
Compliance

Shionogi Compliance Handbook

Handbook 5th edition



How to use this handbook

This handbook was created for Shionogi personnel, to gain knowledge and understand the importance of compliance at Shionogi.

We have divided it into six categories: Work environment, Asset/information, Activities, Business Relationship, Shareholders and communities.

Each category includes policies, activities, and also self-check items.

This 5th edition includes “discussion points” for compliance at work. Please discuss within your department.

When you face any cases that you need to evaluate, please check “V. Way for the action to comply” in Shionogi compliance policy.

Steps

(1) At first, consider on your own

There are key points in each of the five items in the handbook. Please refer to them and discuss within your department.

(2) Talk to your supervisor

If you are not sure and cannot evaluate, please talk to your supervisor. We encourage communicating through the report line.

(3) Talk to the specialist and /or Compliance Officer

If you are not satisfied with your conversation with your supervisors, please feel free to go to the specialist at the department which relates to the issue, and /or Compliance Officer.

When you face any cases that need to be reported, please refer Compliance Hotline page.

A Compliance violation is never another person’s matter. It’s important to recognize what could happen around you, learning how violations affect society and the Shionogi family. Let’s learn what we need to do to protect you and your family.

Shionogi’s Purpose

Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.

Because of this, Shionogi needs to:

- Pursue the search for even better medicines.
- Produce even better medicines.
- Promote awareness of these better medicines to more people so that more people will be able to use these medicines.
- Research, produce and promote in an even more economical manner.

Because of this, Shionogi employees will need to:

- Strive ceaselessly day after day to improve their skills.
- Strive ceaselessly day after day to improve as human beings.

As a result, Shionogi personnel will:

- Find even greater satisfaction in their daily work and in their daily lives.
- Find even greater improvement in the quality of their lives.
- Find even greater prosperity in their lives.

Code of Conduct

Shionogi has enacted this Code of Conduct to ensure that our daily work contributes to the patients we serve, stakeholders and society, provides self-improvement for our employees, and contributes to people's health and quality of life.

【1】 Behavior as a corporate citizen

We pledge that all Shionogi personnel follows the spirit of this Charter , and the management team leads and is responsible for having the entire organization thoroughly informed of this charter.

1. Compliance

We recognize that Compliance is indispensable for corporate survival and development. In addition to observing laws and regulations based on "Shionogi Group Compliance Policy", take ethical actions required as a company/social worker.

In overseas activities, observe the laws/regulations and understand the ethics/morality of the country as a good corporate citizen.

2. External Relationship

Needless to say that we do not provide or receive unfair profits in relationships with outside persons such as business contacts, public officials, politicians, etc. We always maintain a transparent and healthy relationship that we can explain and justify.

3. Trade and Distribution

In sales and procurement, in accordance with laws such as the Antimonopoly Act and Shionogi Group Procurement Policy, we conduct appropriate trading and procurement for fair and free competition.

4. Information management and disclosure

Comply with insider trading prevention rules, report and manage internal information appropriately, and do not conduct transactions that violate insider trading regulations. Business information and personal information are properly protected / managed by information security policy, privacy policy and personal information protection law. We disclose important information that may have a significant influence on stock price in a timely, appropriate and fair manner in accordance with our disclosure policy and actively disclose information that we believe is necessary for shareholder / investor decisions in easy-to-understand context.

5. Antisocial Forces

We recognize that having something connected with antisocial forces will fall to an antisocial existence and respond with a resolute attitude at all times without giving them a chance to interrupt us by according to organized crime group excluding ordinance.

6. Environmental Protection

In accordance with the Shionogi Group Basic Environmental Policy, we will contribute actively to a sustainable society with consideration for conservation of the global environment, protection of resources and harmony with the natural environment in all activities.

7. Social Contribution Activities

As a good corporate citizen, we will actively contribute to social activities and the development of the local community. While respecting the culture and customs in overseas activities, we will actively contribute to the development of that country.

【2】 Behavior as a pharmaceutical company

1. Offering creative, innovative and economical drugs

As professionals, we actively work and develop creative and innovative drugs, and offer the best medicines necessary to protect people's health, in an economical way and saving medical resources.

