Quality System Manual

In accordance with AS9100:D

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Contents

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Section 1. Release and Approval

Revision	Date	Section	Revision Description	Release	
A	03/25/2021	All	Initial Release of Document	Review:	David McGorrin
				Approve:	Carl Kirkconnell
B	07/03/2022	11.6, 8.7.1.2	11.6 Reference corrected, added 8.7.1.2 authority for dispositioning non-conforming outputs	Review:	David McGorrin
				Approve:	Carl Kirkconnell

Section 2. Corporate Overview

West Coast Solutions was founded in June 2015 by Dr. Carl Kirkconnell. The team is comprised of the founding group of Hughes/Raytheon colleagues with decades of demonstrated success together, now augmented by a growing number of high performing technical professionals from a wide range of backgrounds, resulting in a team with both technical breadth and depth. Together, we have become a talented multidisciplinary team of experienced aerospace and defense professionals committed to solving developmental challenges including conceptual design, detailed design, proof of concept experimentation, and prototyping.

Our mission is to provide product development and technical services in three main categories: Cryogenics, Expeditionary Power Systems, and Space Electronics.

Section 3. Scope and Applicability

The scope of West Coast Solutions' Quality System derived from our business model in Section 2 Corporate Overview is defined as:

The Design, Manufacture, and Test of Electronic and Electromechanical Products and Systems.

The quality management system as defined in this manual is relevant to the nature of our organization and considers customer and regulatory requirements where necessary. For this reason, all sections of AS9100:D will be applicable to this Quality System unless that requirement is not relevant and its exclusion will not result in failure to achieve conformity of products and services.

This Quality System applies to the site(s) located at:
17682 Gothard Street
Huntington Beach, CA 92647

AS9100:D sections deemed not applicable:
None

Section 4. Context of the Organization

4.1. The Organization and Its Context

4.1.1. General

4.1.1.1. West Coast Solutions has defined its essential context within Section 2 'Corporate Overview' and Section 3 'Scope and Applicability'.
4.1.1.2. This context has considered our industry, environment, company marketplace and capabilities. As such, this context defines company issues which shall be identified and reviewed, both positive and negative, as they relate to our business model, strategic direction, effectiveness of the Quality System, and our ability to provide conforming products and services to our customers.
4.1.1.3. Those issues that directly affect the conformity of products and services will be detailed on each program's Risk Register.
4.1.1.4. Issues that affect the overall company and our integrity are identified on the organization's Risk Register and reviewed during the management review meeting addressed in Section 9.3 'Management Review'.

4.2. Interested Parties

4.2.1. General

4.2.1.1. Any party whose involvement will affect, or potentially affect the integrity of services from West Coast Solutions are considered Interested Parties.
4.2.1.2. Interested parties are defined in our organization's Risk Register, including the requirements and impacts of those interested parties as they apply to our organization.
4.2.1.3. The parties identified, and their respective impacts, are periodically reviewed according to Section 9.3 'Management Review' to ensure they are continuously monitored and acted upon as necessary.

4.3. System Scope

4.3.1. General

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4.3.1.1. The scope of the quality management system includes the documentation, processes, and controls required by our customers, our outlined Quality System and AS9100:D.
4.3.1.2. Section 3 'Scope and Applicability' defines the scope relating to products and services. This definition will be maintained as a record through this manual and shall be available to all personnel.
4.3.1.3. Any product or service offered outside of the scope of this Quality System will be excluded from its controls and not considered relevant to the performance of this Quality System.

4.4. Quality Management System and Its Processes

4.4.1. The Quality System

4.4.1.1. The quality management system is defined within this quality manual with reference to other documentation as applicable.
4.4.1.2. Where a second level procedure or third level work instruction is not referenced, the quality manual content serves as the procedure. Where the quality manual, procedure and/or work instruction is referenced, they are to be utilized together to form complete control.
4.4.1.3. The Quality System and its processes take into account, and capture as required, any customer and regulatory requirements imposed.

4.4.2. Quality System Processes

4.4.2.1. The primary source defining the necessary processes needed for the organization is Illustration 11.1 'Operational Process Flow'. This flow, along with the associated quality manual, procedures, illustrations, and work instructions (as appropriate) provide detailed guidance on fulfilling product realization steps, which serves as the general overview of our quality management system.
4.4.2.2. The Operational Process Flow includes the correct sequence and interaction of processes, all inputs and outputs required, and the responsible authority. All records produced from these processes are maintained to provide confidence that the process planning, and activity has occurred correctly and effectively.

Section 5. Leadership

5.1. Leadership and Commitment

5.1.1. General Leadership

5.1.1.1. Top management, as defined in Illustration 11.6 'Organizational Chart', will be directly accountable for the implementation, control, and effectiveness of the quality management system.
5.1.1.2. It is top management's responsibility to ensure that:
- This Quality System is communicated and understood.
- Any support needed is directed or obtained.
- The Quality Policy and objectives are established and monitored.
- Any resources needed are available or obtained.
- The Quality System has the ability to achieve its intended results.

5.1.1.3. This will be achieved through the promotion of risk-based thinking, striving for continuous improvement throughout the Quality System and ensuring that all relevant functions are supported as needed so they understand the importance of the system and the unintended consequences of failing to follow its requirements.

5.1.2. Customer Focus

5.1.2.1. Top management is directly responsible for the organization's commitment and focus to the customer.
5.1.2.2. Customer focus includes ensuring that any customer, regulatory or statutory, international, and AS9100 requirements are met.
5.1.2.3. Indicators of the degree to which we maintain customer focus is derived by our customer satisfaction which include, at a minimum, review of:
- On-time delivery.
- Product conformity.
- Customer complaints or feedback.
- Corrective actions requested.

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5.1.2.4. Customer satisfaction, including risks and opportunities, will be monitored and addressed according to Section 9.3 'Management Review' as a means of monitoring top management's commitment to customer focus.

5.2. The Quality Policy

5.2.1. General

5.2.1.1. The Quality Policy, Illustration 11.7 'Quality Policy' in this manual, has been established by top management and approved under the release of this manual.
5.2.1.2. The Quality Policy will be periodically reviewed to ensure that it is appropriate to our context and our interested parties under Section 9.3 Management Review.
5.2.1.3. This policy defines the company's commitment to satisfying any applicable requirements, continually improving the quality management system, provide measurable process objectives and a framework for ensuring that those objectives are met.
5.2.1.4. The Quality Policy is one of the core philosophies that we operate under and, as such, is understood at all levels of the organization, as well as any interested parties.

5.3. Organizational Roles and Responsibilities

5.3.1. General Communication

5.3.1.1. The general communication necessary for our organization will be expressed through the respective Quality System documentation directed as well as all other communication methods necessary at the discretion of the person to convey information
5.3.1.2. Customer focus is the responsibility of all departments.

5.3.2. Roles and Responsibilities

5.3.2.1. Top management has established the roles necessary for our organization on Illustration 11.1 'Operational Process Flow' and Illustration 11.6 'Organizational Chart'. Roles and responsibilities, including their interrelation, are communicated with the use of this manual and referenced documentation.
5.3.2.2. The responsibility of each role is communicated within the Quality System documentation, relevant job descriptions, or other methods as needed by top management.
5.3.2.3. Process owners as defined on the Operational Process Flow, are responsible for the outputs as well as the necessary communication and control of their respective process.

