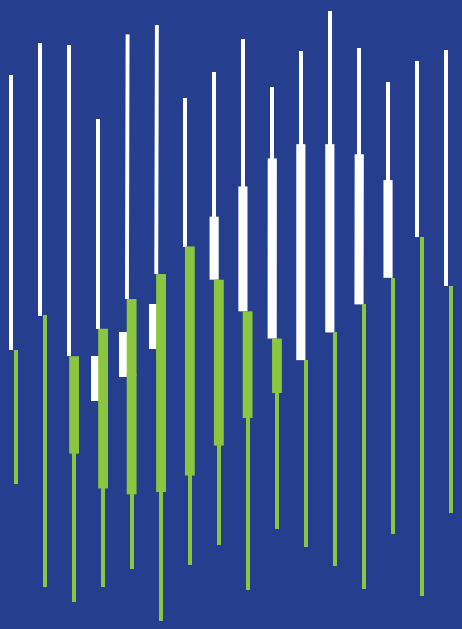
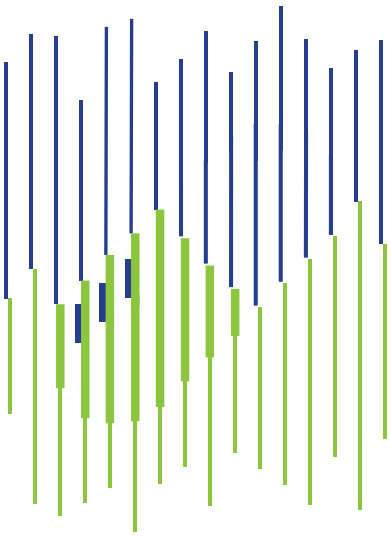
NIPPON EXPRESS

We Find the Way

NX-Pharma Global Quality Manual

NIPPON EXPRESS HOLDINGS, INC.





CONTENTS

1. Forward

Message from the
Group Top Management

Chief Managing Officer of
Global Business Headquarters
Tadahiro Furue

I'm pleased to share with you the NX-Pharma Global Quality Manual. This quality manual serves as a common guide across the NX Group to perform GDP and GMP operations of medicinal products globally with standardized quality.

At the NX Group, as a leading global logistics company, it is our mission to be a driving force for social development by creating new values through our logistics services. The pharmaceutical industry is one of our priority industries of the group. We support our customers in the global pharmaceutical industry from a logistical perspective, by building a reliable and safe global pharmaceutical supply network to deliver their medicinal products safely and timely with assured integrity to patients/ medical professionals across the world. By doing so, we aim to "Contribute to the health of people" around the world.

Medicinal products require strict temperature control and security control during transportation and storage. In addition, for many of the medicinal products, the supply chain from raw material procurement to drug manufacturing through finished product delivery has been extended globally, and various risks need to be controlled, such as deterioration of quality due to deviation of storage conditions during transportation of raw materials/ intermediates and finished products, compromise of product integrity, entry of falsified medicinal product into the legal route during transportation, and theft of medicinal products.

For this reason, the NX Group has established an independent organization for quality assurance of the pharmaceutical supply network at the global headquarters and has a quality assurance organization at pharmaceutical business locations throughout the world to promote quality assurance activities.

The NX-Pharma Global Quality Manual provides an overview of the organization, responsibilities, and processes of the Pharmaceutical Quality Management System of the NX Group for all personnel involved in the pharmaceutical business, in order to ensure a standardized operation of the pharmaceutical supply network quality assurance activities at the global level.

We are confident that compliance with this quality manual enables all personnel at every level of pharmaceutical business of the NX Group to recognize their responsibilities and thereby to "Contribute to the health of people" through provision of reliable and safe global pharmaceutical logistics services.

2. Introduction

2.1 Purpose

The purpose of this NX-Pharma Global Quality Manual is to describe the framework and principles of the Pharmaceutical Quality Management System (PQMS) of the NX Group. The Manual is to be implemented and maintained at each global business location of the NX Group, and is entrusted upon performing the operations related to accepting orders, packaging/ labeling, import/export, storage and transportation of medicinal products conducted based on GDP and GMP standards.

2.2 Scope

This NX-Pharma Global Quality Manual applies to the entire pharmaceutical logistics business of the NX Group.

2.3 Applicable Laws and Regulations

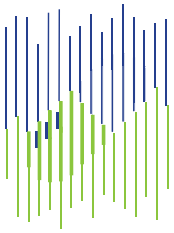
The following laws, regulations, and guidelines shall be applied in the pharmaceutical business conducted in the NX Group, where applicable.

