

Document:		QUALITY MANUAL	
Revision:	AE	Date:	01/03/2019



Revision History

Revision	Date	Changes	Approved by	Title
AD	10/31/18	Complete rewrite for AS9100D	Ken Hicks	Director of Quality
AE	01/03/2019	Quality Objectives: revised "sales goals" to "Sales dollars." Added statement about communication of Key Process graphs. Deleted ISO 13485 statement on 8.2.3 exception.	Ken Hicks	Director of Quality

NOTE: This manual is designed to address key requirements, not ALL requirements for their QMS. It meets the basic quality manual requirements for all standards indicated in the scope. Blue text refers to ISO 13485

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.

Context of the Organization

For more than 50 years, Gowanda Electronics has been a leading manufacturer of board-level magnetic inductive components for the OEM electronics marketplace. Our extensive product line includes axial-lead & surface mount RF and power inductors, chip coils, conicals, lead and lead-free designs, pot cores, qualified product list (QPL) components, shielded/unshielded designs, switching power supply magnetics, toroids, transformers, tunable coils, and application-specific configurations.

Dramatic changes have occurred in electronic technology over the years, and Gowanda has kept pace with - and in many cases stayed ahead of - these changes via ongoing research and development. The steady stream of new products, new technology and engineering advancements at Gowanda has resulted in the company becoming the "supplier of choice" for fortune 500 and Global 1000 companies around the world. For these companies the need for a component solution, not just a product, has made Gowanda an essential partner in their corporate product development teams.

Over the years, Gowanda has earned the reputation of being a customer-driven supplier of high quality, highly reliable, ruggedized electronic components. Our time-tested ability to support our customers is the key reason that Gowanda continues to enjoy long-term contract relationships with these major companies.

Precision magnetic components manufactured by Gowanda combined with our industry leading expertise and service offer OEMs the unique opportunity to address their special product needs and challenges supported by a partner with a long-term view and commitment to excellence. Such a relationship is especially important when off-the-shelf, mass produced components do not address the quality and performance requirements of demanding applications.

Such applications include high-performance equipment and instrumentation in the fields of aerospace, military/defense, communication, computers & peripherals, consumer products, diagnostic, education, industrial automation, control & monitoring, medical, security, space, and test & measurement.

Internal issues Gowanda considers relevant to their QMS include:

- Employees (monitored through employee turnover, training records and reviews)
- Customers (monitored through customer satisfaction scorecards)
- Establishment and maintenance of the QMS including the Quality policy, Quality objectives, internal audits, corrective actions and data analysis (all topics monitored during management review).

External issues considered relevant include:

- Competition (monitored through sales)
- Community (monitored through fund raisers and community involvement)
- Supply chain (monitored through supplier performance)
- Customers (monitored through customer satisfaction scorecards, returns, complaints, etc.)
- Changes related to new technology, or statutory/regulatory requirements (These topics are monitored and discussed during contract review and/or management review.)

Interested Parties

Interested parties that have the ability to affect our organization's ability to consistently provide products that meet customer and other requirements include:

- Employees (monitored through employee turnover, training records and reviews)
- Customers (monitored through customer satisfaction scorecards, returns, complaints, etc.)
- Community (monitored through fund raisers and community involvement)
- Competition (monitored through sales)
- Regulatory/statutory agencies (monitored and discussed during contract review and/or management review.)

Scope

The Scope of our company activities are indicated in the Context of our Organization. Gowanda is certified to AS 9100D, ISO 9001:2015, and [ISO 13485:2016](#). We follow a process approach with Risk based thinking.

Our scope of certification for ISO 9001 and AS9100 is as follows:

Design and Manufacture of RF and Magnetic Components

Gowanda considers that there are no requirements that do not apply to their QMS for ISO 9001 and AS 9100.

Our scope of certification for ISO 13485 is as follows:

Design and manufacture of RF and magnetic components for medical device applications.

For ISO 13485, the following requirements are considered not applicable:

7.5.2 – NA – We perform no cleaning or sterilizing functions.

7.5.3 – NA – We perform no installation activities.

7.5.4 – NA – We do not service any medical devices

7.5.5 – NA – We have no sterile medical devices to maintain records of.

7.5.7 – NA – We have no process for sterilization or sterile barrier systems, and have no products that require same.

7.5.9.2 – NA – We are not making any implantable medical devices so this requirement does not apply.

