Document:	
QUALITY MANUAL	
Revision:	Date:
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Electronics

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Introduction

Gowanda Electronics has developed and implemented a Quality Management System (QMS) in order to document the company's best business practices, to better satisfy the requirements and expectations of its customers and improve the overall management of the company. The QMS of Gowanda Electronics meets the requirements of the international standards ISO 9000, ISO 13485, and AS 9100. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correspond to the QMS sections of the quality standards. This manual describes the QMS interdepartmental relationships and responsibilities of the personnel responsible for performing the system requirements. The manual also provides procedures or references for all activities used within the QMS to ensure compliance to the necessary requirements of the standards.

This manual is used both internally to guide the employees of Gowanda Electronics through the various requirements of the quality standards and externally to familiarize or customers with our QMS practices and controls.

Mission Statement

To provide our customers with market-leading product solutions to their specific design and application needs; and in doing so, establish ourselves as the market leader in quality, delivery, and customer-focused service.

Environmental Policy

We take our responsibility as a company towards protecting, nurturing, and improving our natural environment very seriously. To this end, we:

- Work aggressively to reduce our waste stream by all means possible, including finding recycling methods for all unused materials possible.
- Work aggressively to replace ozone depleting chemicals, other environmentally-harmful products, and potentially human harmful chemicals from our processes and operations.
- Diligently monitor our processes and operations to verify that we are in full compliance with the spirit, intent, and letter of all laws dealing with the protection of the environment.

RoHS Policy

In its ongoing commitment in supplying superior quality products and meeting the ever changing global environmental regulations, Gowanda Electronics offers RoHS compliant products that meet the requirements as defined in the EU Directive 2002/95/EC. Details of specific RoHS products solder finishes, marking, and packaging methods can be found at *www.gowanda.com*.

1. Scope

1.1. General

Gowanda Electronics is a World Class Manufacturer of Magnetic Components and has developed and implemented the Quality Management System (QMS) described in this manual to help our organization operate with increased effectiveness, consistency, and customer satisfaction. Our QMS utilizes the process approach and quality management principles contained in the international standards ISO 9000, ISO 9001, ISO 9004, ISO 13485, and AS 9100 to enhance our ability to continually improve as an organization. This document is color coded to aid in the distinction between quality standards. Items in blue text refer only to products under the AS 9100 standard, and items in green text apply only to products under the ISO 13485 standard. The remaining black text applies to all ISO 9001 basic requirements.

1.2. Application

Our QMS complies with all applicable requirements contained in ISO 9000, ISO 9001, ISO 9004, ISO 13485, and AS 9100, covers the design and provisions of all company products, and encompasses all operations at our facility located at One Magnetics Parkway, Gowanda NY, USA 14070. Gowanda Electronics also owns a sister company named Chiptek, which also complies with the standards listed above with the exception of ISO 13485. The following table identifies the latest revision of all quality standard requirements not applicable to our organization and provides a brief explanation justifying their exclusion from the scope of our QMS:

Requirements Exclusion Table

Location	Quality Standard	Clause or Sub-clause	Exclusion	Justification
All Facilities	ISO13485	7.5.1.2 thru 7.5.1.2.3	Control of production and service provision – Specific Requirements – All section requirements	Gowanda Electronics products do not require any sterilization, installation, or servicing activities.
All Facilities	ISO13485	7.5.1.3	Particular Requirements for sterile medical devices	Gowanda Electronics products does not produce any sterile medical devices
All Facilities	ISO13485	7.5.2.2	Particular Requirements for sterile medical devices	Gowanda Electronics products does not produce any sterile medical devices
All Facilities	ISO13485	7.5.3.2.2	Particular Requirements for active implantable medical devices.	Gowanda Electronics does not have any product requirements for implantable medical devices

2. Reference Documents

The following documents were used as reference during the preparation of the QMS (Latest revision applies):

- ISO 9000, Quality management systems – Fundamentals and vocabulary
- ISO 9001, Quality management systems – Requirements
- ISO 9004, Quality management systems – Guidelines for performance improvements
- ISO 13485 Quality management systems – Medical devices
- SAE AS 9100 – Quality Management Systems – Requirements
- CFR21 Part 820

