



# DDi Corporate Quality System Manual

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## **AMENDMENT STATUS**

<b>Section</b>	<b>Revision</b>	<b>Change</b>	<b>Authorization/Date</b>
All	A	Original Release Consolidating Cuplex, DCI, DDi & NTI Quality Manuals	L. Hook 03/01/99
All	B	Grammar errors, added CO-QP-#'s Updated Executive Management Organizational Chart	L. Hook 08/01/00
All	C	Annual Review Minor Grammar Corrections, Two additional Approval Signatures and changed Executive Quality Representative to Senior Quality Representative	L. Hook 11/01/01
All	D	Conversion for ISO 9002:1994 to ISO 9001:2000	I. Dotiu 06/01/03
All	E	Corrections on section 4.2.3 & 5.4.1	I. Dotiu 08/11/03
All	F	Updated to conform to AS9100 Rev A, Section 1 Requirement. Changes to scope section 3.0, 07/12/04 Section 5.4.1 Quality Objectives & Process Flow	I. Dotiu
All 03/14/05	G	Updated to conform to AS9100 Rev B	I. Dotiu
All 05/08/06	H	Updated to new Mission Statement; Changed  references of AS9100 from "Conforms to" to 'aligns with', Update Senior Management (pg 4); update Company name from Dynamic Details, Inc. to DDi Company name from Dynamic Details, Inc.	A. Fry
All 09/06/06	I	Changes to Configuration Management;  Correction to the Table of Contents/Pages; Update senior management (pg. 4)	D.Brenes
All 11/20/2006	J	Remove DDi Value-Add QMS Process Interaction Chart.  Revised QMS Process Chart. Revised Section 4.2.2 by by adding reference to DDi site specific "List of Controlled Documents and Records" ref. AH-ML-4.2, SV-ML-4.2 & VA-ML-4.2.	D.Brenes
All 06/26/09	K	Conversion for ISO 9001:2000 to ISO 9001:2008	D.Brenes



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All 09/25/09	L	4.2.2 revised to state a hard copy of the Qlty Manuel With approval signatures shall be maintained in the Corporate offices. 7.5.1.5C addresses limitations to Service Provisions. D.Brenes 9/25/09	D.	Brenes
All 11/21/09	M	7.5.1.5C References exclusion to the Servicing Provision Clause.	D.	Brenes

### **1.0 STATEMENT OF COMMITMENT**

The Quality Team, representing Executive Management of DDi is the approval authority for the Quality System operating throughout all divisions of DDi. The signatures below signify approval and commitment to adhere to the contents of this manual.

_____	_____	_____	_____
Chief Executive Officer / President Mikel Williams	Date	Senior Vice President of Operations Michael Mathews	Date

This manual is issued to ensure DDi’s ability to meet customer, statutory and regulatory requirements applicable to the product inclusive of the corporate requirements. It is designed to be in alignment with the AS9100 Rev B requirements and describes the Quality System deployed by DDi. The term product only applies to product intended for, or required by, a customer or any intended output resulting from the product realization processes.

*Issued by:*

_____	_____
Corporate Quality Management Representative	Date



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### **2.0 MISSION STATEMENT**

The following mission statement has been established by the executive management of DDi and delivered to all employees through quality related training:

*Be the best-in-class provider of advanced, time-critical electronic manufacturing solutions to the global marketplace.*

*Promote and maintain a culture that respects and rewards the skill, loyalty and dedication of employees.*

*Provide investors with a superior rate of return.*

### **QUALITY POLICY**

The following quality policy has been established by the executive management of DDi and is posted in conspicuous locations throughout the facilities and delivered to all employees through quality related training:

*We, the employees of DDi are dedicated to excellence through on-time delivery, continuous improvement, defect free products and services that meet our customer's expectations.*

### **ENVIRONMENTAL POLICY (ISO 14001 4.2)**

The following environmental policy has been established by the executive management of DDi and is posted in conspicuous locations throughout the facilities and delivered to all employees through quality related training:

*DDi is dedicated to preserving and protecting the health and safety of our employees and the environment. We are committed to complying with all applicable regulatory, environmental, health, and safety requirements, and to continual improvement of our management systems.*

We will take the following actions to accomplish these goals:

- Reduce risks to employee health and safety by systematically managing health and safety risks.
- Promote recycling whenever possible.
- Prevent pollution in the manufacturing of our products.
- Actively promote responsible action among our employees through awareness and training.
- Clearly communicate our policy and goals to suppliers, contractors, customers, and the community.