Quality Policy

Gowanda Electronics has established a Quality Policy that has been approved by Top Management. It is posted throughout our facility and is available to interested parties upon request. It states:

“A commitment to continuously improve our QMS to supply 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.”

Quality Objectives

Gowanda Electronics has established Quality objectives to measure our key processes. We include the following:

Sales/Contract

- Order Entry Errors

Purchasing

- Vendor Rating (Supplier Quality + Delivery)

Engineering

- Time to close ECN's

Production

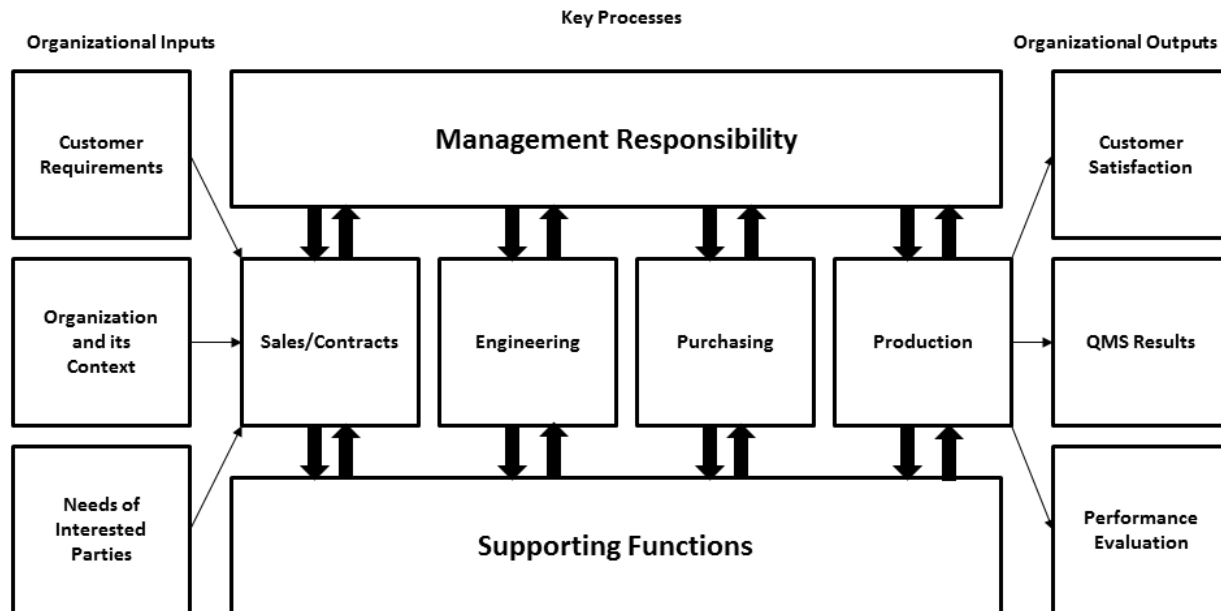
- Returns as % of sales dollars

Planning

- On Time Delivery (OTD)

Each of these Key Processes is tracked on a monthly basis and graphical summaries are posted to promote employee awareness of their contributions to achievement of Quality Goals.

QMS Process Map



Process Information(4.4.1) (note: clauses indicated refer to ISO 9001/AS9100 – **Blue text refers to ISO 13485**)

Management Responsibility includes: clauses 4.0, 5.0, 6.0, 9.3 – 4.0, 5.0

Supporting Functions includes: clauses 7, 9.1, 9.2, 10 - 6.0, 8.0

Sales/Contracts (8.2 - 7.2)

- Responsibility - Operations manager and customer service employees.
- Inputs - RFQ, customer requirements and/or prints and specs, material requirements, review for statutory & regulatory requirements
- Outputs - Accept customer enquiries, process RFQ, contract review, accrue customer satisfaction information
- Resources - input from customer service and engineering, AS 400 System
- Risks –new or repeat parts, lead times, supplier availability - assessed at contract review and depending on part requirements
- Opportunities - Customer satisfaction metrics, customer complaints, onsite visits.
- Measurement - See quality objectives

Engineering (8.1, 8.3 - 7.1, 7.3)

- Responsibility –Engineering Manager and support staff
- Inputs - PO and Customer requirements, Project scope/objectives, statutory/regulatory requirements, safety requirements, previous similar designs, acceptance criteria, Project schedule, resources
- Outputs - Product meets requirements, specifications / acceptance criteria, information for purchasing (BOM) and Production, drawings, FMEAs, Design reviews, establish the job package and release to production
- Resources - project manager, business unit manager, AS400 system, Autocad
- Risks - risks indicated on project Risk Management Plan, DFMEA, and PFMEA's, as applicable
- Opportunities - include ability to reach new markets based on new product designs.
- Measurement - See Quality objectives.

