US DIGITAL

# Quality Manual

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# 1.0 Introduction

US Digital precision position sensors and inclinometers are used in a wide variety of places: stepper motors, concentrated solar and solar thermal systems, manufacturing machinery, medical devices, and many other automation applications requiring position feedback.

US Digital is in the business of solving motion control problems by employing the best minds with the most advanced manufacturing facility and persistent attention to detail in the industry. Products are designed, manufactured, supported and shipped directly from the US Digital site in Vancouver, WA.

US Digital developed and implemented a Quality Management System to better satisfy the needs of its customers and to create a responsive, flexible system that enables us to achieve high quality and efficiency. Utilizing this Quality Management System, US Digital intends to follow a path of continuous improvement aligned with our company values.

The primary philosophy is to design, manufacture and quickly deliver the most practical motion control components world-wide.

The objective of the Quality Manual is to define and document the Quality Management System of US Digital compliant with ISO 9001:2015. The Quality Manual will be reviewed at least once per year, the review committee is comprised, at a minimum, of:

- Quality Manager

The guidelines and procedures outlined in this manual will be adhered to at all times by US Digital personnel. It is the responsibility of every employee to ensure that all products designed, manufactured, assembled and shipped meet the standards and specifications of our customers.

## 1.1 Quality Manual Distribution

The latest approved revision of the Quality Manual is available to employees on the company internal network.

Copies of the Quality Manual are provided to customers and all other interested parties on request, and through access online at usdigital.com.

Any printed copy will be uncontrolled and shall be kept as a reference document only.

# 2.0 Scope of the Quality Management System

US Digital Corporation maintains a documented Quality Management System designed and implemented to ensure conformance to the entire ISO 9001:2015 standard in the manufacturing, design and servicing of motion control products in a variety of applications for multiple industries. Where required by contract or law, US Digital Corporation is compliant with regulatory and statutory requirements.

The system applies to all employees and is supported and endorsed by all management of US Digital Corporation. Its entire content is primarily focused toward meeting the expectations and needs of our customers and a road map to pursue continuous improvement in our products and services.

It is a System used daily, creating a framework for clearly defining the control of materials, processes and verification activities, thus providing our customers with confidence in US Digital Corporation products and ensuring processes are performed in a well-defined and controlled environment.

# 3.0 References

ISO 9001:2015 International Organization of Standards Document

# 4.0 Context of the Organization

## 4.1 Understanding the Organization and its Context

Annually, at the Management Review Meeting US Digital Corporation reviews both the Internal and External issues that are relevant to its purpose and strategic direction, and that can affect its ability to achieve its objectives. The issues identified are the following:

a. US Digital Corporation Culture and maintaining employee morale
b. Ensuring training to meet changing technology and manufacturing methods
c. Growing the organization in a profitable way
d. Working to facilitate customers' success
e. Responding to changes in the economy and in industry
f. Responding to Government regulations and changes.
g. Responding to Environmental Compliance Requirements and changes

US Digital Corporation monitors and reviews information about these internal and external issues primarily through the Company Metrics and the Management Review Process.

US Digital Corporation recognizes that these issues could change over time. When changes do occur the impact on the company and the Management System are assessed and changes are planned and made accordingly.

## 4.2 Understanding the Needs and Expectations of Interested Parties

Annually, at the Management Review Meeting**.** US Digital reviews the needs of interested parties that are relevant to its purpose and its strategic direction and that can affect its ability to achieve its mission and values.

| Interested Party | Impacts/Expectations |
|---|---|
| Customer | Quality, Delivery of Products, Environmental and Regulatory Compliance. |
| Owners/Executive Management | Sustain Profitability<br>Strategic Growth |
| US Digital Employees | Good work environment<br>US Digital Culture<br>Employee Morale<br>Fair compensation and benefits |
| Suppliers and Partners | Mutual Benefit and continuity |
| Government, Regulatory and Environmental Agencies | Compliance to Environmental Regulations<br>Required Regulatory Requirements |

US Digital Corporation recognizes that these interested parties and needs could change over time. When changes do occur, the impact on the company and the Management System are assessed and changes are planned and made accordingly.

