Title:	Quality Manual – ISO 13485: 2003 and 21 CFR, Part 820

Table of Contents

Purpose

CGL is a medical device company all falls under the jurisdiction of FDA as stated in 21 CFR, Part 820. CGL is a contract packaging company, providing decontamination, and laboratory services such as biological, bioburden, sterility, and physical testing for the medical device industry. This Quality Manual outlines policies, procedures and responsibilities for implementing and managing quality related activities for CG LABORATORIES. This manual describes our Quality Management System (QMS) and reflects all elements of the ISO 13485:2003 International Standard and the cGMP-QSR (21 CFR, Part 820).

The Process Owner of Quality Systems will coordinate the review and re-issue of the manual at least once each calendar year to insure that current practices are reflected and continual improvement of the QMS is pursued. Changes occurring between reviews will be documented and filed. The appropriate personnel will be notified of the changes through documented procedures outlined in this manual.

Exclusion is claimed to the Installation (7.5.1.2.2) and Service Provision (7.5.1.2.3), Implantable Devices (7.5.3.2.2). and Design Provision (7.3) of this standard. CGL does not manufacture devices requiring Installation and Servicing nor does it manufacture implantable devices. Design is not performed at CGL because is provided specifications by Customers. These are not aspects of the CGL Business Strategy.

For information regarding this manual, write to CG LABORATORIES, Granbury, TX.

Scope

This Quality Manual and the information contained herein directly affect all company departments, the CGL QMS and ISO 13485: 2003 International Standard and the cGMP-QSR. This manual describes the manners in which CG LABORATORIES will consistently provide product that meets or exceeds customer and applicable regulatory requirements, and how all company personnel contribute to the constant drive towards the enhancement of customer satisfaction. This will be demonstrated by actions such as:

- effective application of the system
- effective application of continual improvement processes
- assurance to conformity to customer and applicable regulatory requirements

All copies of this document, which are externally distributed, will be uncontrolled.

CG Laboratories has two facilities;

- 1410 Southtown Granbury, TX 76048
- 2249 Bob White Granbury, TX 76049

CGL performs decontamination and medical device testing at 1410 Southtown and medical device manufacturing and packaging at 2449 Bob White.

References

All applicable level 2 reference documentation is contained at the conclusion of each Quality Manual section contained within the manual overview. Certain sections may also contain documentation references within the text body.

Quality Management System (QMS)
General Requirements
The CGL Quality Manual is a level one document in accordance with the ISO 13485:2003 International Standard and the cGMP-QSR. This manual defines an outline structure of the QMS and its processes and serves as a direct reference for implementation and maintenance of the QMS. The Quality Manual insures that all processes, work instructions and documentation satisfy the specified requirements of the customer and the ISO 13485:2003 International Standards and the cGMP-QSR. The Management Representative is responsible for establishing, implementing and maintaining the QMS that is defined and documented in this Quality Manual.

- Documentation Requirements
- General
- Quality Manual

The CGL QMS is defined, implemented and supported through a structure of procedural documentation that is organized into various levels and categories. The levels are defined as follows;

Level #

LEVEL #		DOCUMENTS
1	The CG LABORATORIES Quality Manual,	82005
2	Procedures supporting the ISO 13485:2003 International Standards and the cGMP-QSR (21 CFR, Part 820 for Medical Devices)	820XX & 820XXX
3	Work instructions, test methods, process details, forms and engineering drawings	820XX-X & 820XXX-X

Note: Records are an output of achieving results from tasks (can also be called documentation)

The categories are characterized by a document identification system that utilizes a unique number that relates to a primary focus area of the cGMP-QSR.

A complete description of the specification control procedures utilized can be found in Document and Data Control.

All procedures referenced are consistent with the CGL Quality Policy CGL Management Representative is committed to implementing and supporting this QMS and associated procedures effectively.

Certain military specifications may also be referenced in this manual if applicable.

Control of Documents- CGL Procedure 82040
All documentation and data are controlled under the direction of the Process Owner of Document and Data Control and Records. Controlled documentation and data changes are the responsibility of key departmental personnel. The approval process can include both electronic or hard copy review and approval of the proposed change by affected personnel. The Management Representative has authorized certain CGL personnel to check and approve controlled documentation. It is the responsibility of the key departmental personnel to insure

that the revised documents replace obsolete documents and are readily available for general access.

The QMS documentation will continually reflect the size and complexity of the CGL organization.

Control of Records- CGL Procedure 820180
CGL has established a procedure that details the control of quality records including their identification, collection, indexing, access, filing, storage, maintenance and disposition. The purpose of these records is to demonstrate conformance to the specified requirements of our QMS and therefore must be legible, retrievable and preserved. Retention times for each record have been established and recorded per the applicable procedure. As a minimum, all quality records are retained for a period of ten (10) years. Supplier assessment records are also retained and are available for customer review. Additional records which are retained as required include management reviews, internal audits, corrective actions, supplier assessments, calibration, training, customer contracts, and verification, product inspection records (includes records of nonconforming product), product identification and qualified process equipment and personnel. All non-records such as procedures, forms, passed revisions or obsoleted documents, etc. will be retained for the life of the company.

As 21 CFR, Part 820 Subpart M mandates that the following records be maintained:
DHF Design History File
DMR Device Master Record
DHR Device History Record
QSR Quality System Record
Complaint Files (see section 7.2.3, this manual)

Management Responsibility
Management Commitment
The CGL Management Representative is responsible for:

- Providing resources to implement and maintain a QMS that meets or exceeds the requirements of the ISO 13485: 2003 International Standard(s)
- Communicating the importance of meeting customer as well as statutory and regulatory requirements
- Ensuring the pursuit of continual improvement
- Ensuring the pursuit of established CGL Quality Policy.
- Ensuring the pursuit of established CGL Quality Objectives
- Attending management reviews as outlined in this manual
- The responsibility for insuring the implementation and maintenance of the QMS and that it meets or exceeds the requirements of the ISO 13485:2003 Standard rests with the CGL Management Representative.