5.3.3. Management Representative

5.3.3.1. Top management has appointed the quality manager as the management representative responsible for communicating and resolving issues related to the Quality System.
5.3.3.2. Issues regarding the Quality System are communicated internally though the distribution of pertinent documents, meetings, training and awareness programs, and management reviews.
5.3.3.3. The management representative is structured as a member of top management and has unrestricted access to all employees and management personnel as necessary to maintain their responsibility unhindered.

Section 6. Planning

6.1. Actions to Address Risks and Opportunities

6.1.1. Identification of Risks and Opportunities

6.1.1.1. Any risks or opportunities identified relating to the organization, its context, its interested parties, or Quality System are documented on our organization's Risk Register.
6.1.1.2. Risks and opportunities are reviewed and addressed according to Section 9.3 'Management Review'.
6.1.1.3. Risks and opportunities which require immediate actions due to the perceived impact on the organization are addressed by the process owner according to Section 10 'Improvements'.
6.1.1.4. Risks regarding product and service provision are controlled in accordance with Section 8.1.2 'Operational Risk Management'.

6.1.2. Implementation of Actions

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6.1.2.1. Actions to address risks and opportunities are defined in Procedure 500 Quality Management.

6.2. Quality Objectives

6.2.1. Establishing Objectives

6.2.1.1. Quality objectives are the key determination of assessing the organizations performance and effectiveness.
6.2.1.2. Multiple quality objectives are established for our organization and our Quality System Processes.
6.2.1.3. These objectives are determined by ensuring they support the quality policy, address any applicable requirements, maintain relevance to the performance of the organization, and strive to improve customer satisfaction.
6.2.1.4. Objectives are defined in accordance within our organization's Key Objectives Map, measured against defined criteria addressed in Section 9.3 Management Review and communicated as required by Section 7.3 Awareness.

6.2.2. Planning Objectives

6.2.2.1. Planning includes identification and determination of Quality System processes, the resources needed to achieve those objectives, who is the party responsible for maintaining process objectives, and how they will be monitored.
6.2.2.2. Organizational objectives are the responsibility of all personnel at West Coast Solutions. Process objectives, authorities, and resources are established in Illustration 11.1 'Operational Process Flow'. The process for monitoring and updating these objectives as needed are defined in Section 9.3 'Management Review'.
6.2.2.3. Objective planning is reviewed by top management and updated by their relevant functions.
6.2.2.4. These reviews and any changes identified will be documented according to Section 9.3 Management Review.

6.3. Planning of Changes

6.3.1. General

6.3.1.1. Any changes identified for the quality management system are carried out in an organized manner based on the change required.
6.3.1.2. Necessary changes are typically identified by their affected process and reviewed by the process owner for all applicable changes identified. It is the process owner's responsibility to forward the identified changes and any review to the quality manager for implementation.
6.3.1.3. Changes may also be identified through customer communication, audit results, corrective action requests, or the results of monitoring and measuring the Quality System.
6.3.1.4. Changes will be approved, based on their purpose and impact, by the quality manager. The quality manager is responsible for ensuring that changes are appropriately implemented, do not affect the overall integrity of the Quality System, and the availability of resources is appropriate for the change.
6.3.1.5. The president is responsible for the procurement of resources and/or allocation of authority needed for the identified change.

Section 7. Support

7.1. Resources

7.1.1. Resource Planning

7.1.1.1. Resource planning shall be conducted by top management throughout the product realization process and outline the resources needed for the establishment, implementation, maintenance, and improvement of the Quality System.
7.1.1.2. This planning will include the capabilities of existing internal resources and any resources needed by or provided by suppliers.

7.1.2. Personnel

7.1.2.1. The president or their designee is responsible for the procurement of all personnel resources need to maintain our Quality System.
7.1.2.2. The requirements for personnel are defined throughout this manual or externally by customer requirements as they apply.

7.1.3. Infrastructure

7.1.3.1. The president or their designee is responsible for providing the basic infrastructure needed for the provision of products and services, and the conformity of our Quality System.
7.1.3.2. Infrastructure for West Coast Solutions includes any buildings or space needed for its operation, including:

- Utilities.
- Production, testing, and servicing equipment.
- Transportation necessities.

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- IT systems and communication.

7.1.3.3. West Coast Solutions maintains two different types of equipment:
- Critical equipment, defined as any equipment whose unexpected failure can affect or potentially affect the customer's product or delivery.
- Non-critical equipment defined as any equipment not identified as critical.

7.1.3.4. Critical equipment is maintained based on the original equipment manufacturer's guidance. Records of this maintenance are required and retained in the WCS Tooling and Equipment Inventory.

7.1.3.5. Non-critical equipment is maintained as appropriate by top management. Records of this maintenance may be documented if deemed necessary but are not required.

7.1.3.6. West Coast Solutions maintains a clean desk policy. Administrative areas are maintained and organized to ensure they are clean, safe, and controlled including the restricted use and availability of controlled documents.

7.1.3.7. Operational areas are organized and maintained to maximize safety, improve efficiency, and reduce the risk of contaminants. Section 8.1.6 'Foreign Object Debris Control' identifies the methods and process for controlling and reviewing FOD related activities.

7.1.3.8. No contamination control areas or environmentally managed areas are maintained. Areas used for inspection and quality control purposes are segregated with physical distance where reasonable from production areas to reduce contamination.

7.1.4. Environment

7.1.4.1. Top management is responsible for providing and maintaining a safe and inclusive working environment suitable for the scope and operation of its processes.

7.1.4.2. The work environment has been defined within the employee handbook and shall be non-discriminatory, appropriate for the work being performed, ethically managed, and physically maintained as needed.

7.1.4.3. A review of the overall work environment shall be conducted per Section 9.3 Management Review.

7.1.5. Monitoring and Measuring Resources

7.1.5.1. Any resource used to verify or validate the conformance of, or part of the conformance of, a product or service is considered a calibrated resource.

7.1.5.2. Any resource that is not used to verify or validate the conformance of, or part of the conformance of, a product or service is considered a reference resource and will be maintained as deemed appropriate by the organization.

7.1.5.3. Calibrated resources are provided by top management according to Section 7.1.3 Infrastructure.

7.1.5.4. Calibrated resources are reviewed for the specific type of monitoring or measurement activity being undertaken prior to use for suitability. These resources are also protected to ensure their suitability is not jeopardized.

7.1.5.5. Calibrated resources are maintained on the Tooling Inventory list which includes, at a minimum:
- The unique equipment/resource ID.
- Description.
- Evaluation date.
- Calibration/verification interval.
- Next evaluation date based on the stated interval.
- Location of the resource.
- Status of the resource. At a minimum, the status should include "In Use", "Recalled", or "Out of Service".

7.1.5.6. Calibrated resources shall be compared to national or international standards, if available. If no standard is available, the technique used to calibrate/verify the resource will be documented and maintained on the calibration record.

7.1.5.7. All calibrated resources will be labeled to identify their unique identification, status, and calibration period.

7.1.5.8. Resources found to be damaged, or out of calibration tolerance, will be evaluated by the quality manager to ensure that previous measurements have not adversely affected product and service conformity.

7.1.5.9. These results will be documented and reviewed by applicable management to determine the appropriate actions necessary if products or services are found to be jeopardized.

7.1.6. Organizational Knowledge

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7.1.6.1. Knowledge or guidance needed for the conformance of quality processes are determined by process owners and documented in their respective guidance documents. This can include the quality manual, procedures, work instructions, training materials, or any other information forms given or made available.

