



Chemyx Inc, North America

THE **ISO 9001:2015**

QUALITY MANUAL

**CHEMYX INC,
NORTH AMERICA**

ISO 9001:2015
Quality
Management
Systems Certified
Business™

1st Edition

ISO 9001:2015

Quality Management Standard
Quality Manual

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Table Of Contents

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Version History _____ **3**

Table Of Contents _____ **4**

General _____ **10**

1. Scope _____ **11**

2. Normative References _____ **12**

3. Terms and Definitions _____ **13**

4. Context of the Organization _____ **14**

4.1. Understanding the Organization and its Context _____ **14**

4.2. Understanding the Needs and Expectations of Interested Parties _____ **14**

4.3. Determining the Scope of the Quality Management System _____ **15**

4.4. Quality Management System and its Processes _____ **16**

5. Leadership	18
5.1. Leadership and Commitment	18
5.1.1. General	18
5.1.2. Customer Focus	19
5.2. Policy	19
5.2.1. Developing the Quality Policy	19
5.2.2. Communicating the Quality Policy	20
5.3. Organizational Roles, Responsibilities, and Authorities	20
6. Planning	22
6.1. Actions to Address Risks and Opportunities	22
6.2. Quality Objectives and Planning to Achieve Them	22
6.3. Planning of Changes	23
7. Support	24
7.1. Resources	24
7.1.1. General	24

7.1.2. People	24
7.1.3. Infrastructure	24
7.1.4. Environment for the Operation of Processes	25
7.1.5. Monitoring and Measuring Resources	25
7.1.6. Organizational Knowledge	26
7.2. Competence	27
7.3. Awareness	27
7.4. Communication	27
7.5. Documented Information	28
7.5.1. General	28
7.5.2. Creating and Updating	28
7.5.3. Control of Documented Information	28
8. Operation	30
8.1. Operational Planning and Control	30
8.2. Requirements for Products and Services	31
8.2.1. Customer Communication	31

8.2.2. Determining the Requirements Related to Products and Services	31
8.2.3. Review of Requirements Related to Products and Services	32
8.2.4. Changes to Requirements for Products and Services	33
8.3. Design and Development of Products and Services	33
8.3.1. General	33
8.3.2. Design and Development Planning	33
8.3.3. Design and Development Inputs	34
8.3.4. Design and Development Controls	34
8.3.5. Design and Development Outputs	35
8.3.6. Design and Development Changes	36
8.4. Control of Externally Provided Processes, Products, and Services	36
8.4.1. General	36
8.4.2. Type of Extent Control	37
8.4.3. Information for External Providers	38
8.5. Production and Service Provision	38
8.5.1. Control of Production and Service Provision	38

8.5.2. Identification and Traceability	39
8.5.3. Property Belonging to Customers or External Providers	40
8.5.4. Preservation	40
8.5.5. Post-delivery Activities	40
8.5.6. Control of Changes	41
8.6. Release of Products and Service	41
8.7. Control of Nonconforming Outputs	42
9. Performance Evaluation	43
9.1. Monitoring, Measurement, Analysis and Evaluation	43
9.1.1. General	43
9.1.2. Customer Satisfaction	43
9.1.3. Analysis and Evaluation	43
9.2. Internal Audit	44
9.3. Management Review	45
9.3.1. General	45
9.3.2. Management Review Inputs	45

9.3.3. Management Review Outputs_____46

10. Improvement _____47

10.1 General _____47

10.2. Nonconformity and Corrective Action_____47

10.3. Continual Improvement _____48

General

At Chemyx Inc, North America we know that an inferior product or service can cost you money, time and credibility. In business, the only tolerance is zero defects. We understand the importance of prompt client response, quality and on time delivery. Chemyx Inc, North America has achieved customer loyalty by practicing a policy of strong communication and working closely with customers to deliver to their exact expectations.

Our investment in people, tools and skills allow our company to communicate with customers efficiently throughout the entire processes of our company.

Chemyx Inc, North America

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

This Quality Manual specifies the general requirements for Chemyx Inc, North America competence towards a management system for quality, administrative and technical operations.