Customer Focus CGL Procedure 82020-11
The CGL Management Representative meets or exceeds Customer Satisfaction by:

- Review and approval of customer contracts.
- Establishment of and adherence to customer service policies.

- Resolution of differences between quotation and contract.
- Assurance that CGL can meet the customer contract requirements.

Quality Policy CGL Procedure 82020-1

The C.G. Laboratories, Inc. objective is to offer ***Service and Guidance*** that shall meet customer requirements while striving to exceed customer expectations.
To help achieve our ongoing commitment of customer fulfillment and confidence, the Management and staff of C.G. Laboratories, Inc. are committed to complying with the requirements of ISO 13485:2003. The culture within our company is built around our ***Never Stop*** dynamic which encompasses:

- Guidance through every process
- Beneficial Supplier Relationships
- Impeccable Product Quality
- Competitive Pricing
- Reasonable Lead-time
- On-time Delivery
- Cycle Time Reduction
- Cost Reduction
- Customer Satisfaction

Through our Quality Management System, we monitor our own performance, set and monitor objectives, measure the satisfaction of our clients, and strive to maintain a clear company-wide focus on excellence.
C.G. Laboratories, Inc……. where ***Service and Guidance Never Stops.***

The Quality Policy has been established with the pursuit for continual improvement of the QMS as the focal point. This policy provided and continually provides the structure for the establishment and review of the CG LABORATORIES' Quality Objectives.

Business and Quality Objectives

❖ Quality Objectives

- **Preventive maintenance**
  - Late preventive Maintenance numbers are not trending upwards three quarters in a row
- **Calibration**
  - Late calibration numbers are not trending three upwards quarters in a row
- **Laboratory Department**
  - Laboratory Testing at least 95% for on-time reporting
  - N/Cs, CAPAs, & complaints in OPEN status are not trending upwards 3 QTRs in a row
  - N/Cs, CAPAs, & complaints issued are not trending upwards 3 QTRs in a row
  - Complaints with a Severity of 9 or greater will be trended
- **Packaging Department**
  - At least 90% on-time delivery
  - N/Cs, CAPAs, & complaints in OPEN status are not trending upwards 3 QTRs in a row
  - N/Cs, CAPAs, & complaints issued are not trending upwards 3 QTRs in a row

- Complaints with a Severity of 9 or greater will be trended

- **Decontamination Department**
  - N/Cs, CAPAs, & complaints in OPEN status are not trending upwards 3 QTRs in a row
  - N/Cs, CAPAs, & complaints issued are not trending upwards 3 QTRs in a row
  - Complaints with a Severity of 9 or greater will be trended
  - Decon- I/Misc 1
    - At least 90% with 1-3 day TAT
    - Less than 9% with 4-5 day TAT
    - Less than 1% with 5+ day TAT
  - Decon-II/ Misc 2
    - Same unless specified below
    - Product discards >95% 1-5 TAT, <5% 5+ TAT
    - Bier Vessel catheter decontamination >95% 1-5 TAT, <5% 5+ TAT
    - Medical Device trays >95% 1-5 TAT, <5% 5+ TAT

Handling audits anytime and constant cleanliness and organization are hallmarks for meeting the needs of our customers and creating an enjoyable workplace. If quality system items are an ongoing process instead of doing these quality items all at one time, then the workplace will be less stressful and quality will increase. This creates an atmosphere that is proactive and quality-driven.

QMS planning activities at least include identifying activities and resources needed to establish and improve the quality system itself. In fact, this requirement is met through completion of other activities required by the standard:
CG Laboratories plans to achieve the quality objectives and ensure continual improvement through the management review process. Outputs of quality planning can at least include:

- the quality system itself (i.e. the quality manual and associated procedures)
- resources for establishing, maintaining and improving the quality system

QMS planning at CG Laboratories applies to achieving quality objectives, but also to organizational change. Changes in the CG Laboratory's organization are planned in order to minimize the risk of negative effects on quality of product and/or service. This is accomplished through a strategic planning process. Changes and their impact on the CG Laboratory organization and the quality system is an agenda item for every management review meeting and certain QRB meetings. The results of management reviews are in the form of specific actions, ensuring that improvements are made in products/services and processes/systems, and that resource needs are identified. Management review outputs at CG Laboratories will set the direction for the future (i.e. new/revised policy can be issued, improvement objectives can be established, and/or specific improvement initiatives can be approved).

Quality Management System Planning CGL Procedure 82020-9
This Quality Manual and all supporting procedures will be referred to as the Quality Plan. The Management Representative will define planning and implementation. All Quality Manual elements and referenced level II procedural documentation are means for insuring that products and processes are in conformance to ISO 13485:2003 International Standards, the cGMP-QSR and customer specified requirements.

The preparation of the plan shall be the Management Representative and those process owners affected by these standards and requirements. This plan will be maintained in conjunction with the management review meetings.

The Quality Manual is an overview of the CGL Quality System and describes our conformance to these standards and requirements. It is the responsibility of the CGL Management Representative to maintain this manual as necessary.

The QMS is a formally documented process of planned activities established to provide evidence of compliance to, ISO 13485, cGMP-QSR, contractual specifications, codes, standards, military specifications, drawings, Quality Policy and Quality Objectives.

All of these activities are governed by procedures, written instructions supported by records of training and the successful compliance of products and processes.