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### **3.0 SCOPE**

*The scope of the Quality Management System includes all processes that produce the products and/or services.* The scope of the Quality Management System does not include processes that are governed by other management systems, such as environmental management, occupational safety and health, or financial management.

DDi is committed to maintain its industry leadership in high technology, high reliability, manufacture time-critical printed circuit boards and interconnect solutions.

DDi demonstrates the ability to consistently provide product of the highest quality and aims to enhance customer satisfaction through the effective application of the Quality Management System, consistently meeting customer requirements, ISO 9001:2008, and AS9100 Rev B, statutory and regulatory requirements and continual improvement, applicable to the product. At this time, any reference in the QMS in regards to “alignment with AS9100 Rev. B” is specific to the Anaheim, Milpitas, and Virginia campuses.

### **3.1 Application/Exclusions**

The QMS meets all requirements of the ISO 9001:2008 with the exclusion of “Design and Development”, Section 7.3. The QMS is in alignment with AS9100 Rev. B with the exclusion of “Design and Development”, Section 7.3. DDi receives electronic data from customers that is of a finished circuit design variant. The customer will make any changes, as necessary and new data will be supplied to facilitate further manufacture. DDi is accordingly excluded from this clause.

## **4.0 QUALITY MANAGEMENT SYSTEM**

### **4.1 General Requirements**

DDi has established, documented, implemented, and maintains a Quality Management System (QMS) as a means of meeting the Quality Policy, achieving the Quality Objectives, and ensuring that products/services conform to customer requirements. The QMS is continually improved for effectiveness and meets all ISO 9001:2008 and regulatory requirements, and is in alignment with the requirements of AS9100 rev B. In effect, each Department Manager/Supervisor has the responsibility to align his/her department with the Quality Manual, Quality Policy and top-level Quality Objectives. Level II Quality Procedures (QP) and related work instructions accomplish this alignment.

Management, utilizing a process approach system, has identified and actively manages a set of activities using resources in order to enable the transformation of inputs into outputs (i.e. processes) throughout the organization, necessary to ensure products and/or services conform to customer, statutory, regulatory and QMS requirements. Documented procedures and related documentation that describe the processes of the Quality Management System have been implemented and are continually maintained and controlled by the Quality Systems Department or Document Control function. The procedures describe the sequence and interactive nature of the processes necessary to ensure the conformity of the product and/or service. DDi has determined the criteria and methods needed to ensure that both the operation and control of these processes is effective.

DDi ensures the availability of resources and information necessary to support the operation and monitoring of these processes, while monitoring, measuring where applicable and analyzing these processes, and



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implementing actions necessary to achieve planned results and continual improvement. DDi manages these processes in accordance with the requirements of ISO 9001:2008, AS9100 Rev B, statutory and regulatory requirements.

Instructions and related documentation that describe the operating practice and control of process activities have been implemented and are an integral part of the Quality Management System.

Where DDi chooses to outsource any process that affects product conformity with requirements by an external party, DDi ensures control over such processes recognizing our responsibility of ensuring conformity to all customers, statutory and regulatory requirements. Control of such outsourced processes is identified within the QMS.

### **4.2 Documentation Requirements**

#### **4.2.1 General**

The QMS includes documented statements of the DDi Quality Policy and Quality Objectives, a quality manual, documented procedures required by ISO 9001:2008, AS9100 Rev B and other statutory or regulatory requirements to ensure effective planning, operation and control of processes; inclusive of documents and records, determined by DDi to be necessary for the effective planning, operation and control of the processes.

DDi shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authority's representatives shall have access to quality management system documentation.

#### **4.2.2 Quality Systems Manual**

DDi has established and maintained this Quality Manual, which includes the scope of the QMS in Section 3.0, with details of and justification for any exclusions listed in Section 3.1, 'Application/Exclusions', of this Quality Manual. This manual includes documented procedures established for the QMS, or reference to them. All documented procedures established for the QMS are listed in CO-ML-4.2 "List of Controlled Corporate Documents and Records" in addition to DDi site specific "List of Controlled Documents and Records" referenced as AH-ML-4.2, SV-ML-4.2 and VA-ML-4.2 as they correlate to the corporate CO-ML-4.2 (these list are available upon request). This manual also provides a description of the interaction between the processes of the QMS, attached as "Appendix A".