7.1.6.2. Any changes to operational knowledge identified through corrective actions, continual improvements, experience, risks, or opportunities is identified and documented by the process owner, when that information is considered essential to the organization.

7.1.6.3. Additional knowledge which is necessary to West Coast Solutions is acquired from its originating or distributing source, reviewed for compliance by top management, and implemented into the Quality System by its process owner when approved.

7.2. Competence

7.2.1. Determining Competency

7.2.1.1. The competency needed for personnel performing work that affect the performance of this Quality System is defined:

- In various Quality System documentation.
- On relevant job descriptions.
- On our organization's Training Matrix.

7.2.1.2. The quality manager is responsible to ensure that these definitions are accurate, and the Training Matrix is maintained.

7.2.2. Training and Competency Review

7.2.2.1. Competency is determined by reviewing existing skills and experience of the individual, provided necessary training internally, or supplemental education received.

7.2.2.2. Where it is determined that competency of personnel is not sufficient, actions will be taken to ensure the necessary skills required for the process are obtained and evaluated. All records of personnel competency are retained by the quality manager.

7.2.2.3. The Training Matrix is our tool to identify the required competency needed, document an individual's current levels of competency, and indicate areas of insufficient competency.

7.3. Awareness

7.3.1. General

7.3.1.1. All personnel directly under the control of West Coast Solutions are made aware of:

- The Quality System.
- The Quality Policy.
- Quality objectives as they apply to that person.
- Their involvement and effect on the Quality System.
- Their contribution to the performance of the system as it relates to the improvement or non-conformance of its requirements.

7.3.1.2. All West Coast Solutions personnel are additionally trained on their relevant Quality System documentation, their contribution to product conformity in relation to Illustration 11.1 Operational Process Flow, their contribution to product safety as applicable, and the importance of ethical behavior.

7.3.1.3. These areas of awareness are scheduled and reviewed according to Section 7.2 'Competence'.

7.3.1.4. As changes to quality or process guidance documents occur, training for all relevant personnel regarding the changes will occur within a timely manner by the quality manager or process owner.

7.4. Communication

7.4.1. General

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7.4.1.1. Communication relevant to the Quality System and the effectiveness of its results are controlled throughout this manual as they pertain to the communication given.
7.4.1.2. Methods, frequency, and responsibility are controlled through its respective process.
7.4.1.3. This communication can include changes to the Quality System, product and service information, relevant guidance documentation, non-conforming products or services, customer communication, risks and opportunities, and any other information needed or expressed.
7.4.1.4. It is the quality managers responsibility to relay any changes from the Quality System, its certification, or it's processes to the appropriate party within a timely manner, or as required by regulatory and customer requirements if applicable.

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7.5. Documented Information

7.5.1. Document Identification

7.5.1.1. Documented information will include all necessary documentation required by AS9100:D, the Quality System, the product realization process, customers or regulatory agencies, and other parties seen as necessary for the maintenance of the quality management system.
7.5.1.2. Documented information, in any format, required to control, manage, guide, present, or maintain information applicable to the Quality System or a process shall be considered a controlled document.
7.5.1.3. Controlled documents include forms, work instructions, and production controls.
7.5.1.4. Documented information that is created to provide additional temporary information that does not conflict with a controlled document, or provide controls to manage a process, is considered a reference document.
7.5.1.5. Reference documents can include notebooks, spreadsheets, temporary notes, or other media.
7.5.1.6. All controlled documents must meet the requirements 7.5.2 and 7.5.3. Reference documents do not need to meet the requirements of this section, but must be clearly labeled as “reference only” documentation.
7.5.1.7. It is the responsibility of top management to ensure that all personnel are aware of all relevant controlled documents as it pertains to the system, their processes, their requirements, and those of our customers and regulatory agencies.

7.5.2. Document Requirements

7.5.2.1. Controlled documents must be approved for use prior to issuance by the process owner or quality manager.
7.5.2.2. Controlled documents will contain, at a minimum, the identification and/or title of the document, its revision or status, and approval for use.
7.5.2.3. Documents which are modified frequently as information changes are considered living documents. Living documents, such as the Critical Supplier List, are maintained by the process owner and do not contain revision levels, but rather revision control denoted through date stamp or available version.
7.5.2.4. Internal process specific controlled documentation including the quality manual, procedures, and work instructions are created by their originating department and approved by the quality manager or process owner prior to issuance.
7.5.2.5. Internal product specific controlled documentation including drawings, bills of material, and specifications are created and approved by the applicable engineer.
7.5.2.6. Any change to internally controlled documentation must include the change made, review and approval applied to or referenced on the document. This change requirement does not apply to forms with the exception of evidence of approval.
7.5.2.7. Changes made to documents referred to in 7.5.2.4 and 7.5.2.5 are reviewed and approved prior to issuance and communicated to all relevant parties after release.
7.5.2.8. Controlled documents of an external nature are retrieved from the customer, original publisher, or other parties based on the documents need and controlled as such by the process owner.
7.5.2.9. All documents are controlled by issuance date or revision level as necessary for the conformity of this Quality System and customer requirements.

7.5.3. Document Control

7.5.3.1. Master document control will be maintained on designated network folders with only the most current revision being available.
7.5.3.2. Documents are distributed to, or accessed by, personnel in locations where they are used.
7.5.3.3. Paper documents must be protected to preserve the integrity and readability of the information.
7.5.3.4. Paper documents distributed for use are required to be controlled as such and removed when obsolete.
7.5.3.5. Electronic documents are available on the network to preserve the integrity of the document and are made readable to relevant users.
7.5.3.6. Electronic documents are protected from tampering or loss using password protected folders and regular backups of the entire data system.
7.5.3.7. All documents are retained until their suitability has expired. Obsolete documents are removed from points of use to prevent unintended utilization. Retained masters or copies of obsolete documents are properly marked as such and kept separate from active documents. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.
7.5.3.8. Documents of an external origin including standards, customer specifications, or other information are identified as such within the document control folders with their distribution controlled.
7.5.3.9. When it is determined that a document is no longer necessary for the Quality System, the document is to be disposed of in a manner that prevents their unintended reappearance or risk of proprietary information becoming public.

7.5.4. Record Control

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7.5.4.1. Documented information which is used as evidence of process conformity are considered records.
7.5.4.2. Records are stored by the same process that initially established the document.
7.5.4.3. All records, both paper and electronic, are protected from alterations once the record has been completed.
7.5.4.4. Only the process owner, original record creator, or top management may make changes to a record. Any changes made must include a single line through the incorrect entry, the corrected entry, initials, and date of the person changing the record.
7.5.4.5. All records produced by the Quality System are retained for a minimum of 10 years, or customer designated retention period if applicable, from its date of origination.
7.5.4.6. Records of an electronic nature are backed up to off-site locations for protection and recovery as needed. In the case of lost or corrupted record entries, back-up copies can be made available as part of the disaster recovery effort.
7.5.4.7. When it is determined that records are no longer required to be retained, all records will be disposed of in a manner that prevents their unintended reappearance or risk of proprietary information becoming public. This is generally considered shredding or permanently deleting files.