## 4.3 Determining the Scope of the Quality Management System

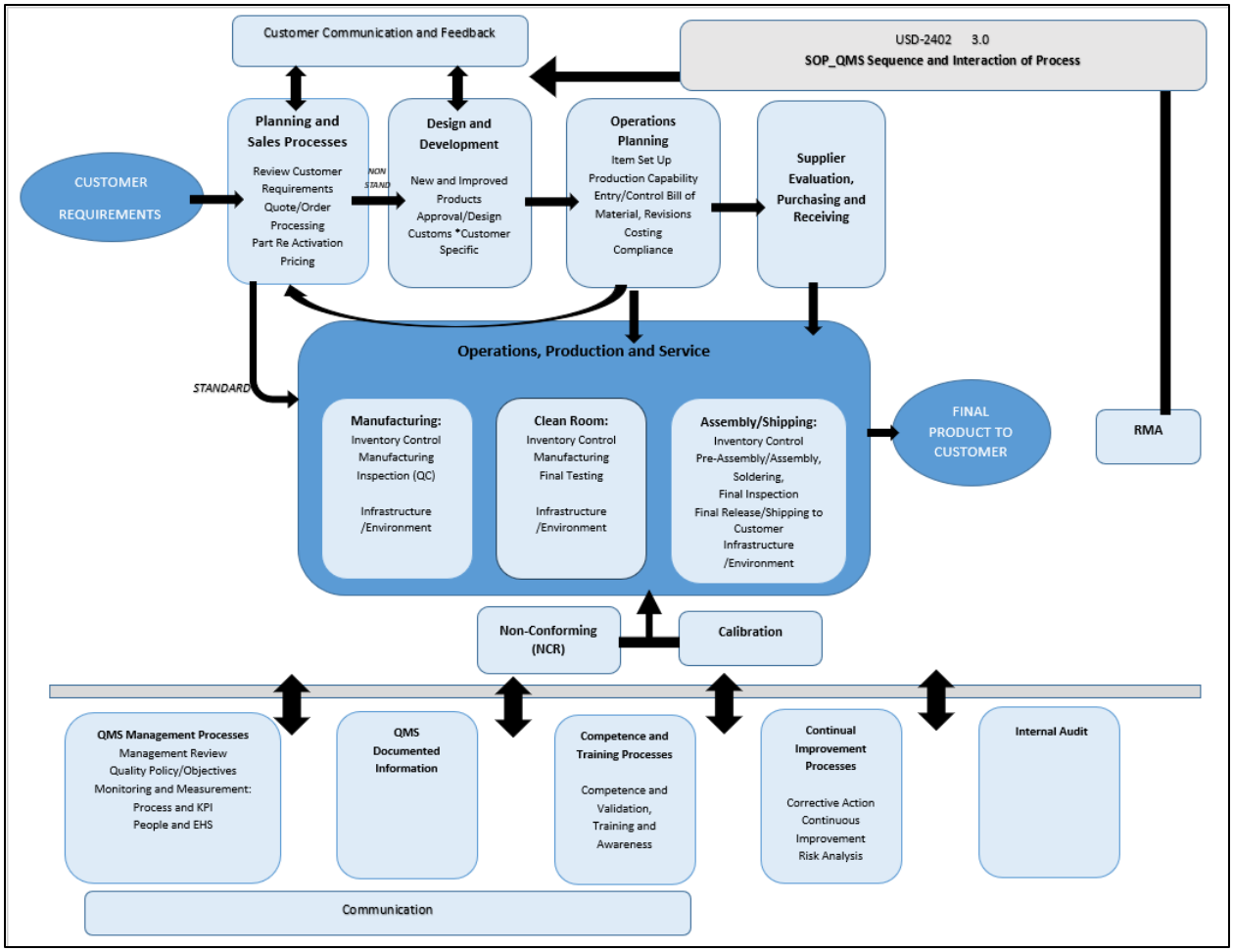
The scope of the Management System is documented in this manual**.** When documenting the scope, US Digital considers the relevant internal and external issues, the requirements of relevant interested parties and the products and services it provides.

Annually, as part of the Management Review Meeting and the Internal Audit Process US Digital ensures that the documented scope of the Management System is suitable and appropriate.

## 4.4 Quality Management System and Its Processes

## 4.4.1 Process Identification and Responsibility

US Digital Corporation has adopted a process approach for its management system and determined the process needed for the Management System. The sequence and interaction of these processes is documented per **USD-2402 SOP_QMS_Sequence and Interaction of Process. See below:**




Workflow Diagrams have been documented for core business processes and identify the following:

a) The process inputs and deliverables expected for the process
b) The criteria, methods, and if applicable key performance indicators needed to evaluate and ensure the effective operation and control of the process

The following is a list of Workflow Diagrams:

| USD Document Number | Title |
|---|---|
| USD-4852 | Workflow_ Planning and Sales Process Standard_USD-4852 |
| USD-5371 | Workflow _ Training and Competence Process |
| USD-5423 | Workflow_Purchasing and Receiving |
| USD-5637 | QMS Support, Structure and Documented Information Policy |
| USD-5638 | Workflow_Design and Development |
| USD-5639 | Workflow_RMA |
| USD-5744 | Workflow_Calibration |
| USD-5745 | Workflow_Customer Communication |

| | |
|---|---|
| USD-5806 | Workflow_ContinuousImprovement |
| USD-5808 | Workflow_Operations Assembly and Shipping |
| USD-5812 | Workflow_SupplierEvaluation |
| USD-5819 | Workflow_Internal Audit |
| USD-5820 | Worfklow_QMS Management |
| USD-5821 | Workflow_NonConforming Product |
| USD-5822 | Workflow_Manufacturing |
| USD-6295 | Workflow_Operations Planning |
| USD-6659 | Workflow_Operations_Cleanroom |

US Digital maintains **USD-6294 QMS Matrix** as a tool to identify any gaps in system, and safeguard that all ISO 9001:2015 requirements are addressed within US Digital Quality Management System Processes (See **USD-2402 Sequence and Interaction**)

Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes and each process may be supported by other activities, such as tasks or sub-processes.