The Quality Manual is reviewed annually to ensure that the requirements of ISO 9001:2008 and AS9100B are being met. Any planned revisions to the Quality Manual shall be reviewed by the Corporate Quality Management Representative to ensure that the integrity of the Quality Management System is not compromised.

Note: Copies of this Quality Systems Manual are available both in electronic and hard copy media maintained by Quality Systems Department. A hard copy of the Quality Systems Manual with all applicable approvals shall be maintained on file in the Corporate Office. Uncontrolled copies may be issued to customers upon request. Copies will not be maintained.

#### **4.2.3 Control of Documents**



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Documents required for the planning and operation of the Quality Management System are identified and their distribution is controlled by the Quality Systems Department or Document Control function. Records are a special type of document and are controlled according to section 4.2.4 of this Manual.

A documented procedure is established to define the controls needed to approve documents for adequacy prior to use, and to review and update as necessary and re-approve documents. This procedure also ensures that changes and current revision status of documents is identified, and that relevant versions are available at points of use. This procedure ensures documents remain legible and readily identifiable and that documents of external origin are identified with distribution controlled while preventing the unintended use of obsolete documents with suitable identification applied to them, if they are retained for any purpose. DDi will coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

The QMS documentation is organized as:

- **Level One:** Quality Systems Manual
- **Level Two:** Quality Procedures (QP)
- **Level Three:** Work Instructions (WI)
- **Level Four:** Records (e.g., completed forms, databases, etc).

Reference: Quality Procedure “Document and Record Control” (CO-QP-4.1) has been established and is available in hard copy and electronic media and is maintained by the Quality Systems Department. A site-specific master list of documents may be provided upon request.

### **4.2.4 Control of Records**

Records required for the Quality Management System (QMS) are controlled. Such records are established and maintained to provide evidence of conformance to requirements and the effective operation of the QMS. Records are legible, readily identifiable, and retrievable. A documented procedure is established which defines the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

Reference: Quality Procedure “Document and Record Control” (CO-QP-4.1) has been established and is available in hard copy and electronic media and is maintained by the Quality Systems Department.

### **4.3 Configuration Management**

The organization shall establish, document and maintain a configuration management process appropriate to the product providing identification and traceability, the status of achievement of its physical and functional requirements, and access to accurate information in all phases of the life cycle.



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The output of configuration management planning is the configuration management plan, which is documented, approved, controlled, identifying the configuration management procedures to be used, referencing relevant procedures and describing the responsibilities and authorities for carrying out configuration management throughout the life cycle of the product.

After initial release of product configuration information, all changes are controlled, identifying and documenting the need for the change and submitted to the customer for approval.

During the configuration identification each change control activities, records shall be maintained for traceability and efficient management of the evolving configuration.

To protect the integrity of the product configuration information and to provide a basis for control of the changes, the information and records shall be maintained in an environment that shall provide protection from corruption, that is retrievable in which there is a disaster recovery plan.

Configuration audits shall be performed to ensure that the product conforms to its requirements and product configuration information. A configuration audit is not intended to replace other forms of verification, review, test or inspection but shall be affected by the results of those activities.

### **5.0 MANAGEMENT RESPONSIBILITY**

#### **5.1 Management Commitment**

Executive management is committed to the development and implementation of the Quality Management System and continually improving its effectiveness by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements; by establishing the quality policy, and ensuring that quality objectives are established; conducting management reviews; and ensuring the availability of resources.

#### **5.2 Customer Focus**

Executive Management ensures that customer needs and expectations are determined, converted into requirements and met with the aim of achieving customer satisfaction. (Ref. Section 7.2.1 and 8.2.1)

#### **5.3 Quality Policy**

Executive Management has ensured that the Quality Policy is appropriate to the purpose of DDi and includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS. Furthermore, executive management has ensured this policy provides a framework for establishing and reviewing quality objectives and is communicated and understood within the organization and is reviewed for continuing suitability. The Quality Policy is documented in Section 2.0, of this manual.

#### **5.4 Planning**

##### **5.4.1 Quality Objectives**

Executive Management is responsible for establishing and ensuring that top-level quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The Quality Objectives are measurable and consistent with the Quality Policy. The corporate Quality Objectives established by Executive Management have been identified in the *Metric Consolidation Report* and are measured weekly. These objectives may include, but are not limited to:



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Bookings, RMAs, Material Remakes, Shipments, On Time Delivery, Inner Layer Yield (FP) and Overall Yield.