- PIC/s GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS June 2014 (PIC/s GDP June 2014)
- GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS PART I and Part 2 (PIC/s GMP)
- Current Good Manufacturing Practice (CGMP) Regulations

2.4 Reference Laws, Regulations, and Guidelines

In addition, the following laws, regulations, and guidelines related to GDP and GMP standards applied in each country shall be referenced.

- Good Distribution Practices for Pharmaceutical Products (Annex 5, WHO Technical Report Series, No.957, 2010)
- EU Guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use (2013/C 343/01)
- Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)



- PIC/s GUIDELINES ON THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICE OF ACTIVE SUBSTANCES FOR MEDICINAL PRODUCTS FOR HUMAN USE (July 2013)
- USP<1079> Good Storage and Distribution Practices for Drug Products
- USP<1083> Good Distribution Practice
- ICH Q9 Guidelines for Quality Risk Management
- ICH Q10 Guideline for Pharmaceutical Quality System
- PIC/s GMP Annex15 QUALIFICATION AND VALIDATION
- Eudralex – Volume 4 - Good Manufacturing Practice (GMP) guidelines
- 21 CFR 210, cGMP for Manufacturing, Processing, Packing, or Holding of Drugs
- 21 CFR 211, cGMP for Finished Pharmaceuticals
- 21 CFR Part 11 Electronic Records, Electronic Signatures

Pharmaceutical quality management is established based on the ISO9001 system. While ISO9001 is a request for a general quality system applicable in many areas and requirements for medicinal products are not clear, GDP/GMP guidelines stipulate requirements exclusively for medicinal products. Among all the business locations in which the NX Group is involved, those in which operations are performed under ISO9001 are required to prepare operating procedures in accordance with the GDP/GMP quality system for each location either by using the existing functions of ISO9001 or independently and to perform the pharmaceutical quality management.

3. NX-Pharma Quality Policy

At the NX Group, the mission of our pharmaceutical logistics services (NX-Pharma) is to support our Pharma Customers to deliver the needed medicines to patients, globally, in a secure and reliable way, while maintaining the quality and integrity as we received them from our Pharma Customers.

We make every effort to develop and implement the Pharmaceutical Quality Management System (PQMS) that employs high standards and best practices and complies with all laws, regulations, and guidelines related to pharmaceutical logistics in order to ensure quality, product integrity, prevention of falsified medicinal products entering the legal supply chain, and traceability.

These stringent GDP/GMP requirements are critical throughout the supply chain. Operations are performed in compliance with quality systems for all phases of transport including: Land, air, ocean transportation, storage at the logistics service provider, or short interim storage at the handling hub. Consistent implementation and maintenance of GDP/GMP requirements are one of our critical duties as a global pharma logistics provider.

As the logistics process becomes more complex as globalization progresses, we are committed to maintaining a safe, secure, and stable supply chain and meeting the expectations of the people in need of medicinal products by continually improving the PQMS.

The NX-Pharma Quality Policy is communicated to and understood by each personnel at all levels of the NX Group.

4. Management Responsibilities

4.1 Global and Regional Senior Management Responsibilities

4.1.1 Senior management refers to the officers of NXHD and NX Group companies who are in such positions designated by the Head of NX-Pharma Global Quality concerning pharmaceutical quality.

4.1.2 Leadership of senior management is essential for establishing and maintaining NX Group-wide commitment to quality and for the effectiveness of the PQMS.

4.1.3 Senior management has the ultimate responsibility to ensure that the PQMS is effective, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the organization concerned. Senior management should demonstrate strong and visible support for the PQMS and ensure its implementation throughout the organization.

4.1.4 Senior management should ensure that all areas of the PQMS are adequately resourced with competent personnel in addition to suitable and sufficient premises, facilities, and equipment.

4.2 Global and Regional Management Responsibilities

4.2.1 Management refers to the president of a group company that handles the pharmaceutical distribution business or the manager who is in charge of each business unit, of those who is in such a position designated by the senior management and to complete the prescribed training.

4.2.2 It should be ensured that a timely and effective communication and escalation process exists to raise quality issues to the appropriate level of management.

4.2.3 Management should appoint a responsible person(s) who has clearly specified authority and responsibility for ensuring that the PQMS is implemented and maintained.

4.2.4 They should implement continuous improvement.

4.2.5 They should define the roles, responsibilities, authorities, and mutual relationships of organizations and personnel related to the PQMS.