The responsibility to effectively implement the Management System processes necessary to achieve the company Quality Policy and overall strategic plan is held by the Process Owners.

Each Process Owner, for their assigned process, has the responsibility and authority to:

a) Determine the extent of control required on their process. The degree of control is dependent upon the methods used, skills needed and the training required of personnel involved in performing the activity.
b) Ensure the processes needed for the Management System are established, implemented, and maintained.
c) Report to the Management Team the performance of the Management System and any need for improvement.
d) Ensure the promotion of awareness of management system and contractual requirements throughout the organization.

# 5.0 Leadership

## 5.1 Leadership and Commitment

### 5.1.1. General

The dedication of the executive management team in establishing, implementing and improving the Quality System is proven through US Digitals quality policy and outstanding product quality. The commitment is demonstrated through:

a) taking accountability of the effectiveness of the management system;
b) ensuring that the **Quality Policy** and quality objectives are established for the management system and are compatible with the strategic direction and the context of

the organization;
c) ensuring that the quality policy is communicated, understood and applied within the organization;
d) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate
e) promoting awareness of the process approach;
f) ensuring that the resources needed for the management system are available;
g) communicating the importance of effective quality management and of conforming to the management system requirements;
h) ensuring that the management system achieves its intended results;
i) engaging, directing and supporting persons to contribute to the effectiveness of the management system;
j) promoting continual improvement;
k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

### 5.1.2 Customer Focus

US Digital adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction. This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained.

## 5.2 Quality Policy

US Digital has developed a quality policy creating a standard when creating measurable quality objectives by executive management and the company as a whole.

**US Digital Quality Policy is:**

"US Digital strives to provide customers with consistently high quality products with little or no lead time. Processes are continuously analyzed for improvement opportunities that allow us to exceed our customers' expectations today and into the future."

The **Quality Policy** is released as a standalone document as well, and is communicated and implemented throughout the organization.

The policy is maintained through the system of internal audits, corrective and continuous improvement actions, and is reviewed for continuing suitability through management reviews. The policy is supported through the continual improvement of the quality system. **See USD-2441 SOP_Quality Policy and Objectives**

### 5.2.2 Communicating the quality policy

US Digital Management team ensures the quality policy is available and communicated to all employees through various ways of internal communication listed in this manual.

## 5.3 Organizational roles, responsibilities and authorities

US Digital has assigned responsibilities and authorities for all relevant roles in the company. Departments, groups and functions within the company, and their interrelations are defined in the organizational chart. The Human Resources department maintains job descriptions for each function within the Quality Management System.

The US Digital Executive and Management team accepts responsibility and authority for:

a) ensuring that the management system conforms to applicable standards;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the management system
d) providing opportunities for improvement for the management system;
e) ensuring the promotion of customer focus throughout the organization;
f) ensuring that the integrity of the management system is maintained when changes are planned and implemented.

# 6.0 Planning

## 6.1 Actions to address risks and opportunities

The ISO 9001:2015 International Standard requires the organization to understand its context and determine the risks and opportunities that need to be addressed.

US Digital considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of Management defining Context of the Organization as well as throughout all other activities of the Quality Management System.

In US Digitals approach to Risk and Opportunity, the definitions are “uncertainty” as neutral, but defines “risk” as a negative effect of uncertainty, and “opportunity” as a positive effect of uncertainty. US Digital has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application

Appropriate implementation of planning processes are reviewed through process Key Performance Indicators (KPIs) and at time of Internal Audit.

## 6.2. Quality Objectives and planning to achieve them

### 6.2.1 Establishing Quality Objectives

The strategic Quality Objectives of US Digital Quality Policy are as follows:

1. High Quality Products
2. On Time Shipping
3. Customer Satisfaction

They are established by the management at US Digital, with final approval by the Owner/CEO of US Digital. The Objectives are reviewed and maintained as part of the Management Review process. These objectives flow down to departments and functions, and they are developed to be measurable at relevant functions within the organization.

Note: Key Performance Indicators (KPI) are process specific and should be used to support Quality Objectives.

### 6.2.2 Planning and Achievement Quality Objectives

US Digital has determined that the responsibility of reporting, analysis and review is that of the process owner. For more information on how US Digital plans to achieve its quality objectives and KPIs.

## 6.3 Planning of Changes

The planning process considers the continual improvement of the quality management system. When US Digital determines the need for changes to the management system or its processes, the changes will be planned and implemented based on the extent of the change and effect to the following:

a) the purpose of the changes and their potential consequences
b) the integrity of the Quality Management System
c) The availability of resources
d) The allocation or reallocation of responsibilities and authorities

US Digital uses several methods to determine type of control necessary when planning changes. Those guidelines are in the Workflow Diagram for Continuous Improvement and are proportionate to the potential impact on the conformity of products and services.

Prior to closing change activities, such as continuous improvement or corrective actions, effectiveness will be evaluated. Summary of the changes will be monitored through metrics and Internal Audits and reviewed at time of Management Review meetings.

Product changes are controlled through the Engineering Design and Development Process. Production Changes are controlled through the Operations Planning Process.