Typically, QMS output planning would be in the form of the following:

- the quality manual
- operating procedures
- work instructions

- flow charts
- process routings
- quality plans

Planning for resources can involve:

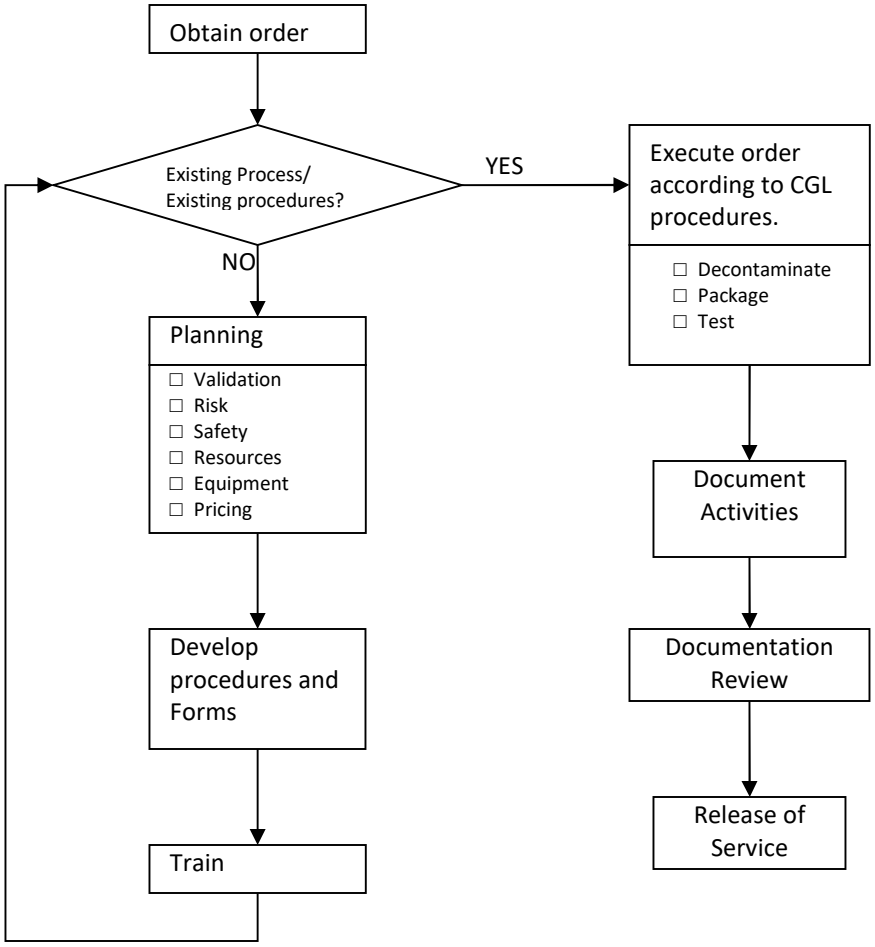
- personnel performing the verification activities
- personnel managing and performing the work
- sufficient time to do the work and verification
- identification of training needs
- obtaining appropriate equipment
- when applicable, development of documented procedures
- means of recording and accessing records

Considerations in the quality planning process may include the following:

- needs and expectations of the customers
- performance of the products
- performance operational processes
- learning from previous experiences
- risk identification and management (as well as analysis)

The Management Representative will control the planning, changes and implementation, of procedures along with the documentation that will insure compliance to the Quality Objectives. When changes are made to the QMS, care will be taken to insure integrity of the system.
The identification of controls and equipment needed to insure conformance to customer requirements is the responsibility of the organizations or departments assigned to the immediate task in conjunction with the appropriate Quality Systems' Process Owners.

Planning Flow



Responsibility, Authority and Communication

Responsibility and Authority

The QMS Management Representative is responsible for insuring that the QMS is implemented and maintained and that it meets or exceeds the requirements of the ISO 13485:2003International Standards and 21 CFR, Part 820 and achieves CGL Quality Policy and Quality Objectives.

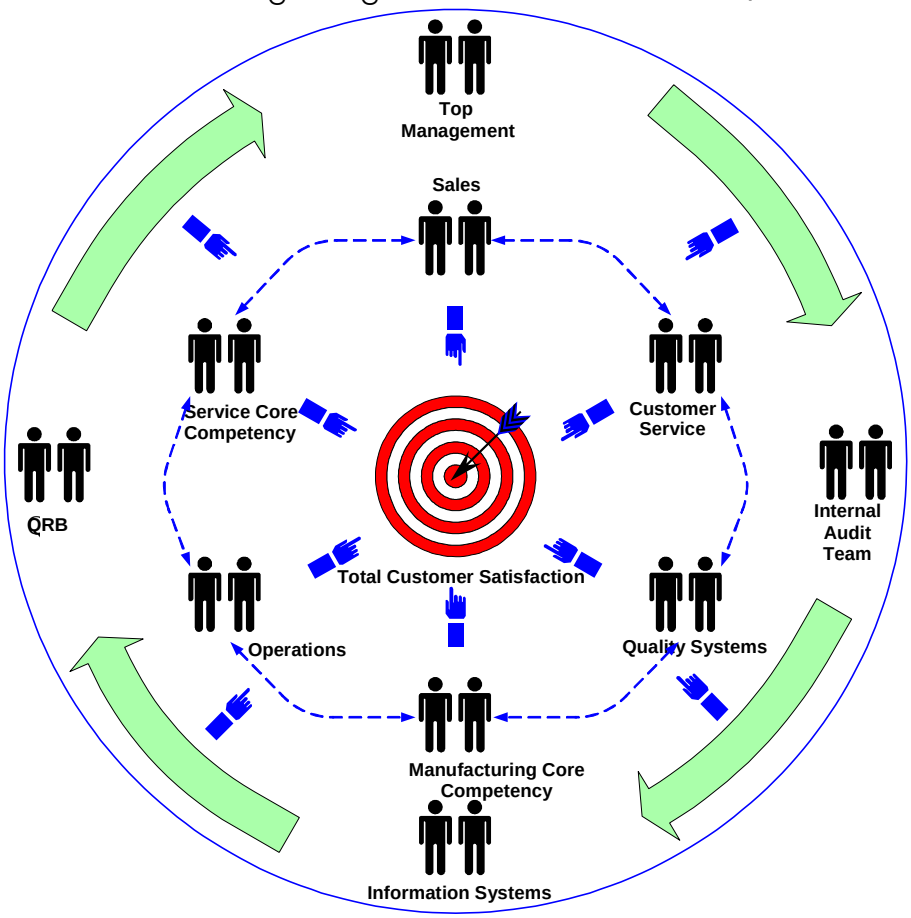
Management Representative
The GM of CG LABORATORIES is the Management Representative. The Management Representative will inform top Management of:

