

QUALITY MANUAL



Quality Management System

Owner

Dhanima Inc.

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Introduction

01. General

Dhanima Inc. is in the greater Houston, TX area. We are trusted partners in manufacturing, contract manufacturing, strategic supply partnerships, channel partnerships, and strategic sourcing. Our product range includes industrial, food, and USP grades of Castor Oil & Derivatives, Guar gum, chemicals, intermediates, additives, one-pack chemicals, catalysts, packaging products, and customized solutions. We also offer private label packaging and ensure that our products are manufactured in ISO-certified high-tech facilities in India under the supervision of experienced technologists, with distribution throughout North America. Additionally, we provide DDP (Delivered Duty Paid) delivery and have established a reliable network for logistics, transportation, and customs clearances. Our offerings extend beyond the products listed here.

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This Quality Manual specifies requirements that Dhanima Inc. uses to address customer satisfaction, meet customer and applicable regulatory and statutory requirements, and meet ISO 9001:2015 requirements. It is supported by additional procedures where necessary. The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this Quality Policy Manual.

This Quality Manual specifies the general requirements for Dhanima Inc.'s competence in managing quality, administrative, and business services operations.

1. Scope

This Quality Manual specifies requirements for a quality management system where Dhanima Inc.:

- a. Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- b. Aim to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size or the products and services it provides.

2. Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9001:2015, Quality management systems — Fundamentals and vocabulary

3. Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

4. Context of the Organization

4.1 Understanding the Organization and its Context

Dhanima Inc. has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Dhanima Inc. monitors and reviews information about these external and internal issues and the **monitoring frequency** is annual, but may be required more frequently if needed.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Dhanima Inc.'s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Dhanima Inc. determined:

- a. The interested parties that are relevant to the quality management system.
- b. The requirements of these interested parties are relevant to the quality management system.

Dhanima Inc. monitors and reviews the information about these **interested parties** and their relevant requirements.

Interested Parties:

Provider Name	Service/Products Provided	Evaluation Date	Performance Rating	Comments	Corrective Actions
Aarti Chemicals, India	Chemicals	01/12/2023	4/5	On-time delivery, quality issues noted	Quality improvement plan requested
TGV Group	Water Chemicals	08/11/2024	4/5	Water chemicals met requirements but occasional delays in supply.	Improve supply chain reliability and expedite delivery schedules.
Girnar	Castor Derivatives	12/07/2024	3/5	High-quality castor derivatives, delivered on time and as per	Maintain current service level; explore expanding product range.

				specifications.	
Sayaji Pails	Metal Pails	03/06/2023	4/5	Metal pails were durable, but packaging could be more robust during transport.	Improve packaging to ensure safe transport of products.
Sameer Gediya	Website Designing & IT	04/01/2025	5/5	Website development met expectations, but support response time could be quicker.	Provide faster customer support.
Pacific Organics	Bromide Chemicals	06/09/2023	3/5	Bromide chemicals were delivered as requested, though labelling was unclear.	Implement more precise and more detailed labeling on shipments.

4.3 Determining the Scope of the Quality Management System

Dhanima Inc. has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, Dhanima Inc. considered:

- a. The external and internal issues referred to in [4.1](#);
- b. The requirements of relevant interested parties referred to in [4.2](#);
- c. The products and services of Dhanima Inc.

Dhanima Inc. applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of Dhanima Inc.'s quality management system is available and maintained as documented information. The scope states the types of products and services covered and provides justification for any requirements that Dhanima Inc. has determined are not applicable to the scope of its quality management system.

Conformity to ISO 9001 is only claimed if the requirements determined as not being applicable do not affect Dhanima Inc.'s ability to ensure the conformity of its product and services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with Dhanima Inc. activities and registration is:

Provision of International Trade Services, including Import, Export, Supply, and Indenting of Chemicals, Catalysts, Additives, Intermediates, Solvents, Raw Materials, Finished Products, Medical Supplies, and Industrial Supplies, as well as Contract Manufacturing and Channel Partnership Services.