2. Drug development under appropriate procedures

In clinical trials, with the cooperation of medical institutions, we pay attention to human rights, assuring the safety of subjects and carrying them out with scientific rigor.

In animal experiments, we follow the basic philosophy of animal experiments responsibility, taking maximum care and respecting animal wellbeing.

3. Strict compliance with pharmaceutical related laws and regulations

When we apply for approval to manufacture and commercialize a pharmaceutical product, we have a high sense of ethics and handle data appropriately based on scientific validity and strictly complying with relevant laws and internal rules.

4. Stable Supply of High-Quality Medicines

We promptly and in a stable way highly effective, safe and high-quality pharmaceutical products manufactured under the "Shionogi Product Policy", that comply with global standards and regulations.

5. Sales promotion for proper use

From the viewpoint of practicing risk management and assuring proper use of medicines, we provide domestic and international information on quality, effectiveness and safety of our products that is scientifically backed up and up to date.

We will promptly collect, evaluate, and communicate post-marketing information.

【3】 Behavior as a Shionogi Group Family

1. The meaning to exist

As a pharmaceutical company that always serves people's health, we will continue to develop, manufacture and produce the best medicines that are truly needed.

2. Trust from society

The Shionogi Group and Shionogi personnel will practice Compliance on a daily basis and aim to become a company and business individuals highly trusted by society.

3. Growth of individuals and organizations

Growth of individuals and the organization will result in the delivery of the best medicines and be great power and asset to continue in that path. In total synergy, this path will be linked to the growth of the Shionogi Group and contribution to society.

4. Acceptance of individuals and diversity

We respect individuals accepting diversity positively, and provide a great value to the society by educating and utilizing human resources to add value in a creative way.

5. Tradition and Transformation

We will inherit the good cultivated tradition and continue to transform and grow.

6. Realization of work and richness

Shionogi people are proud of their work; they will realize a rich life full of work and living worth.

How to use this handbook

Shionogi's Purpose

Code of Conduct

Message from Top Management

Table of contents

Importance and Position of Compliance

Shionogi Group Compliance Policy

Shionogi Group Anti-corruption / Anti-bribery Policy

Report, Consultation

I. Workplace Environment

1. Activities for safety and sanitation
2. Activities for compliance with labor-related laws
3. No harassment at work
4. Workplace that respects diversity without gender discrimination
5. Conflict of interest

II. Assets & Information of Shionogi

1. Company Property
2. Intellectual Property Right
3. Confidential Information
4. Personal Information
5. Accuracy of records and compliance with tax law
6. Compliance with insider trading regulations

III. Shionogi Business Activities

1. Research activities
 - 1-1. Drug Discovery and Exploration Research
 - 1-2. Non Clinical Studies
 - 1-3. Handling of research samples and regulated substances
 - 1-4. Animals
2. Development activities
 - 2-1. Clinical study
3. Manufacturing activities
 - 3-1. Manufacturing
 - 3-2. Secure product quality and safety
4. Distribution and Procurement activities
 - 4-1. Procurement of raw and other materials · Purchase of products
 - 4-2. Logistics and import / export
5. Sales Activities
 - 5-1. Pharmaceutical information activities
 - 5-2. Safety management information collecting activity
 - 5-3. Information dissemination activities

IV. Business Relationships

1. Implementation of rights and obligations under contract with external organizations
2. Antitrust law · The Fair Competition Code etc.
3. Prohibition of corruption and bribery

V. Relationship with shareholders / investors

1. Management with focusing on the shareholders and investors
2. Fair disclosure
3. Payoffs

VI. Relationships with society

1. As a member of society
2. Using Social Media
3. Environmental protection
4. Contribution to Society (Donations etc.)
5. Relationships with Government Officials
6. Relationship with politicians / political organizations
7. Relationships with antisocial forces and organizations
8. International Standards and Foreign Laws
9. Respect local culture
10. Secure transparency

VII. Dealing with a violation

Discipline

Importance and Position of Compliance

Compliance in English means "to obey orders and requests". It is used in the meaning of "compliance" in Japan, interpreted according to the word "to not violate laws", in other words, "comply with laws and regulations, government ordinance, ministerial ordinance etc." However, that is not just a point to emphasize "Compliance". Shionogi considers it does not merely mean to comply such as laws, government ordinances, ministerial ordinances, industry standards and guidelines, internal regulations and manuals, but also includes social norms such as social morals and common sense, and follow ethical behavior as a company, society and individuals.

