



# **DDi Corporate Quality System Manual**

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## Appendix A



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## REVISION RECORD

Rev:	Description:	Date:	Revision Author:
A	Original Release: Consolidating Cuplex, DCI, DDi and NTI Quality Manuals	3/1/99	L. Hook
B	Added CO-QP-#'s, Updated Executive Management Orgaizational Chart	8/1/00	L. Hook
C	Two additional Approval Signatures added, Changed Executive Quality Representative to Senior Quality Representative	11/01/01	L. Hook
D	Conversion of ISO 9002:1994 to ISO 9001:2000	6/01/03	I. Dotiu
E	Revised Section 4.2.3 and 5.4.1	8/11/03	I. Dotiu
F	Updated to conform to AS9100 A (Section 1) and Revision to Scope (Section 3.0) and Quality Objectives & Process Flow (Section 5.4.1)	7/12/04	I. Dotiu
G	Updated to conform to AS9100B	3/14/05	I. Dotiu
H	Updated Mission Statement, Changed references of AS9100 from "Conforms to" to "aligns with", Updated Senior Management and revised Company name from Dynamic Details, Inc to DDi	5/08/06	A. Fry
I	Revision to Configuration Management, Table of Contents/Pages and Updated Senior Management	9/06/06	D. Brenes
J	Removed DDi Value Add QMS Process Interaction Chart. Revised QMS Process Chart. Revised Section 4.2.2 with reference to DDi site specific "List of Controlled Documents & Records" AH-ML-4.2, SV-ML-4.2 & VA-ML-4.2	11/20/06	D. Brenes
K	Conversion of ISO 9001:2000 to ISO 9001:2008	6/26/09	D. Brenes
L	Revised Section 4.2.2 to state a hard copy of the Qlty Manual with approval signatures are maintained in the Corporate Office. 7.5.1.5C addresses limitations to Service Provisions	9/25/09	D. Brenes
M	Revised Section 7.5.1.5C to reference exclusion to the Servicing Provision Clause	11/21/09	D. Brenes
N	Rewrite, Conversion of ISO 9001:2008 / AS9100B to ISO 9001:2008 / AS9100C & Revised Scope	7/15/11	D. Brenes
O	Typo error corrected on 3.1 b); Typo Correction to 7.5.1.1 - Production Process Verification title revised with additional detail added to the Section; Section 8.1 Corrected subtitle to Test Optimization	11/30/11	D. Brenes



# DDi Corporate Quality System Manual

## 1.0 APPROVAL RECORD / STATEMENT OF COMMITMENT

The Quality Team, representing Executive Management of DDi Global Corp and its subsidiaries “DDi”, are the approval authority for the Quality Management System operating throughout the divisions. The signatures below signify approval and commitment to adhere to the contents of this Manual.

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

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 ISO 9001:2008 / AS9100C Aerospace, ISO 13485, MIL-PRF-55110 and MIL-PRF-31032 requirements and describes the Quality Management 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 of time-critical printed circuit boards and interconnect solutions.

The Quality Management System outlined in this Quality Manual and supporting QMS documents is designed and developed to comply with the ISO 9001:2008 / AS9100 quality system standards, ISO 13485, MIL-PRF-55110 and MIL-PRF-31032 specifications to ensure that we meet the customers requirements and comply with all statutory and regulatory requirements, applicable to the product.

## 3.1 Exclusions

### ISO 9001:2008 / AS9100C:

The QMS meets all requirements of the ISO 9001:2008 / AS9100C with the exclusion of

a) Section 7.3 “Design and Development”

Note: DDi does not perform design and development. Product is manufactured from design data provided by the customer.

b) Section 7.5.1.4 “Post Delivery Support”

Note: DDi does not provide post delivery support

### ISO 13485:2003:

a) Section 7.3 “Design and Development”

b) Section 7.5.1.2.1 “Cleaning of Product and Contamination Control”

c) Section 7.5.1.2.2 “Installation Activities”

d) Section 7.5.1.2.3 “Servicing Activities”

e) Section 7.5.1.3 & 7.5.2.2 “Particular requirements for sterile medical devices”

f) Section 7.5.3.2.2 & 8.2.4.2 “Particular requirements for active implantable medical devices and implantable medical”

Note: DDi Toronto is the only DDi division currently certified to ISO 13485:2003

## 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 / AS9100C, ISO 13485, MIL-PRF-55110 and MIL-PRF-31032 requirements.