1. Scope

This Quality Manual specifies requirements for a quality management system where Chemyx Inc, North America:

- a) Needs to demonstrate its ability to consistently provide product and services that meet customer and applicable statutory and regulatory requirements, and
- b) Aims 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

Chemyx Inc, North America 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.

Chemyx Inc, North America monitors and reviews information about these external and internal issues.

4.2. Understanding the Needs and Expectations of Interested Parties

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

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

Chemyx Inc, North America monitors and reviews the information about these interested parties and their relevant requirements.

4.3. Determining the Scope of the Quality Management System

Chemyx Inc, North America has determined the boundaries and applicability of the quality management system to establish its scope. When determining this scope, Chemyx Inc, North America 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 Chemyx Inc, North America.

Chemyx Inc, North America applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management

system.

The scope of Chemyx Inc, North America'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 Chemyx Inc, North America has determined is not applicable to the scope of its quality management system. Conformity to ISO 9001 are only claimed if the requirements determined as not being applicable do not affect Chemyx Inc, North America's ability to ensure the conformity of its product and services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with Chemyx Inc, North America activities and registration is:

**Business Supplies & Equipment:
Provide proprietary equipment for
Industrial and Academic applications**

4.4. Quality Management System and its Processes

4.4.1. Chemyx Inc, North America 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.

Chemyx Inc, North America has determined the processes needed for the quality management system and their application throughout Chemyx Inc, North America, 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 monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) Determined the resources needed for these processes and ensure their availability;
 - e) Assigns the responsibilities and authorities for these processes;
 - f) Addresses the risks and opportunities as determined in accordance with the requirements of 6.1;
 - g) Evaluates 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, Chemyx Inc, North America:

- 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 Chemyx Inc, North America;
- c) Ensuring the integration of the quality management system requirements into Chemyx Inc, North America'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) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement; and
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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 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 Chemyx Inc, North America and supports its strategic direction;
- b) Provides a framework for setting quality objectives;
- c) Includes a commitment to satisfy applicable requirements; and
- d) Includes a commitment to 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.

Our quality policy ensures that quality is present from inception to completion in all that we do.

5.3. Organizational Roles, Responsibilities, and Authorities

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

Top management assigns the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of this International Standard;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for

improvement (see 10.1), in particular to top management;

- d) Ensuring the promotion of customer focus throughout Chemyx Inc, North America; and
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6. Planning

6.1. Actions to Address Risks and Opportunities

6.1.1. When planning for the quality management system, Chemyx Inc, North America 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 to:

- 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. Chemyx Inc, North America plans:

- a) Actions to address these risks and opportunities;
- b) How to:
 - 1. Integrate and implement the actions into its quality management system processes (See 4.4)
 - 2. 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. Quality Objectives and Planning to Achieve Them

6.2.1. Chemyx Inc, North America 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 conformity of products and services and to enhancement of customer satisfaction;
- e) Monitored;
- f) Communicated; and
- g) Updated as appropriate.

Chemyx Inc, North America maintains documented information on the quality objectives.

6.2.2. When planning how to achieve its quality objectives, Chemyx Inc, North America has determined:

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

6.3. Planning of Changes

When Chemyx Inc, North America determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

Chemyx Inc, North America considers:

- a) The purpose of the changes and their potential consequences;
- b) The integrity of the quality management system;
- c) The availability of resources; and
- d) The allocation or reallocation of responsibilities and authorities.

7. Support

7.1. Resources

7.1.1. General

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

Chemyx Inc, North America considers:

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

7.1.2. People

Chemyx Inc, North America determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3. Infrastructure

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

- a) Buildings 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

Chemyx Inc, North America determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of 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

Chemyx Inc, North America 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.

Chemyx Inc, North America 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.

Chemyx Inc, North America retains appropriate documented information as evidence of fitness for

purpose of the monitoring and measurement resources.

7.1.5.2. Measurement Traceability

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

- 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 exist, 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.

Chemyx Inc, North America 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.

7.1.6. Organizational Knowledge

Chemyx Inc, North America 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, Chemyx Inc, North America considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2. Competence

Chemyx Inc, North America:

- 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; and
- d) Retain appropriate documented information as evidence of competence.