3. Terms & Definitions

Our QMS uses the same internationally recognized terms, vocabulary, and definitions given in the quality standards:

- Customer owned property – Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product – Any type of service or material supplied to be utilized in the manufacture, modification, or repair of customer-owned property.
- Product – The end item, a result of meeting all contract terms and conditions. (E.g.: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
- Counterfeit Part – An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. Note: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labelling, grade, serial number, data code, documentation, or performance characteristics.
- Critical Items – Those items (e.g., functions, parts, software, and characteristic, process) having significant effect on the provision and use of the products and services; including safety, performance form, fit, function, or producibility , service life, etc.; that requires specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.
- Product Safety – The state in which a product is able to perform it's designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.
- Key Characteristics – An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility that requires specific actions for the purpose of controlling variation.
- Special Requirements – Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance product or process complexity, past experience, and product or process maturity. Examples of special requirements of special requirements include performance requirements imposed by the customer that are at the limit of the industries capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

- Acronyms: QMS – Quality Management System
  GEC – Gowanda Electronics Corporation

4. Quality Management System

4.1. General Requirements

Gowanda Electronics has established, documented, and implemented a QMS in accordance with the requirements of ISO 9000, ISO 13485, and AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

Context of the Organization

Understanding the Organization and its Context

To understand the Organization and its Context, Gowanda Electronics has determined relevant external and internal issues and items that may become relevant to the company's purpose and strategic direction, and may affect our ability to achieve the intended results of the QMS. These issues are reviewed during regularly scheduled staff meetings, top management meetings and management review meetings.

Understanding the Needs and Expectations of Interested Parties

In order to understand the effect or potential effect on Gowanda Electronics' ability to consistently provide products that meet our customers and applicable statutory and regulatory requirements, our company has determined the following:

The interested parties relevant to the QMS

The requirements of the interested parties relevant to the QMS.

The needs and expectations of these interested parties are reviewed during regularly scheduled staff meetings, top management meetings and management review meetings.

Gowanda Electronics is committed to continually monitoring, reviewing and analyzing information and relevant requirements of the interested parties to assure their requirements are effectively managed in the QMS.

5. Leadership

5.1.1. -Leadership and Commitment

Senior management is actively involved in implementing the QMS. It has provided the vision and strategic direction for the growth of the company and QMS, and established quality objectives and the quality policy. Any interaction or interdepartmental responsibilities and associated procedures can be seen in Appendix A.

To continue to provide leadership and show commitment to the improvement of the QMS, management will perform the following as required:

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct annual management reviews.
- Ensure the availability of resources.

Each year, senior management meets to discuss the objectives for each department. The quality objectives are recorded on Quality Form QF 5.4.1-1 and stored on Gowanda's internal computer server at \\Gowanda-01\quality\Departmental Goals & Objectives.

5.1.2. Customer Focus

Gowanda strives to identify current and future customer needs to meet customer requirements and exceed customer expectations. Senior management also holds weekly staff meetings to review any customer concerns and/or needs.

Senior management ensures that customer requirements are determined and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization.

5.2. Quality Policy

The quality policy adopted by Gowanda Electronics is "A commitment to continuous improvement in supplying superior quality products and services to our customers that will meet or exceed their requirements, both real and perceived, recognizing that every employee must share in the responsibility of producing a quality product."

5.3. Organizational Roles, Responsibilities, and Authorities

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

The quality system has been planned and implemented to meet our quality objectives and the requirements of the quality standards. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.4. Responsibility, Authority and Communication

Senior Management ensures that responsibilities and authorities are defined, documented, and communicated within the organization.

Senior management has established the interrelation of personnel in the organization. Job descriptions are reviewed and approved by top management for adequacy. An organization chart has been created to model the interrelations within the organization. The organization chart is located in Appendix C.

The Quality Manager has been appointed by senior management as the QMS management representative and has the following responsibility and authority to:

- Ensure that processes needed for the QMS are established and implemented.
- Report to top management on the performance of the QMS, and note needed improvements.
- Promote awareness of customer and regulatory requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

– Have the organizational freedom to resolve matters pertaining to quality issues.