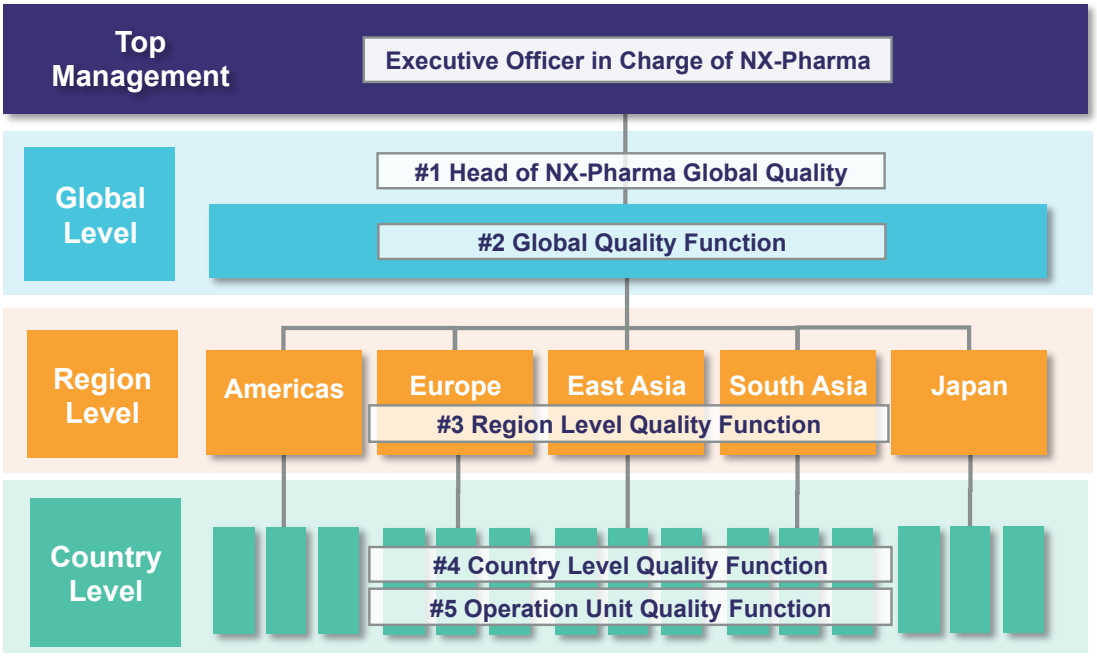
4.3 Responsibility for Compliance with GDP/GMP Related Laws and Regulations of Each Country

4.3.1 At the NX Group, the GMP and GDP guidelines applied in each country, where pharmaceutical operations are conducted, shall be fully complied with through the operations. In consultation with the Global Quality Function, senior management and management of each region make various modifications as necessary to comply with the related laws and regulations applied in the relevant countries.

5. NX Pharma Quality Organization and Responsibilities

NX Group Pharmaceutical Quality Organization Chart

The structure of the pharmaceutical quality organization of the NX Group is as shown below.



The responsibilities of Quality Assurance Manager or the department at each level are as follows.

5.1 Head of NX-Pharma Global Quality (Head of NPGQ): [#1]

5.1.1 Reporting directly to the responsible officer

5.1.2 Preparation of the quality policy and its dissemination into the NX group

5.1.3 Dissemination of laws and regulations and group policies

5.2 Global Quality Function: [#2]

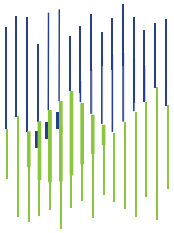
Supervising the quality assurance of the NX Group pharmaceutical logistics globally in accordance with harmonized pharmaceutical logistics quality standards.

5.2.1 Reporting directly to Head of NPGQ

5.2.2 Planning and designing the Global PQMS

5.2.3 Making confirmation, correction and approval of the operation status of the Global PQMS through each region

5.2.4 Monitoring important management items in cooperation with Quality Function in each Region, Country



5.2.5 Implementation of global internal quality audits

5.2.6 Liaison for external pharmaceutical industry associations and authorities

5.2.7 Quality-related planning and operation

5.2.8 Quality-related digital transformation

5.2.9 Management of information on recall, shortage, falsified medicinal products

5.2.10 Planning of global level quality risk management

5.2.11 Global level quality education and training for personnel including senior managements/officers

5.2.12 Planning of global quality document management system

5.2.13 Planning of promotion of quality culture

5.3 Region Level Quality Function : [#3]

Responsible for the design and operation of the globally standardized regional PQMS.