Exclusion for Monitoring and Measuring Resources:

"Due to current resource constraints and the scale of our import-export operations, Dhanima Inc. has made the decision to exclude formal Monitoring and Measuring Resources for our operations at this time. This exclusion includes, but is not limited to, performance tracking, compliance monitoring, and quality control systems. We acknowledge that while this exclusion minimizes operational costs, it may present risks in areas such as regulatory compliance and product quality. We will review this policy annually to determine if reintegrating these resources is necessary as the business scales or as external factors evolve."

Exclusion for Customized and Development of Products and Services:

Dhanima Inc. does not offer product customization for items that are non-compliant, sanctioned, environmentally hazardous, or in violation of local and international laws.

4.4 Quality Management System and its Processes

4.4.1 Dhanima Inc. has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

Dhanima Inc. has determined the processes needed for the quality management system and their application throughout Dhanima Inc. and

- a. Determined the inputs required and the outputs expected from these processes;
- b. Determined the sequence and interaction of these processes;
- c. Determined and applied the criteria and methods (including purchase, sales, and business performance indicators) needed to ensure the effective operation and control of these processes.
- d. Determined the resources required for these processes and ensure their availability.
- e. Assign the responsibilities and authorities for these processes.
- f. Addresses the risks and opportunities as determined in accordance with the requirements of [6.1](#);
- g. Evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results.
- h. Improves the processes and the quality management system.

4.4.2 To the extent necessary, Dhanima Inc.:

- a. Maintains documented information to support the operation of its processes
- b. Retain documented information to have confidence that the processes are being carried out as planned

5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality management system by:

- a. Taking accountability for the effectiveness of the quality management system;
- b. Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of Dhanima Inc.;
- c. Ensuring the integration of the quality management system requirements into Dhanima Inc.'s business process.
- d. Promoting the use of the process approach and risk-based thinking.
- e. Ensuring that the resources needed for the quality management system are available.
- f. Communicate the importance of effective quality management and conforming to the quality management system requirements.
- g. Ensuring that the quality management system achieves its intended results.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

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

5.2 Policy

5.2.1 Developing the Quality Policy

Top management has established, implemented, and maintains a quality policy that:

- a. Is appropriate to the purpose and context of Dhanima Inc. and supports its strategic direction.
- b. Provides a framework for setting quality objectives.
- c. Includes a commitment to satisfy applicable requirements; and
- d. This includes a commitment to the continual improvement of the quality management system.

5.2.2. Communicating the Quality Policy

The Quality Policy:

- a. is available and maintained as documented information;
- b. is communicated, understood, and applied within the organization; and
- c. is available to relevant interested parties, as appropriate.

Quality Policy

At Dhanima Inc., we are committed to delivering high-quality products and services to our customers. To achieve this, we:

- Develop and implement a comprehensive quality management system and procedures to ensure the delivery of products and services that meet both national and international standards.
- Effectively communicate this Quality Policy to all employees and relevant stakeholders.

- Provide a structured framework for establishing, monitoring, and reviewing quality objectives.
- Offer appropriate training to our employees and other relevant personnel to maintain high standards.
- Standardize, regularly update, review, and continually improve our quality management system, business processes, and services.
- Actively seek customer feedback and take appropriate action to address their concerns.

HARESH CHOTALIYA

President

5.3 Organizational Roles, Responsibilities, and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within Dhanima Inc.

Top management assigns the responsibility and authority to:

1. **Mr. Haresh Chotaliya (President/CEO)** has the highest authority in terms of **strategic vision, financial oversight, stakeholder relations, and major decision-making** in the organization. His role as CEO provides him with the ultimate decision-making power and accountability for the company's overall direction.
2. **Mrs. Tejal Parmar (Member/Executive Director/Manager)** has significant authority over the **day-to-day operations, sales, and business development, customer/vendor relations, compliance, and human resources** within her division. Her authority primarily focuses on operational excellence and ensuring that the company's logistical, sales and financial transactions run smoothly.
3. **Mr. Paril Gediya (General Manager India)** has authority over **operational management** in India, including **logistics, inventory, customer service, staff management, and quality control**. His authority is essential to ensuring that all operational functions are running efficiently and that product quality is maintained.

6. Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, Dhanima Inc. considered the issues referred to in [4.1](#) and the requirements referred to in [4.2](#) and determined the risks and opportunities that need to be addressed:

- a. Give assurance that the quality management system can achieve its intended results;
- b. Enhance desirable effects.
- c. Prevent, or reduce, undesired effects; and
- d. Achieve improvement.

6.1.2 Dhanima Inc. plans:

- a. Actions to address these risks and opportunities.
- b. How to:
 - i. Integrate and implement the actions into its quality management system processes (See [4.4](#))
 - ii. Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

6.2 Objectives and Planning to Achieve Them

6.2.1 Dhanima Inc. has established quality objectives at relevant functions, levels, and processes needed for the quality management system.

The quality objectives are:

- a. Consistent with the quality policy
- b. Measurable
- c. Taken into account applicable requirements
- d. Relevant to the conformity of products and services and to the enhancement of customer satisfaction
- e. , Monitored
- f. Communicated
- g. Updated as appropriate.

Dhanima Inc. maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, Dhanima Inc. has determined:

- a. What will be done;
- b. What resources will be required;
- c. Who will be responsible;
- d. When will it be completed?
- e. How the results will be evaluated.

6.3 Planning of Changes

When Dhanima Inc. determines the need for changes to the quality management system, the changes are carried out in a planned manner (see [4.4](#)).

Dhanima Inc. considers:

- a. The purpose of the changes and their potential consequences
 - b. The integrity of the quality management system
 - c. The availability of resources
 - d. The allocation or reallocation of responsibilities and authorities.
- At our company, changes are typically implemented through internal audits, Management Review Meetings (MRM), or team discussions. Given our organization's size, a detailed, extensive plan is not required for every change. This process ensures that changes are thoroughly discussed and aligned with company goals without the need for unnecessary complexity.

7. Support

7.1 Resources

7.1.1 General

Dhanima Inc. determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

Dhanima Inc. considers:

- a. The capabilities of, and constraints on, existing internal resources
- b. What needs to be obtained from the external providers

7.1.2 people

Dhanima Inc. determines and provides the people necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

Dhanima Inc. determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

- a. Rented warehouses and associated utilities.
- b. Equipment, including hardware and software.
- c. Transportation resources; and
- d. Information and communication technology.

7.1.4 Environment for the Operation of Processes

Dhanima Inc. determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity with its products and services.

- a. Social (e.g., non-discriminatory, calm, non-confrontational)
- b. Psychological (e.g., stress-reducing, burnout prevention, emotionally protective);
- c. Physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Dhanima Inc. determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Dhanima Inc. ensures that the resources provided:

- a. Are suitable for the specific type of monitoring and measurement activities being undertaken; and
- b. Are maintained to ensure their continuing fitness for their purpose.

Dhanima Inc. retains appropriate documented information as evidence of fitness for the purpose of monitoring and measurement resources.

7.1.5.2 Measurement Traceability (for Tools & equipment sales)

When measurement traceability is a requirement or is considered by Dhanima Inc. to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- a. Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standard exists, the basis used for calibration or verification is retained as documented information.
- b. Identified in order to determine their status; and
- c. Safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

Dhanima Inc. determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and takes appropriate action as necessary.

Exclusion:

"Due to current resource constraints and the scale of our import-export operations, Dhanima Inc. has made the decision to exclude formal Monitoring and Measuring Resources for our operations at this time. This exclusion includes, but is not limited to, performance tracking, compliance monitoring, and quality control systems. We acknowledge that while this exclusion minimizes operational costs, it may present risks in areas such as regulatory compliance and product quality. We will review this policy annually to determine if reintegrating these resources is necessary as the business scales or as external factors evolve."

