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1 GENERAL

1.1. Index and Revision Status

The numbering of this Quality Manual directly corresponds to the numbering of ISO9001: 2000

This QM is only valid if all pages are at the same issue level as shown in D0001, Index Quality Manual.
Updates to this manual will be made by re-issuing the relevant section of this manual and adapting the issue level in the index.

1.2. Purpose and Scope

This QM documents TCM's quality system to demonstrate the company's ability to consistently provide products that meet customer and regulatory requirements. This manual establishes compliance with ISO 9001:2000. This QM applies to our production, sales, marketing, installation and servicing activities.

1.3. Exclusions

Where any requirement of ISO 9001:2000 cannot be applied due to the nature of our organization, its activities and products, they will be considered for exclusion.

An ISO 9001:2000 requirement may be excluded only when both of the following conditions are met.

a. The requirement must be with ISO9001 clause 7, Product Realization; and
b. The exclusion may not affect our ability, nor absolves us from the responsibility, to provide products that meet customers and applicable regulatory requirements.

The Quality Assurance Manager is responsible for identifying those requirements of ISO9001 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.

2 COMPANY BACKGROUND

2.1 Company Information

TCM is located at 2554 Commercial St. in San Diego, California, 92113.

3 DEFINITIONS AND CONVENTIONS

3.1 Definitions and terminology

All applicable standards:

- Where the term All Applicable Standards is used, in the QM, all listed in the Applicable Standards and Regulations section of this document apply.

Management Team

- President and Director from the Management Team. The Management Team has executive responsibility for performance of the business and quality system.

"XYZ Procedure"

- Parenthesized procedures and standards in the body of the QM identify reference documents supporting a particular element of the manual. These parentheses lead to corresponding sections of the QM, documents or to the "Documentation Master List" for external documents

3.2 Abbreviations

BPI Matrix – Business Performance Indicator Matrix
CAPA - Corrective and Prevention Action
QMS - Quality Management System

4 QUALITY MANAGEMENT SYSTEMS

4.1 General requirements

TCM has established, documented, implemented and maintains a QM System in accordance with the requirement of all applicable standards and regulations. TCM continually improves the effectiveness of its QMS.

Trans-Continental Manufacturing QMS:

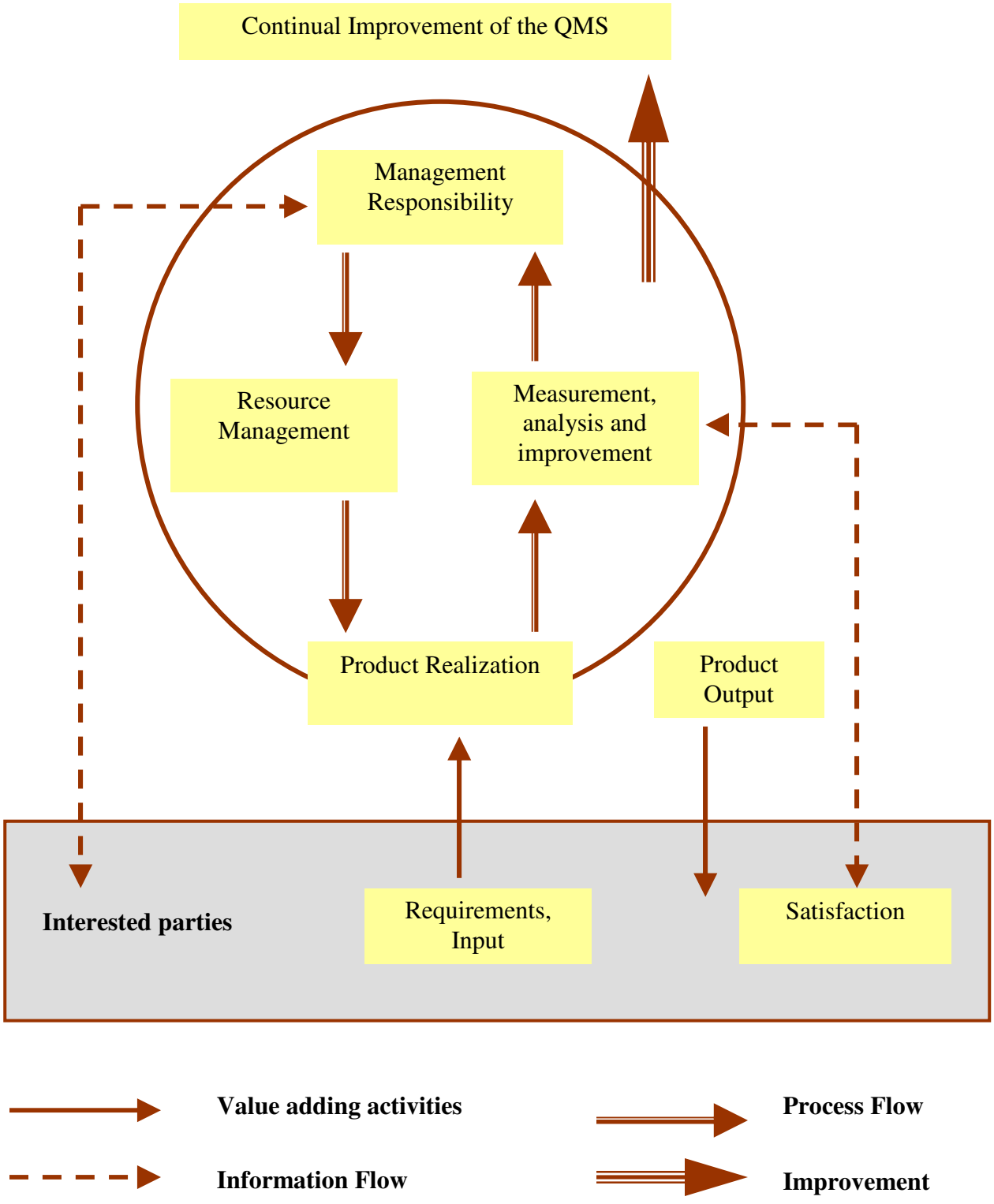
a. Identifies the processes needed for its operations and their application throughout the organization
b. Determines the sequence and interaction of these primary processes
c. Determines criteria and methods needed to ensure that both the operation and management of these processes are effective
d. Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
e. Ensures monitoring, measurement and analyses of these processes , and
f. Ensures implementation of actions necessary to achieve planned results and continual improvement of these processes.