# 7.0 Support

## 7.1 Resources

### 7.1.1 General

US Digital determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness
b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to other interested parties.

Resources and resource allocations are assessed during management reviews.

### 7.1.2 People

US Digital has determined and assigned process owners with the responsibility to implement and maintain the effective operation and control of processes. Control includes implementing and maintaining KPIs where required, identifying required competencies and training, and to determine the extent and control to which documented information is required.

Management works with Human Resources to ensure that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

US Digital has designated the Quality Manager to facilitate activities and communication for the Quality Management System.

### 7.1.3 Infrastructure

US Digital management provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) Buildings, workspace and associated utilities,
b) Process equipment (both hardware and software),
c) Transportation Resources and
d) Information and Communication Technology.

US Digital deploys industry standard processes to ensure customer and business data is protected and compliant with regulatory requirements. Information Technology processes control the “backing up” of data for record controls and retrieval **See USD-3753 SOP_Data Backup Policy** for more information, internal (US Digital website) and external security (payment processing).

Equipment is validated and maintained per procedures **USD-5738 SOP_Calibration** and/or **USD-2344 SOP_MachineMaintenance.**

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification.

### 7.1.3.1 Preventative Maintenance

Preventive Maintenance will maintain, and prevent the failure of US Digital equipment before it actually occurs. This ensures equipment reliability, therefore warranting product quality stability.

Maintenance will be performed in any case where equipment requires repair out of the planned preventive maintenance procedure.

Preventive Maintenance is a schedule of planned maintenance actions aimed at the prevention of breakdowns and failures. It is designed to preserve and enhance equipment reliability by replacing worn components before they actually fail. See procedure **USD-2344 SOP_MachineMaintenance** for further detail

## 7.1.4 Environment for the operation of processes

US Digital strives to provide a safe and positive environment for employees. US Digital has a published Employee handbook with policies around social factors such as anti-harassment, paid time-off and benefits, and lists employee rights and responsibilities to ensure the desired environment and culture is maintained.

US Digital recognizes the importance of an employee's psychological health. It is this reason USD has an in house gym, as well as an Employee Assistance Program (EAP) service available to all employees.

US Digital provides a clean, safe and well-lit working environment. The management team manages the work environment needed to achieve the conformity to product requirements.

## 7.1.5 Monitoring and measuring resources

US Digital has determined the devices or software that are necessary to ensure valid and reliable results when monitoring or measuring is used to verify conformity to products/process.

US Digital ensures that calibration is carried out to ensure equipment and/or software:

a) is suitable for the specific type of activity being undertaken,
b) be 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 shall be recorded;
c) be adjusted or re-adjusted as necessary;
d) be identified to enable calibration status to be determined;
e) be safeguarded from adjustments that would invalidate the measurement result;
f) be protected from damage and deterioration during handling, maintenance and storage.

See procedure **USD-5738 SOP_Calibration**.

## 7.1.6 Organizational knowledge

US Digital also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This is determined by process owners' and US Digital management considering and controlling past, existing and additional knowledge and taking into account the organization's context, including size and complexity, the risks and opportunities needed to be addressed, and the need for accessibility of knowledge.

This may include knowledge and information obtained from:

a) Internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property; or as an output from a corrective or continuous improvement action.
b) External sources such as standards, consultants, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary. Knowledge may be documented in system notes, procedure documents, New Hire training material, or may utilize a formalized training approach with appropriate training material. More information is held in the Workflow Diagram for Training and Competency.

When addressing changing needs and trends, US Digital shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge. Opportunities may come from established processes such as corrective or continual improvement actions, and Internal Audits.

Appropriate Identification and implementation of organizational knowledge is reviewed at time of Internal Audit.

## 7.2 Competence

The management team ensures that necessary competencies shall be determined for personnel performing activities affecting product quality, and training shall be provided.

a) Consideration of competency may also be associated with the subjects addressed in this Quality Manual in the following :
    - 5.3 Organizational Roles
    - 7.1.2 People
    - 7.1.6 Organizational Knowledge
    - 7.3 Awareness

## 7.2.1 Determination of Competence

a) The personnel/function required competency can be determined from respective Job Descriptions (JD). Job Description details the qualifications needed for employees performing work under their control that affects the performance and effectiveness of the quality management system. Competency is also determined through the hiring process and review of job requirements and recorded is US Digital SharePoint.
    - Competency of employees are also important to ensure process control as it is defined.

## 7.2.2 Maintaining the competency

a) Job Description describes the key functions in addition to education, experience and related skill.
b) Functional skills may be achieved by the training attended to demonstrate appropriate expertise to provide effectiveness of QMS.
c) Where training is required, evaluation of effectiveness to measure the positive impact after the personnel attended the training.
d) Updating job description's as necessary
e) Retain appropriate documented information such as Personnel Files, and/or SharePoint Records for each employee containing objective evidence as to education, training, skills and experience.