7.1.6 Organizational Knowledge

Dhanima Inc. determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, Dhanima Inc. considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

Dhanima Inc.:

- a. Determines the competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system
- b. Ensures that these persons are competent on the basis of appropriate education, training, or experience
- c. Where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken
- d. Retain appropriate documented information as evidence of competence.

7.3 Awareness

Dhanima Inc. ensures that persons doing work under Dhanima Inc.'s control are aware of the following:

- a. The quality policy;
- b. Relevant quality objectives;
- c. Their contribution to the effectiveness of the quality management system, including the benefits of improved performance; and

- d. The implication of not conforming with the quality management system requirements.

7.4 Communication

Dhanima Inc. determined the internal and external communications relevant to the quality management system, including:

1. On what it will communicate:

- **Internal Communication:** Primarily focuses on topics such as policies, procedures, operational plans, internal audits, performance results, employee well-being, safety protocols, quality metrics, and non-conformities.
- **External Communication:** Involves conveying information about the organization's products, services, compliance with legal and regulatory requirements, sustainability initiatives, and interaction with customers, suppliers, and other stakeholders.

2. When to communicate:

- **Internal Communication:** This could be in response to new projects, updates, reports, feedback, or during key events like audits, meetings, or operational reviews.
- **External Communication:** Typically occurs in response to customer inquiries, regulatory requirements, public reporting, marketing, product releases, or crisis management.

3. With whom to communicate:

- **Internal Communication:** Employees, management, and departments within the organization.
- **External Communication:** Customers, suppliers, regulatory bodies, stakeholders, and the public.

4. How to communicate:

- **Internal Communication:** This can be through formal or informal meetings, reports, emails, intranet systems, training, notice boards, and discussions.
- **External Communication:** Involves methods such as emails, official reports, website updates, social media, public announcements, newsletters, direct mail, and calls with clients or regulatory bodies.

5. Who communicates:

- **Internal Communication:** It could be communicated by department heads, quality managers, HR, safety officers, or team leaders depending on the topic.
- **External Communication:** Typically handled by communication specialists, managers, customer service representatives, compliance officers, or top management for sensitive or high-level matters.

7.5 Documented Information

7.5.1 General

Dhanima Inc.'s quality management system includes the following:

- a. Documented information required by ISO 9001:2015; and
- b. Documented information determined by Dhanima Inc. as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating and updating documented information, Dhanima Inc. ensures appropriate:

- a. Identification and description (e.g., title, date, author, or reference number);
- b. Format (e.g., language, software version, graphics) and media (e.g., paper, electronic); and
- c. Review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 are controlled to ensure:

- a. Availability and suitable for use, where and when it is needed; and
- b. It is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, Dhanima Inc. has addressed the following activities, as applicable.

- a. Distribution, access, retrieval, and use;
- b. Storage and preservation, including preservation of legibility.
- c. Control of changes (e.g., version control); and
- d. Retention and disposition.

Documented information of external origin determined by Dhanima Inc. to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

8. Operation

8.1 Operational Planning and Control

Dhanima Inc. planned, implemented, and controlled the processes (see [4.4](#)) needed to meet the requirements for the provision of products and services and implemented the actions determined in [Clause 6](#) by:

- a. Determining the requirements for the products and services;
- b. Establishing criteria for:
 - i. The processes;
 - ii. The acceptance of products and services;
- c. Determining the resources needed to achieve conformity to the product and service requirements;
- d. Implementing control of the processes in accordance with the criteria; and
- e. Determining and keeping documented information to the extent necessary:
 - i. To have confidence that the processes have been carried out as planned;
 - ii. To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to Dhanima Inc.'s method of operations. Dhanima Inc. ensures that outsourced processes are controlled (See [8.4](#)).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with Customers includes:

- a. Providing information relating to products and services.
- b. Handling inquiries, contracts, or orders, including changes;
- c. Obtaining customer feedback relating to products and services, including customer complaints;
- d. Handling or controlling customer property; and
- e. Establish specific requirements for contingency actions when relevant.