Section 8. Operation

8.1. Operational Planning

8.1.1. General

8.1.1.1. General process controls and program management is defined in Procedure 300 Process Control..

8.1.2. Operational Risk Management

8.1.2.1. Operational risk management begins at the request for quote or order phase of our organization, evidenced by requests to the prospective customer for clarifying documents, contract exception, or other obvious operational challenges.
8.1.2.2. There are inherent risks in all activities performed by our organization which have been accounted for in our normal process planning.
8.1.2.3. Risks of significant magnitude outside of normal processing risks are formally identified on the program's Kick-Off Meeting and documented on the program's Risk Register including the risk criteria and acceptance authority.
8.1.2.4. Risk criteria is identified by determining the potential severity, occurrence, and current detection methods available.
8.1.2.5. High risks require mitigation plans that are determined by relevant personnel as needed. Mitigation plans are documented on the program's Risk Register and communicated throughout subsequent processes by the program manager.
8.1.2.6. Risks encountered after the program launch are controlled in the same manner as initial risks.
8.1.2.7. The quality manager is ultimately responsible for effectiveness of operational risk management.

8.1.3. Configuration Management

8.1.3.1. Program configuration management is established during the development and release of program documentation.
8.1.3.2. As design documents are approved, the correct configuration of program documents is established and maintained for each program.
8.1.3.3. As changes are made to program documents, the program manager or applicable engineer responsible for the change is responsible to ensure the program configuration is updated to match the approved changes.
8.1.3.4. Production and service provision is implemented against the latest program configuration documented, or per the customers requested configuration if different.
8.1.3.5. The configuration of prototype and production outputs is clearly defined in the related documentation accompanying the physical product.
8.1.3.6. Additional configuration management controls are documented in Work Instruction 0301 Configuration Management.

8.1.4. Product Safety

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8.1.4.1. Product safety is incorporated into the design and development of our customer's products throughout its planning.
8.1.4.2. Product safety is defined as the state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.
8.1.4.3. Any function or feature of a product's design that can affect the safe use of the product is initially identified as a safety concern.
8.1.4.4. The relevant engineer shall review all design safety concerns and make a determination if the feature or function must be identified as a Safety Critical Feature.
8.1.4.5. Safety Critical Features are documented on the relevant design outputs such as the drawing, bill of material, engineering order, drawing notes, or equivalent, including the method to control the feature during production.
8.1.4.6. All services provided to our customers are at the direction of our customer, and the resulting output is confirmed by the customer. Once the customer confirms our product or service, West Coast Solutions is not responsible for monitoring or revision of the product or service's safe use. This includes the collection of data regarding in-service failures or product recalls, unless directly required by customer contract.
8.1.4.7. Information regarding the product or service's intended safe use will be provided If our customer requires, or if offered by West Coast Solutions for that particular program.

8.1.5. Counterfeit Part Prevention

8.1.5.1. Counterfeit part prevention is monitored during the purchasing and receiving processes.
8.1.5.2. Quality requirements regarding the avoidance and mitigation of receiving, storage, and shipment of counterfeit parts are issued to our supply chain on each supplier purchase orders.
8.1.5.3. The purchasing manager will reduce the risk of buying from suspect suppliers by the controls implemented in Section 8.4 'Control of Externally Provided Processes and Products'.
8.1.5.4. Receiving Inspectors certify the validity of purchased products and services by inspecting for apparent falsification of material labeling, material traceability to the original manufacturer, suspicious packaging, and discrepancies between appearance and supporting documentation.
8.1.5.5. Should any purchased product be suspected as counterfeit, the receiving inspector will quarantine the parts and remove them from use by initiating a non-conformance report outlined in Section 8.7 'Control of Non-Conforming Outputs'.
8.1.5.6. Confirmed counterfeit materials will be reported back to the supplier and any affected customers, if delivered.

8.1.6. Foreign Object Debris Control

8.1.6.1. Foreign Object Debris, or FOD, is considered the presence and likely entrapment of dust, debris, particles and equivalent into materials received and the final customer product.
8.1.6.2. Activities which may directly impact or produce FOD such as grinding, sanding, and machining have been isolated by operational distance from assembly, inspection, and packaging areas.
8.1.6.3. FOD controls and awareness training are required for all personnel according to Section 7.2 'Competency'.
8.1.6.4. It is the requirement of all personnel to assist in the maintenance and cleanliness of our infrastructure. All personnel are responsible to abide by the "clean as you go" policy as well as complete any scheduling cleaning practices.
8.1.6.5. It is the process owner's responsibility to ensure that their process area is cleaned at the end of every shift and is maintained throughout its daily activities.
8.1.6.6. It is the quality manager's responsibility to ensure the entire manufacturing floor is maintained and scheduled cleanups are completed.
8.1.6.7. Materials, customer products, and process areas with detected FOD are to be cleaned immediately by the process owner, or designee.
8.1.6.8. Materials and customer products affected by FOD entrapment are considered suspect and segregated per Section 8.7 'Control of Non-Conforming Outputs'.

8.2. Product and Service Requirements

8.2.1. General

8.2.1.1. The president or leading program manager is responsible to determine the appropriate communication and methods with the customer regarding program requirements.
8.2.1.2. The process of being awarded a customer program, and the methods of determining program requirements are defined in Procedure 100 Business Development.

8.3. Design and Development

8.3.1. General

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8.3.1.1. The design and development process has been defined and documented in Procedure 200 Design and Development.

8.4. Externally Provided Processes and Products

8.4.1. Control of External Providers

8.4.1.1. Externally Provided Processes and Products, or Purchased Products, are defined as any product or service which enters or affects the final product to the customer.
8.4.1.2. External providers, or suppliers, are identified and selected for their ability to provide purchased products against requirements.
8.4.1.3. Suppliers are evaluated and approved for use, including any identified risks associated with them, on the Critical Supplier List.
8.4.1.4. Any customer designated suppliers required for use by the program's contract take precedent and must be used, unless concession is obtained in writing. Customer designated suppliers are established on the Critical Supplier List and controlled using the same criteria as internally designated suppliers.
8.4.1.5. Supplier controls including monitoring, evaluating, and re-evaluating have been established in Procedure 400 Purchasing.

8.4.2. Control of Purchased Products

8.4.2.1. Verification of purchased products are conducted according to Procedure 400 Purchasing.

8.4.3. Purchasing Information

8.4.3.1. Information relayed to suppliers regarding our purchased product, and the requirements of our Organization are defined in Procedure 400 Purchasing.

8.5. Production and Service Provision

8.5.1. Control of Provisions

8.5.1.1. The controls necessary for the provision of products after development activities have been completed is defined in Procedure 300 Process Control.

8.5.2. Identification and Traceability

8.5.2.1. The identification and traceability of design and development activities is documented in Procedure 200 Design and Development, in regard to program status.
8.5.2.2. Production and service traceability is documented in Procedure 300 Process Control.

8.5.3. External Property

8.5.3.1. Resources not owned by West Coast Solutions, that is provided by an external party for the use in product or service provision is considered external property.
8.5.3.2. External property is maintained and cared for under our organization's control until its suitability has expired.
8.5.3.3. External property must be labeled with the property owners name and any other relevant information such as related purchase order, program name, contract agreement number, or similar.
8.5.3.4. The quality manager must notify the owner when external property is lost, damaged, or otherwise found unsuitable for use. This notification will be retained as a record.

8.5.4. Preservation

8.5.4.1. Preservation of products and services during product realization and until delivery to the customer is established in Procedure 300 Process Control.