During the Management Review meeting the training processes shall be evaluated for its effectiveness and training needs will be reviewed, as well as the actions taken to improve process. Continuous evaluations of the effectiveness of training shall be performed during internal audits

Competency Requirements, Training and Records provides the guidelines to carry out and meet the requirements of the ISO 9001:2015 standard.

## 7.3 Awareness

Managers ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives through training and other types of communication.

Individual employee QMS Process Awareness, and their impact on Quality Management System, is made initially, at the time of New Hire Training.

Ongoing Awareness, Training and subsequent communication are completed through multiple activities and ensure that staff are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the management system, including the benefits of improved performance;
d) The implications of not conforming to the management system requirements.

## 7.4 Communication

The US Digital Management team ensures internal communication takes place regarding the effectiveness of the management system and the quality policy.

Internal communication methods include (modify as appropriate):

| To Whom: | By Who: | Method | What | When |
|---|---|---|---|---|
| Employees | Process Owners | Verbal/Email | Corrective and improvement action processes to report nonconformities or suggestions for improvement | As Required |
| Employees | Managers, Supervisors | Meetings - Scheduled or Ad Hoc) | Discussions of aspects of QMS, Effectiveness and Impact. Corrective Actions/Continuous Improvements. Assignment and Review of Tasks | As Required |
| Management, Process Owners and Audit Teams | Internal Auditors | Audit Meetings | Results of Internal Audit's and actions required. | Each Process Internal Audit |
| Employees | Executive management | Regular Company Meetings with All Employees (Company Lunches) | Status of USD, Improvement Activities, Updates, and Information | Quarterly |
| Employee | Employee | Internal Emails | Information, Tasks, updates to processes or documents. SharePoint notifications. | As Required |
| Employee | Quality Manager | Posted Information (Paper or Electronic Screens) | Quality Policy, Quality Objectives and Status | Updated at new version. Sales reported real time, Objectives Monthly. |
| Employees - All | Managers, Supervisors | QMS Training/Meeting | Quality Policy, Status of QMS, Audit Information, Employee Feedback | Annually |
| External Parties/Employees | Quality Manager | Quality Manual | Quality Policy, and other Information about US Digital Quality Management System | As Required *New Hire Required |

## 7.5 Documented information

The management system documentation includes both documents and records. ISO 9001:2015 standard uses the term “documented information”; US Digital continues to use the standards terms “document” and “record” to avoid confusion. In this context the terms are defined by US Digital as

Document – written information used to describe how an activity is done
Record – captured evidence of an activity having been done

See **USD-5637 QMS Support, Structure and Documented Information Policy** on instruction of document and record control. Master Documented Information List located in SharePoint stores controls specific to types of Document and Records US Digital maintains.

# 8.0 Operation

## 8.1 Operational planning and control

US Digital defines the expectation and implements controls for each of our Quality Management System processes. The planning of controls is required to ensure consistent acceptability of products and services. Planning processes include the definition of quality objectives, development for required processes, establishment for appropriate verification programs and the requirement for records necessary to demonstrate the process and products conform to the intended requirements. Operational planning and control is required prior to new and/or revised products or processes being implemented. During the planning phase, management with the input of their teams will identify:

a) Quality objectives and requirements for the product.
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 the criteria for product acceptance.
d) Records needed to provide evidence that the realization processes and resulting product meet requirements.

Evidence of the planning is the procedures, records, and measurements currently in place. Product realization records are maintained in the US Digital business systems (ERP and Intranet) and company server.

Specific to the planning of product realization, US Digital maintains process that are consistent with requirements of the management system. US Digital refers to the planning of product realization process, with scope of activities post-design and development and pre-production, as Operations Planning, The process encompasses the above requirements along with other necessary components of operations such as item set up, compliance status, bill of material set up, along with resource allocation among other things. See **USD-6295 Workflow_Operations Planning** for more information.

## 8.2 Determination of requirements for products and services

## 8.2.1 Customer communication

US Digital has implemented effective communication with customers in relation to:

a) providing information relating to products and services;
b) handling inquiries, contracts or orders, including changes;

See **USD-5745 Workflow_Customer Communication and Feedback** for further detail on US Digitals process for communication, and the management of customer feedback

## 8.2.2 Determination of requirements related to products and services

US Digital determines:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities.
b) Requirements not stated by the customer but necessary for product realization.
c) Statutory and regulatory requirements related to the product.
d) Any additional requirements determined by the organization.

See **USD-4852 Workflow_Planning and Sales Process** for further details on US Digitals review and decision, and change processes around product and services.

## 8.2.3. Review of requirements related to products and services

US Digital reviews the requirements related to the product. This review is conducted prior to its commitment to supply product to the customer.

Each contract or order is reviewed by US Digital to ensure that:

a) Product requirements are adequately defined.
b) Differences between order requirements and quotations are resolved.
c) US Digital has the capacity to meet the defined requirements stated on the contracts or orders.

## 8.2.4 Changes to requirements for products and services

Where amendments to sales orders are required, these requests for changes are reviewed. If request is approved, the relevant documents are amended and customers, as well as relevant personnel, are made aware of the changed requirements. If US Digital cannot fulfill the request, communication is given to the customer and further actions may be taken to assist customer. Records and actions arising from the review and any new requirements for the order are maintained.