5.3.1 Reporting to the business head in the region, as well as communicating with the Global Quality Function for their oversight

5.3.2 Establishment of the regional PQMS according to the local situation and service contents in each region

5.3.3 Maintaining and overseeing the compliance at local subsidiaries and the compliance with pharmaceutical laws and regulations in each country within the region

5.3.4 Management and operation of quality in Region Business Unit which is set for each region

5.3.5 Responsibility for maintaining the compliance with GDP/GMP and the compliance with laws and regulations in each country within the region

5.3.6 Implementation and maintenance of the NX-Pharma Global Quality Manual at region level

5.3.7 Introduction and maintenance of ICH Q10 concepts (quality system maintenance, continuous improvement) at region level

5.3.8 Supporting quality operations at country level for each business

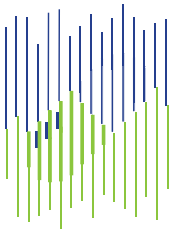
5.3.9 Introduction of risk management in regional quality system

5.3.10 Assessment of regional KPIs

5.3.11 Implementation of management review within the organization

5.3.12 Leading resource allocation and continuous improvement required in ICH Q10

5.3.13 Preparation and support for response for regulatory inspections or customer audits



5.4 Country Level Quality Function : [#4]

Implementation of globally standardized country level PQMS in cooperation with the Region Level Quality Function.

5.4.1 Reporting to the Country Level Function head at each country, as well as communicating with the Region Level Quality Function for their oversight

5.4.2 Responsibility for implementation of the compliance with local regulations and the compliance with pharmaceutical laws and regulations

5.4.3 Leading audits conducted in each country and each business location

5.4.4 Escalation of quality problems that occurred to a higher level organization and report to the Region Level Quality Function head at an appropriate timing

5.4.5 Assuring that the regulations of each country are complied. Confirming when qualifications such as responsible person or pharmacist are required

5.4.6 Implementation of management review within the organization

5.4.7 Leading resource allocation and continuous improvement required in ICH Q10

5.5 Operation Unit Quality Function : [#5]

5.5.1 Implementation of the compliance with local regulations and the compliance with pharmaceutical laws and regulations