- QMS performance
- state of the QMS
- the need for improvement (as needed)

Through ongoing review of Quality Objectives, Customer Satisfaction monitoring and analysis, the Management Representative will promote customer requirements awareness throughout the organization.

Internal Communication CGL Procedure 82005-2
The CGL General Manager and Management Representative, are responsible for providing resources to communicate, implement and maintain the QMS that meets or exceeds the requirements of the ISO 13485:2003International Standards and the cGMP-QSR, and achieves our Quality Policy and Quality Objectives.

Communication regarding the effectiveness of the QMS is enacted and documented.



Management Review CGL Procedure 82020-5

General

Quality System audits are performed regularly by either internal resources or external sources to provide management with feedback and to insure its continuing suitability, adequacy and effectiveness of the Quality System. Internal audits are used to evaluate the implementation and the effectiveness of the Quality System and compliance of the Quality System against criteria based on ISO and cGMP-QSR. The Management Representative will review the Quality System for effectiveness at a minimum of two times every twelve- (12) months. In addition, management will review performance relative to quality and other business metrics at the Management review meetings.

Review Input

During specified CGL QMS management reviews, the Management Representative will present at least the following information on:

- audit results
- customer feedback
- process performance and product conformity
- status of preventive and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the QMS and recommendations for improvement

Other considerations for information may be, but not limited to, the following:

- market place evaluation including the performance of competitors
- results of benchmarking activities
- performance of suppliers
- status of achieving the Quality Objectives
- changes in original assumptions, arising from new technologies, outputs of R & D, quality concepts, financial, social, environmental conditions and legislative or regulatory changes

The review process may also revolve around the consideration of the following when applicable:

- checking the relevance and the achievement of the existing Quality Policy and Quality Objectives
- updating policies and objectives as necessary
- Improvement plans for the overall effectiveness, adequacy and suitability of the QMS.
- measures to insure satisfaction of customers
- improvement to production processes, including reduction of scrap

Review Output

The Management Representative will take actions, relevant to the applicable review input criteria, related to improvement of the QMS and its processes, improvement of product related to customer requirements, and resource needs. These actions, at a minimum, will meet the requirements of the ISO 13485:2003International Standards and 21 CFR, Part 820.

Records of management reviews will be maintained and may be in the form of, but not limited to, one or more of the following:

- minutes potentially leading to CAPA initiatives
- agenda
- attendance list

Information contained in the records may include, but not limited to, one or more of the following:

- who performed the review
- when the review occurred
- what was reviewed
- results of the review
- action items
- assignment of action items into the corrective and preventative action process (CAPA)
- status of previously assigned items
- conclusions

Resource Management
Provision of Resources
The Management Representative is responsible for identifying and making available the necessary resources for performing Quality System activities that will meet or exceed the requirements for products and service that will enhance customer satisfaction. Appropriate training will be given to company personnel in their specific work functions and associated Quality System activities.

Human Resources
General
When personnel are given assigned responsibilities that may have an effect on product quality, the assigned responsibilities will be defined and be based on appropriate education, training, skills and experience.

Note: Where the expression "or equivalent" is used, as it relates to competence requirements, it may be defined as one of the following:

- quantitative – an x number of years experience in lieu of formal education
- a determination made by the interviewer, Management Representative, or top management as a result of the interview process

Competence, Awareness and Training CGL Procedure 82025
The training of CGL personnel is focused on achieving the required skills necessary to supply products and services that meet or exceed customer expectations.

The identification and approval of the required training is the responsibility of the Training Process Owner, Supervisors, and potentially the Management Representative.

The assigned responsibilities will be determined and documented and may be in the form of, but not limited to, the following:

- job descriptions by function and responsibilities
- second-level procedures
- work instructions
- specifications

A variety of external and internal sources including procedural documentation, work instructions, courses, seminars, conferences and individual study programs are utilized. Training for subcontractors or temporary employees is always administered where appropriate.

The Document and Data Control Process Owner retains all training records of education, experience, skills, training and qualifications including certifications, registrations and degrees granted. Records can be in the form of:

- CGL training record
- signed application
- resume/CV
- copies of certificates
- diploma
- training attendance sheets

Personnel effectiveness training can be measured by, but not limited to, one or more of the following:

- pre and post training testing
- internal auditing
- Monitoring of process performance in terms of defectives and responsibility for same.

Infrastructure

All buildings, workspaces, utilities, process equipment and associated supporting services which directly affect quality, have been identified and planned to insure that conformity of product requirements is achieved and maintained.