### **5.4.2 Quality Management System Planning**

Executive Management ensures that the planning of the QMS is carried out in order to meet the requirements given in section 4.1 of this manual, as well as the Quality Objectives. Executive Management has the responsibility to ensure that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

*Quality Planning is performed through Management Reviews and is used to ensure that the customer's requirements and the company's objectives for quality are both met. Customer-specific quality plans shall be developed if required by contract.* Records of quality planning activities are recorded on the Management Review Agenda, with records maintained in accordance to section 4.2.4, Control of Records, of this manual.

### **5.5 Responsibility, Authority and Communication**

#### **5.5.1 Responsibility and Authority**

To ensure effective administration of the Quality Management System, responsibilities and authorities have been defined and communicated within the organization. A Management Representative has been designated, effective internal communications have been implemented, and documentation and records are effectively controlled. The primary method of communicating responsibilities and authority to relevant levels of the organization is through Quality Management System documentation. Quality procedures and work instructions define roles, responsibilities, and authorities.

#### **5.5.2 Management Representative**

DDi's executive management has appointed a Corporate Management Representative who, irrespective of other responsibilities, has the responsibility and authority to ensure that the processes needed for the QMS are established, implemented, and maintained. This function reports to Executive Management on the performance of the QMS, including needs for improvement and for ensuring the promotion of awareness of customer requirements throughout the organization, and has the organizational freedom to resolve matters pertaining to quality. In addition, this function has the responsibility to serve as the liaison with external parties on matters relating to the QMS.

DDi has appointed a Director/Manager of Quality or appointee at each facility who is the local Management Representative for the QMS who, irrespective of other responsibilities, has the responsibility and authority to ensure that the processes needed for the QMS are established, implemented and maintained. This function reports to local executive management on the performance of the QMS, including needs for improvement and for ensuring the promotion of awareness of customer requirements throughout the organization, and has the organizational freedom to resolve local matters pertaining to quality. In addition, this function has the responsibility to serve as the liaison with external parties on matters relating to the QMS.

#### **5.5.3 Internal Communication**

DDi ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS. The primary method of communicating this information to relevant levels is through QMS documentation. Other essential processes for communicating the effectiveness of the QMS include, but are not limited to, training, organizational meetings, internal audits, and management reviews.



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### **5.6 Management Review**

#### **5.6.1 General**

Executive management conducts a management review of the Quality Management System (QMS) at least annually (or more frequently, as required) to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy and Quality Objectives. Records from management reviews are maintained.

#### **5.6.2 Review Input**

Reports generated by the ISO Management Representative(s) are used as a primary input to determine the effectiveness of the Quality Management System. Additionally, input shall include results of audits, related customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews and changes that could affect the QMS and recommendations for improvement.

#### **5.6.3 Review Output**

The output from the management review includes any decisions and actions related to improvement of the effectiveness of the QMS and its processes, improvement of product related to customer requirements, and resource needs.

## **6.0 RESOURCE MANAGEMENT**

### **6.1 Provision of Resources**

Management determines and provides the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements. An annual operating plan is developed and establishes the requirements for personnel staffing, inventory, training and other direct costs needed to accomplish the forecast and production schedules.

### **6.2 Human Resources**

#### **6.2.1 General**

Management assigns personnel performing work affecting conformity to product requirements are competent on the basis of applicable education, training, skills, and experience. Human Resources maintains job descriptions that contain the minimum requirements for education and experience that must be met before an individual is hired, promoted, and/or performs job tasks recognizing that conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system. .

#### **6.2.2 Competence, Awareness and Training**

Management identifies the competency needs for personnel performing work affecting conformity to product requirements and where applicable shall; provide training or takes other actions to achieve the necessary competence... Management also ensures that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives. Appropriate records of education, training, skills, and experience are maintained.



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### **6.3 Infrastructure**

Management determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements, including buildings, workspace and associated utilities, process equipment, both hardware and software, and supporting services such as transport or communication.

### **6.4 Work Environment**

Management determines and manages the work environment as it relates to those conditions under which work is performed inclusive of physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather) to achieve conformity to product requirements.

## **7.0 PRODUCT REALIZATION**

### **7.1 Planning of Product Realization**

Management shall plan and develop the processes needed for product realization. Planning of the product realization is consistent with the requirements of the other processes of the QMS and the requirements given in section 4.1 of this manual.