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, internal audit results, and other routine business communication.

5.5. Management Review

Management reviews are performed in accordance with Quality Procedure QP 5.6.

6. Planning

6.1. Actions to Address Risks and Opportunities

Gowanda Electronics considers the Context of the Organization and the Needs of Interested Parties in determining how to address risks and opportunities as defined below.

Context of the Organization

Type	Internal or External	Issue
Customers	I/E	Sufficient resources are available to address relevant issues
Employees	I	Competent staff is available and turnover is manageable
Competition	E	Status on competition
Community	E	Impact in community
Supply Chain	E	Performance issues relating to products and services

Interested Parties

Type	Internal or External	Issue
Customers	E	Obtaining products and expecting safety, compliance to regulations/standards, quality assurance, customer service, & on time delivery
QA/QC	I/E	Quality Assurance & Quality Control
Auditors	I/E	Compliance to regulations/standards/policies & procedures

Employees	I	Meeting customer expectations – efficiency and effectiveness of processes
External Providers	E	Providing supporting products and services
Regulatory/Statutory Agencies	E	Dictate regulatory /statutory requirements related to the QMS
Community	E	Good neighbor – reputation in community
Competition	E	Direct and indirect competition to the organization

Risks Related to Key Processes

Risk	**Key Process**	**Mitigation**
Availability of Human Resources	Management	Maintaining/ developing competent employees
Relevant product and process technology	Engineering/Calibration	Maintain sufficient technological resources
Competition	Sales/Contracts	Monitor status of competition
Rejection or Delay Due to External Provider	Purchasing	Performance monitoring of top 5 suppliers
Delay or Rejection Due to Internal Constraints	Production	Monitoring Performance
Variation in process performance	Support Functions	Monitor quality objectives

7. Support

7.1. Provision of resources

To effectively maintain and continually improve the system, management determines and provides the necessary resources needed to:

- Implement and maintain the QMS and to maintain its effectiveness.
- Retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.
- Enhance customer satisfaction by meeting customer requirements.
- Meet regulatory and customer requirements.

7.2. Human resources

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills, and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

Training and evaluation are conducted according to the training procedure as outlined in Quality Procedure QP 6.2.2.

7.3. Infrastructure

To meet quality objectives and product requirements, Gowanda Electronics has provided an adequate infrastructure according to Quality Procedure QP 6.3.

7.4. Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

8. Operation

8.1. Planning of Product Realization

Quality planning is required before new products or processes are implemented. The quality planning takes place according to Quality Procedure QP 7.1.

Risk management is performed in accordance with Quality Procedure QP 7.1.2.

Configuration management is planned according to Quality Procedure QP 7.1.3.

Control of work transfers are handled according to Quality Procedure QP 7.1.4.

8.2. Customer-Related Processes

The determination and review of customer requirements is performed according to Quality Procedure QP 7.2.

The arrangements for customer communication are determined and implemented according to Quality Procedure QP 7.2.

8.3. Design and Development

Quality Procedure QP 7.3 specifies the requirements for design and development planning, inputs, outputs, review, verification, validation, testing, and documentation.

8.4. Purchasing

Quality Procedure QP 7.4 is followed to ensure that purchased product conforms to the specified purchase requirements.

8.5. Documented Information

The QMS documentation includes:

- A documented quality policy.
- This quality manual.
- Documented procedures.
- Documents identified as needed for the effective planning, operation, and control of our processes.
- Quality records.
- Records required by regulatory authorities.
- Any other documentation specified by national or regional regulations.

The document structure is located in Appendix B.

The control of documents is maintained in accordance with Quality Procedure QP 7.5.3

The control of records is maintained in accordance with Quality Procedure QP 7.5.4 4.2.4.

Control of production and service provision is performed in accordance with Quality Procedure QP 7.5.1.

Validation of processes for production and service provision are undertaken in accordance with Quality Procedure QP 7.5.2.

Gowanda maintains identification and traceability in accordance with Quality Procedure QP 7.5.3.

Quality Procedure QP 7.5.4 identifies the method of handling customer property.

Product is preserved according to Quality Procedure QP 7.5.5.