TCM manages these processes in accordance with the requirements of all applicable standards.

Where any process, that affects product conformity with requirements are outsourced, TCM ensures management of such processes. Methods of management of such outsourced processes are identified within QMS per the "Supplier Evaluation Procedure".

Processes needed for the QMS referred to above include processes for management activities, provision of resources, product realization and measurement.

4.1.1 Figure 1, Model of a process-based QMS



4.2 Documentation requirements

4.1.2 General

TCM, Documentation includes

a. Documented statements of "Quality Policy" and quality objectives per the "BPI Matrix
b. This QM
c. Documented procedures required by all applicable standards
d. Documents needed by the organization to ensure the effective planning, operation and management of it's process, and
e. Records required by applicable standards per "Records Procedure."

Where the term documented procedure appears within this QM, the procedure is established, documented, implemented and maintained

The extent of the TCM QMS is based on:

a. The size of the organization and type of activities
b. The complexity of processes and their interactions, and
c. The competence of personnel per the "Training Procedure".

TCM maintains its documents on various media such as paper, electronic, optical etc.

4.1.3 Quality Manual

Trans-Continental Manufacturing has established and maintains this Quality Control Manual that includes:

a. The scope of the QMS, including details of justification for any exclusion per the application section of this Quality Control Manual.
b. Reference to the documented procedures established for the QMS, and
c. A description of the interaction between the processes of the QMS.

4.1.4 Management of Documents

Documents required by the QMS are managed per "Documentation Management Procedure". Records are a special type of document and are also managed per the "Records Procedure."

The "Documentation Management Procedure" is established to define the means needed to:

a. Approve documents for adequacy prior to issue
b. Review and update as necessary and re-approve documents
c. Ensure that changes and the current revision status of documents are identified.
d. Ensure that relevant versions of applicable documents are available at points of use
e. Ensure that documents remain legible and readily identifiable
f. Ensure that documents of external origin are identified and their distribution managed using the "Document Master List" and

g. Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.1.5 Management Of Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Mechanisms are established for records to remain legible, readily identifiable and retrievable. A documented "Records Procedure" is established to define the means needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Responsibility

Trans-Continental Manufacturing Management Team provides its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

a. Communication to the organization regarding the importance of meeting customer as well as statutory and regulatory requirements per the "Communication Procedure",
b. Establishing the "Quality Policy",
c. Ensuring that quality objectives are established per the "BPI Matrix"
d. Conducting management reviews per the "Management Review Procedure", and
e. Ensuring the availability or resources per the "Resource Management Procedure."

5.2 Customer Focus

Trans-Continental Manufacturing management team ensures that customer requirements are determined and fulfilled with the objective of enhancing customer satisfaction per the "Contract Review Procedure".