8.5.5. Post Delivery Activities

8.5.5.1. West Coast Solutions' will determine its scope of post delivery activities as they apply to each individual program.
8.5.5.2. Customers who request additional services beyond the initial deliverables including warranties, obsolescence management, program maintenance and updating, or similar will be reviewed and documented during the program Kick-Off Meeting.
8.5.5.3. Actions required from the meeting will be captured on its relevant documentation as it relates to the program.
8.5.5.4. These actions can include review of in-service failures, achieving necessary regulatory certifications after development, or as requested by the customer and agreed to by West Coast Solutions.
8.5.5.5. If it is determined that post delivery activities are required by the contract, the Program Manager will ensure the post delivery commitments made are formally documented and approved.

8.5.6. Control of Changes

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8.5.6.1. Change control regarding design and development activities is documented in Procedure 200 Design and Development.
8.5.6.2. Change control regarding production and service provision is documented in Procedure 300 Process Control.

8.6. Release of Products and Services

8.6.1. General

8.6.1.1. Products and services can not be released to the customer until all planned arrangements have been met, unless agreed to by the customer and program manager.
8.6.1.2. Planned arrangements include the completion of all design phases outlined in the program Kick-Off Meeting, the verification and validation of the resulting output, the verification of any additional products subsequent to the prototype, and any planned customer buy-off(s).
8.6.1.3. The program manager is responsible to ensure all planned arrangements for the program have been met, and records related to the conformance of these outputs are retained and available.
8.6.1.4. The program manager retains final authority to approve and release products and services to the customer, and their approval must be recorded on the relevant documentation as evidence of release.

8.7. Control of Non-Conforming Outputs

8.7.1. General

8.7.1.1. The control of non-conforming process outputs is maintained in Procedure 500 Quality Management.
8.7.1.2. The program manager with the assistance of the Quality System Manager or SME will assign authority for dispositioning nonconforming outputs based upon qualifications within the person's resume, experience and/or skillset.

Section 9. Performance Evaluation

9.1. Quality System Monitoring and Measuring

9.1.1. Quality System Performance

9.1.1.1. The performance of the Quality System is monitored and measured to ensure its effective use.
9.1.1.2. The primary source for measuring the Quality System are the quality objectives identified per Section 6.2 Quality Objectives.
9.1.1.3. Quality objectives are continuously monitored by their process owner according to the objective defined on the organization's Key Objectives Map.
9.1.1.4. Additionally, customer satisfaction is measured according to Section 5.1.2 'Customer Focus'.
9.1.1.5. Relevant product and service conformance information is captured through inspections, tests, and other product verification activities, as specified in the program.
9.1.1.6. Product and service conformity is monitored according to Section 8.7 Control of Non-Conforming Outputs on the Non-Conformance Report.

9.1.2. Customer Satisfaction

9.1.2.1. Customer satisfaction is the principal goal of the Quality System, and the level of customer satisfaction is the most important measure of the effectiveness of the system.
9.1.2.2. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction defined in Section 5.1.2 'Customer Focus'.
9.1.2.3. Customer satisfaction data is used by the top management to identify opportunities and priorities for improvement and to identify customer misperceptions regarding our organization.
9.1.2.4. Top management is responsible for developing suitable goals for customer satisfaction, and for defining methods for collecting and analyzing the pertinent information. Acceptance criteria and analysis methods for customer satisfaction performance is defined in Section 9.3 'Management Review'.

9.1.3. Analysis and Evaluation

9.1.3.1. Data collected from Section 9.1.1 'Quality System Performance' and Section 9.1.2 'Customer Satisfaction' are used to evaluate the effectiveness of the Quality System.
9.1.3.2. This evaluation will also include the performance of suppliers, and the need for improvements and risk mitigation.
9.1.3.3. Analysis and reporting of Quality System performance is performed in Section 9.3 'Management Review' with all necessary actions outlined as needed.

9.2. Internal Audits

9.2.1. General

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9.2.1.1. Internal audits are planned, implemented, and reported to top management to assess the degree of conformance of the Quality System.
9.2.1.2. These audits will be conducted against the requirements of AS9100, our organization's Quality System, and customer and regulatory requirements as applicable.
9.2.1.3. The quality manager is responsible for the internal audit program.
9.2.1.4. Internal audits are planned and executed in accordance with Procedure 500 Quality Management.

9.3. Management Review

9.3.1. Management Review Meeting

9.3.1.1. Management Review Meetings are scheduled to review the performance, adequacy, and effectiveness of the quality management system. The meeting will take into consideration the data and time period relevant to the interval of the meetings.
9.3.1.2. At a minimum, a Management Review Meeting is held by top management annually. The meeting must include all members of Top Management as defined in Illustration 11.6 'Organizational Chart'.
9.3.1.3. The meeting is typically chaired by the president and may be documented by any member of the meeting.
9.3.1.4. The Management Review Meeting must be documented as a meeting report and retained as a record by the quality manager.

9.3.2. Meeting Agenda

9.3.2.1. The Management Review Meeting agenda is established within the meeting report. The agenda will include topics required for discussion, as well as any additional topic or information presented by the meeting attendees as appropriate.
9.3.2.2. The required agenda topics must include discussions regarding:
- The status actions to be taken from previous management reviews.
- Review of the organization's Risk Register to identify any changes regarding internal and external issues, including the effectiveness of actions taken to address previous risks and opportunities.
- Customer satisfaction data derived from Section 9.1.2 'Customer Satisfaction'.
- The organization's Key Objectives Map, and the extent to which those objectives were met.
- The conformity of products and services outlined in Section 9.1.1 'Quality System Performance'.
- Identified non-conformities and corrective actions.
- Feedback from relevant interested parties, including customer complaints.
- Audit results from internal and external audits performed, including any opportunities for improvement or observations.
- Supplier performance, including supply chain on-time delivery and quality performance.
- Our organizations on-time performance.
- The adequacy of resources.
- Any perceived opportunities for improvement to the organization.

9.3.2.3. The additional topics can include relevant business decisions, financial assessments, or other pertinent information not addressed in the required topics.

9.3.3. Meeting Decisions

9.3.3.1. The meeting report should include an outline of the topics discussed, and statement of consensus regarding the status of the topic.
9.3.3.2. Following the discussion of all meeting topics, the end of the Management Review Meeting will determine action items to be taken based on the status of the topic.
9.3.3.3. Meeting attendees are encouraged to present action items they deem important for the organization to consider and the agreed action items will be included in the meeting report for implementation and review during the next scheduled meeting.
9.3.3.4. At a minimum, action items to consider must include:
- Any opportunities for improvement beneficial to the organization.
- Any need for changes to the quality management system.
- Any resource needs.
- Any identified risks to the organization.

Section 10. Performance Development

10.1. Actions

10.1.1. General

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10.1.1.1. The outputs of the Quality System, Management Review Meeting, and the results of Section 9 'Performance Evaluation', shall be used to determine actions needed to identify necessary changes to the Quality Management System.
10.1.1.2. These actions will be taken to ensure the organization is continuously improving customer satisfaction and improving our services and products.
10.1.1.3. Actions will be identified:
- To address meeting requirements as well as future needs and expectations.
- Correct, prevent, or reduce undesired outcomes.
- Improve the performance of the Quality System and our organization.

10.1.1.4. Formal actions taken to correct the Quality System are defined in Section 10.1.2 'Corrections'.
10.1.1.5. Formal actions taken to improve the Quality System are defined in Section 10.1.3 'Improvements'.
10.1.1.6. Actions taken to a specific program or product are implemented by the program manager and documented where applicable.