Stock rotation is monitored through the use of cycle counts, outlined in Quality Procedure QP 7.4.1.

8.6. Control of Monitoring and Measuring Devices

The control of monitoring and measurement equipment is handled according to Quality Procedure QP 7.6.

9. Measurement, Analysis, and Improvement

9.1. General

The statistical techniques Gowanda utilizes to monitor and measure are described in Quality Procedure QP 8.1.

9.2. Monitoring and Measurement

Customer satisfaction information is collected and analyzed according to Quality Procedure QP 8.2.1.

The QMS is audited to determine conformance according to Quality Procedure QP 8.2.2.

The monitoring and measurement of products and processes are performed according to Quality Procedure QP 8.2.3.

9.3. Control of Nonconforming Product

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in Quality Procedure QP 8.3.

9.4. Analysis of Data

Gowanda determines, collects, and analyzes data in accordance with Quality Procedure QP 8.4.

9.5. Improvement

Gowanda is continually improving the effectiveness of the QMS by following Quality Procedure QP 8.5.

10. Established Reliability and QPL Products

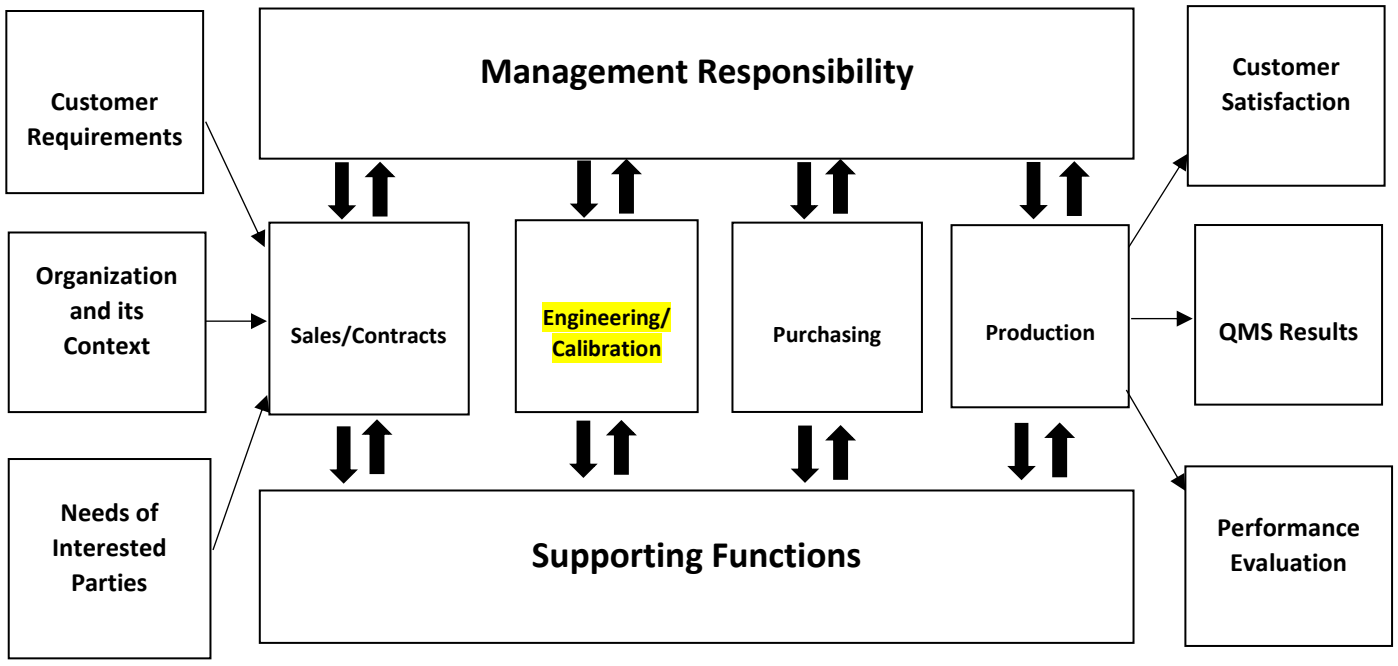
Gowanda Electronics produces and supports Qualified Product Listing (QPL) product by the guidelines outlined in Quality Procedure QP 9.1.