5.3 Quality Policy

Trans-Continental Manufacturing management team ensures that Trans-Continental Manufacturing quality policy is documented in the "Quality Policy" and it:

a. Is appropriate the purpose of Trans-Continental Manufacturing activities
b. Includes commitments to comply with requirements of all applicable standards and regulations and continually improve the effectiveness of the QMS,
c. Provides a framework for establishing and reviewing quality objective per the "Management Review Procedure"
d. Is communicated and understood within the organization per "Training Procedure" and "Communication Procedure", and

e. Is reviewed for continuing suitability per the "Management Review Procedure".

5.4 Quality System Planning

5.4.1 Quality Objectives

Trans-Continental Manufacturing Management Team ensures that quality objectives, including those needed to meet requirements for product, are established and documented for relevant functions and levels within the organization per the "Management Review Procedure" and the "BPI Matrix", and that Quality objectives are measurable and consistent with quality policy.

5.4.2 QMS Planning

Trans-Continental Manufacturing Management team ensures that:

a. The planning of the QMS is carried out in order to meet the requirements given in section 4.1 of this Quality Control Manual, as well as the quality objectives, and
b. The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

5.5 Organization and Communication

5.5.1 Responsibility and Authority

Trans-Continental Manufacturing Management Team ensures that the responsibility and authorities are defined and communicated within the organization per the "Resource Management Procedure" and the "Organization Chart".

5.5.2 Management Representative

Trans-Continental Manufacturing Management Team has appointed the Manger of Quality as management representative who, irrespective of other duties, has responsibility and authority for:

a. Ensuring that processes needed for the QMS are established, implemented and maintained
b. Reporting to Management Team on the performance of the QMS and any need for improvement per "Management Review Procedure". And
c. Ensuring the promotion of awareness to customer requirements throughout the organization per the "Communication Procedure".

Responsibility of the Management Representative also include liaison with external parties on matters relating to the QMS.

5.5.3 Internal Communication

Trans-Continental Manufacturing Management Team ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS per the "Communication Procedure".

5.6 Management review

5.6.1 General

Trans-Continental Manufacturing Management Team reviews the organization's QMS per the "Management Review Procedure". The management Team conducts these reviews on at least a quarterly basis to ensure continuing suitability, adequacy and effectiveness of the QMS. This review includes assessing opportunity for improvement and the need for changes to the QMS, including the quality policy and quality objectives. Records of management reviews are maintained per the "Records Procedure".

5.6.2 Review Input

The output from the management review, as a minimum, includes any decisions and actions related to:

a. Improvement of the effectiveness of the QMS and its processes.
b. Improvement of product related to customers' requirements, and
c. Resources needs.

6 RESOURCE MANAGEMENT

6.1 Provision resources

Trans-Continental Manufacturing management team determines and provides the resources per the "Resource Management Procedure" to:

a. Implement and maintain the QMS and continually improve its effectiveness, and
b. Enhance customer satisfaction by meeting customer requirements

6.2 Human resources and training

6.2.1 General

Trans-Continental Manufacturing management team ensures that personnel performing work that affects quality of component have the appropriate education, training, skills and experience per the "Resource Management Procedure" and the "Training Procedure."

6.2.2 Competence, Awareness, and Training

Trans-Continental Manufacturing

a. Determines the necessary competence of personnel performing work affecting component quality per the "Resource Management Procedure
b. Provides training or takes other actions to satisfy these needs per the "Training Procedure".
c. Evaluates the effectiveness of the actions taken per the "Resource Management Procedure".
d. Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives per the "Training Procedure", and
e. Maintains appropriate records of education, training, skills and experience per the "Resource Management Procedure" and the "Records Procedure".

6.3 Infrastructure and work environment

6.3.1 Infrastructure

Trans-Continental Manufacturing determines, provides and maintains the infrastructure needed to achieve conformity to product requirements per the "Infrastructure Procedure". Infrastructure includes, as applicable:

a. Buildings, workspace and associated utilities,
b. Process equipment, both hardware and software, and
c. Supporting services such as transport or communication

6.3.2 Work Environment

Trans-Continental Manufacturing has determined and manages the work environment needed to achieve conformity to product requirement per the "Infrastructure Procedure".

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

Trans-Continental Manufacturing has established and maintains documented procedures to ensure that the sequence of processes is conducted in a controlled manner. Planning of the realization processes is consistent with other requirements of the QMS. Plan of product realization determines the following:

a. Quality objectives and requirements for the product per the "Inspection Procedure"
b. The need to establish processes, documents, and provide resources specific to the product

c. Required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance per the "Validation Procedure" and the "Inspection Procedure", and
d. Records needed to provide evidence that the realization processes and resulting product fulfill requirements per "Records Procedure".