Work Environment

CG LABORATORIES employs a work environment that is suitable for all activities performed that may affect product quality and ultimately customer satisfaction. Taken into consideration are environmental conditions such as:

- lighting
- ergonomics
- work area cleanliness
- equipment orientation
- health, cleanliness and clothing of personnel
- spatial separation of product
- documented requirements for environmental conditions in assembly and component areas
- temporary employees follow the same rules as full and part-time employees and are trained accordingly

For calibration, consideration is given to environmental conditions such as:

- ambient temperature
- humidity
- vibration
- equipment proximity

Product Realization

Planning for Product Realization

This Quality Manual and all supporting procedures will be referred to as the Quality Plan. The Management Representative will define planning and implementation

CGL documents all procedures and records for inspection and testing to verify that the specified requirements have been met and to confirm achievement of process and product conformity. Acceptance criteria for all activities as they relate to the verification, validation, monitoring, inspection and testing of product, along with the related project(s) and contract(s), have been determined with the quality objectives in mind.

As part of product realization, when a new product is introduced at CGL, or an existing product is considered for modification, consideration will be given to the need for new processes and resources or the modification of existing processes and resources to fit the needs of the specific product. More preventive requirements considered are, but not limited to:

- criteria for workmanship
- environmental control
- personnel requirements
- contamination control
- buildings
- equipment
- automated processes

Risk Management:

ISO 13485 requires that organization establish documented requirements for risk management in the product realization process. In the case of C.G. Laboratories, Inc. this has a direct impact on process-related assessments. Directly, product-related risk management is the customer's responsibility unless contractually established for each unique situation. Risk management includes risk assessment, risk analysis and risk reduction. Risk Assessment is identifying risks. Risk Analysis is looking at the probability and severity of all hazardous situations. Risk reduction is reduction, mitigation, elimination of risk as much as possible.

Risk management applies to quality management system processes in the case of C.G. Laboratories Inc. and it also applies to the design of the device, manufacturing and supporting services as delineated by C.G. Laboratories, Inc. customers in their formal requirements' documentation. Risk management is such an important process that ISO 13485 requires risk management is done in accordance with ISO 14971. The international standard for medical device risk management is ISO 14971:2007 and EN ISO 14971:2012 (for customers requiring same for CE Marking in Europe).

Risk Management provisions will be employed throughout these processes.

Customer-Related Processes

Determination of Requirements Related to the Product/ Service

It is the joint responsibility of every employee to insure that, while interfacing with the customer, the product/service requirements are identified and documented, from conception to customer receipt to the intended use of the product. Additionally, this joint responsibility encompasses any statutory and regulatory requirements related to the product.

Review of Requirements relating to the Product/ Service

All customer requirements reviews take place prior to order acceptance. An amendment to a contract is initiated using the same procedures followed when establishing the initial contract.

Records of new and current contracts including amendments to those contracts are retained and the full responsibility by and of the Process Owner for Records.

The responsibility of reviewing customer requirements can be a combined or the sole effort of the Management Representative.

Customer Communication

The first point of customer contact as it relates to product information, inquiries, contracts or order handling, including amendments, customer feedback and customer complaints will be the sales personnel or customer service for that department. Determination of inquiry assignment will be as per CGL documented procedures.

Complaint files CGL Procedure 820100

The CGL organization has made provisions for the following requirements:
Complaint files and procedures are established and maintained for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures ensure that:

- all complaints are processed in a uniform and timely manner;
- oral complaints are documented upon receipt; and
- Complaints are evaluated by QRB to determine whether the complaint represents an event, which is required to be reported to FDA, Medical Device Reporting.
- The QRB shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation takes place, the CGL shall maintain a record that includes the reason no investigation occurred and the name of the individual responsible for the decision not to investigate.
- Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.
- Any complaint that represents an event which must be reported to FDA under part 803 or 804, shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and will be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by Sec. 820.198(e) of cGMP Title 21 CFR part 820, records of investigation under this paragraph will include a determination of:

- whether the device failed to meet specifications
- whether the device was being used for treatment or diagnosis; and
- the relationship, if any, of the device to the reported incident or adverse event

When an investigation takes place under this section, the formally designated unit for handling complaints will maintain a record of the investigation. The record of investigation will include, but not limited to:

- the name of the device;
- the date the complaint was received;
- any device identification(s) and control number(s) used;
- the name, address, and phone number of the complainant;
- the nature and details of the complaint;
- the dates and results of the investigation;
- any corrective action taken; and
- any reply to the complainant
- If, in the event a the formally designated complaint unit is located at a site separate from the CGL manufacturing establishment, the investigated complaint(s) and the record(s) of investigation will be reasonably accessible to the manufacturing establishment.
- If, in the event a the formally designated complaint unit is located outside of the United States, required records will be reasonably accessible in the United States at one of the following locations:
  - in the United States where the manufacturer's records are regularly kept; or
  - the location of the initial distributor

Purchasing

Purchasing Process CGL Procedure 82050

Purchasing activities include selection, evaluation and assessment of suppliers, contractors, consultants, etc., i.e. product and/or service procurement and verification that purchased product and/or service conforms to specified requirements. This applies to all inventory items, supplies and capital equipment for CGL.

CGL evaluates and selects subcontractors based on their ability to meet CGL Quality, Cost and Delivery requirements.

Continued use of a supplier, contractor and/or consultant will depend on product or service quality, delivery and cost.

Quality records for all suppliers supplying inventory materials are maintained.

CGL maintains supplier evaluation categories. Suppliers' categories are updated by QRB, when product or equipment is supplied to CGL.

Purchasing Information

CGL purchase orders and/or included documentation contain a clear definition and/or description of all requirements. This includes:

- price and delivery
- part number or model number

- material description
- specifications and drawings (revisions, thereof)
- inspection instructions or specific requirements
  any other technical or contractual requirements that may apply

Purchasing documentation will include, where possible, an agreement that suppliers, contractors, and consultants agree to notify and obtain explicit written approval from CG LABORATORIES of any changes in the product or service so that it may be determined whether the changes affect the quality of a finished device and / or service performed.