10.1.2. CORRECTIONS

10.1.2.1. Failure to meet a requirement of the Quality System, customer, or AS9100 will generally require formal corrective actions to be taken to address the discrepancy
10.1.2.2. The quality manager is responsible for the corrective action program.
10.1.2.3. The corrective action process is defined on Procedure 500 Quality Management.

10.1.3. IMPROVEMENT

10.1.3.1. West Coast Solutions will always strive for continuous improvement by reviewing the suitability, adequacy, and effectiveness of the Quality System.
10.1.3.2. It is top managements responsibility to determine what opportunities will be acted upon according to Section 10.1 Opportunities for Improvement.
10.1.3.3. The improvement process is defined on Procedure 500 Quality Management.

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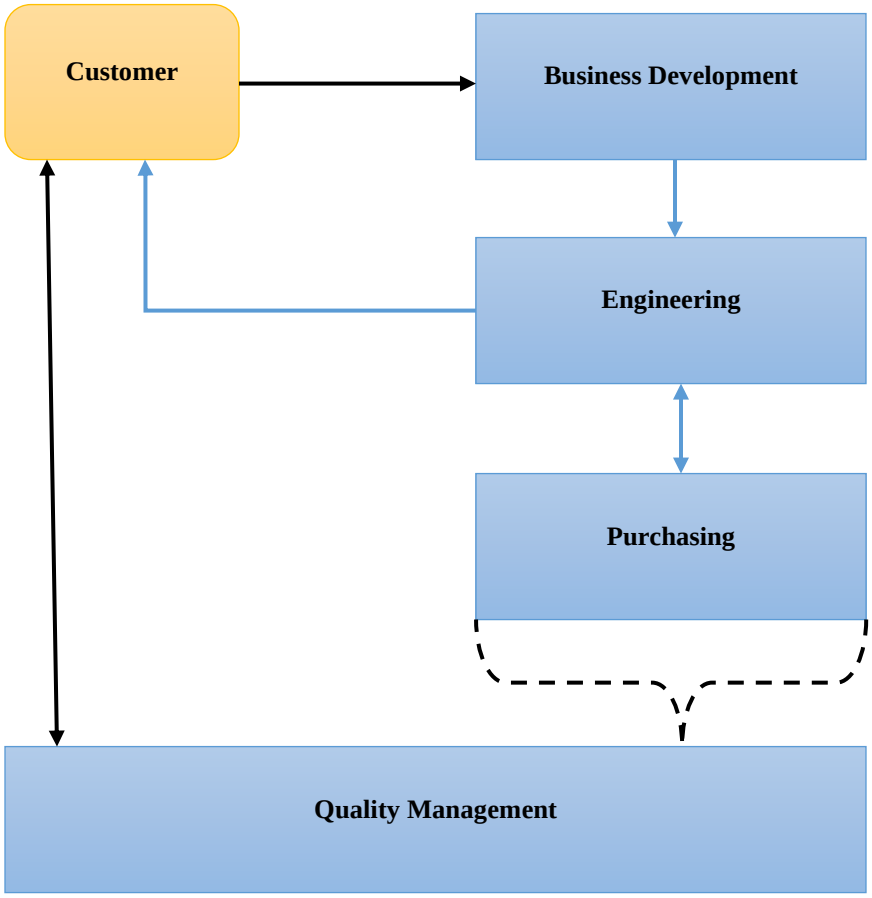
Section 11. Illustrations

11.1. Operational Process Flow



Part Flow
Communication Flow
Relationship

QMS Application
8.2
8.1, 8.3, 8.5 - 8.7
8.4
4.1 - 7.5, 9.1 - 10.3

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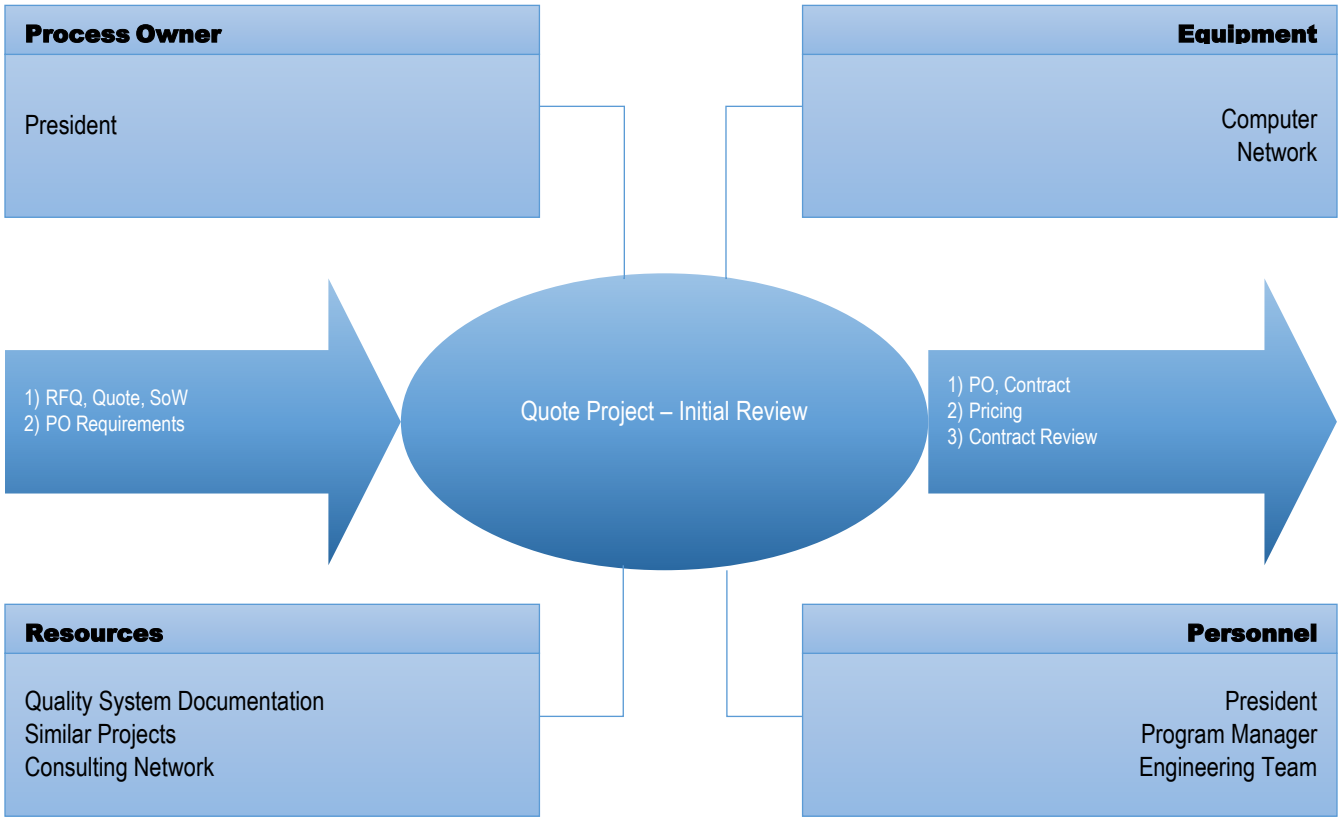
11.2. Business Development Process Map