## 8.3 Design and development of products and services

## 8.3.1 General

The engineering team is responsible for controlling, verifying, reviewing and ensuring that designed products meet specified requirements. See procedure **USD-2466 SOP_Engineering_DesignAndDevelopment.**

## 8.3.2 Design and development planning

For each engineering product, a Design and Development Plan is documented for new product using a New Product Information (NPI) fact sheet, or an already released product using an

Engineering Change Request (ECR). Design and Development documentation is updated as the design evolves. The design and development plan ensures that the following is established:

a) The design development stages
b) The review and verification are appropriate to the design and development stage
c) The responsibilities and authorities for the design and development project

After requirements have been reviewed, a lead engineer from each relevant department (electrical, software or mechanical) is assigned to the product. Additional engineers may be assigned as needed. The lead engineers work together and are responsible for designing and implementing the product, verification of the design to requirements, modifying the design if needed and testing.

Identification of technical interfaces between Departments that provide input into the design and development process, support design and development reviews, and approvals are defined during design and development planning.

## 8.3.3 Design and development Inputs

The design and development inputs, at a minimum, shall include:

a) Functional and performance requirements
b) Applicable statutory and regulatory requirements
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development

The design and development inputs are documented as appropriate.

Incomplete, ambiguous, or conflicting design input requirements are resolved with the originators of the design or specifications.

## 8.3.4 Design and development controls

At suitable stages, the design team includes all affected departments when reviewing the design and development of the product. All participants discuss if the design meets requirements and identify if there are any issues or risks associated with design along with possible solutions. The design and development verification and validation activities are performed in accordance with the design and development plan.

Design verification consists of ensuring the design and development input requirements meet the design and development output requirements. The design and development verification activity may include:

a) Performing design and development reviews;
b) Comparing the design with a similar proven design;
c) Planned testing and demonstrations;
d) Reviewing the design and development-stage documents before release

Validation ensures that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, the validation is completed prior to the delivery or implementation of the product. When customer validation is appropriate, feedback will be given and any actions arising from review of feedback will be recorded.

Design and Development verification and validation measures are identified and recorded within the appropriate design and development documents

## 8.3.5 Design and development outputs

Design and development outputs shall be provided in a form that enables verification against the design and development input, acceptable design outputs with Drawings, Specifications, Test Procedures, or Processes. The outputs shall be listed either on the ECR or final test documentation/records.

Design Output documents are reviewed by all affected groups within US Digital to establish, as applicable:

a) Meet the input requirements for design and development;
b) Provide appropriate information for purchasing, production and for service provision;
c) Design and development outputs contain or make reference to acceptance criteria;
d) Design and development outputs identify those characteristics of the design that are crucial to the safe and proper function of the product.

## 8.3.6 Design and development changes

All design and development changes are identified and documented within the ECR.

All design and development changes are reviewed, verified and validated, as appropriate, for adequacy. Incomplete, ambiguous, or conflicting design and development changes are resolved with the originators of the change before implementation

## 8.4 Control of externally provided products and services

## 8.4.1 General

US Digital includes procedures that define methodologies for the control of externally provided products and services, addressing all forms of external provision, whether it is by purchasing from a supplier, or through an arrangement with an associated company.

US Digital has documented procedures to support these requirements, see **USD-6058 SOP_Purchasing Operating Procedures**

## 8.4.2 Type and extent of control of external provision

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements (Risk-based approach),
b) the degree to which the control for the process is shared,
c) the capability of achieving the necessary control through the purchasing contract requirements.

## 8.4.3 Information for external providers

US Digital ensures that purchased products and services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent on the effect on subsequent product realization or the final product. US Digital evaluates and selects suppliers based on their ability to supply product and service in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products and services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not providing conforming products or services may be requested to conduct formal corrective action.

## 8.5 Production and service provision

## 8.5.1 Control of production and service provision

US Digital identifies and plans the production for executing control on the operations. Controlled conditions shall include the following:

a) The availability of information that describes the characteristics of the products to be produced, the services to be provided, or the activities to be performed, and the results to be achieved.
    - Documents relating to the process such as Production Work Instructions, Inspection Procedures, Bill of Materials, will be reviewed, verified and approved according to the appropriate US Digital Documented Information standard operating procedure to ensure it meets requirements and has appropriate information.
b) The availability of and use of suitable monitoring and measuring equipment.
    - Equipment that is required to be used by process will be maintained at periodic intervals and follow appropriate Maintenance and/or Calibration procedures recorded.
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met.

- Processes will be performed in accordance with approved work instruction that has been properly qualified in accordance with validation and inspection procedures.
- Nonconformance's' follow the nonconforming process. See procedure **USD-2345 SOP_NonConforming Procedure.** See Workflow Diagrams from Manufacturing and Assembly, as well as Quality Procedure for more information.

d) The use of suitable infrastructure and environment for the operation of processes.
e) The appointment of competent persons, including any required qualification.
f) The validation, and periodic revalidation, of the ability to achieve planning results for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.
    - Processes will be revalidated by US Digital on an as-needed basis, where process or process conformance data indicates the need exists. A Corrective or Preventative Action record will be used to plan, implement and validate process change. Process personnel and equipment shall be re-qualified on a periodic basis
g) The implementation of actions to prevent human error.
h) The implementation of release, delivery and post-delivery activities. For more information see **USD-5808 Workflow_Operations Assembly and Shipping**

## 8.5.2 Identification and traceability

Where appropriate, US Digital identifies its products, services, or other critical process outputs by suitable means. Such identification includes the status of the products and services with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all product and services shall be considered conforming and suitable for use.