The Purchasing Process Owner is responsible for reviewing and approving purchasing documents for accuracy of specified requirements prior to release.

Verification of Purchased Product
Where specified in the contract, CGL has the authority to verify at the supplier's facility, that purchased product conforms to specified requirements.

Incoming product will be inspected by receiving inspection. Verification of conformance to specified requirements is in accordance with CGL documented procedures. Retention of verification records will follow the section for Records of this document.

Suppliers, subcontractors and consultants will assure quality of product and/or service through a quality system that meets CGL quality requirements. Evidence of compliance to these requirements will be determined through the Certificate of Conformance and/or Certificate of Analysis, audits as necessary and continued monitoring of certain aspects of quality, cost, and schedule.

Production and Service Provision
Control of Production and Service Provision CGL Procedure 82070
All production processes, which directly affect quality, have been identified and planned to insure that these processes are carried out under controlled conditions.

Included with needed process controls are:

- documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production
- monitoring and control of process parameters and component and device characteristics during production
- workmanship criteria
- compliance with specified reference standards or codes
- the approval of processes and process equipment

As product is prepared for delivery, manual or electronic systems provide current shipping and routing information. With implemented and defined labeling and packaging operations, shipping labels and documents are generated electronically utilizing bar code technology, if

specified by the customer, to prevent errors. The customer determines the transportation type and site destination of product via the desired carrier.

CGL guarantees its devices according to the terms and conditions of its order acknowledgement and invoice documents.

The Quality System's Process Owner is responsible for resolving all quality related customer complaints.

Customer quality inquiries are reviewed by the GM. Appropriate action is taken by the department supervisor to evaluate and resolve the customer's problem. Quality Systems may be contacted for customer consultation. CGL Quality Systems may be called on for evaluation and support.

Quality Systems may generate return Material Authorization (RMA) numbers. Purchasing can initiate credit memos for valid return of goods, price corrections or other customer service related reasons. The General Manager is responsible for final approval of customer credits and generates the credit document.

Document and Data Control maintains records of all quality related customer problems as well as records of non-quality related customer problems in a controlled file. Accounting retains all credit memos on file.

Validation of Processes for Production and Service Provision

Qualified operators will enact the validation of any process where deficiencies may only be apparent after the product is in use. The validation process will include (as applicable), but not limited to:

- manufacturing orders, product drawings, process specifications, procedures and work instructions that have defined workmanship criteria that is subject to review and approval
- the master validation plans for process, product and software
- specific methods and procedures such as selection and control of equipment used in the manufacture of product, which is accomplished through calibration, maintenance and preventive maintenance programs to insure capability and product quality. Provisions for controlled environments are available when necessary
- qualification records for processes and key personnel, as necessary

When changes or process deviations occur, CGL Process Owner of Validation reviews and evaluates the process and performs revalidation where appropriate and documents these activities. The master validation plan(s) for process, product and / or software are the drivers for the validation efforts at CG LABORATORIES.

Exclusion

Due to the nature of CGL Products and their end use by the customer, exclusion is claimed to the Installation and Service Provision of this section. CGL products are not installed and/or serviceable, but rather replaceable.

Identification and Traceability CGL Procedure 82060

Product identification and traceability is facilitated manually or using validated software and maintained at all stages, from receiving to delivery into the marketplace. The means by which product is identified are manufacturing orders, move documentation, identification tags and/or labels. Product status is also identified with respect to monitoring and measurement requirements. Subassembly parts, assemblies or final products that have passed required tests or inspection, and in the process of being moved to the next production phase or final disposition are identified to indicate inspection status. One or more of the following methods may be used:

- tags
- stamps
- labels
- inspection and test records
- move documentation
- process worksheets
- corrective action/rejection reports and/or status

CGL has established and maintains procedures to insure that Device History Records (DHR) for each batch, lot, or unit are maintained and verified to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this section.

Manually derived and administered documentation, as it relates to inspection and test results of product, are maintained for the release of conforming product. Inspection records are maintained by Document and Data Control to show that the product has passed all defined acceptance criteria.

All devices will be traceable to the supplier lot. All products will be identified with an inspection and item number.

To show that product has been inspected and/or tested, Document and Data Control maintains the records that provide this evidence. These records indicate whether product conforms to established quality standards. Where the product fails to pass any inspection and/or test, the procedures for nonconforming product shall apply. Records identify the inspection authority responsible for the release of the product.

Customer Property

When required by the contract, the customer may furnish material to CGL for specific production purposes.

Such materials are subjected to the same control measures as subcontractor and in-house produced product. This includes receiving inspection for verification of conformance, material identification and traceability, controlled and protected stock or storage, manufacturing control and final or completed product inspection.

Records detailing the control of customer-supplied product per the above-described areas are available for customer review.

With the identification of any nonconformance during the inspection and handling of these materials, immediate notification of the customer takes place for purposes of product lot disposition. CGL has and maintains a record of such occurrences.

Preservation of Product

CGL has established procedures for handling, storage, packaging, preservation and delivery of product.

Products that require special handling have detailed requirements as part of the customer specification, manufacturing order or engineering drawing. In the absence of a specified requirement, the utilization of standard operating procedures will become the default to maintain product integrity.

The use of controlled and secure stock locations is to prevent product damage or deterioration and to maintain lot control. Product issued to the production floor or for customer delivery is stored separately and handled by warehousing and manufacturing personnel. CGL products are handled on a first in, first out basis. In-process or final product that require non-standard storage to prolong or protect product shelf life and general integrity, has such requirements specified per the appropriate product documentation. Where appropriate, an assessment of product shelf life will be done.

All standard in process and final product packaging is designed to protect the material from damage or deterioration and maintain lot control. Non-standard packaging or marking requirements as specified per customer specifications or contracts are controlled by appropriate procedures.