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

Trans-Continental Manufacturing determines:

a. Requirement specified by the customer, including the requirements for delivery and post-delivery activities per the "Contract Review Procedure",
b. Requirements not stated by the customer but necessary for specified or intended use, where known
c. Statutory and regulatory requirement related to the product and
d. Any additional requirements determined by the organization.

7.2.2 Review of requirement related to the product

Trans-Continental Manufacturing reviews the requirements related to the product per the "Contract Review Procedure". This review is conducted prior to Trans-Continental Manufacturing's commitment to supply a product to the customer. It relates to such activities as submission of tenders, acceptance of contracts or orders and acceptance of changes to contracts or orders. This review ensures that:

a. Product requirements are defined per the "Contract Review Procedure",
b. Contract or order requirement differing from those previously expresses are resolved and
c. Trans-Continental Manufacturing has the ability to meet the defined requirements

Records of the results of the review and actions arising from the review are maintained per the "Contract Review Procedure" and the "Record Procedure".

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Trans-Continental Manufacturing before acceptance per the "Contract Review Procedure."

Where the product requirements are changed, Trans-Continental Manufacturing ensures that the relevant documents are amended and that relevant personnel are made aware of the changed requirements per the "Contract Review Procedure".

7.3 Design

Trans-Continental Manufacturing can provide you with creative and cost-effective designs of parts tailored to your needs. Our long history of experience in manufacturing and design can help you design the most efficient part for what you want.

7.4 Purchasing

7.4.1 Purchasing Process

Trans-Continental Manufacturing ensures that purchased product conforms to specified purchase requirements per the "Inspection Procedure". The type and extent of control applied to the supplier and purchased product depends on the effect of the purchased product on subsequent product realization or the final product.
Trans-Continental Manufacturing evaluates and selects suppliers based on their ability to supply product in accordance with Trans-Continental Manufacturing's requirements per "Supplier Evaluation Procedure". Criteria for selection, evaluation and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained per the "Records Procedure".

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased per the "Purchasing Procedure". It includes, where appropriate:

a. Requirement for approval of product, procedures, processes and equipment
b. Requirements for qualification of personnel and
c. QMS requirements

Trans-Continental Manufacturing ensures the adequacy of specified purchase requirements prior to their communication to the supplier per the "Purchasing Procedure"

7.4.3 Verification or purchased product and/or services

Trans-Continental Manufacturing has established and implemented the inspection or other activities necessary for ensuring that purchased product meet specified purchased requirements per the "Inspection Procedure".

Where Trans-Continental Manufacturing or its customer intends to perform verification at the supplier's premises, Trans-Continental Manufacturing states the intended verification arrangements and methods of product release in the purchasing information per the "Purchasing Procedure".

7.5 Operation

7.5.1 Management of Production

Trans-Continental Manufacturing plans and carries out production under managed conditions per the "Production Realization Procedure' Controlled conditions includes, as applicable, the:

a. Availability of information that describes the characteristics of the product
b. Availability of work instructions, as necessary
c. Use of suitable equipment
d. Availability and use of monitoring and measuring devices
e. Implementation of monitoring and measurement, and
f. Implementation of release, delivery and post-delivery activities.

7.5.2 Validation of Processes for production

Trans-Continental Manufacturing validates any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement per the "Validation Procedure". This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

Trans-Continental Manufacturing has established arrangements for these processes, including, as applicable;

a. Defined criteria for review and approval of the processes
b. Approval of equipment and qualification of personnel
c. Use of specific methods and procedures
d. Requirements for the records per the "Records Procedure", and
e. Re-validation

7.5.3 Identification and Traceability

Trans-Continental Manufacturing, where appropriate, identifies the product by suitable means throughout production realization per the "Production Identification Procedure".

Trans-Continental Manufacturing identifies the products status with respect to monitoring and measurement requirements

Where traceability is required, Trans-Continental Manufacturing established means and records the unique identification of the product per the "Product Identification Procedure"

7.5.4 Customer Property

Trans-Continental Manufacturing exercises care with customer property while it is under the organization's management or being used by the organization. Trans-Continental Manufacturing identifies, verifies, protects and safeguards customer property provided for use of incorporation into the product per "Customer Property Procedure". If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer per the "CAPA procedure". Records of such reports are maintained per "Records Procedure".

7.5.5 Preservation of Product

Trans-Continental Manufacturing preserves the conformity of product during internal processing and delivery to the intended destination per the "Material Handling Procedure." This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Inspection, measurement and test equipment

Trans-Continental Manufacturing determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product of determined requirement per the "Measuring Equipment Procedure".