5.5.2 Implementation and completion of quality operations within the Operation Unit

5.5.3 Introduction and maintenance of quality systems within the Operation unit

5.5.4 Escalation of quality problems that occurred to a higher level organization at an appropriate timing

5.5.5 Implementation of management review within the organization

5.5.6 Leading appropriate resource allocation and continuous improvement required in ICH Q10

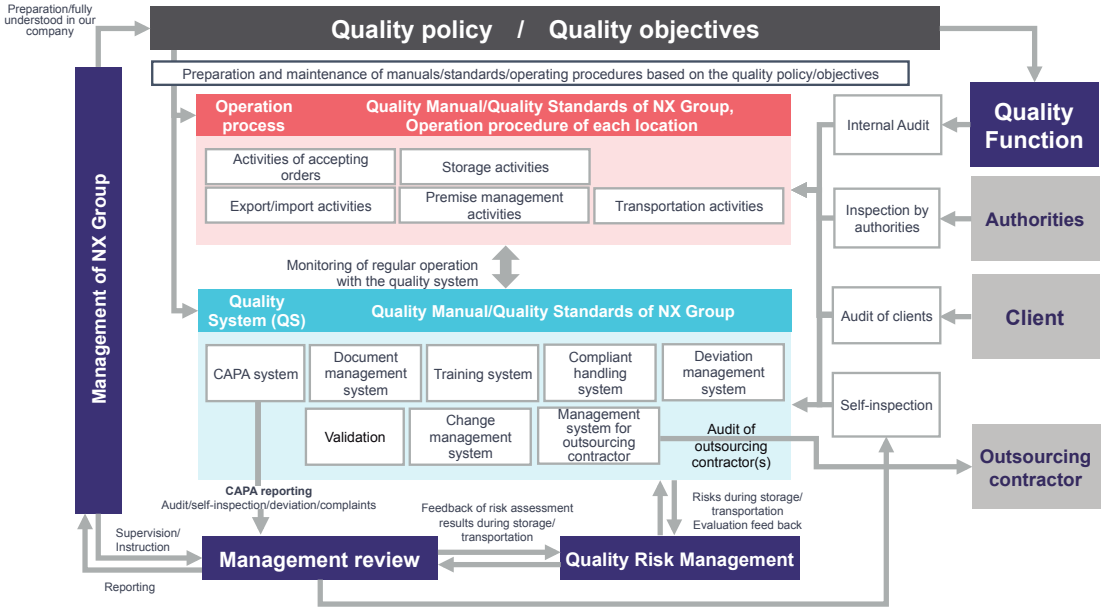
6. NX-Pharma Quality Management System

Appropriate maintenance and control of the PQMS are indispensable for stable provision of quality pharmaceutical logistics services that meet the needs of patients and healthcare professionals. For that purpose, it is important to establish a state of control of logistics operation processes, operational quality, and logistics service environment. The logistics operation processes and the quality of logistics services are monitored to ensure that they are in a controlled state, and if any issues are found, they will be improved. In addition, in order to ensure such continuous improvement, enhancement of the PQMS by continuous improvement is specified as one of the objectives.

The PQMS at each business location of the NX Group has been established with reference to the ICH Q10 Guideline that shows a model of quality management in pharmaceutical companies.

The PQMS operated by each business location in the NX Group shall require, in addition to the quality system elements described in ICH Q10 and employed at the pharmaceutical companies, such as control of GMP activities, change control, deviation control, CAPA, contractor management, education, and training operated, items concerning activities to ensure that the products are stored and transported while maintaining their quality and integrity, and that they remain within the legal logistics route during transportation and storage.

The structure of the PQMS at the NX Group and the relationship between processes are shown in the following process map.



Initiatives by the Management

6.1 Establishment of the Quality Policy

6.1.1 Global and regional senior management must establish a pharmaceutical quality policy that describes the overall intentions and direction of the company related to quality.

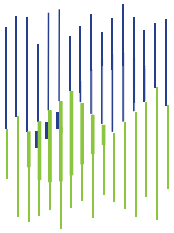
6.1.2 The pharmaceutical quality policy must be understood by all personnel involved in the pharmaceutical business and reviewed periodically.

6.2 Establishment of the Quality Objective

6.2.1 Global and regional management should establish pharmaceutical quality objectives that are required to implement the pharmaceutical quality policy.

6.2.2 Management should provide appropriate resources and training to achieve the pharmaceutical quality objectives.

6.2.3 The pharmaceutical quality objectives must be reported periodically at the management review.



6.3 Appointment and Authority of Responsible Person(s) at Each Level

6.3.1 Management at each level appoints a responsible person(s) who has knowledge of GDP/GMP and received education and training as well as appropriate abilities and experiences.

6.3.2 Management defines the range of authority to make decisions on responsibilities of the appointed responsible person(s) in his/her job description.

6.3.3 In addition, management assigns the authority, sufficient resources and the responsibility necessary to perform the duties to the appointed responsible person(s).

6.4 Management Review and Monitoring

6.4.1 Management is responsible for the overall management of the PQMS through management review to ensure its continuing suitability and effectiveness.

6.4.2 The following items shall be reviewed and evaluated in the management review.

6.4.2.1 Evaluation of achievement status of the quality objectives.

6.4.2.2 Assessment of performance indicators that can be used to monitor the effectiveness of processes within the PQMS, such as GMP activities, complaints, recalls, returns, deviations, CAPA, and process changes; feedback on outsourced activities; sub-contractor performance; self-assessment processes including risk assessments and audits; external assessments such as inspections, findings, and customer audits.

6.4.2.3 New regulations, guidance, and quality information that may affect the PQMS

6.4.2.4 Innovations that may improve the PQMS

6.4.2.5 Changes in business environment and objectives

Key Quality System Elements

The main elements of the quality system used at the NX Group are as shown below. The NX-Pharma Global Standards describes further details of the quality systems,

such as control of GDP/GMP activities, training, change control, deviation control, and CAPA, which are necessary to be implemented at the NX Group globally.