Appropriate and necessary methods and practices are utilized in the preservation and segregation of product

Control of Inspection, Measuring and Test Equipment CGL Procedure 82072

CGL has established documented procedures, with guidance from ISO 17025, for controlling the calibration of all test and measurement instrumentation. This includes gages, instruments, sensors, test equipment and related software used in the development, production, installation and servicing of product. The objective of our calibration program is to provide a system that assures conformance to specified requirements, calibrated standards and confidence in measurement data.

Quality Systems determines the pertinent measurements and the degree of accuracy required by appropriate inspection and measuring test equipment.
Standards and equipment used for calibration are traceable to N.I.S.T. Measuring and test equipment is tagged as follows, indicating calibration status:

- Calibration date
- Next calibration date
- Serial and asset numbers (original manufacturer S/N if applicable and an CGL asset #)

- Calibrated by

Calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory are described in Calibration System Requirements delineated for each unique and / or particular measuring device.
CGL maintains calibration records of all inspection, measuring and test equipment. These include records of equipment calibrated on or off site.
When out of calibration conditions are detected, inspection, measuring and test equipment is re-calibrated, repaired or replaced and affected product re-tested per CGL procedures.
Environmental conditions suitable for calibration, inspection and measurement are defined in CGL procedures.
To insure that accuracy and fitness for use is maintained, inspection test and measurement equipment is located in secured areas and handled by authorized personnel.
Inspection measuring and test facilities, including both test hardware and test software are protected from adjustments that would invalidate the calibration setting per the CGL procedure.

Measurement, Analysis and Improvement
General
In an effort to meet the specified requirements of the International Standards and 21 CFR, Part 820, CGL has planned, implemented and performs the measurement and analysis activities to assure product conformity and efforts toward continual improvement of the QMS.

The use of statistical methods, among other techniques, is beneficial to establish, control and confirm desired process and product characteristics. Statistical tools such as histograms, process control charts, trend analysis and / or praeto charts, etc. may be utilized as appropriate in the following areas:

- Quality Systems
- Manufacturing
- Internal audit results assessment
- Product performance assessment
- Supplier Performance
- Complaints and Adverse Events

Procedures describing applicable statistical techniques are contained in the production, inspection and design review procedures.

Monitoring and Measuring
Customer Feedback and Satisfaction
CGL will assume a proactive role in the determining the level of customer satisfaction and/or dissatisfaction. This will be accomplished by measuring these levels and monitoring whether the customers needs are being met. The acquisition of data will be centered on areas that are important to our customer base and may come from, but not limited to, methods such as:
focus groups

- customer visits – regional sales managers, key account managers, company representatives, quality system personnel
- customer satisfaction surveys
- customer complaints
- direct communication with customers – account managers, quality system personnel
- customer organization reports
- media reports
- sector studies

Internal Audit CGL Procedure 82022
The QMS is monitored for, ISO 13485:2003 and 21 CFR, Part 820 compliance by an internal audit process and cross-functional audit team (seeks guidance from ISO 19011). This process includes audits designed to evaluate all systems, policies, procedures, processes and products within the organization that affect product quality or service.

The audit process covers quality system audits in compliance with IS0 and cGMP-QSR Quality System requirements. This includes audits of procedures and work instructions as well.

Internal audits are scheduled and conducted based on previous audit results and the status and importance of the activity. Personnel independent of those audits having direct responsibility for the audited activity conduct them.

Audit results including required improvements become a matter of record and then forwarded to the management personnel having responsibility for the area audited.

Specific management personnel responsible for the area under audit will take the necessary corrective action without undue delay to eliminate the nonconformities and report the verification results.
Follow-up audit activities are performed to verify the results and effectiveness of the corrective action taken.

The internal audit process results are reviewed at least four times every twelve (12) months during management review. This review is an integral part of the input and output to management review activities and general QMS improvements.

Monitoring and Measuring of Processes
In determining if a CGL process has the ability to satisfy its intended use / purpose, which includes active implantable devices and / or one-use devices, consideration may be given to all or part of the following attributes:

- repeatability
- timeliness in a process or personnel performing a task
- the competency level of personnel performing tasks
- process constraints related to equipment and / or material availability
- revalidation opportunities

Where needed, essential process controls and validation are:

- documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;
- monitoring and control of process parameters and component and device characteristics during production;
- compliance with specified reference standards or codes;
- the approval of processes and process equipment; and
- criteria for workmanship that shall be expressed in documented standards or by means of identified and approved representative samples.

Depending on product type, the use of suitable methods for monitoring, and if applicable, the measuring of the QMS processes may include, but not limited to, one or more of the following:

- measuring reaction time
- cycle time
- measurable aspects of dependability
- efficiency of the process
- waste reduction
- cost allocation and reduction

When planned results are not achieved when using the decided methods, correction will be made and corrective action will be taken.

Monitoring and Measuring of Product

Incoming Inspection – incoming product and raw material requires inspection, testing, or otherwise verified as conforming to specified requirements prior to release. Verification of conformance to specified requirements is in accordance with the CGL quality plan and documented procedures.

Suppliers, subcontractors and consultants will assure quality of product and/or service through a quality system that meets or exceeds CGL quality requirements. Evidence of compliance to these requirements will be determined through the Approved Supplier process (list).

There will be no use, processing or release of incoming product until its verification as conforming to established requirements by means of inspection is complete.

Sampling Plans – reference to ANSI Z1.4 or Z 1.9 will be made for sampling plans.

First Article Inspection – is the submission of product to inspection prior to the start of any manufacturing order to confirm process control and product conformance. The start of a manufacturing order will not be granted until approval of first piece inspection is granted.

In-Process Inspection - confirms in-process manufacturing control by periodic operator on-line inspection and submittal of product for final in-process inspection. Recording of these results is limited to final in-process inspection only.