The Quality Management System, utilizing a process approach system, has identified and actively manages a set of activities using appropriate resources to enable the transformation of inputs into



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outputs (i.e. processes) throughout the organization, necessary to ensure products and/or services conform to customer, statutory, regulatory and QMS requirements. The QMS

- a) Determines the processes needed for the QMS and their application throughout the facility.
- b) Determines the sequence and interaction of each process to ensure conformity of product.
- c) Determines criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of the processes.
- e) Monitors, measures (where applicable) and analyzes the processes.
- f) Implements actions necessary to achieve planned results and continual improvement of the processes

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 / AS9100C, ISO 13485, MIL-PRF-55110 and MIL-PRF-31032 as well as 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 ensures that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authority's representatives 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, '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" as they correlate to the corporate CO-ML-4.2 (these lists 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 / AS9100C, ISO 13485 and Military Standards are being met. Any planned revisions to the Quality Manual are reviewed by the Corporate Quality Management Representative and the TRB to ensure that the integrity of the Quality Management System is not compromised.



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**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 is maintained on file in the Corporate Office. Uncontrolled copies may be issued to customers upon request but these copies will not be maintained.

### **4.2.3 Control of Documents**

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 has been established to define the following requirements:

- a) Controls needed to approve documents for adequacy prior to use.
- b) Documents are reviewed and updated as necessary and reapproved if revised.
- c) Ensures that changes and the current revision status of the documents are identified.
- d) Ensures that relevant versions are available at points of use.
- e) Ensures that documents remain legible and readily identifiable
- f) Ensures that documents of external origin, determined by DDi to be necessary for the planning and operation of the QMS, are identified and their distribution controlled.
- g) Prevents the unintended use of obsolete documents with suitable identification applied to them, if they are retained for any purpose.
- h) DDi will coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.
- i) Traceability is retained by DDi for a minimum of three years after delivery of the compliant printed circuit boards and the records are readily available for review upon request of the acquiring activity or qualifying activity.

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 (CO-QP-4.1) is established which defines the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records. The documented procedure defines the method for controlling records that are created by and/or retained by suppliers. Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.



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## **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). Executive Management ensures that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not achieved.

### **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 and goals include, but are not limited to the following:

- a) On-Time Delivery
- b) Bookings
- c) Inner Layer Yields (First Pass)
- d) Outer Layer Yields
- e) Overall Yield
- f) Material Remakes
- g) Shipments
- h) RMA Data (Number of RMAs issued, RMA Loss, Value Add Loss)

Customer Satisfaction Surveys are deployed on a yearly basis and a Report is released. The information is maintained on the Quality Portal. A Continuous Improvement Strategy is developed in response to the customer's statements and category / attribute ratings.



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### **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 are 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. Organizational Charts are maintained and available upon request. 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 the 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 and unrestricted access to top management to resolve quality management issues. 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



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processes for communicating the effectiveness of the QMS include, but are not limited to, training, organizational meetings, internal audits, and management reviews.

### **5.5.4 Qualifying Authority Communication**

The Quality Director, the Process Engineering Director or Quality Manager is the designated TRB Representation responsible for keeping the qualifying activity updated on the status of the Quality Management Systems. A Quarterly Report will be submitted to the qualifying activity by the TRB Representative no later than 45 days after the end of the reporting period.

### **5.6 Management Review**

#### **5.6.1 General**

Executive management conducts a management review of the Quality Management System (QMS) at a minimum once per year (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 the management reviews are maintained and readily accessible.

#### **5.6.2 Review Input**

The input for the Management Reviews to determine the effectiveness of the Quality Management System include at a minimum, the following:

- a) Results of audits
- b) Customer feedback
- c) Process performance and product conformity
- d) Status of preventive and corrective actions
- e) Follow-up actions from previous management reviews
- f) Changes that could affect the QMS
- g) Recommendations for improvement
- h) Process trends
- i) Supplier performance

#### **5.6.3 Review Output**

The output from the management review includes any decisions and actions related to the following:

- a) Improvement of the effectiveness of the QMS and its processes
- b) Improvement of product related to customer requirements
- c) 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



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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**

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate 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 provides 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.