In planning product realization, management determines, as appropriate, the quality objectives and requirements for the product; the need to establish processes and documentation and provide resources specific to the product; required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; the records needed to provide evidence that the realization processes and resulting product meet requirements and the identification of resources to support operation and maintenance of the product.

The output of this planning is in a form suitable for the method of operation of DDi.

### **7.2 Customer-Related Processes**

#### **7.2.1 Determination of Requirements Related to the Product**

DDi has defined and established a process and procedure whereby customer requirements are identified, reviewed, communicated, and recorded as considered necessary by the organization. Customer requirements are identified by contract review activities. These include requirements for delivery and post-delivery activities, requirements not stated by the customer but necessary for specified or intended use, where known, statutory and regulatory requirements related to the product are required (for example, actions under warranty provisions, contractual obligations such as maintenance services or supplementary services such as recycling or final disposal)..

#### **7.2.2 Review of Requirements Related to the Product**

DDi reviews the requirements related to the product. This review is conducted prior to the organization's commitment to supply a product to the customer, ensuring that the product requirements are defined, and contract or ordering requirements differing from those previously expressed are resolved. This review also ensures that the organization has the ability to meet the defined requirements and risks such as new technology, short delivery time scale are evaluated and records of the results of the review and actions arising from the review maintained.



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Where the customer provides no documented statement of requirements, DDi shall confirm the customer requirements before acceptance. Where product requirements are changed, DDi ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

### **7.2.3 Customer Communication**

DDi determines and implements effective arrangements for communicating with customers in relation to product information, inquiries, contracts or order handling, including amendments and customer feedback, including customer complaints.

### **7.3 Design and Development**

This clause is excluded. DDi receives electronic data from customers that is of a finished circuit design variant. The customer will make any changes, as necessary and new data will be supplied to facilitate further manufacture. DDi is accordingly excluded from this clause.

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**

The Purchasing Department controls purchasing processes to ensure that purchased product conforms to specified purchased requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product. DDi is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

The Purchasing and Quality Departments shall evaluate and select suppliers based on their ability to supply product in accordance with DDi requirements. Purchasing has established criteria for selection, evaluation, and re-evaluation. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

DDi shall:

- a. Maintain a register of approved suppliers that include the scope of the approval.
- b. Periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented.
- c. Define the necessary actions to take when dealing with suppliers that do not meet requirements.
- d. Ensure where required that both the organization and all supplier use customer-approved special process sources.
- e. Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

#### **7.4.2 Purchasing Information**

Purchasing information describes the product to be purchased including where appropriate:

- a. The requirements for approval of product, procedures, processes and equipment.
- b. Requirements for qualifications of personnel.
- c. QMS requirements.
- d. The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.
- e. Requirements for design, test, examination, inspection and related instructions for acceptance.
- f. Requirements for test specimens for design approval, inspections, investigation or auditing.



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- g. Requirements relative to supplier notification of non-conforming product and arrangements for approval of supplier non-conforming material.
- h. Requirements for the supplier to notify DDi of changes in product and/or process definition and where required, obtain DDi approval.
- i. Right of access by DDi, DDi customers and regulatory authorities to all facilities involved in the order and to all applicable records.
- j. Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents including key characteristics where required.

DDi shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

### **7.4.3 Verification of Purchased Product**

DDi has established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. In cases where DDi or its customer intends to perform verification at the supplier's premises, the Purchasing Section ensures that the intended verification arrangements and method of product release is specified in the purchasing information.

Verification activities may include:

- a. Obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records & process control).
- b. Inspection and audit at supplier's premises.
- c. Review of the required documentation.
- d. Inspection of products upon receipt.
- e. Delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where DDi utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. DDi shall periodically validate test reports for raw material.

Where DDi delegates verification activities to the supplier, the requirements for delegation shall be defined and a register to delegations maintained.

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and DDi premises that subcontracted product conforms to the specified requirements.

## **7.5 Product and Service Provision**

### **7.5.1 Control of Production and Service Provision**

Planning shall consider, as applicable,

- a. Establishment of process controls and development of control plans where key characteristics have been identified.
- b. Identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization.



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- c. Design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics.
- d. Special processes (see 7.5.2).