Final Inspection – confirms final assembly control by testing in accordance with the CGL Quality Plan under the guidelines of the inspection process and DHR review/disposition. Finished product is not shipped pending review of documentation requirements as designated by 21 CFR, Part 820.80.

Note: Acceptance status is documented for all inspections.

Inspection records provide evidence that product verification as it relates to in-house, customer and regulatory requirements and that testing was completed. These records indicate whether product conforms to established quality standards and CGL specifications. Where the product fails to pass any conformity requirements and/or test, the procedures for nonconforming product shall apply. Records identify the inspection authority responsible for the release of the product.

When planned results are not achieved when using the decided methods, correction will be made and corrective action will be taken.

Other methods of measuring and/or monitoring not mentioned above may include, but not limited to, the following:

- product audits monitoring specified activities
- operator in-process inspection
- automated inspection and test
- monitoring in-process instrumentation that controls processes or testing samples taken at defined locations and intervals
- fixed inspection stations at intervals throughout the process

Control of Nonconforming Product 82090-2

This section covers nonconforming product from suppliers, in-process and final product with the following criteria and/or noteworthy points:

- that does not conform to specified requirements
- nonconforming issues address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, including a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance
- nonconformities are reviewed and achieve disposition and are documented
- responsibility for review and the authority for the disposition of nonconforming product is defined
- documentation includes the justification for use of nonconforming product and the signature of the individual(s) authorizing the use
- rework procedures exist and include retesting and reevaluation of the nonconforming product to insure that the product meets its current approved specifications; these activities are documented
- documentation within the DHR will apply to all medical devices

Procedures are implemented to insure that products that do not conform to specified requirements are prevented from unintended use. These procedures provide identification, documentation, evaluation, segregation and disposition of nonconforming product.

CGL Quality Systems' is responsible for the disposition of nonconforming product. Purchased in process and final inspection components, assemblies and / or devices are subject to test and inspection according to applicable procedures as documented in the applicable procedures. Department Supervisors will identify and segregate nonconforming product for disposition by the Process Owner for Quality Systems. If nonconforming product is found during production processing, a decision concerning product disposition is then made. Upon determination of status, a rejection/corrective action request is issued and one of the following occurs:

- units are re-worked to meet the specified requirements
- units are accepted by concession with the customer
- units are reviewed for concessions with the customer
- units are rejected by using the concession tool (with the customer)
- units are rejected or scrapped by CGL

Where required by the contract, the proposed use or repair of product that does not conform to the specified requirements will be reported to the customer. Records are kept describing the nonconformity which has been accepted, including any repairs for denoting the actual condition.

Re-inspection will occur for all repaired and/or re-worked product in accordance with applicable procedures and specifications.

Analysis of Data

In an effort to drive improvement efforts within CGL, the data that is accumulated through internal monitoring of processes and other sources, which may include but not limited to:

- surveys
- internal evaluations
- customer focus surveys
- customer complaints and feedback
- marketing department input
- third party audits

The data that is accumulated will be relevant to continual improvement as it relates to customer satisfaction and/or dissatisfaction, conformance or customer requirements, characteristics of processes, product and trends and suppliers.

Improvement and
Continual Improvement

It is the intention of CGL that continual improvement to the QMS shall occur regularly and frequently, but not necessarily without interruption. When opportunities for improvement are realized, they will be prioritized focusing on the ones that will produce the greatest return on investment. These activities will be delineated and facilitated via the Process Owner of Quality Systems.

To facilitate a well-rounded continual improvement effort, the focus will not be centered on the nonconformance identified with the system, but rather inclusive of, and not necessarily simultaneously, the following areas:

- quality policy
- quality objectives
- analysis of data
- management reviews
- corrective and preventive actions
- internal audit results
- employee suggestions

Corrective Action CGL Procedure 820100

CGL has established documented procedures for the implementation of corrective action. Quality Systems evaluates discrepant inspected product or process and determines lot disposition, effectiveness and corrective action, respectively. Procedures for corrective action include, but not limited to:

- the effective handling of customer complaints and reports of product nonconformities
- investigation and documentation of the cause of nonconformities relating to product, process and the quality system)
- determination of the corrective action needed to eliminate the cause of nonconformities,
- application of controls to insure that effective corrective action is taken

Management review sessions conducted in accordance with QMS will be used to evaluate the needs for corrective and preventive action through the analysis of various system measurement resources and may include, but not limited to:

- customer return records
- customer product complaints
- supplier corrective actions
- corrective action reports that deal with detected nonconformities relating to products, processes and the QMS
- purchasing (supplier) history
- customer quality/delivery reports
- process control deviations

Preventive Action

CGL has established documented procedures for the implementation of preventive action. Procedures for preventive action include, but not limited to:

- The use of information, such as processes and work instructions which affect product quality, concessions, audit results, quality records and customer complaints, to detect, analyze and eliminate potential causes of nonconformities.
- Determination of the steps needed to deal with any problems requiring preventive action,
- Initiation of preventive action and application of effective controls,

- Insurance that relevant information on action taken is submitted for management review
- Sources of information that may be analyzed in order to detect and eliminate potential causes of nonconformities include, but not limited to:
  - nonconformity records
  - inspection and test records
  - process monitoring results
  - audit observations
  - results of customer satisfaction surveys
  - customer complaints/records
  - regulatory authority or customer observations
  - observations and reports by personnel
  - sub-contractor problems

Statistical Techniques CGL Procedure 820250

CGL will establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics. Sampling plans shall be written and base on ANSI Z 1.4 logic and rationale. CGL will make sure that these sampling methods are adequate for their intended use and ensure that when changes occur the sampling plans are reviewed and revised accordingly. These activities shall be documented.