### **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 plans and develops 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 following:

- a) Quality Objectives and requirements for the product, inclusive of



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- Product and personnel safety
  - Reliability, availability and maintainability
  - Producability and inspectability
  - Suitability of parts and materials used in the product
  - Selection and development of the embedded software
  - Recycling or final disposal of product at the end of its life
- b) Need to establish processes and documents and to provide resources specific to the product
- c) Required verification, validation, monitoring, measurement, 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 the requirements (4.2.4)
- e) Configuration management appropriate to the product
- f) Resources to support the use and maintenance of the product

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

### **7.1.1 Product Management**

DDi plans and manages product realization in a structured and controlled manner to meet requirements at an acceptable risk, within the available resources and scheduled constraints.

### **7.1.2 Risk Management**

DDi established, implemented and maintains processes for managing risk to the achievement of applicable requirements, which includes as appropriate to the organization and the product, as follows:

- a) Assignment of responsibilities for Risk Management.
- b) Definition of risk criteria (e.g. likelihood, consequences, risk acceptance).
- c) Identification, assessment and communication of risks throughout product realization.
- d) Identification, implementation and management of actions to mitigate risks which exceed the defined risk acceptance criteria.
- e) Acceptance of risks remaining after implementation of mitigating actions.

### **7.1.3 Configuration Management**

DDi has established, implemented and maintains 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 its life cycle.

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



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During the configuration identification, each change control activity is recorded and 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 are maintained in an environment that provides protection from corruption, that is retrievable and in which there is a disaster recovery plan.

Configuration audits are 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 will be affected by the results of those activities.

### **7.1.4 Control of Work Transfers**

DDi has established, implemented and maintains a process to plan and control the temporary or permanent transfer of work (e.g., from one division to another or from a division to a supplier) and to verify the conformity of the work to the requirements.

## **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 necessary by the organization. Customer requirements are identified by contract review activities. These include the following:

- a) Requirements for delivery and post delivery activities
- b) Requirements not stated by the customer but necessary for specified or intended use, where known
- c) Statutory and regulatory requirements related to the product (ex. Warranty provisions, contractual obligations such as maintenance services or supplementary services such as recycling or final disposal)
- d) Any additional requirements considered necessary by DDi

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

DDi reviews the requirements related to the product prior to the organization's commitment to supply a product to the customer, to ensure the following:

- a) The product requirements are defined
- b) Contract or ordering requirements differing from those previously expressed are resolved
- c) DDi has the ability to meet the defined requirements
- d) Special requirements of the product are determined
- e) Risks (such as new technology, short delivery time frame) are identified and evaluated

Records of the results of the review and actions arising from the review are maintained.

Where the customer provides no documented statement of requirements, DDi will 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.



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### **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, customer feedback, and 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 and is not included in the AS9100 scope.

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**

The Purchasing Department ensures 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 conformity of all products purchased from suppliers, including customer-designated sources.

The Purchasing and Quality Departments 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.

At a minimum DDi:

- a) Maintains a register of approved suppliers that include the scope of the approval.
- b) Periodically reviews supplier performance; records of these reviews will be used as a basis for establishing the level of controls to be implemented.
- c) Defines the necessary actions to take when dealing with suppliers that do not meet requirements.
- d) Ensures where required that both DDi and all suppliers use customer-approved special process sources.
- e) Defines the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status.
- f) Determines and manages the risk when selecting and using suppliers.

#### **7.4.2 Purchasing Information**

Purchasing describes the product to be purchased including where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment
- b) Requirements for qualifications of personnel
- c) The identification and revision status of specifications, drawings, process requirements, inspection or verification instructions and other relevant technical data



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- d) Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance
- e) Requirements for test specimens (production method, number, storage conditions) for design approval, inspections, investigation or auditing
- f) Requirements relative to supplier notification of non-conforming product and arrangements for approval of supplier non-conforming material
- g) Requirements for the supplier to notify DDi of changes in product and/or process definition, changes of suppliers, or manufacturing facility locations and where required, obtain DDi approval.
- h) Record retention requirements
- 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 ensures 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, Purchasing states the intended verification arrangements and method of product release 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 will 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 will be acceptable per applicable specifications. DDi periodically validates test reports for raw material.