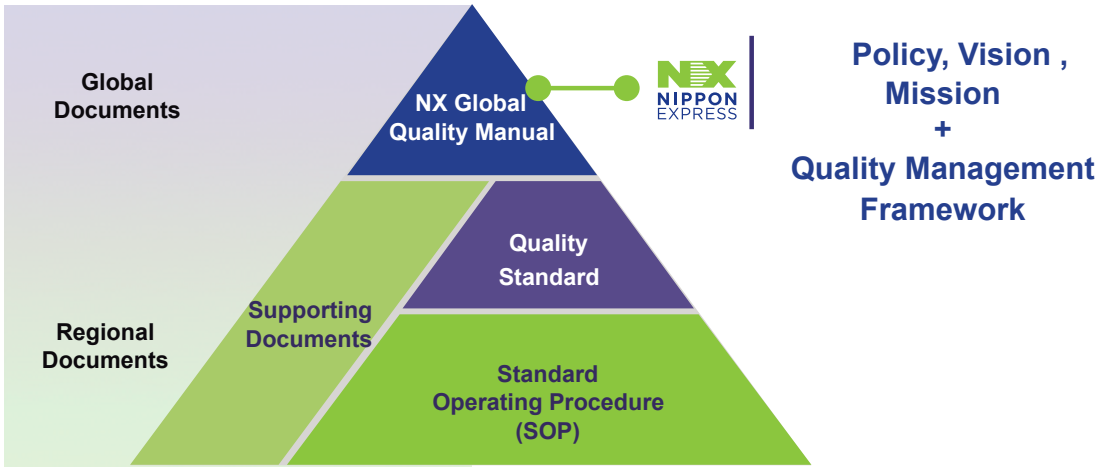
6.5 Document Management

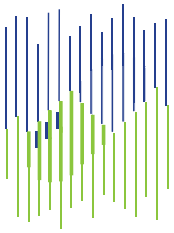
6.5.1 The NX Group has established and is implementing a group-wide documentation system based on the quality policy established by senior management.

6.5.2 The NX-Pharma Global Quality Manual, together with the NX-Pharma Global Standards, is the highest level document that describes the framework and principles of the NX Global PQMS, which is to be implemented and maintained at each business location of the NX Group, and is entrusted upon performing the operations related to accepting orders, packaging/ labeling, import/export, storage and transportation of medicinal products conducted according to the GDP and GMP standards.

6.5.3 The NX-Pharma Global Quality Manual may be supported by relevant regional documents such as standards to further address regional regulations or requirements.

6.5.4 Each business location should prepare operating procedures and forms necessary for operations, issue them upon approval of the responsible person(s), and maintain and control them such as reviewing for an appropriate period of time, and store the forms that need to be stored for a period based on the contract with customers or laws and regulations.





6.6 Training for Personnel

6.6.1 All personnel involved in pharmaceutical/GDP/GMP related activities in the NX Group are required to receive appropriate education and training, including laws and regulations related to their operations and operating procedures of the NX Group, and they are required to improve their knowledge and skills in storage and handling medicinal products.

6.6.2 Management at each level should appoint an appropriate person(s) who is responsible for education and training as well as receive reports on the annual plan for education of personnel and the results of training. The responsible person(s) plans an education program necessary for the operations of personnel and conducts training at an appropriate frequency.

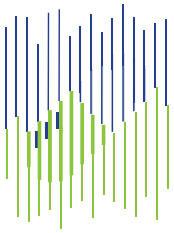
6.7 Response to Falsified Medicinal Products

6.7.1 Falsified medicinal products are medicinal products that use falsified labeling and that do not contain the correct ingredients or contain insufficient or no active ingredients, and include smuggled or illegally diverted medicines. The introduction of falsified medicinal products into the legal logistics route is a serious problem worldwide because it not only loses the opportunity for patients to receive effective treatments but also may cause severe health damage.

6.7.2 In order to prevent the entry of falsified medicinal products in the legal supply chain, the NX Group takes sufficient care of security during GDP/GMP activities and transportation/storage, conducts qualification of suppliers, conducts risk assessment of transportation vehicles and transportation routes to establish countermeasures, and uses qualified warehouses to prevent theft and unauthorized access.

6.7.3 Education and training on falsified medicinal products and security are conducted for personnel who handle medicinal products.

6.7.4 Qualification of suppliers and sub-contractors are conducted.



6.8 Internal Quality Audit and Self-inspection at Each Business Location

6.8.1 The internal quality audit by the Global Quality Function is to provide senior management with accurate information on whether the quality assurance activities of the pharma businesses carried out by the NX Group are appropriately implemented.

6.8.2 A qualified auditor of the Global Quality Function or the Region Level Quality Function conducts internal quality audits under the direction of the senior management periodically at each business location where pharmaceutical operations are conducted.

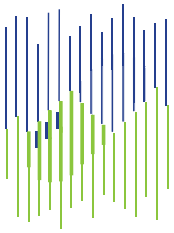
6.8.3 At each business location where pharmaceutical operations are performed, it should be confirmed by self-inspection that quality-related operations are performed appropriately at each business location periodically.

6.9 Management of Contractors

6.9.1 When GDP/GMP activities are outsourced, sufficient preliminary investigation and management after operation is required to maintain the quality of medicinal products even in the outsourced operations.