Appendix A – Gowanda Components Group Process Map

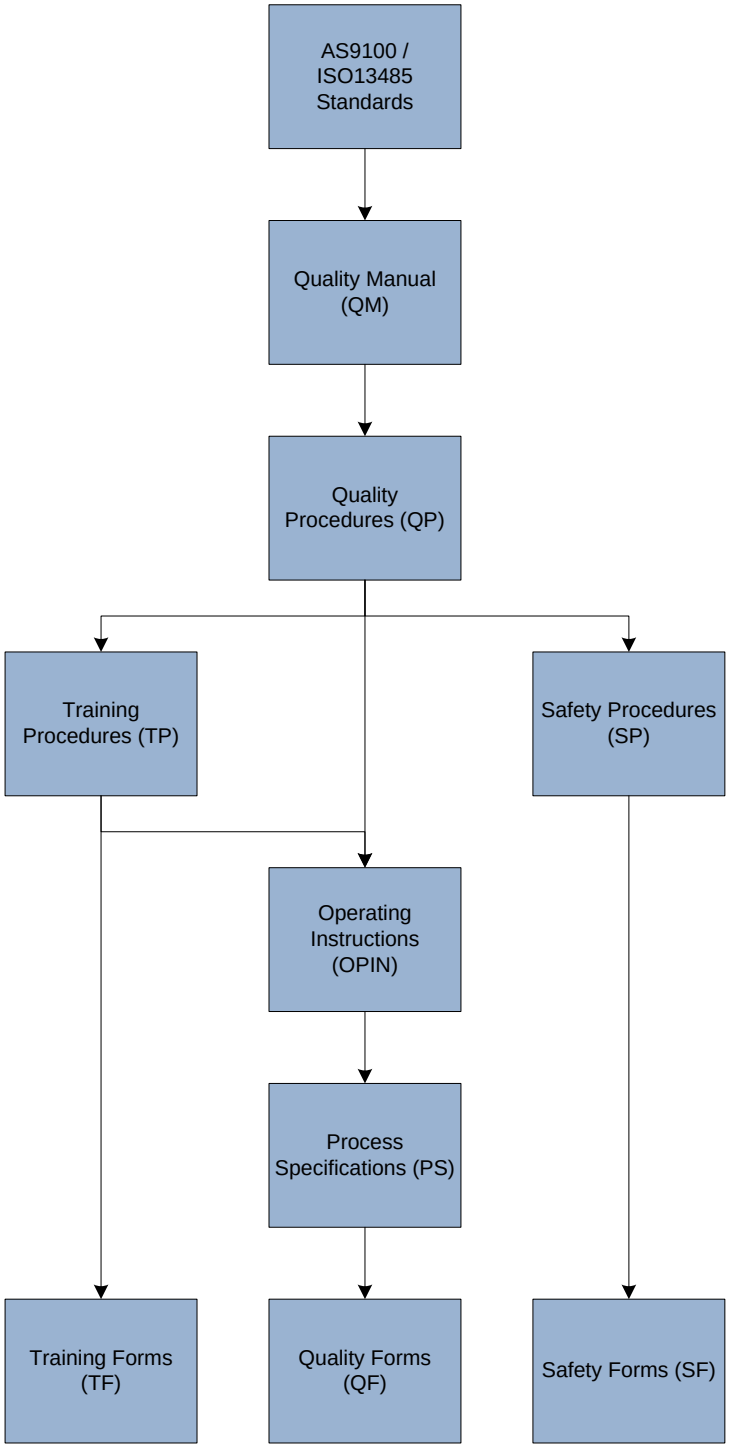
Gowanda Electronics has adopted a process approach in our daily operations, including the PDCA (plan-do-check-act) cycle. Gowanda Electronics considers the use of risk based thinking when developing, implementing and improving the effectiveness of our QMS. This approach will enable Gowanda Electronics to continually improve the overall performance of the company by effectively managing the interrelationships and interdependencies among the QMS Process

Key Processes

Organization Inputs **Organization Outputs**



Appendix B – QMS Document Structure



Appendix C – Organizational Chart