If unique traceability is required US Digital controls and records the unique identification of the products and services using lot numbers or serialization. As required, lot numbers are assigned at receipt, and tracked throughout production process. Unique identification of outputs where traceability is a requirement is recorded per our documented information record.

## 8.5.3 Property belonging to customers or external providers

US Digital exercises care with customer or supplier property while it is under the organization's control or being used by the organization.

Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

Product shall remain identified either by the use of labels or segregated area.

For customer intellectual property, including customer furnished data used for design, production and/or inspection, is identified by customer and maintained and preserved by secured environments to prevent accidental loss, damage or inappropriate use.

See procedure **USD-4739 SOP_Customer Property**.

## 8.5.4 Preservation

US Digital preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection such as Electro-Static Discharge (ESD) and moisture sensitivity. All applicable employees are trained on the appropriate processes to ensure all products are treated in this manner.

## 8.5.5 Post-delivery activities

US Digital determines the extent of post-delivery activities based on the criteria including: statutory and regulatory requirements, the potential undesired consequences associated with its products and services, the nature, use and intended lifetime of product, and customer requirements and feedback. Where post-delivery activities are required, US Digital ensures they are conducted in compliance with requirements.

Customers who wish to return product may contact US Digital and request a Return Material Authorizations (RMA). US Digital will review request and process RMA if it falls within warranty and RMA guidelines. See **USD-4851 Work Instruction_RMA Process** for further information.

Post Delivery Activities include the review and actions (where required) of customer feedback.

## 8.5.6 Control of changes

US Digital reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Where it has been determined that changes will affect continuing conformity of product, changes are controlled through various methods within the Quality Management System and it is the process owner's responsibility to select the most appropriate method controlled through the Operations Planning process supported by the Continuous Improvement process. See **USD-6295 Workflow_Operations Planning** and changes Matrix in **USD-5806 Workflow_ContinuousImprovement** for more information.

## 8.6 Release of products and services

US Digital monitors and measures the characteristics of product to verify that requirements have been met. Inspection requirements specific to product is documented in Inspection procedures and/or work instructions.

Inspection is carried out at appropriate stages of the product realization process in accordance with the planned arrangements and documented procedures. Evidence of conformity with the acceptance criteria is maintained. The records indicate the person(s) authorizing release of product. Products that fail the specified requirements are placed in the non-conforming product system, processed and documented accordingly.

Product release and delivery do not proceed until the planned arrangements have been satisfactorily completed.

For more information on the Monitoring and Measuring of product, please see**, USD-5670 SOP_QC Inspection and USD-2350 SOP_AssemblyInspectionProcedures**.

## 8.7 Control of nonconforming process outputs, products and services

US Digital ensures that products or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

a) See **USD-2345 SOP_NonConforming Procedure** and **USD-5821 Workflow_NonConforming Product** for procedures of non-conforming product.
b) See **USD-5806 Workflow_ContinuousImprovement** for control process outputs of corrective or preventative actions.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, and verification of corrections shall be maintained in accordance with required post-delivery activities and procedures listed above.

# 9.0 Performance evaluation

## 9.1 Monitoring, measurement, analysis and evaluation

US Digital is committed to plan and implement the inspection, test, measurement, analysis and improvement activities needed to:

a) assure that products meets product requirements
b) assure the Quality Management System works as planned
c) continually improve the Quality Management System

### 9.1.1 General

Process leaders are responsible for what is monitored and measured for process. It is recorded in workflow diagrams and reported in SharePoint “KPI” sites at scheduled frequency. Upon reporting data, process owners are required to evaluate required actions when necessary. US Digital ensures that Objective/KPI’s are at least established for the following:

| Process | Measurement (KPI or Objective) |
|---|---|
| Conformity of Products | Product Quality – Parts Within Spec. |
| Degree of Customer Satisfaction | Customer Satisfaction-RMA<br>Customer Feedback |
| Effective implementation of planning | On Time Shipping<br>Product Quality – Parts Within Spec |
| Performance of External Suppliers | Supplier On Time Delivery |

US Digital evaluates the performance and effectiveness of the Quality Management System at least annually at the Management Review meeting using the data from the monitoring and measurement activities.

Documented evidence is recorded for specific KPI measurements and actions arising from review in SharePoint, and annual review is recorded in Management Review minutes.

Product measurement data is stored in the appropriate inspection, test or validation records specific to operational process. Process owners are responsible for ensuring operators are trained how and where to monitor and record. Product conformity trend data is recorded in High Quality Products objective.