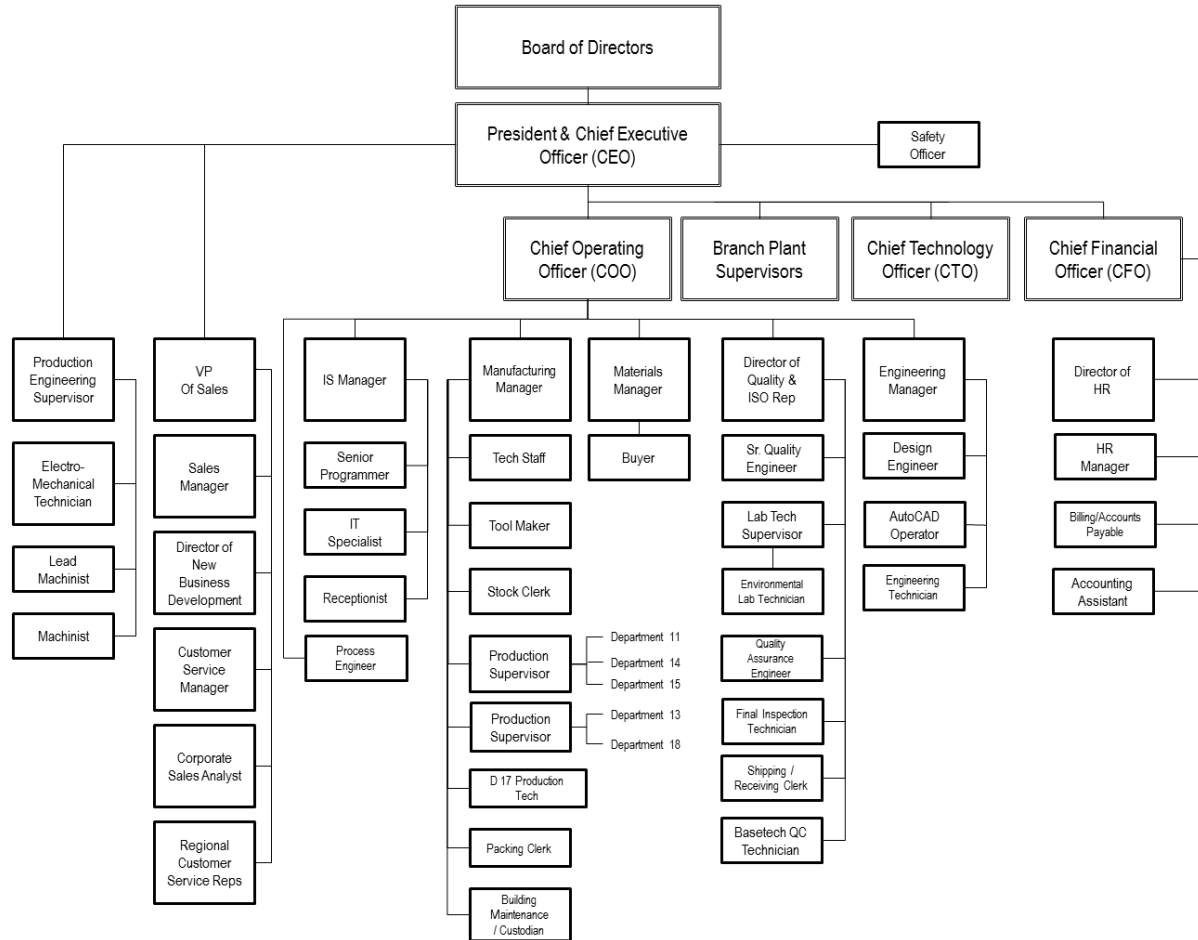
Purchasing (8.4 – 7.4)

