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Quality Assurance

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*For chemical product safety, see Environment (\rightarrow P. 22)

Basic Approach and System

Quality Assurance Policies

In accordance with our basic philosophy and Sustainability Policy, we define our basic policy for quality assurance as follows.

Basic Policy for Quality Assurance

- 1. We contribute to society by providing high-quality products, goods and services with excellent reliability and safety to the market.
- 2. We fully understand and predict user demands and provide products, goods and services that users can use with satisfaction.
- 3. In each quality assurance step, we establish an internal system that can assuredly evaluate highquality products, goods and services with excellent reliability and safety.
- 4. We establish technologies that can produce products, goods and services with the target quality in terms of reliability and safety.

Quality Assurance System

To consistently manufacture products that reflect the needs and wants of customers and to ensure product quality, Zeon is advancing integrated quality assurance activities group-wide, across manufacturing, sales, and engineering functions, by strengthening cooperation between plants, departments and research units (R&D Center).

Quality Assurance System



Quality Assurance Initiatives

Targets and Results of Major Quality Assurance Initiatives

Initiative (topic)	Target	Results	Assessment
Timely responses to com- plaints, opinions from custom- ers, etc.	Complete responses within a single year	While some cases temporar- ily exceeded a single year, no long-term delays occurred	Partially Achieved – Achieved
Enhance customer satisfaction	Analysis on customer satisfac- tion and initiatives for im- provements	All business divisions con- ducted analyses on customer satisfaction through manage- ment reviews to determine and engage with topics that required a response	Achieved

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Framework Supporting Quality Assurance

To ensure a consistent supply of high-quality products to our customers, we have put in place various quality assurance systems in accordance with internal regulations on quality assurance and conforming to the ISO 9001:2015 international standard for quality management systems. In 2010, we consolidated our ISO 9001 certification across the Group, and have maintained this since then. Zeon Group companies have also obtained global standard certifications related to quality.

In addition, to prevent quality issues from occurring, we offer commentaries on actual case studies for issues that could potentially arise as part of annual e-learning compliance checks to confirm levels of understanding for all employees. We are working to ensure that every employee performs their duties based on an accurate understanding of quality assurance.

Status of Zeon Group Certifications for International Quality Standards

Site	ISO 9001 :2015*1	ISO 13485 :2016* ²	IATF 16949 :2016* ³	FSSC 22000 v5*4
Japan				
Zeon Corporation	0			
Zeon Kasei Co., Ltd.	O*5			
Zeon Polymix Inc.	0			
Zeon Opto Bio Lab Co., Ltd.	0	0		
Tokyo Zairyo Co., Ltd.	0			
Tohpe Corporation	0			
Zeon Medical Inc.		0		
Zeon North Co., Ltd.	0			
Zeon Chemicals Yonezawa Co., Ltd.	0			0
Outside Japan				
Zeon Chemicals L.P.	0			
Zeon Chemicals (Thailand) Co., Ltd.	0			
Zeon Advanced Polymix Co., Ltd.	0			
Zeon Chemicals Singapore Pte. Ltd.	0			
Zeon Europe GmbH	0			
Zeon Chemicals Asia Co., Ltd.	*6			
Zeon Kasei (Changshu) Co., Ltd.			0	
Zeon Kasei Mexico S.A. de C.V.	0			

*1 ISO 9001 is the international standard for achieving ongoing improvements in enhancing customer satisfaction and quality management systems through product and services quality assurance.

- *2 ISO 13485 is the global standard for quality management systems in the field of medical devices for the purpose of continued manufacture and provision of safe and useful medical devices. The standard has added requirements specific to medical devices while omitting some of the ISO 9001 requirements.
- *3 IATF 16949 is a standard issued by the International Automotive Task Force (IATF) for the automobile industry sector, and which is intended as a supplement to the requirements of ISO 9001 for automobile manufacturers.
- *4 FSSC 22000 (Food Safety System Certification 22000) is a standard developed by the Foundation of Food Safety Certification to certify management systems for the production of safe food.
- *5 The logistical materials division has acquired certification limited to STEC®.
- *6 Preparations to obtain certification currently underway (as of November 2022).

Framework to Achieve Product Safety

1. Product safety reviews

We strive to ensure product safety in every possible aspect by conducting product safety reviews (PSRs) using our own checklists that consider product safety at every stage of the product lifecycle, from initial product development through planning, design, manufacturing, sales, use, and disposal.

2. Chemical substance regulatory compliance

The regulatory environment for chemical substances management is undergoing major change globally, with laws and regulations on chemical substances being amended not just in the United States and Europe but also in Japan and Southeast Asia. As a result, the number of regulations to comply with is rising sharply. To comply with these regulations at Zeon, we are creating a database of the substances in our raw materials and products, even those present in minute quantities, and building a chemical substances management system capable of continuously tracking the most up-to-date regulatory information, safety information, and other relevant information.

Audits

PL Audits

PL audits are audits performed by an auditing team led by the director in charge of CSR and covering product liability (PL) and product safety. PL audits are conducted for product liability activities for products of Zeon business divisions spanning all stages of development, manufacture, use, final consumption, and disposal.

Quality Audits

Quality audits are audits performed by an auditing team led by the head of the Quality Assurance Department that focus on checking the progress of implementing quality improvement activities. They are conducted at Zeon's business divisions, plants, laboratories, and affiliated companies.