Where purchased product is released for production use pending completion of all required verifications activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

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



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Where specified in the contract, the customer or the customer's representative are 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

**Note: Following Specific Requirements for ISO 13485:2003 (specific to Toronto) are excluded**

#### 7.5.1.2.1 Cleaning of Product and Contamination Control

**Note: DDi does not perform sterilization. General cleaning practices are followed per standard work instructions.**

#### 7.5.1.2.2 Installation Activities

**Note: DDi does not install medical devices. Hence, DDi is excluded from this clause.**

#### 7.5.1.2.3 Servicing Activities

**Note: DDi is excluded from this clause due to the nature of the business.**

#### 7.5.1.3 Particular Requirements for sterile medical devices.

**Note: DDi is excluded from this clause due to the nature of the business.**

#### 7.5.2.2 Particular Requirements for sterile medical devices.

**Note: DDi is excluded from this clause due to the nature of the business.**

#### 7.5.3.2.2 Particular Requirements for active implantable medical devices.

**Note: DDi is excluded from this clause due to the nature of the business.**

### 7.5.1 Control of Production and Service Provision

DDi plans and carries out production provisions under controlled conditions. Controlled conditions include, as applicable:

- a) Availability of information that describes the characteristics of the products (drawings, part lists, material and process specifications)
- b) Availability of work instructions, as necessary (may include process flow charts, production documents such as manufacturing plans, travelers, routers, work orders, process cards, inspection documents, etc)
- c) Use of suitable equipment (jigs, fixtures, molds, software programs)
- d) Availability and use of monitoring and measuring equipment
- e) Implementation of monitoring and measurement
- f) Implementation of product release, delivery and post delivery activities (if applicable)
- g) Accountability for all product during production (e.g. quantities, split orders, non-conforming products)
- h) Evidence that all production and inspection / verification operations have been completed as planned or as otherwise documented and authorized
- i) Provision for the prevention, detection and removal of foreign objects
- j) Monitoring and control of utilities and supplies (e.g. water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements
- k) Criteria for workmanship, specified in the clearest practical way (e.g. written standards, representative samples, illustrations)

Planning considers, when appropriate:



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

### **7.5.1.1 Production Process Verification:**

DDi uses a representative PCB from the first production run of a new part number to verify that the production process, production documentation and tooling are capable of producing parts that meet requirements. This process is repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

Production operations are carried out in accordance with approved data. This data contains as necessary:

- a) Drawings, parts list, process flow charts including first article inspection for critical processes (i.e. lamination, copper plating, solder mask, via fill etc.) & 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 intended use

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

Persons authorized to approve changes to production processes are identified.

DDi identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

DDi controls and documents changes affecting processes, production requirement, tools and software programs are documented. Procedures are available to control their implementation.

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

The change control plan describes the process by which DDi monitors and addresses changes to the QML program and the certified and qualified technology.

Notifications of major changes are made concurrently to the qualifying activity. A summary of all changes are made in the QML status.

- a) Major changes are those that may affect the performance, quality or reliability of the printed board. Major changes also include changes to the QM Plan.
- b) Minor changes are changes that do not affect performance or quality of the printed board or are editorial in nature.



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

Production equipment, tools and programs used to automate and control / monitor product realization processes, are validated prior to use and maintained and inspected periodically according to documented procedures. Validations prior to production use include verification of the first article produced to the design data/specification in accordance with the established procedures.

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

### **7.5.1.4 Post Delivery Support**

DDi does not provide Post Delivery Support for its products

### **7.5.2 Validation of Processes for Production and Service Provision (Special Processes)**

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

- a) Defined criteria for review and approval of these processes
- b) Approval of equipment and qualification of personnel
- c) Use of specific methods and procedures for control of special processes in accordance with documented process specifications and changes to specifications
- d) Requirements for records
- e) Revalidation

Note: NTI (New Technology Introduction) and DCN (Document Change Notification) processes support the above requirements.

