Quality assurance

GRI 2-13/416-1

#### Our fundamental view

We have established our Quality Policy in order to "provide the highest quality products and service" as stated in the first clause of the Code of Conduct of the NOF Group Corporate Philosophy and Guiding Framework.

## Organizational setup

In April 2019, NOF established the Quality Control Committee to supervise quality management and continue to secure the trust of society. In April 2023, the Quality Management Department was established in the Corporate Technical Division to

maintain and improve the quality control level of the entire Group.

NOF's quality assurance system is managed based on a quality management system for each business.

# **Quality Policy**

The NOF Group provides the highest quality products and services that are based on our considerations of achieving harmony with society and customer satisfaction through our unrelenting quality management.

## 1. Harmony with society

We shall comply with laws, regulations and rules, respect the environment, and produce safe and secure products using manufacturing processes that themselves are safe and secure.

## 2. Customer satisfaction practices

We shall listen to our customers' requirements and provide products that meet their expectations and useful information.

## 3. Unrelenting quality management

We shall maintain stable quality with continuous improvement and proper process management and enhance the management level through education.

# 4. Execution of quality assurance

We shall fulfill our commitment with our customers and sincerely respond to inquiries and complaints.

# Development status of QMS\*1

NOF is building up the optimal QMS for each product line. The Daishi Plant acquired certificates under FSSC 22000<sup>-2</sup> (Food Safety Management System) in January 2019, in addition to ISO 9001. In addition, the DDS plant is managed in accordance with ICH-Q7 (active pharmaceutical ingredients GMP guidelines). 12 Group companies have acquired external certifications equivalent to ISO 9001.

Rate of acquisition of QMS certification from competent outside bodies (based on production results)

FY2022 98.6%

#### NOF

Works and plants		Quality management systems	Inquiries
Kawasaki Works Chidori Plant		ISO 9001	
	Daishi Plant	FSSC 22000 (Food Safety Management System)	https://www.nof.co.jp/company/plant/
	DDS plant	ICH-Q7 (active pharmaceutical ingredients GMP guidelines)	
Aichi Works	Taketoyo Plant	JIS Q 9100	
	Kinuura Plant	ISO 9001	
Amagasaki Plant (Functional Materials Division)		ISO 9001	
	(Life Science Division)	ICH-Q7 (active pharmaceutical ingredients GMP guidelines)	
Oita Plant		ISO 9001	

## Group companies

Quality management systems	Inquiries
ISO 9001	https://www.nippon-koki.co.jp
ISO 9001	https://www.nichigi.co.jp
ISO 9001	https://www.nofmetalcoatings.com/asia-pacific/
ISO 9001	https://www.shokin.co.jp/
ISO 9001	https://www.yuka-sangyo.co.jp/index.html
ISO 9001	http://nikkacoating.com/company/
ISO 9001	https://www.nof-cs.com.cn/
ISO 9001	https://www.nof.co.jp/company/group-companies
ISO 9001	https://www.nofmetalcoatings.com/north-america/
ISO 9001	https://www.nof.co.jp/company/group-companies
IATF 16949	https://www.nofmetalcoatings.com/korea/en/
ISO 9001	https://www.nofmetalcoatings.com/south-america/
	ISO 9001

<sup>\*1</sup> Acronym for quality management system. A system by which an organization formulates policies and sets targets in order to dictate and manage its quality, and achieve such targets.

<sup>\*2</sup> Acronym for Food Safety System Certification 22000. It comprises individual specifications established for each food industry as Prerequisite Programs (PRP) based on ISO22000 (Food Safety Management System) and original FSSC22000 standards as additional requirements. Through food defense and management including management of allergens, more reliable food safety management can be ensured. (A certification scheme recognized by non-profit organization GFSI)

# Approach to pharmaceutical-related business

NOF currently handles pharmaceutical-related products and has obtained the various business licenses listed below. In order to properly carry out these licensed business operations (hereinafter referred to as "pharmaceutical-related operations"), the Pharmaceutical Management Task Force has been established under the Quality Management Committee to maintain and improve the quality management level of pharmaceutical products.

#### Licensing status of pharmaceutical-related business

Category		Works/Plants
Marketing	Second-class marketing license for pharmaceuticals	NOF
Warketing	Marketing license for quasi- pharmaceutical products	NOF
Sales	Pharmaceutical sales (wholesale)	NOF
	Pharmaceutical manufacturing	Kawasaki Works
Manufacturing		Aichi Works, Taketoyo Plant
		Amagasaki Plant

#### Basic Policy on **Pharmaceutical-Related Business**

Based on our Corporate Philosophy which states, "The NOF Group is dedicated to contributing to humanity and society as a corporate group that creates new value through the power of chemistry, from the biosphere to outer space," NOF is developing pharmaceutical-related business that ensures high quality, reliability, and safety to all stakeholders, under our governance system that ensures thorough compliance with laws and regulations.

# Officers and others responsible for pharmaceutical-related operations

Based on the aim of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019, "Amended Pharmaceuticals and Medical Devices Act"), the officers with responsibility for pharmaceutical-related operations are clearly stated in the pharmaceutical management system. In addition, in accordance with the provisions of the Act, for marketing (second-class marketing license for pharmaceuticals, marketing license for quasi-pharmaceutical products), a general marketing manager, a quality assurance manager, and a safety management manager are appointed.

# Pharmaceutical management system

As a specialized task force of the Quality Management Committee, a deliberative body, NOF established the Pharmaceutical Management Task Force to oversee the pharmaceutical-related business of the

#### Pharmaceutical management system



entire company and to manage the manufacturing, marketing, and wholesaling in an integrated manner. The Pharmaceutical Management Task Force inspects the status of compliance with GQP, GVP, and GMP ordinances, and operates to ensure that the general marketing manager, manufacturing manager, and others provide appropriate opinions to the responsible officers regarding issues and problems related to legal compliance.

## Education and training

At NOF, all persons involved in pharmaceuticals take the required training every year.

#### Responsible officers

Take the pharmaceuticals-related training (once per year)

People involved in pharmaceutical-related operations Take training based on GQP, GVP, and GMP ministerial ordinances as needed

After the training, a record is made and stored for use in the next fiscal year's training plan to ensure continued acquisition of the necessary knowledge.

# Internal information sharing

NOF has established an internal network to promptly confirm and evaluate customer inquiries and complaints about our products, and then take necessary corrective actions. We take customer feedback seriously.

## Contact point for inquiries

## Quality Management Department, Corporate Technical Division, NOF CORPORATION

Address: 20-3 Ebisu 4-chome, Shibuya-ku, Tokyo 150- 6012, Japan

**Hours:** 9 AM to 5:30 PM (Monday through Friday)

Tel: 03-5424-6670 Fax: 03-6837-5354

**Email:** Please make inquiries using the NOF website inquiry form