6.9.2 When the NX Group outsources the operations of accepting orders/packaging/labeling/import/export/storage/transportation of medicinal products to external organizations, it is the responsibility of the Operation Unit Quality Function at the business location where the contract is concluded, to select the necessary outsourcing contractor, and a formal quality audit is conducted in advance based on the risk, either in writing, remotely or on-site.

6.9.3 The Operation Unit Quality Function conducts a quality audit periodically depending on the risk to confirm that the quality management system of the outsourcing contractor is appropriately operated and reports it in writing to the related management.



Operations

6.10 Operations of Accepting Orders/Packaging/Labeling/ Storage/Transportation of Medicinal Products

6.10.1 In the operational activities (hereinafter, referred to as “operations”) of the NX Group, such as accepting orders/packaging/labeling/ storage/transportation/import/export of medicinal products, consistent and stable quality should be assured at each global business location.

6.10.2 These operations are carried out in compliance with the Global Standards of the NX Group and by qualified personnel who are trained and competent in the facilities and operation processes in compliance with applicable local GDP/GMP requirements. In addition, we shall realize the handling under appropriate conditions according to the characteristics of medicinal products requested by customers.

6.10.3 The operations should be evaluated properly on a risk basis, and countermeasures should be taken against contamination by falsified medicinal products.

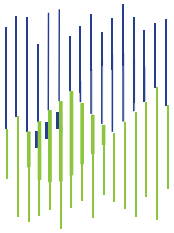
6.10.4 These operations are checked periodically by self-inspections and internal quality audits, and the implementation status is reported to the management as KPI in management reviews.

6.10.5 The NX-Pharma Global Standards describe further details of global standards to be implemented throughout the NX Group.

Enablers

6.11 Appropriate Implementation of Quality Risk Management (ICH Q9)

6.11.1 The quality risk management of medicinal products is defined as “a component of the manufacturing/quality management in GMP (a quality system for proper manufacture of drugs and quasi-drugs), as well as a proactive approach to identify potential quality risks and to establish a scientific review and management for the manufacturing process.”



6.11.2 In quality risk management in the pharmaceutical operations conducted by the NX Group, possible risks in the operations of accepting orders/import/export/storage/transportation of medicinal products are evaluated by taking into consideration storage conditions, packaging forms, transportation routes, transportation methods, etc.

6.11.3 Risk assessment is conducted repeatedly at appropriate intervals. The results of the risk analysis are reported to management and appropriate actions are taken according to the risk.

6.11.4 Evaluation of Business Continuity Plan (BCP) from the viewpoint of quality management: In preparation for disasters such as large-scale earthquakes and risks that make it difficult to continue the business such as pandemic outbreaks, the BCP is evaluated from the viewpoint of quality management so that important functions in pharmaceutical logistics can be continued while ensuring quality.

6.12 Knowledge Management

6.12.1 As a measure for knowledge management, we cultivate a culture of discussion among organizations and business locations. This will drive best practice sharing and improve the level of quality performance across the NX Group.

6.12.2 We aim to strengthen our quality management framework by providing learning solutions that are reasonably designed to meet our objectives. We focus on delivering value to our customers and provide the proper training content to the proper audience at the proper time.

6.13 Quality Culture

6.13.1 Quality culture refers to mindsets, coupled with actions that enable the NX Group to take appropriate actions in a timely manner in accordance with the NX-Pharma Global Quality Manual and quality standards of the NX Group and relevant guidelines.

The quality culture in the NX Group is a code of conduct to support

its pharma customers to ensure patients receive high quality medicines they need, when they need.

We maintain the quality and integrity as we received them from our pharma customers throughout the supply chain by providing safe, secure and reliable transport and logistic solutions.

6.14 Data Integrity

6.14.1 Data integrity requires that all information and data generated in the business accurately, truthfully, and completely reflect the actual facts and these contents are securely stored.

6.14.2 These are very important factors to ensure the accuracy of the fundamental operations in the pharmaceutical business. By ensuring data integrity, we can clearly demonstrate to customers and regulatory authorities that our daily operations are performed in accordance with the procedures, which will increase reliability.

6.14.3 The responsible person(s) at each business location of the NX Group is responsible for establishing procedures and systems to promote data integrity and for training personnel about the compliance.

7. Global Quality Audits and Regulatory Inspections

Activities related to the pharmaceutical businesses conducted by the NX Group must be defined by internal standards such as the NX-Pharma Global Quality Manual and must be fully compliant with local regulations. Quality audits are conducted by the Global Quality Function, the Region Level Quality Function, and Country Level Quality Function at each business location to confirm the compliance status at the business locations including sub-contractors.