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the product and services to be offered to customers, Dhanima Inc. ensures that:

- a. The requirements for the product and services are defined, including:
 - i. Any applicable statutory and regulatory requirements;
 - ii. Those considered necessary by Dhanima Inc.;
- b. Dhanima Inc. can meet the claims for the products and services it offers.

8.2.3 Review of Requirements Related to Products and Services

8.2.3.1 Dhanima Inc. ensures that it can meet the requirements for the products and services offered to customers. Dhanima Inc. conducts a review before committing to supply products and services to a customer, including:

- a. Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b. Requirements not stated by the customer but necessary for the specified intended use when known;
- c. Requirements specified by Dhanima Inc.;
- d. Statutory and regulatory requirements applicable to the products and services; and
- e. Contract or order requirements differing from those previously expressed.

Dhanima Inc. ensures that the contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by Dhanima Inc. before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Dhanima Inc. retains documented information, as applicable:

- a. On the results of the review; and
- b. On any new requirements for the products and services;

8.2.4 Changes to Requirements for Products and Services

Dhanima Inc. ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Customized and Development of Products and Services

8.3.1 General

Dhanima Inc. has established, implemented, and maintains a customized and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Customize and Development Planning

In determining the stages and controls for Customize and development, Dhanima Inc. considers the following:

- a. The nature, duration, and complexity of the customize and development activities;
- b. The required process stages, including applicable customize and development reviews;
- c. The required customized and development verification and validation activities;
- d. The responsibilities and authorities involved in the Customize and development process;
- e. The internal and external resource needs for the Customize and development of products and services;
- f. The need to control interfaces between persons involved in the Customize and development process;
- g. The need for involvement of customers and users in the Customize and development process;
- h. The requirements for subsequent provisions of products and services;
- i. The level of control expected for the Customize and development process by the customer and other relevant interested parties; and
- j. The documented information is needed to demonstrate that customization and development requirements have been met.

8.3.3 Customize and Development Inputs

Dhanima Inc. determines the requirements essential for the specific types of products and services to be Customized and developed. Dhanima Inc. considers:

- a. Functional and performance requirements;
- b. Information derived from previous similar Customize and development activities;
- c. Statutory and regulatory requirements.
- d. Standards or codes of practice that Dhanima Inc. has committed to implement; and
- e. Potential consequences of failure due to the nature of the products and services.

Inputs are adequate for Customize and development purposes, complete, and unambiguous. Conflicting Customize and development inputs are resolved.

Dhanima Inc. retains documented information on Customize and development inputs.

8.3.4 Customize and Development Controls

Dhanima Inc. applies controls to the Customize and development process to ensure that:

- a. The results achieved are defined,
- b. Reviews are conducted to evaluate the ability of the results of Customize and Development to meet requirements;
- c. Verification activities are conducted to ensure that the Customize and development outputs meet the input requirements;
- d. Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

- e. Any necessary actions are taken on problems determined during the reviews or verification and validation activities; and
- f. Documented information on these activities is retained.

8.3.5 Customize and Development Outputs

Dhanima Inc. ensures that customized and development outputs:

- a. meet the input requirements;
- b. are adequate for the subsequent processes for the provision of products and services;
- c. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d. specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Dhanima Inc. retains documented information on customization and development outputs.

8.3.6 Customize and development changes

Dhanima Inc. identifies, reviews, and controls changes made during, or subsequent to, the Customize and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Dhanima Inc. retains documented information on:

- a. Customize and development changes;
- b. The results of reviews;
- c. The authorization of the changes; and
- d. The actions taken to prevent adverse impacts.

Exclusion:

Dhanima Inc. does not offer product customization for items that are non-compliant, sanctioned, environmentally hazardous, or in violation of local and international laws.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Dhanima Inc. ensures that externally provided processes, products, and services conform to requirements.