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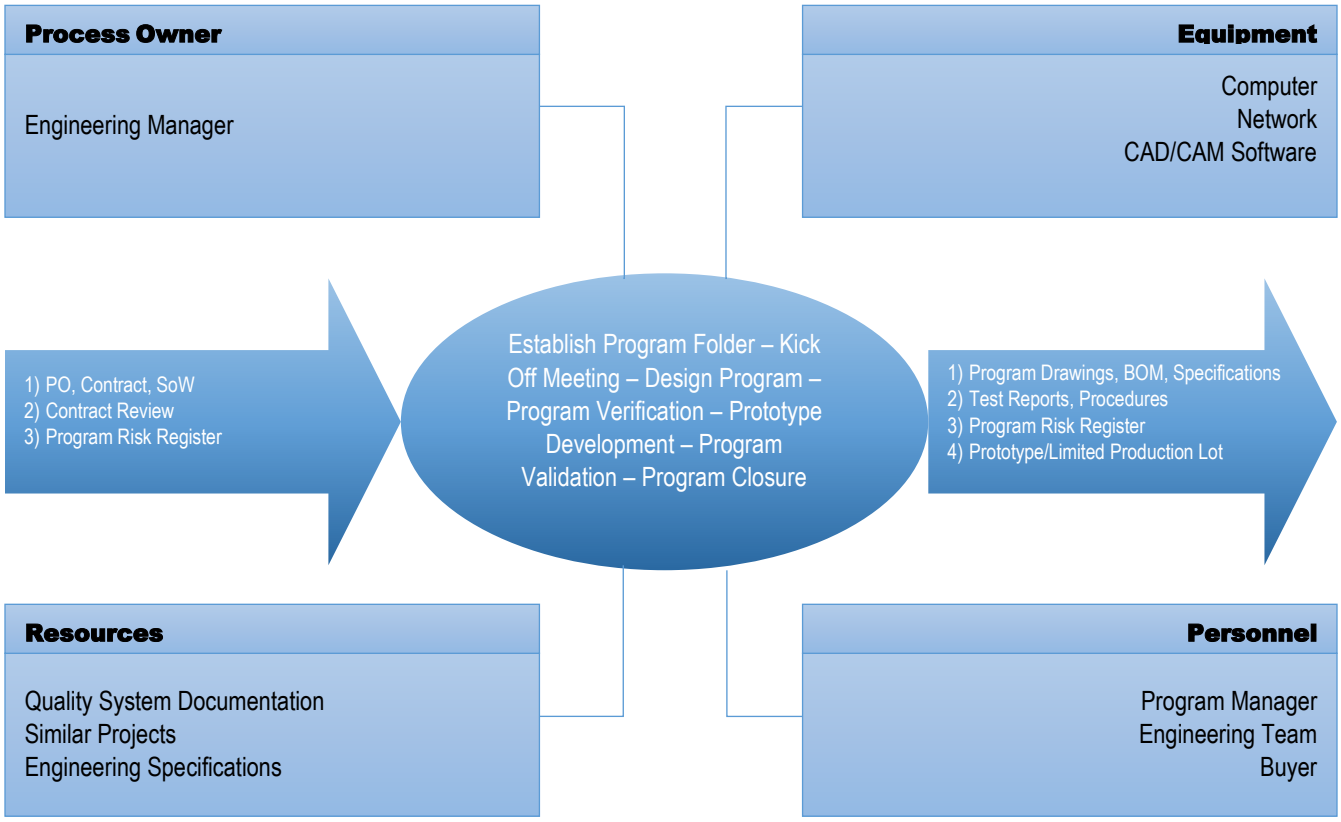
11.3. Engineering Process Flow



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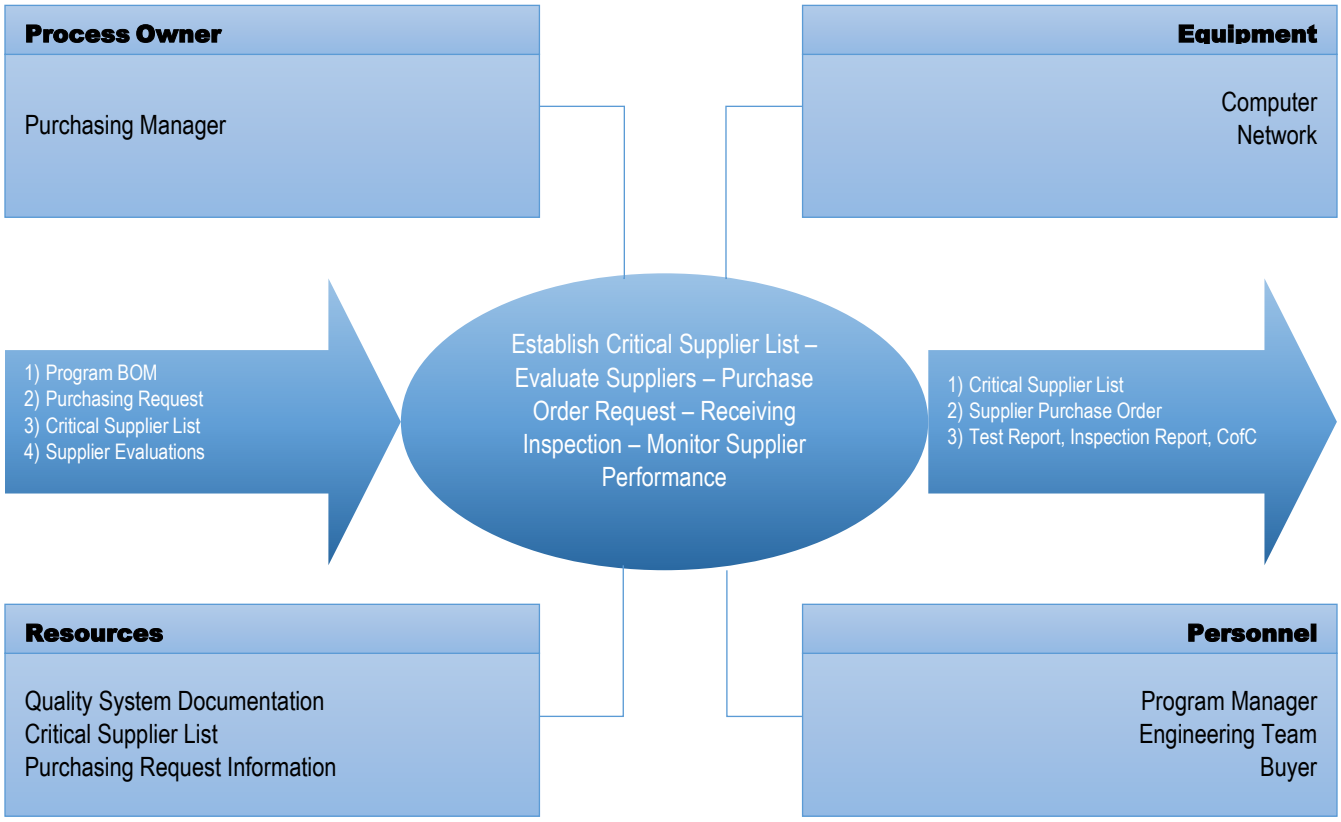
11.4. Purchasing Process Map