7.3. Awareness

Chemyx Inc, North America ensures that persons doing

work under the Chemyx Inc, North America's control are aware of:

- 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

Chemyx Inc, North America determined the internal and external communications relevant to the quality management system, including:

- a) On what it will communicate;
- b) When to communicate;

- c) With whom to communicate;
- d) How to communicate; and
- e) Who communicates.

7.5. Documented Information

7.5.1. General

Chemyx Inc, North America's quality management system includes:

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

7.5.2. Creating and Updating

When creating an updating documented information, Chemyx Inc, North America 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, Chemyx Inc, North America 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 Chemyx Inc, North America 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 are protected from unintended alterations.

8. Operation

8.1. Operational Planning and Control

Chemyx Inc, North America planned, implemented and controls 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:
 - 1. The processes;
 - 2. 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:
 - 1. To have confidence that the processes have been carried out as planned;
 - 2. To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to Chemyx Inc, North America's method of operations. Chemyx Inc, North America 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) Establishing 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, Chemyx Inc, North America ensures that:

- a) The requirements for the product and services are defined, including:
 - 1. Any applicable statutory and regulatory requirements;
 - 2. Those considered necessary by Chemyx Inc, North America;
- b) Chemyx Inc, North America can meet the claims for the product and services it offers.

8.2.3. Review of Requirements Related to Products and Services

8.2.3.1. Chemyx Inc, North America ensures that it has the ability to meet the requirements for products and services offered to customers. Chemyx Inc, North America conducts a review before committing to supply products and services to a customer, to include:

- a) Requirements specified by 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 Chemyx Inc, North America;
- d) Statutory and regulatory requirements applicable to the products and services; and

- e) Contract or order requirements differing from those previously expressed.

Chemyx Inc, North America ensures that the contract or order requirements differing from those previously defined are resolved.

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

8.2.3.2. Chemyx Inc, North America 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

Chemyx Inc, North America 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. Design and Development of Products and Services

8.3.1. General

Chemyx Inc, North America has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2. Design and Development Planning

In determining the stages and controls for design and development, Chemyx Inc, North America considers:

- a) The nature, duration, and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification and validation activities;
- d) The responsibilities and authorities involved in the design and development process;
- e) The internal and external resource needs for the design and development of products and services;
- f) The need to control interfaces between persons involved in the design and development process;
- g) The need for involvement of customers and users in

- the design and development process;
- h) The requirements for subsequent provisions of products and services;
 - i) The level of control expected for the design and development process by customer and other relevant interested parties; and
 - j) The documented information needed to demonstrate that design and development requirements have been met.

8.3.3. Design and Development Inputs

Chemyx Inc, North America determines the requirements essential for the specific types of products and services to be designed and developed. Chemyx Inc, North America considers:

- a) Functional and performance requirements;

- b) Information derived from previous similar design and development activities;
- c) Statutory and regulatory requirements;
- d) Standards or codes of practice that Chemyx Inc, North America has committed to implement; and
- e) Potential consequences of failure due to the nature of the products and services.

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

Chemyx Inc, North America retains documented information on design and development inputs.

8.3.4. Design and Development Controls

Chemyx Inc, North America applies controls to the

design and development process to ensure that:

- a) The results achieved are defined,
- b) Reviews are conducted to evaluate the ability of the results of design and development meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) Validation activities are conducted to ensure that the resulting products and service 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 of these activities is retained.

8.3.5. Design and Development Outputs

Chemyx Inc, North America ensures that design 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.

The Chemyx Inc, North America retains documented information on design and development outputs.

8.3.6. Design and Development Changes

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

Chemyx Inc, North America retains documented information on:

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

8.4. Control of Externally Provided Processes, Products, and Services

8.4.1. General

Chemyx Inc, North America ensures that externally provided processes, products, and services conform to requirements.

Chemyx Inc, North America determines the control applied to externally provided processes, products, and services when:

- a) Products and services from external providers are intended for incorporation into Chemyx Inc, North America's own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of Chemyx Inc, North America; and

- c) A process, or part of a process, is provided by an external provider as a result of a decision by Chemyx Inc, North America.