### **7.5.3 Identification and Traceability**

Management identifies, where appropriate, the product by suitable means throughout product realization. DDi maintains 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 has established and documented 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's QMS provides for:

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



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- c) For a given product, a sequential record of its production (manufacture, inspection) is retrievable.

### **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 includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, 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 ensures 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 maintains a register of these monitoring and measuring devices, and defines 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.



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Management 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:

- a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist the basis used for calibration or verification is recorded
- b) Measuring equipment is adjusted or re-adjusted as necessary
- c) Measuring equipment is identified to enable the calibration status to be determined
- d) Safeguarded from adjustments that would invalidate the measurement result
- e) Protected from damage and deterioration during handling, maintenance and storage

DDi has established, implemented and maintains a process for the recall of monitoring and measuring equipment requiring calibration verifications.

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 (4.2.4).

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 maintains its suitability for use. This is undertaken prior to initial use and reconfirmed as necessary.

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

#### **8.1 Test Optimization**

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.

According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- a) Process Control
  - Selection and inspection of key characteristics
  - Process capability measurements
  - Statistical process controls
  - Design of Experiments
- b) Inspection and Failure Mode Effect and Criticality Analysis

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

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



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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 customer score cards.

The customer satisfaction and/or dissatisfaction data is compiled and subsequently used as an input to Management Review. DDi implements plans for customer satisfaction improvement that addresses deficiencies identified by these evaluations and assesses the effectiveness of the results.

### **8.2.2 Internal Audit**

Internal Audits are conducted at planned intervals to determine whether the quality management system

- a) Conforms to the planned arrangements (see 7.1), to the requirements of AS9100 Standards, and to the QMS requirements established by DDi
- b) Confirm that QMS 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 the audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

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 are 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 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 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 are maintained indicating the person(s) authorizing release

of product for delivery to the customer per section 4.2.4. The monitoring and measurement methods 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.



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In the event of process nonconformity, DDi:

- a) Take appropriate action to correct the nonconforming process
- b) Evaluate whether the process nonconformity has resulted in product nonconformity
- c) Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products
- d) 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). This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained.

- a) Criteria for acceptance and/or rejection
- b) Where in the sequence measurement and testing operations are performed
- c) Record of the measurement results (at a minimum, indication of acceptance or rejection)
- d) Specific measurement instruments required and any specific instructions associated with their use
- e) Capability verification inspection

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

When critical items, including key characteristics, have been identified, DDi ensures that they are controlled and monitored in accordance with the established processes.

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

Product will 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.

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.

DDi ensures that all documents required to accompany the product are present at delivery.

### **8.2.5 Periodic Conformance Inspection (PCI) and Lot Conformance Inspection (LCI)**



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8.2.5.1 PCI and LCI are defined in the Procedures and Work Instructions for each DDi division.

### **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 (CO-QP-8.7). The procedure defines 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:

- a) Taking action to eliminate the detected nonconformity
- b) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- c) Taking action to preclude its original intended use or application
- d) Taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- e) Taking action necessary to contain the effect of the nonconformity on other processes or products
- f) Records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained are maintained, monitored and controlled

Product given a 'scrap' disposition is 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.

In addition to any contract or regulatory authority reporting requirements, DDi takes 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 or safety to the customer. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer, part numbers, quantity, and date(s) delivered.

### **8.4 Analysis of Data**

Management determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and evaluates 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

- a) Customer Satisfaction/dissatisfaction (see 8.2.1)
- b) Conformity to product requirements (see 8.2.4)
- c) Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4)
- d) Suppliers (see 7.4).

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**



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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), BPk Audits and periodic management review. Improvement activities will be monitored and evaluated for effectiveness of the results.

### **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 (CO-QP-8.10) is established and defines requirements for

- a) Review nonconformities (including customer complaints)
- b) Determine the causes of nonconformities
- c) Evaluate the need for action to ensure nonconformities do not recur
- d) Determine and implement action as needed
- e) Record the results of actions taken
- f) Review 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
- i) Determine if additional nonconforming product exists, based on the root cause and take further action as needed

### **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 (CO-QP-8.10) 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.