Management plan and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable:

- 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.
- f. Implementation of release, delivery and post-delivery activities.
- g. Accountability for all products during manufacture (e.g., parts quantities, split orders, nonconforming product).
- h. Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized.
- i. Provision for the preventive, detection, and removal of foreign objects.
- j. Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality.
- k. Criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

Production Documentation:

Production operations shall be carried out in accordance with approved data. This data shall contain as necessary:

- a. Drawings, parts list, process flow charts including inspection operations, production documents and inspection documents,
- b. List of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

### **7.5.1.2 Control of Production Process Changes:**

Persons authorized to approve changes to production processes shall be identified.

DDi shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production requirement, tools and programs shall be documented. Procedures shall be available to control their implementation.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

### **7.5.1.3 Control of Production Equipment, Tools & Numerical Control Machine Programs:**

Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include



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verification of the first article procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.

Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.

### **7.5.1.4 Control of Work Transferred, on a temporary basis, outside DDi Facilities:**

When temporarily transferring work to a location outside the DDi facilities, DDi shall define the process and validate the quality of the work.

### **7.5.1.5 Control of Service Operations: DDi does not provide field services to our customer base other than that referenced below and as such takes exclusion to Clause 7.5.1.5.**

- a. Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements.
- b. Control and updating of technical documentation and technical presentations provided as a service to our customer base.
- c. On site field services are not performed and as such DDi takes exclusion to Clause 7.5.1.5.

### **7.5.2 Validation of Processes for Production and Service Provision**

DDi validates any processes for production and service provisions where the resulting output cannot be verified by subsequent monitoring or measurement. 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.

DDi has established arrangements for these processes including, as applicable, defined criteria for review and approval of these processes, qualification and approval of special processes prior to use approval of equipment and qualification of personnel, use of specific methods and procedures control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto requirements for records and revalidation.

### **7.5.3 Identification and Traceability**

Management identifies, where appropriate, the product by suitable means throughout product realization. DDi shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration. The product status is identified with respect to monitoring and measurement requirements through out product realization. When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), DDi shall establish and document controls for the media.

Where traceability is a requirement, the unique identification of the product is controlled and recorded.

According to the level of traceability required by contract, regulatory, or other established requirement, DDi system shall provide for:

- a. Identification to be maintained throughout the product life;



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- b. All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- c. For a given product, a sequential record of its production (manufacture, inspection) to be retrieved.

### **7.5.4 Customer Property**

DDi exercises care with customer property while it is under our control or being used by our organization. Management ensures the identification, verification, protection, and safeguard of customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

Note: Customer property can include intellectual property and personal data, including customer furnished data used for design, production and / or inspection.

### **7.5.5 Preservation of Product**

Management preserves the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements... As applicable, preservation shall include identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Preservation of product shall also include, where applicable in accordance with product specifications and / or applicable regulations, provisions for:

- a. Cleaning;
- b. Prevention, detection and removal of foreign objects;
- c. Special handling for sensitive products;
- d. Marking and labeling including safety warnings;
- e. Shelf life control and stock rotation;
- f. Special handling for hazardous materials.

DDi shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

### **7.6 Control of Monitoring and Measuring Devices**

Management has determined the monitoring and measurements to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). DDi shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE: Monitoring and measuring devices include, but are not limited to: test hardware, software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes customer-supplied equipment used to provide evidence of product conformity.

Management has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Management



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ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment is: 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; measuring equipment is adjusted or re-adjusted as necessary; identified to enable the calibration status to be determined; safeguarded from adjustments that would invalidate the measurement result; protected from damage and deterioration during handling, maintenance and storage and recalled to a defined method when requiring calibration.

In addition, management assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Management takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application would typically include its verification and configuration management shall maintain its suitability for use. This is undertaken prior to initial use and reconfirmed as necessary.

### **8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT**

#### **8.1 General**

Management has planned and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product to ensure conformity of the QMS and to continually improve the effectiveness of the QMS. This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

#### **8.2 Monitoring and Measurement**

##### **8.2.1 Customer Satisfaction**

As one of the measurements of the performance of the QMS, DDi monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information have been determined. The primary method for obtaining customer satisfaction/dissatisfaction data is via customer surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and/or customer score cards.. The customer satisfaction and/or dissatisfaction data is compiled and subsequently used as an input to Management Review.