Internal quality audits of the internal organization of the NX Group are conducted according to the annual plan determined according to risks at each business location and as needed when any question arises. The frequency and duration of the audits are determined by the risk involved and the audit outcome is escalated to senior management. This will allow senior management to review global operations and respond promptly if necessary.

Similarly, a document/remote or on-site quality audit of sub-contractors is performed by the contract body at a frequency depending on risks.
In addition, if each business location is inspected by the regulatory authorities of each country, the Global Quality Function and the Region Level Quality Function will collaborate where necessary and provide appropriate support from the preparation stage such as conducting a mock audit.

Regarding the audit findings from internal quality audits, external audits and regulatory inspections, their implementation status is continuously monitored through internal quality audits until they are confirmed in accordance with the quality system and corrective actions are completed.

8. NX-Pharma Quality : Forwarding the Future of Pharma

The NX Group Quality vision for the future

At the NX group, because of our commitment to continuous improvement of our pharma logistics services and the quality, we aim to keep introducing innovative technologies.

For each of the five elements of the logistics service, which are: global network, carrier management, temperature-controlled containers, digital platform and quality, we will continue to make efforts to introduce innovation for better and quality pharma logistics services.

By doing so, we will support the evolution of life science and contribute to the health of people around the world.

Logistics service composed of five elements

The “NX-Pharma TempSure” pharmaceutical logistics service of the NX group is a unique service that consists of five elements, a global network, quality, carrier management, temperature-controlled transport containers, and digital platform.

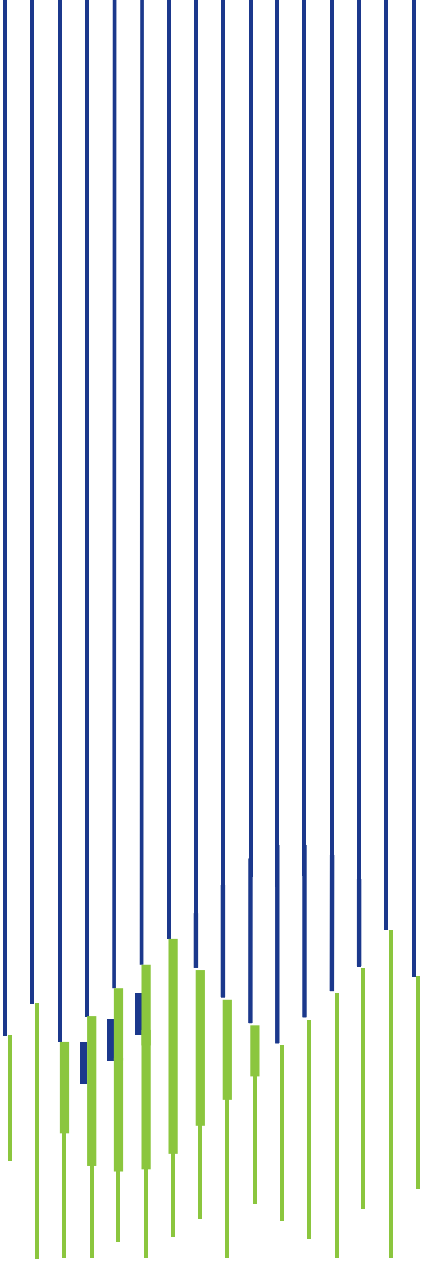
This service thus meets the various needs of the pharmaceutical industry.

Appendix : Glossary

Sr. No.	Name	Description / Definition
1	NX	NIPPON EXPRESS
2	NX-Pharma	Pharmaceutical logistics services of the NX Group
3	medicinal products	Include raw materials, intermediates and finished products
4	GDP	Good Distribution Practice
5	GMP	Good Manufacturing Practice
6	ICH	International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
7	WHO	World Health Organization
8	QMS	Quality Management System
9	CAPA	Corrective Action and Preventive Action
10	Enablers	A tool or process which provides the means to achieve an objective. (ICH Q10)
11	Quality Culture	Faith, values and code of conducts which employees involved in quality hold in common

NX-Pharma
Global Quality Manual

NIPPON EXPRESS HOLDINGS, INC.



NIPPON EXPRESS
We Find the Way

NIPPON EXPRESS HOLDINGS, INC.
Kanda-Izumicho 2, Chiyoda-ku, Tokyo 101-0024, Japan
+81-3-5801-1000
URL : http://www.nipponexpress-holdings.com/en/

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