Dhanima Inc. determines the control applied to externally provided processes, products, and services when:

- a. Products and services from external providers are intended for incorporation into Dhanima Inc.'s own products and services;
- b. Products and services are provided directly to the customer(s) by external providers on behalf of Dhanima Inc., and
- c. A process, or part of a process, is provided by an external provider as a result of a decision by Dhanima Inc.

Dhanima Inc. determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Dhanima Inc. retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type of Extent Control

Dhanima Inc. ensures that externally provided processes, products, and services do not adversely affect.

Dhanima Inc.'s ability to consistently deliver conforming products and services to its customers.

Dhanima Inc.:

- a. Ensures that externally provided processes remain within the control of its quality management system;
- b. Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c. Takes into consideration:
 - i. The potential impact of the externally provided processes, products and services on Dhanima Inc.'s ability to consistently meet customer and applicable statutory and regulatory requirements;
 - ii. The effectiveness of the controls applied by the external provider;
- d. Determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

8.4.3 Information for External Providers

Dhanima Inc. ensures the adequacy of requirements prior to their communication to the external provider.

Dhanima Inc. communicates to external providers its requirements for:

- a. The processes, products and services to be provided;
- b. The approval of:
 - i. Products and services;
 - ii. Methods, processes and equipment;
 - iii. The release of products and services;
- c. Competence, including any required qualification of persons;
- d. The external providers' interactions with Dhanima Inc.;
- e. Control and monitoring of the external providers' performance to be applied by Dhanima Inc.; and
- f. Verification or validation activities that Dhanima Inc., or its customer, intends to perform at the external providers' premises.

8.5 Third Party contract Production and Service Provision

8.5.1 Control of third-party Production and Service Provision

Dhanima Inc. implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a. The availability of documented information that defines:
 - i. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - ii. The results to be achieved;
- b. The availability and use of suitable monitoring and measuring resources;
- c. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
- d. The use of suitable infrastructure and environment for the operation of processes;
- e. The appointment of competent persons, including any required qualification;
- f. The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g. The implementation of actions to prevent human error; and
- h. The implementation of release, delivery and post-delivery activities.

8.5.2 Identification and Traceability

Dhanima Inc. uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Dhanima Inc. identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Dhanima Inc. controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

Dhanima Inc. exercises care with property belonging to customer or external providers while it is under Dhanima Inc.'s control or being used by Dhanima Inc.

Dhanima Inc. identifies, verifies, protects and safeguards customer's or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Dhanima Inc. reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4 Preservation

Dhanima Inc. preserves the outputs during production and service provision to the extent necessary to ensure conformity to requirements.

8.5.5 Post-delivery Activities

Dhanima Inc. meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, Dhanima Inc. considers:

- a. Statutory and regulatory requirements;
- b. The potential undesired consequences associated with its products and services;

- c. The nature, use, and intended lifetime of its products and services;
- d. Customer requirements; and
- e. Customer Feedback.

8.5.6 Control of Changes

Dhanima Inc. reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Dhanima Inc. retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

Dhanima Inc. has implemented planned arrangements at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Dhanima Inc. retains documented information on the release of products and services. The documented information includes:

- a. Evidence of conformity with the acceptance criteria;
- b. Traceability to the person(s) authorizing the release.

8.7 Control of Nonconforming Outputs

8.7.1 Dhanima Inc. ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Dhanima Inc. takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after the delivery of products, during or after the provision of services.

Dhanima Inc. deals with nonconforming outputs in one or more of the following ways: a)

Correction;

- a. Segregation, containment, return, or suspension of provision of products and services;
- b. Informing the customer; and
- c. Obtaining authorization for acceptance under concession.

Conformity to the requirements is verified when nonconforming outputs are corrected.

8.7.2 Dhanima Inc. retains documented information that:

- a. Describes the nonconformity;
- b. Describes the actions taken;
- c. Describes any concessions obtained; and
- d. Identifies the authority deciding the action in respect of the nonconformity.