Therefore, it includes the broad meaning such as taking fair actions as a social worker or a business person. On the other hand, because of the flurry of corporate scandals, companies are required to manage risks by strengthening monitoring and supervisory functions from inside and outside the company. It is required to maintain an internal control system by Companies Act, Financial Instruments and Exchange Act. For that reason, companies need to manage the various risks surrounding them to establish and operate a system that ensures the appropriateness of work and the reliability of financial reporting. Compliance is an important foundation for it.

In recent years, the demand from society for thorough compliance at companies has gained prominent attention due to repeated corporate misconducts.

Recently, incidents such as GMP violations related to product quality and inappropriate handling of data used for manufacturing approval applications, should not have happened at pharmaceutical companies dealing with life-related products.

The meaning of working at pharmaceutical companies;

- (1) You are in a role that has the heavy responsibility of dealing with medicines related to human life and health
- (2) Making one mistake will cause serious problem translated into human life and health
- (3) To develop and manufacture good medicines used it by many people. Contribute to the welfare of the world population, improve medical care, and the realization of a healthy quality of life

It is necessary to fully understand that compliance violations by pharmaceutical companies will affect people's lives and health failing to fulfill social responsibility and high ethical standards!

If Shionogi's activities (process) were a tree, compliance becomes the soil for growing that "tree". No matter how wonderful the tree is, if the soil is not great, the tree will rot away.

In other words, compliance is the most important matter for a solid foundation for corporate activities.

Compliance violations will result in sanctions, and in order for Shionogi to develop continuously, it is essential to be compliant.

In the event of a scandal, not only will the company's credibility be lost, but the employees may be arrested, in some cases even facing criminal or civil penalties. Family members are exposed to the media and the public eye, making it difficult to continue living. A happy family life can be broken in the blink of an eye. Protecting compliance is not only for your boss, company and society, but also to protect yourself and your family as well.

Shionogi's behavior your attitudes and actions, the compliance of each individual member of the Shionogi family drives Shionogi's behavior.

It is the understanding that compliance is a responsibility that affects your family and Shionogi family members problem, not just a "senior manager's problems".

Let's be excellent business persons who can respond to expectations by being compliant.

Shionogi Group Compliance Policy

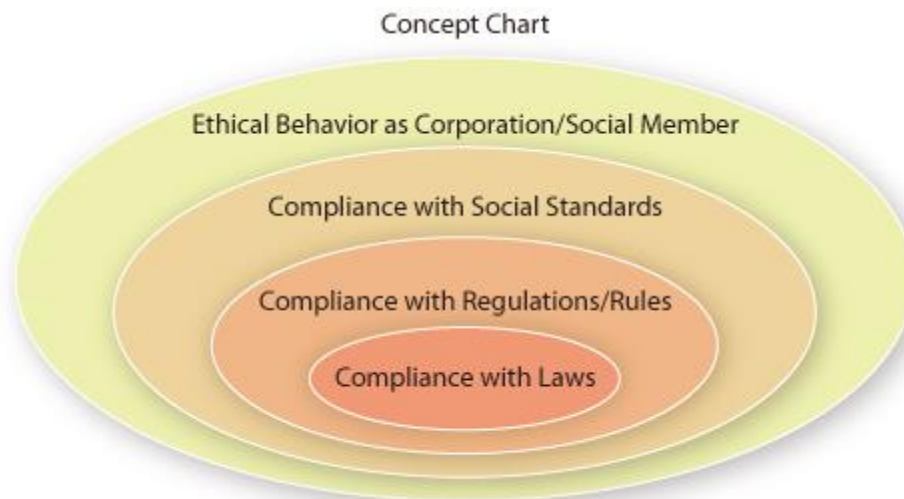
I. Preamble (Purpose)

Shionogi & Co., Ltd. (“Shionogi”) is globalizing its corporate policy as it expands its operations into additional countries. The company’s diverse international activities should function as an integrated whole (the “Shionogi Group”). The Shionogi Group must operate in a controlled, ethical and compliant manner.