Trans-Continental Manufacturing has established process to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment is:

a. Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification is recorded.
b. Adjusted or re-adjusted as necessary
c. Identified with its calibration status
d. Safeguard from adjustments that would invalidate the measurement result, and
e. Protected from damage and deterioration during handling, maintenance and storage.

Trans-Continental Manufacturing assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements per the "Non-Conformity Procedure". Trans-Continental Manufacturing takes appropriate action on the equipment and product affected. Records of the results of calibration and verification are maintained per the "Records Procedure". When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed per the "Validation Procedure". This is undertaken prior to initial use and re-confirmed as necessary.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Trans-Continental Manufacturing has established and maintains a documented continuous improvement procedure to define, plan, and implement the measurement and monitoring activities needed to assure conformity and achieve improvement. This includes the determination of the need for, and use of, applicable methodologies including statistical methods.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Trans-Continental Manufacturing has established and maintains a documented continuous improvement procedure to define, plan, and implement the measurement and monitoring activities needed to assure conformity and achieve improvement. This includes the determination of the need for, and use of, applicable methodologies including statistical methods.

8.2.2 Internal Audits

Trans-Continental Manufacturing conducts internal audits at planned intervals per the "Audit Procedure" to determine whether the QMS:

a. Conforms to the planned arrangements, to the requirements of all applicable standard and QMS requirements established by Trans-Continental Manufacturing, and
b. Is effectively implemented and maintained.

The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records are defined in a documented "Audit Procedure".

The management responsible for the area audited ensures that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include the verification of the actions taken and reporting of verification result per the "CAPA Procedure".

8.2.3 Monitoring and measurement of processes

Trans-Continental Manufacturing applies suitable methods for monitoring and, where applicable, measurement of QMS process. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product per the "CAPA Procedure".

8.2.4 Monitoring and measurement of product

Trans-Continental Manufacturing monitors and measure the characteristics of the product verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements per the “Inspection Procedure”, and the “CAPA Procedure”.

Evidence of conformity with the acceptance criteria is maintained per the “Records Procedure”.

Product release does not proceed until the planned arrangements have been satisfactorily completed per the “Inspection Procedure”, unless otherwise approved by a relevant authority per the “CAPA Procedure”, where applicable by the customer per the “Contract Review Procedure”.

8.3 Control of non-conforming product or services

Trans-Continental Manufacturing has established and maintains a documented “Non-Conformity Procedure” to ensure that products that do not meet requirements are identified and corrective actions taken to prevent recurrence, unintended use or delivery. This process identifies related responsibilities and authorities for dealing with non-conforming products.

Trans-Continental Manufacturing processes non-conforming products by one of more of the following ways:

a. Taking action to eliminate the detected non-conformity before delivery
b. Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer, and
c. Taking action to preclude its original intended use or application

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained are maintained per the “Records Procedure”.

When non-conforming product is detected after delivery or use has started, Trans-Continental Manufacturing takes action appropriate to the effects, or potential effects, of the non-conformity per the “CAPA Procedure.”

8.4 Analysis of quality information

Trans-Continental Manufacturing has established and maintains a documented “Management Review Procedure” and “Data Analysis Procedure” to collect and analyze appropriate data to determine the suitability and effectiveness of the QMS to evaluate the areas where continual improvements of effectiveness of the WMS can be made. This includes data generated by monitoring and measurement and other relevant sources.
Trans-Continental Manufacturing analyzes these data to provide information related to:

a. Customer satisfaction and the “CAPA Procedure”

b. Conformity to product requirements per the “Product Realization Procedure” and the “CAPA Procedure”
c. Characteristics and trends of process and products including opportunities for preventive action per the “CAPA Procedure”, and
d. Suppliers per the “Supplier Evaluation Procedure”

8.5 Continual improvement

8.5.1 Continual Improvement

9 Trans-Continental Manufacturing has established and maintains documented procedures to continually improve its QMS through the use of the:

a. Quality Policy
b. Quality Objectives
c. Audit results per the “Audit Procedure”
d. Analysis of data per the “Data Analysis Procedure”
e. Corrective and preventive actions per the “CAPA Procedure” and
f. Management Review Procedure

8.5.2 Corrective Action

Trans-Continental Manufacturing has established and maintains a documented “CAPA Procedure” to eliminate the causes of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered. The “CAPA Procedure” defines requirements for:

a. Reviewing non-conformities, including customer complaints
b. Determining the causes of non-conformities
c. Evaluating of the need for action to ensure that non-conformities do not recur
d. Determining and implementing action needed
e. Records of the results of action taken, and
f. Reviewing corrective action taken

9 PROCEDURE INDEX