**Note:** Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA) and information on product issues reported by external sources.



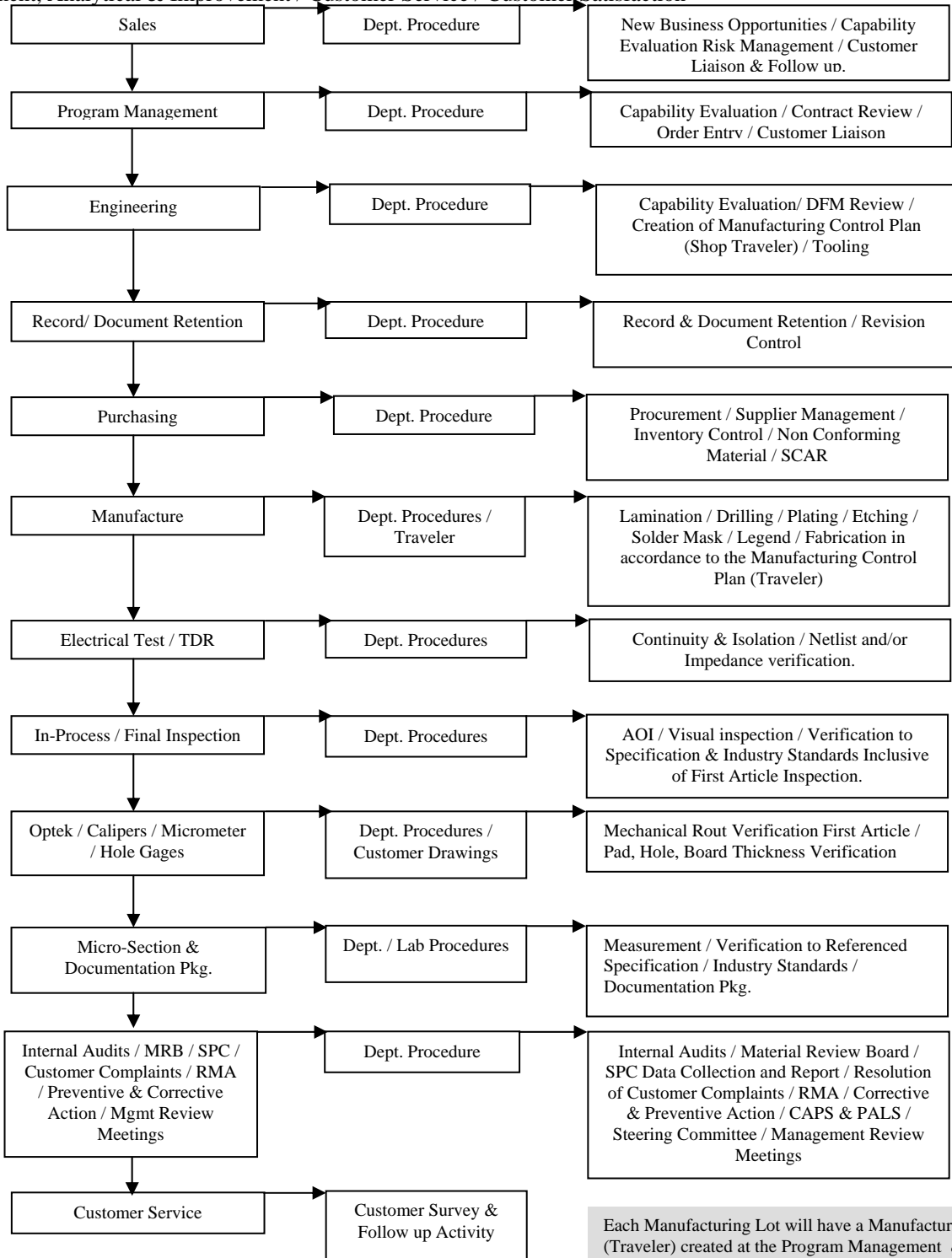
# DDi Corporate Quality System Manual

## Appendix A

### SYSTEM DESIGN AND INTERACTION OF THE ELEMENTS

#### PCB QMS Process Interaction

Quality Management Systems / Management Responsibility / Resource Management / Risk 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.