##### **8.2.2 Internal Audit**

Quality Assurance conducts internal audits at planned intervals to determine QMS conformity to the planned arrangements (see 7.1), to the requirements of this International Standard, and to the QMS requirements established by the organization; and is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. Audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.



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The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records are defined in documented procedures.

Management responsible for the area being audited ensures that necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verifications of the actions taken and the reporting of verification results.

Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against effectiveness of the internal audit process and overall organization performance.

Internal audits shall also meet contract and / or regulatory requirements.

Reference: Quality procedure “Internal Audits” (CO-QP-8.3) is available in electronic and hard copy media and maintained by the Quality Systems Department.

### **8.2.3 Monitoring and Measurement of Processes**

Management applies suitable methods (type and extent) for monitoring and, where applicable, measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the QMS process. Records shall be maintained indicating the person(s) authorizing release of product for delivery to the customer per section 4.2.4. The monitoring and measurement methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

In the event of process nonconformity, DDi shall

- a. Take appropriate action to correct the nonconforming process
- b. Evaluate whether the process nonconformity has resulted in product Nonconformity
- c. Identify and control the nonconforming product in accordance with Clause 8.3.

### **8.2.4 Monitoring and Measurement of Product**

Management monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). When key characteristics have been identified, they shall be monitored and controlled.

When sampling inspection is used as a means of product acceptance, the plan shall be statistically valid and appropriate to for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.



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Evidence of conformity with the acceptance criteria is maintained, and records indicate the person(s) authorizing release of product. Product release and service delivery do not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

### **8.2.4.1 Documentation / Records:**

Measurement requirements for product or service acceptance shall be documented. This documentation may be part of but not limited to the production documentation, and shall include the following:

- a. criteria for acceptance and/or rejection
- b. where in the sequence measurement and testing operations are performed
- c. a record of the measurement results
- d. type of measurement instruments required and any specific instructions associated with their use

Test records shall show actual test results data when required by specification or acceptance test plan. Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

### **8.2.4.2 First Article Inspection:**

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

## **8.3 Control of Nonconforming Product**

Where applicable, DDi ensures that product, which does not conform to product requirements, is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure. The procedure shall define the responsibility for review and authority for the disposition of non-conforming product and the process for approving personnel making those decisions.

DDi deals with nonconforming product by one or more of the following ways: by taking action to eliminate the detected nonconformity; by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; by taking action to preclude its original intended use or application. Records of the nature of the nonconformities of any subsequent actions taken, including concessions obtained, are maintained.

Product given a 'scrap' disposition shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements. When

Non-conforming product is detected after delivery or use has started, DDi takes action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, the DDi system shall take action appropriate to the effect or potential effects, of nonconforming product which is detected after the product has been delivered providing timely reporting of delivered nonconforming product that may affect reliability



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or safety to the customer. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

Reference: Quality procedure “Control of Nonconforming Product” (CO-QP-8.7) is available in electronic and hard copy media and maintained by the Quality Systems Department.

### **8.4 Analysis of Data**

The Quality Management System includes processes to collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to customer satisfaction/dissatisfaction (see 8.2.1), conformity to product requirements (see 8.2.4), characteristics, and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4) and suppliers (see 7.4).

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**

Management plans and manages the processes to continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, CAPS Teams (Continuous Advancement of Processes and Systems), PALs (Process Analysis Logs) and periodic management review.

#### **8.5.2 Corrective Action**

Management takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. A documented procedure is established and defines requirements for

- a. Reviewing nonconformities (including customer complaints),
- b. Determining the causes of nonconformities,
- c. Evaluating the need for action to ensure nonconformities do not recur,
- d. Determining and implementing action needed,
- e. Records of the results of action taken,
- f. Reviewing the effectiveness of the corrective action taken
- g. Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause,
- h. Specific actions when timely and/or effective corrective actions are not achieved.

Reference: Quality procedure “Corrective and Preventive Action” (CO-QP-8.10) is available in electronic and hard copy media and maintained by the Quality Systems Department.

#### **8.5.3 Preventive Action**

Management determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. A documented procedure is established and defines requirements for determining potential nonconformities and their causes, evaluating the need for action to prevent occurrence of nonconformities, determining and implementing action needed, records of results of action taken, and reviewing the effectiveness of the preventive action taken.



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Reference: Quality procedure “Corrective and Preventive Action” (CO-QP-8.10) is available in electronic and hard copy media and maintained by the Quality Systems Department.