Therefore, Shionogi hereby declares its compliance policy.

II. Compliance in Shionogi Group

Compliance in the Shionogi Group does not mean only compliance with Laws, Rules and/or Regulations but also with Social Standards as well as Ethical Behavior.



III. Promotion of Compliance in Shionogi Group

Shionogi faithfully promotes compliance in the Shionogi Group having in mind the following:

- a. Shionogi becomes a company respected from the society.
- b. The employees who are the constituent members of Shionogi Group also act in an ethically appropriate way.
- c. The employees of Shionogi Group will take all steps to make a right judgment and take a right action in securing compliance as described in section V (Approaches to Secure Compliance).

- d. Every group company develops and maintains its own compliance handbook, code of conduct, or the like, respecting and reflecting the spirit and concept of this compliance policy and considering the social, regulatory and legal situation surrounding the group company.

IV. Policy Statements

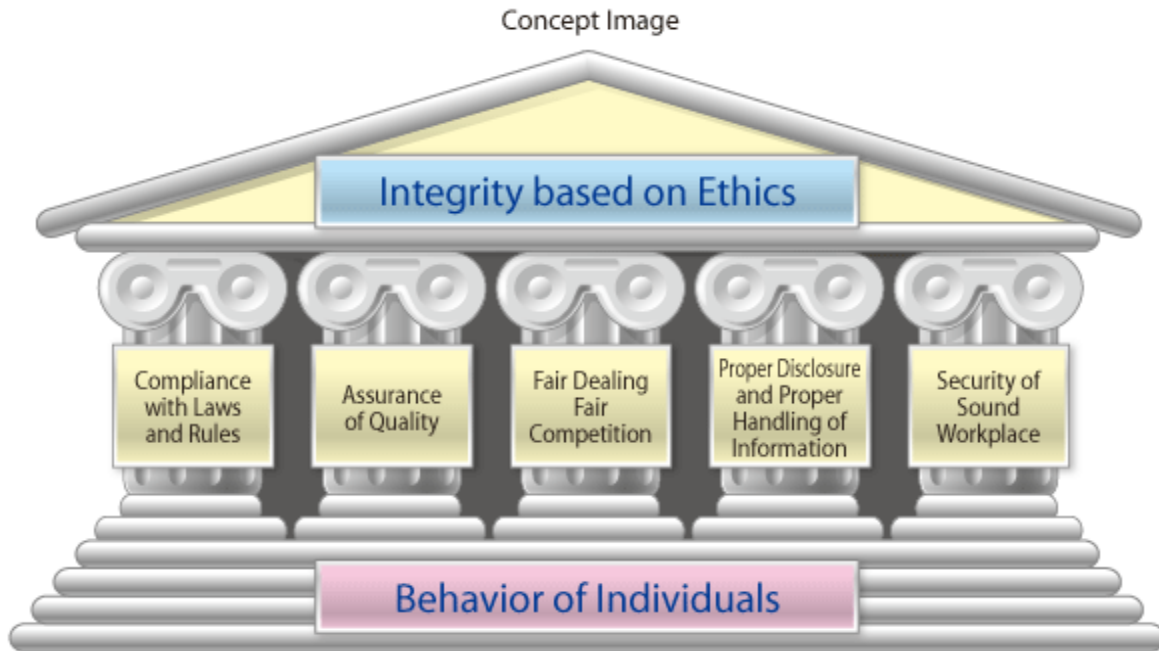
Shionogi's compliance policy is constituted of 2 Fundamentals & 5 Essentials.