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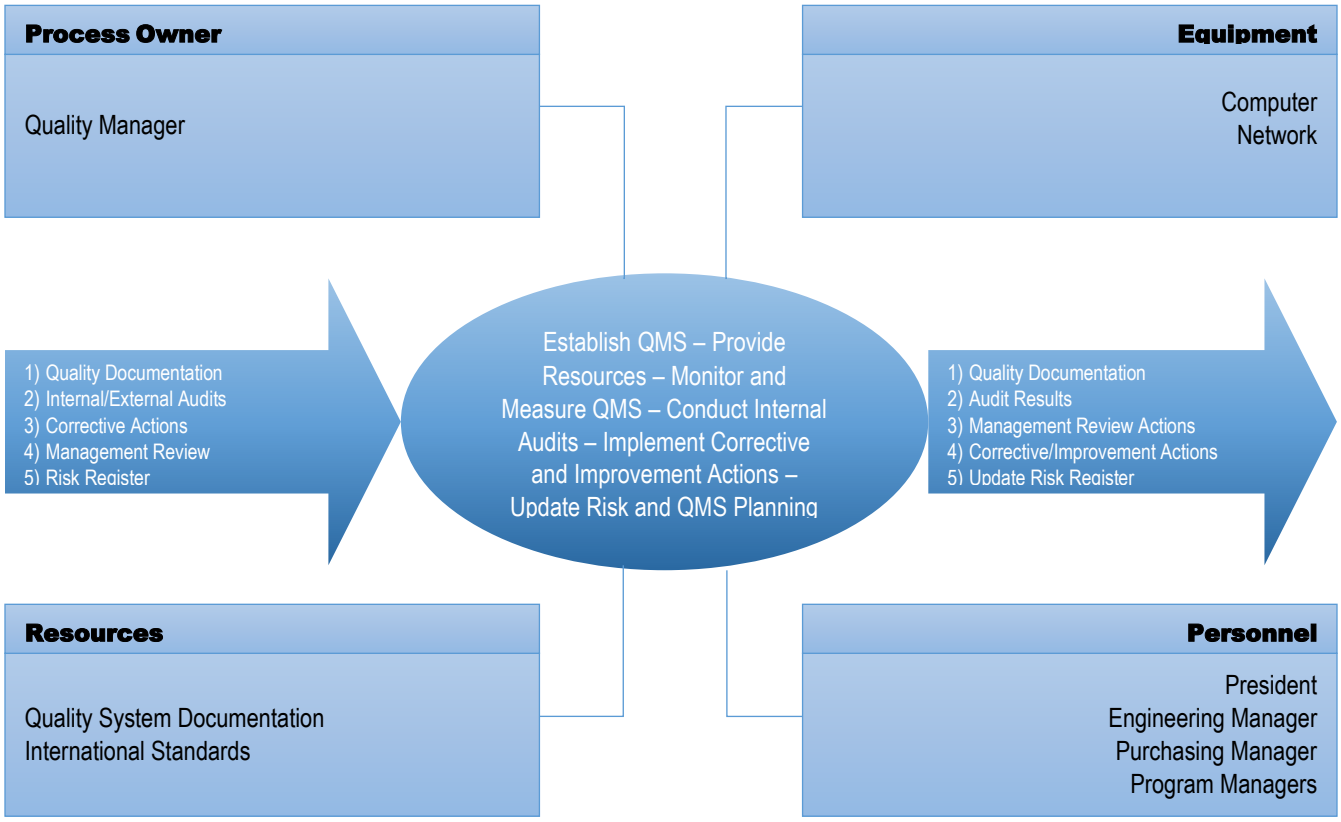
11.5. Quality Management Process Map



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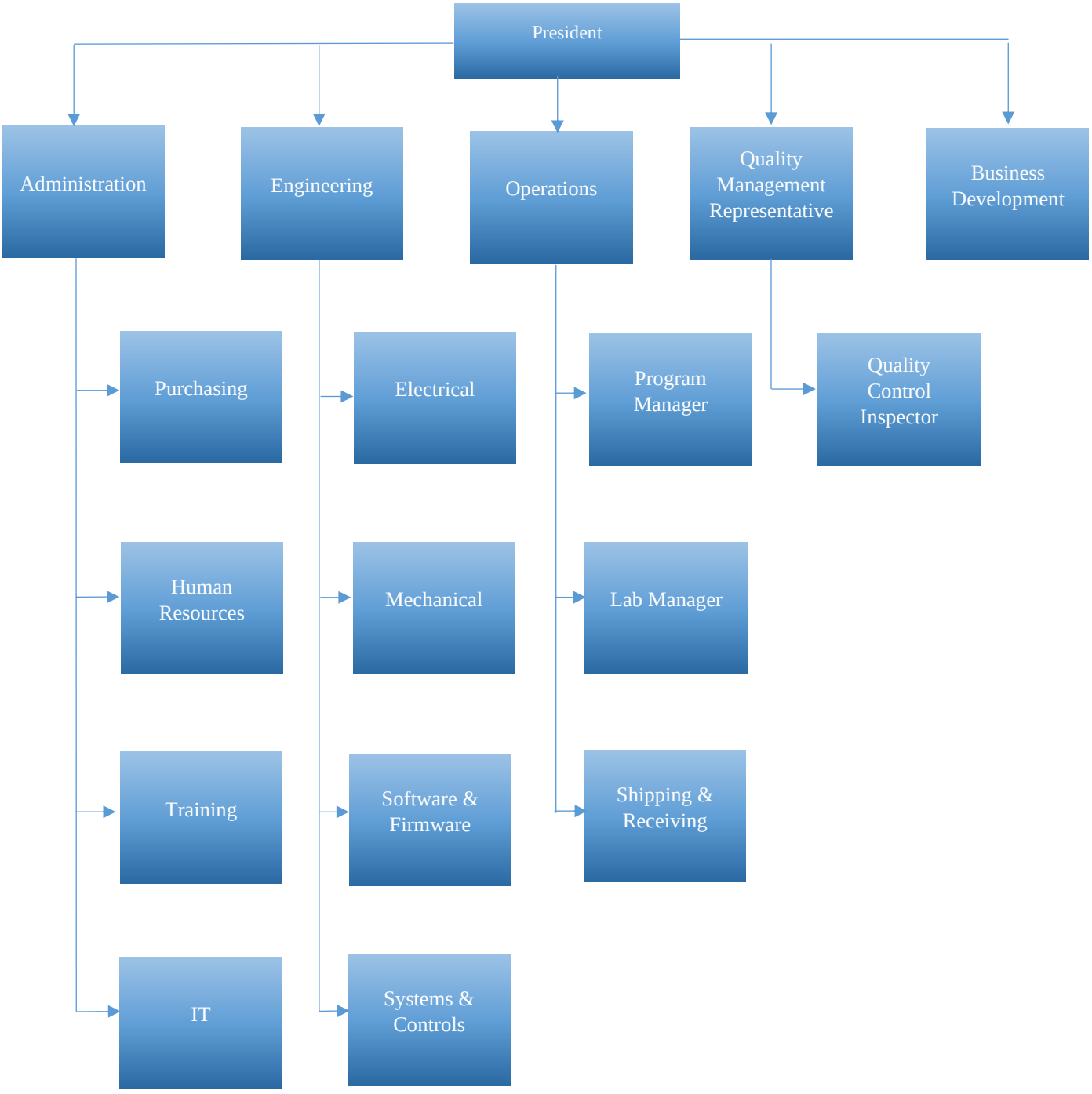
11.6. Organizational Chart



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11.7. QUALITY POLICY

West Coast Solutions is committed to being the leader in providing world class engineering experience and expertise regarding advanced technologies and electronics.

We strive to achieve and exceed the requirements of our interested parties by utilizing a robust quality management system and keeping an undivided focus on our customers' expectations.

We pledge to continuously improve our processes, services and Quality System to advance our organization.

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