classification	01/25/19	004
M-SOP-0165	Depyrogenation Oven Validation	01/25/19	001
M-SOP-0170	Depyrogenation of Metal Utensils	01/25/19	001
M-SOP-0175	LAL Technician Qualification	01/25/19	001
M-SOP-0180	LAL Reagent Storage and Stability	01/25/19	001
M-SOP-0185	LAL Lysate Validation	01/25/19	001
M-SOP-0190	LAL Control Standard Endotoxin/Reference Standard Endotoxin Standardization	01/25/19	001
M-SOP-0195	LAL Product Validation	01/25/19	001
M-SOP-0200	Kinetic Turbidimetric Assay for the Quantitation Bacterial Endotoxin in Medical Devices	01/25/19	004
M-SOP-0201	Procedure for Accelerated Aging of Sterile Barrier Systems for Medical Devices	01/25/19	001
M-SOP-0205	Procedure for Dye Penetration Inspection Test method Rigid or Flexible Packages	01/25/19	003
M-SOP-0210	Procedure for Package Challenge Testing by the Dust Drum Method	01/25/19	001
M-SOP-0215	Gas Chromatography Standards Storage and Stability Procedure	10/16/20	003
M-SOP-0220	Ethylene Oxide Residue Extraction Procedure for Gas Chromatography	01/25/19	002
M-SOP-0225	Gas Chromatography for Quantification of Ethylene Oxide Residue in Medical Devices	01/25/19	004
M-SOP-0230	Procedure for Cytotoxicity – Agar Diffusion	01/25/19	001
M-SOP-0235	Procedure for Cytotoxicity – Elusion Test	01/25/19	001