- Responsibility – Purchasing Manager, Quality Manager
- Inputs - Customer requirements, requisition, Purchase Requirements, Supplier Lead Times, Supplier Performance Data, supplier flow downs
- Outputs - Purchase Orders, flow down to suppliers, Supplier approval and Supplier Performance Analysis, actions taken in response to review of Supplier Performance Analysis
- Resources - Buyers and AS400 System
- Risks - risks include counterfeit or suspect material, supplier performance.
- Opportunities - include ability to approve the supply chain through monitoring performance
- Measurement - see the quality objectives

Production (8.5, 8.6, 8.7 - 7.5, 7.6)

- Responsibility - Operations Managers
- Inputs - Customer requirements, PO's, Required materials/equipment/staff, procedures and work instructions, and job package including work order
- Outputs - Various inspections (first piece, first article, in process, final), Conforming Product, on-time product to the customer,
- Resources -work instructions, vendors for special processes, CNC machines
- Risks - risks are indicated on process FMEA's
- Opportunities –Product yields, employee efficiencies and internal and external complaints
- Measurement - see the quality objectives

Organizational Chart



Organizational Planning (6.1)

When planning the QMS there are organizational risks and opportunities that may affect its effectiveness. To address this we have done a SWOT analysis. The SWOT analysis is reviewed at Management Review for actions necessary to address risks and opportunities.

NOTE: This analysis is the first and may change at management review. This would then be used as a sample of topics to discuss.

Strengths

- A leading manufacturer of board-level RF & Power Inductive components for the OEM electronics marketplace.
- Industry leading product offerings
- Experienced management team
- High level of process automation
- State of the manufacturing art facilities

Weaknesses

- Limited Labor Availability
- Limited Technology
- Understaffed Sales and Marketing Organization
- Inexperienced Direct Labor Workforce

Opportunities

- Expand Markets/Customer Base through AS9100 / ISO9001 / ISO13485 Certification
- Capital Investments in New Technologies/More Efficient Equipment
- Expand Product Development Efforts
- Accelerate R&D Efforts

Threats

- Price Erosion due to Aggressive Domestic/Foreign Competition
- Technology Obsolescence in Certain Markets
- Low Unemployment Rates
- Customer Offshoring

If there should be a Catastrophic Event threatening our business capability, Gowanda has a continuity plan in place. SP16.0 is in place indicating the various risks that could affect the organization such as tornado, freezing rain, flood, hurricane, power failure, fire, or blizzard. It indicates actions that should be taken and a recovery strategy with alternate site setup plans. It includes evacuation and safety plans. It also includes how we will communicate with employees, and suppliers or contractors.

Product Safety (8.1.3)

Gowanda ensures their products meet all customer specifications and are able to perform to their intended use. We control critical items as indicated by internal or customer spec/drawing. We do first article and final inspections to ensure our products meet all required specs, as applicable. In addition we have constructed process FMEA's on the critical manufacturing processes in accordance with our Risk Management Plan. In addition we have safety training that includes MSDS training, split order control, FOD training, forklift safety, personal protective equipment. We have controls in place for product handling under preservation that encompasses packaging, handling, shipping, and storage requirements to prevent any damage to the parts during shipping. We have a clean room available if necessary.

Quality Procedures

- QP 4.2.3 – Control of Documents
- QP 4.2.4 – Control of Records
- QP 5.6 – Management Review
- QP 6.2.2 – Competence, Awareness, and Training
- QP 6.3 – Facilities and Equipment
- QP 7.1 – Planning of Product Realization
 - QP 7.1.2 – Risk Analysis
 - QP 7.1.3 – Configuration Management
 - QP 7.1.4 – Work Transfers
- QP 7.2 – Customer Related Processes
- QP 7.3 – Design and Development
- QP 7.4 – Purchasing
 - QP 7.4.1 – Cycle Count Procedure
- QP 7.5.1 – Control of Production and Service Provision
- QP 7.5.2 – Validation of Processes
- QP 7.5.3 – Product Identification and Traceability
- QP 7.5.4 – Customer Property
- QP 7.5.5 – Preservation of Product
- QP 7.6 – Control of Monitoring and Measuring Devices
- QP 8.1 – Statistical Techniques
 - QP 8.2.1 – Customer Satisfaction
 - QP 8.2.2 – Internal Auditing
 - QP 8.2.3 – Monitoring and Measuring of Product
- QP 8.3 – Control of Nonconforming Product
- QP 8.4 – Analysis of Data
- QP 8.5 – Continual Improvement

QP 9.1 – QPL System Elements
QMS Document Structure