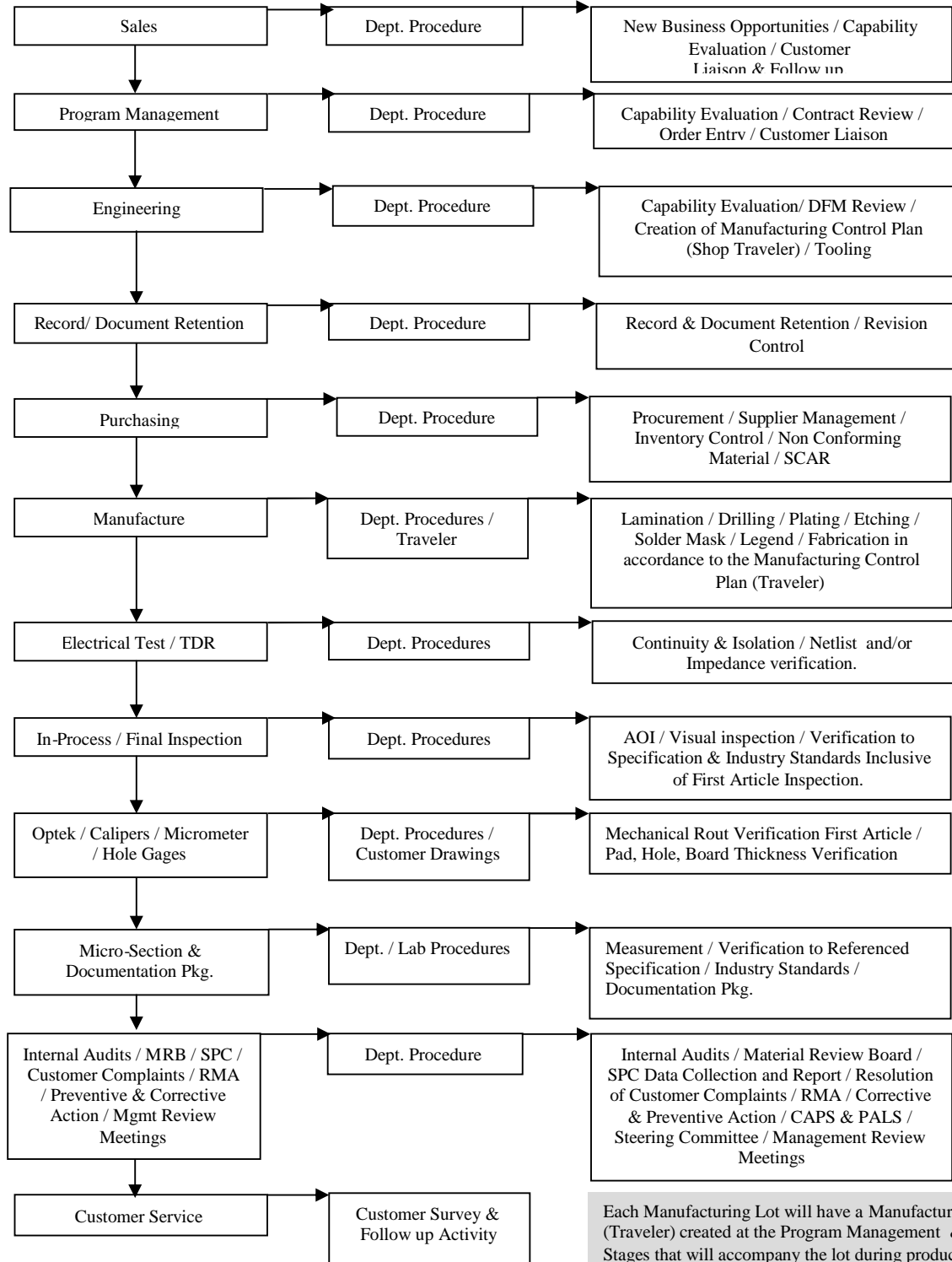
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## Appendix A

### SYSTEM DESIGN AND INTERACTION OF THE ELEMENTS

#### PCB QMS Process Interaction

Quality Management Systems / Management Responsibility / Resource Management / Measurement, Analytical & Improvement/ Customer Service / Customer Satisfaction



Each Manufacturing Lot will have a Manufacturing Control Plan (Traveler) created at the Program Management & Engineering Stages that will accompany the lot during product realisation.