Chemyx Inc, North America 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. Chemyx Inc, North America retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2. Type of Extent Control

Chemyx Inc, North America ensures that externally provided processes, products and services do not adversely affect Chemyx Inc, North America's ability to consistently deliver conforming products and services to its customers.

Chemyx Inc, North America:

- 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:
 1. The potential impact of the externally provided processes, products and services on Chemyx Inc, North America's ability to consistently meet customer and applicable statutory and regulatory requirements;
 2. 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

Chemyx Inc, North America ensures the adequacy of requirements prior to their communication to the external provider.

Chemyx Inc, North America communicates to external providers its requirements for:

- a) The processes, products and services to be provided;
- b) The approval of:
 - 1. Products and services;
 - 2. Methods, processes and equipment;
 - 3. The release of products and services;
- c) Competence, including any required qualification of persons;
- d) The external providers' interactions with Chemyx Inc,

North America;

- e) Control and monitoring of the external providers' performance to be applied by Chemyx Inc, North America; and
- f) Verification or validation activities that Chemyx Inc, North America, or its customer, intends to perform at the external providers' premises.

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

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

- a) The availability of documented information that defines:
 - 1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2. 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

Chemyx Inc, North America uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Chemyx Inc, North America identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Chemyx Inc, North America 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

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

Chemyx Inc, North America 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, Chemyx Inc, North America reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4. Preservation

Chemyx Inc, North America preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5. Post-delivery Activities

Chemyx Inc, North America meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, Chemyx Inc, North America 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

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

Chemyx Inc, North America 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 Service

Chemyx Inc, North America 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.

Chemyx Inc, North America 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. Chemyx Inc, North America ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Chemyx Inc, North America 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 delivery of products, during or after the provision of services.

Chemyx Inc, North America deals with nonconforming outputs in one or more of the following ways:

a) Correction;

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

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

8.7.2. Chemyx Inc, North America 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, Measurement, Analysis and Evaluation

9.1.1. General

Chemyx Inc, North America determines:

- a) What needs to be monitored and measured;
- b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) When the monitoring and measuring is performed;

- d) When the results from monitoring and measurement are analyzed and evaluated.

Chemyx Inc, North America evaluates the performance and the effectiveness of the quality management system. Chemyx Inc, North America retains appropriate documented information as evidence of the results.

9.1.2. Customer Satisfaction

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

9.1.3. Analysis and Evaluation

Chemyx Inc, North America analyzes and evaluates

appropriate data and information arising from monitoring and measurement.

The results of 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. Chemyx Inc, North America conducts internal

audits at planned intervals to provide information on whether the quality management system:

- a) Conforms to:
 - 1. Chemyx Inc, North America's own requirements for its quality management system;
 - 2. The requirements of ISO 9001:2015
- b) Is effectively implemented and maintained.

9.2.2. Chemyx Inc, North America 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 Chemyx Inc, North America, and the results of previous audits;
- b) Defined the audit criteria and scope of each audit;
- c) Selected auditors and conducts audits to ensure objectively and the 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 Chemyx Inc, North America's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Chemyx Inc, North America.

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:
 1. Customer satisfaction and feedback from relevant interested parties;
 2. The extent to which quality objectives have been met;
 3. Process performance and conformity of products and services;
 4. Nonconformities and corrective actions;
 5. Monitoring and measurement results;
 6. Audit results;

7. The performance of external providers;
8. The adequacy of resources;
9. The effectiveness of actions taken to address risks and opportunities (see 6.1); and
10. 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.

Chemyx Inc, North America retains documented information as evidence of the results of management reviews.

10. Improvement

10.1 General

Chemyx Inc, North America 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 a nonconformity occurs, including any arising from complaints, Chemyx Inc, North America:

- a) Reacts to the nonconformity and, as applicable:
 - 1. Takes action to control and correct it;
 - 2. 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:
 - 1. Reviewing and analyzing the nonconformity;
 - 2. Determining the causes of the nonconformity;
 - 3. 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. Chemyx Inc, North America 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

Chemyx Inc, North America continually improves the suitability, adequacy and effectiveness of the quality

management system.

Chemyx Inc, North America 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.