Internal Quality Audits

Internal quality audits are conducted for the purposes of evaluating whether Zeon's quality assurance management system is operating effectively and efficiently based on ISO 9001:2015 and promoting ongoing improvements. The audits are based on ISO 9001, and are structured so that the requirements of ISO 9001 are satisfied as long as Zeon's internal regulations are being complied with. The audits also focus on customer satisfaction and overall optimization. The audits are conducted for the whole of Zeon Group; as far as possible, audits are conducted by an auditing team comprised of auditors from other divisions.

In addition, we provide basic training for internal quality auditor candidates as well as training to raise the overall capacities of internal quality auditors, thereby striving to maintain and refine the competencies and abilities of our internal quality auditors.

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Quality Data Management

At Zeon, we define all customer comments or expressions of dissatisfaction with our products or services as "complaints," and utilize a complaint response system to report, review, approve, and manage delivery.

We have also implemented a standards management system configured to ensure that delivery standards, product standards, and product inspection standards remain consistent, and allow us to remain in compliance with the delivery specifications concluded with our customers. Inspection data is further checked against product inspection standards in the product testing system, with a decision of pass/fail assigned, and results automatically forwarded to the ERP system. Changes to or abnormalities in processes are also reliably managed through the deployment of a system that reports, reviews, and sends out effectiveness evaluations, emergency actions, and remedial measures, to facilitate implementation of assured change control and deviation management. We plan to construct an even more reliable and efficient system for quality assurance by means of linking these systems going forward.

Risk Reduction for New Products

At Zeon, we conduct a comprehensive review (PSTR)* from quality assurance perspectives in addition to a design review (DR) when transitioning from the product design to the production preparations stages, as well as from the production preparations stage to actual production.

This review confirms items related to product quality to ensure that new products satisfy the quality requirements of our customers, and to allow us to fulfill supply obligations. Items subject to review include data on the chemical substances making up the product; 3D-QFD (quality function deployment), for databased clarification of cause-and-effect relationships of information related to manufacturing; failure mode and effects analysis (FMEA), which attempts to prevent potential post-production abnormalities; and testing methodologies and testing facilities to measure product standards and characteristics of critical processes.

*PSTR (Product Stage-gate Transfer Review)

Communicating Safety Information

For more information about safety information for chemical products handled by Zeon, see Chemical Product Safety Information (\rightarrow P. 22).

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Initiatives to Create "Smart Factories" to Simultaneously Improve Plant Efficiency and Realize Workstyle Reforms

At Zeon, we have been working to make our plants "smarter" since 2020. We have already carried out various activities to facilitate production innovation (visualization and utilization of intangible assets, including know-how and expertise of skilled and experienced workers) to date. The creation of smart factories will enable further production innovations and transformations in work tasks by increasing the range of things that can be accomplished by machines through the leveraging of digital technologies. For plants, this will have the effect of streamlining production and continually ensuring product quality. For employees, it will lead to the realization of comfortable and rewarding workplace environments.

As part of the "Smart Factory Realization Project" undertaken throughout the Zeon Group, we initially discussed the "Vision of an Ideal Plant" in six areas (work operations, safety, quality assurance, facilities, personnel, and logistics and warehousing), establishing the specifics of what we hoped to achieve via the creation of smart factories, as well as the steps needed to achieve this. Meanwhile, it is important to organize these various ideas and initiatives to facilitate optimization of the whole, rather than groupings of digitization initiatives partially optimized for individual fields.

Initiatives undertaken over a two-year period as part of this project involved pilot tests ranging from studies on ways to achieve the transition to smart factories to those on optimizing the whole, thereby identifying the topics to be addressed. We also worked out the organizational structures and a visualization of the digital human resources which would be required to achieve these goals. Since April 2022, initiatives to facilitate the creation of smart factories are being continued by the Production Innovation Center based on the Medium-Term Business Plan.

What We Hope to Realize through Smart Factories

Smart Factories



Example 1: Reduction of essential tasks through transition to the use of robotics

Activities for production innovation have to date reduced on-site troubleshooting operations by around 90%. We have now reached a juncture of considering whether to further reduce essential tasks (tasks required for production) to reduce workloads even more. In this context, we conducted deliberations on the potential of adopting digital technologies intended to reduce essential tasks.

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If plant patrols can be replaced with cameras and robots, this would allow the time thus saved by increases in efficiency to be used for other improvement activities (workstyle reforms), while also improving operator safety. In addition, standardization of work tasks and the development of facilities for the transition to the use of robotics would further facilitate improvements in the basic infrastructure of plants.



Robotization experiment

Example 2: Interactive training using VR technology

To operate a plant, it is important acquire the ability to respond in the event of abnormal conditions, in addition to having an understanding of basic rules and principles.

The introduction of VR technology during training drills is expected to facilitate improvements in the efficiency of both instructors and those under their instruction by allowing them to repeatedly be exposed to various situations and facilitate autonomous learning.

The use of 360-degree imaging and VR to enhance efficiency in the training of new employees has been pilottested and formally adopted at the Takaoka Plant, and we are currently preparing to expand this system to other plants. Training for more advanced troubleshooting drills, and launching new plants is under ongoing consideration as the burdens involved in creating training materials is high.



Image from a 360-degree camera