## 9.1.2 Customer satisfaction

As one of the measurements of the performance of the management system, US Digital monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

a) recording customer complaints
b) product rejections or returns
c) repeat orders for product
d) trends in on-time delivery
e) obtain customer scorecards from certain customers and other customer feedback.

The corrective action and continuous improvement system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results

## 9.1.3 Analysis and evaluation

US Digital determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

a) Whereas ISO 9001 discusses process measurements and “quality objectives” as separate concepts, US Digital combines them; i.e., quality objectives are used to control the processes. Additional objectives may be assigned, but these will also be used to measure process effectiveness.

Process analysis and evaluation is completed through Objectives and KPI measurements:

a) The specific quality objectives and goal for are defined in KPI Site in US Digital SharePoint. At the time of implementation, responsibility is given to process owner and others as designated for reporting and review.
b) Metrics information and status along with the goal and required frequency, are recorded in the SharePoint KPI site. Reports of data and the review are held in Management Review Meeting, but are also reviewed and acted upon as part of US Digitals day to day business processes.
c) When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and continuous improvement action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes. It is the responsibility of the process owner to ensure review and actions required are documented with the KPI data.

- KPI's may change goal or frequency with process owners approval at any time, but change is required to be recorded and will be reported at the Management Review meeting as well as Internal Audit.

d) Quality Objectives and KPI's are evaluated annually at the Management Review meeting for suitability. This review will take into consideration measurement data, as well as Internal Audit information.

## 9.2 Internal audit

US Digital conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001: 2015, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained. These activities are defined in the document **USD-5819 Workflow_Internal Audit**

## 9.3 Management Review

The USD Management team reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the **Quality Policy** and quality objectives.
Improvement shall be driven by an analysis of data related to:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the management system;
d) the effectiveness of planning;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) other improvements to the management system.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in **USD-5820 Workflow_QMS Management.** This procedure written in compliance to the requirements of ISO 9001:2015.

Records from management reviews are maintained.

# 10.0 Improvement

## 10.1 General

Continual Improvement may be viewed as opportunities for improvement based on the review of the quality policy, quality objectives, and audit results, analysis of date, corrective actions, continuous improvement actions and management reviews

US Digital's management team, will implement actions to continually improve the effectiveness of the quality management system through the QMS Management Review Meeting.

The management team, process owners, and others designated by process owners are responsible to select the appropriate method to control and implement improvement and corrective actions.

See **USD-5806 Workflow_ContinuousImprovement** for more information on the process to control the application and handling of Continual Improvement (Improvement and Corrective) methods used from implementation through close.

## 10.2 Nonconformity and corrective action

US Digital will take action when a product is found to be non-conforming in order to prevent defect from re-occurring. The cause of nonconformities will be researched and actions will be appropriate to the effects found.

See **USD-5745 Workflow_Customer Communication and Feedback** for more information on process for review and required action for customer feedback/complaints.

See **USD-5821 Workflow_NonConforming Product** for more information on process for Review, root cause, evaluation, record of actions, and verification of nonconformities.

## 10.3 Continual improvement

Continuous Improvement activities are initiated based on trends in data evaluated that may indicate the “potential” for nonconformities in the process or with the product. Processes have been implemented to ensure where potential non conformities are determined, root cause and evaluation will occur to determine actions necessary, record and verification of effectiveness will be completed.

## Annex A: Documents referenced in Quality Manual

| Document Number | Title |
|---|---|
| USD-2344 | SOP_MachineMaintenance |
| USD-2345 | SOP_NonConforming Procedure |
| USD-2350 | AssemblyInspectionProcedures |
| USD-2402 | SOP_QMS_Sequence and Interaction of Process |
| USD-2441 | SOP_Quality Policy and Objectives |
| USD-2466 | SOP_ Design And Development |
| USD-3753 | SOP_Data Backup Policy |
| USD-4739 | SOP_Customer Property |
| USD-4851 | Work Instructions_RMA Process |
| USD-4852 | Workflow_ Planning and Sales Process Standard_USD-4852 |
| USD-5371 | Workflow _Training and Competence Process |
| USD-5423 | Workflow_Purchasing and Receiving |
| USD-5637 | QMS Support, Structure and Documented Information Policy |
| USD-5638 | Workflow_Design and Development |
| USD-5639 | Workflow_RMA |
| USD-5670 | SOP_QC Inspection |
| USD-5738 | SOP_Calibration |
| USD-5744 | Workflow_Calibration |
| USD-5745 | Workflow_Customer Communication and Feedback |
| USD-5806 | Workflow_ContinuousImprovement |
| USD-5808 | Workflow _ Operations Assembly and Shipping |
| USD-5812 | Workflow_SupplierEvaluation |
| USD-5819 | Workflow_Internal Audit |
| USD-5820 | Worfklow_QMS Management |
| USD-5821 | WorkFlow_NonConforming Product |
| USD-5822 | Workflow_Manufacturing |
| USD-6058 | SOP_Purchasing Operating Procedures |
| USD-6294 | QMS Matrix |
| USD-6295 | Workflow_OperationsPlanning |
| USD-6659 | Workflow_Operations_Cleanroom |