9 Performance Evaluation

9.1 Monitoring, Quality, Measurement, Analysis and Evaluation

9.1.1 General

Dhanima Inc. determines:

- a. What needs to be monitored, quality assurance, and measured;
- b. The methods for monitoring, quality, measurement, analysis, and evaluation needed to ensure valid results;
- c. When the monitoring, quality assurance, and measuring are performed.
- d. When the results from monitoring, QA and measurement are analysed and evaluated.

Dhanima Inc. evaluates the performance and the effectiveness of the quality management system. Dhanima Inc. retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

Dhanima Inc. monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled and determines the methods for obtaining, monitoring, and reviewing this information.

9.1.3 Analysis and Evaluation

Dhanima Inc. analyses and evaluates appropriate data and information arising from monitoring and measurement.

The results of the analysis are used to evaluate:

- a. Conformity of products and services;
- b. The degree of customer satisfaction;
- c. The performance and effectiveness of the quality management system;
- d. If planning has been implemented effectively;
- e. The effectiveness of actions taken to address risks and opportunities;
- f. The performance of external providers; and
- g. The need for improvements to the quality management system.

9.2 Internal Audit

9.2.1 Dhanima Inc conducts internal audits at planned intervals to provide information on whether the quality management system:

- a. Conforms to:
 - i. Dhanima Inc.'s own requirements for its quality management system;
 - ii. The requirements of ISO 9001:2015
- b. Is effectively implemented and maintained.

9.2.2 Dhanima Inc. has:

- a. Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting Dhanima Inc, and the results of previous audits;

- b. Defined the audit criteria and scope of each audit;
- c. Selected auditors and conducts audits to ensure objectivity and impartiality of the audit process;
- d. Ensured that the results of the audits are reported to relevant management;
- e. Take appropriate correction and corrective actions without undue delay; and
- f. Retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

Top management reviews Dhanima Inc.'s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Dhanima Inc.

9.3.2 Management Review Inputs

Management review is planned and carried out taking into consideration:

- a. The status of actions from previous management reviews;
- b. Changes in external and internal issues that are relevant to the quality management system;
- c. Information on the performance and effectiveness of the quality management system, including trends in:
 - i. Customer satisfaction and feedback from relevant interested parties;
 - ii. The extent to which quality objectives have been met;
 - iii. Process performance and conformity of products and services;
 - iv. Nonconformities and corrective actions;
 - v. Monitoring and measurement results;
 - vi. Audit results;
 - vii. The performance of external providers;
- d. The adequacy of resources;
- e. The effectiveness of actions taken to address risks and opportunities (see [6.1](#)); and
- f. Opportunities for improvement

9.3.3 Management Review Outputs

The outputs of the management review include decisions and actions related to:

- a. Opportunities for improvement;
- b. Any need for changes to the quality management system; and
- c. Resource needs.

Dhanima Inc. retains documented information as evidence of the results of management reviews.

10. Improvement

10.1 General

Dhanima Inc. determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a. Improving products and services to meet requirements as well as to address future needs and expectations;
- b. Correcting, preventing or reducing undesired effects; and
- c. Improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When an unconformity occurs, including any arising from complaints, Dhanima Inc.:

- a. Reacts to the nonconformity and, as applicable:
 - i. Takes action to control and correct it;
 - ii. Deals with the consequences;
- b. Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - i. Reviewing and analysing the nonconformity;
 - ii. Determining the causes of the nonconformity;
 - iii. Determining if similar nonconformities exist, or could potentially occur;
- c. Implements any action needed;
- d. Reviews the effectiveness of any corrective action taken;
- e. Updates risks and opportunities determined during planning, if necessary; and
- f. Makes changes to the quality management system, if necessary. Corrective actions are appropriate to the effects of the nonconformities encountered.

10.2.2 Dhanima Inc. retains documented information as evidence of:

- a. The nature of the nonconformities and any subsequent actions taken; and
- b. The results of any corrective action.

10.3 Continual Improvement

Dhanima Inc. continually improves the suitability, adequacy, and effectiveness of the quality management system.

Dhanima Inc. considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.