- a. Fundamentals

1. **Integrity based on Ethics (Essential Aspect for Global Operation for a Life Science Company):**
Shionogi regards the integrity of the company based upon ethics, as the essential and most important element to continue to grow further as a global enterprise in the life science industry, making continued efforts to maintain and improve it.
2. **Behavior of Individuals (Foundation of Compliance):**
Shionogi recognizes that behavior of its individual members is the foundation of compliance and directs them to take appropriate actions at all times.

- b. Essentials

3. **Compliance with Laws and Rules (Basis of Compliance):**
Shionogi observes all laws and rules relevant to its operations and business activities.
4. **Assurance of Quality (Basis of Reliance and Safety):**
Shionogi sets forth and complies with the quality standards, quality control rules and standard operating procedures that are globally acceptable to assure the quality of its products and the services associated therewith.
5. **Fair Dealing and Fair Competition (Practices of Reliance):**
Shionogi, in its operations and business activities, deals with customers and suppliers appropriately and fairly competes with competitors.
6. **Proper Disclosure and Proper Handling of Information (Basis of Trust):**
Shionogi recognizes that the accuracy of information it discloses is the basis of trust by all stakeholders including communities, and makes proper disclosure thereof. Shionogi recognizes that information is one of the critical business assets and handles its own proprietary information as well as the proprietary information of others appropriately.
7. **Workplace Safety (Ban on Discrimination and Respect of Diversity):**
Shionogi respects the human rights and diversity of its members and eliminates any type of discrimination, and secures and maintains for its members the work environment appropriate to perform their duties.



V. Approaches to Secure Compliance

The ways and steps for Shionogi Group members to make a right judgment and take a right action in securing compliance are shown below:

- a. Self-Assessment
As a first step, stop and think for yourself. When you are about to do something, or when you see someone in Shionogi about to do something, ask yourself the 5 questions below if you are in doubt as to whether it would be an ethical thing to do. The 5 questions to ask yourself are the following:
 - (1) If you have doubts about whether something is right to do, would you go ahead and do it anyway (because it's just one of those things that needs to get done) or let others go ahead and do it anyway (and overlook what they're doing)?
 - (2) If you do "something", wouldn't that be going against your conscience?
 - (3) Can you tell your family about this "something" in good conscience?
 - (4) If you see other people doing this "something", how would you feel?
 - (5) Wouldn't this "something" cause embarrassment for Shionogi?
- b. Consultation with Supervisors/Managers (Superiors)
You should consult with supervisors/managers (superiors) when self-assessment is difficult or inappropriate.
- c. Consultation with Experts and/or Department/Section in Charge
You should consult with experts and/or department/section in charge (i.e. Legal Dept., Human Resources Dept. or others as appropriate) when self-assessment is difficult or inappropriate and/or consultation with supervisors/managers (superiors) is not sufficient.

Shionogi Group Anti-corruption / Anti-bribery Policy

Shionogi Group Anti-corruption / Anti-bribery Policy is established as of 1st day of April, 2014.

III Shionogi Business Activities

1. Research activities

1-1 Drug Discovery and Exploration Research

*We comply with relevant laws and internal/external roles for testing and research including bioethics,

*We conduct appropriate drug and discovery and exploration research.

*We carefully consider the environment and the safety of relevant and surrounding people, and conduct research on drug discovery and exploration.

- Do you conduct tests and research faithfully and fairly, to be accountable to relevant / surrounding people?
- Do you accurately record your research data and keep it properly?

1-2 Non Clinical Studies

In order to prepare accurate data that can be evaluated on efficacy, safety, etc., we will comply with applicable laws such as the Pharmaceutical and Medical Device Act, the GLP Ministerial Ordinance and other internal and external rules, to conduct appropriate nonclinical studies.

- Do you conduct non-clinical studies without deviating from experimental procedures manual?
- Is there any inconsistency or tampering between the raw data and the report?

IV Business Relationships

3. Prohibition of corruption and bribery

*We do not promise, accept or request illegal or unreasonable gains (money, goods, entertainment, benefits etc.) from individuals in positions of authority within their duties. We maintain a fair and healthy relationship with our business partners.

*When requesting business to HCPs, consultants, advisors, and other experts, we must comply with the relevant laws, regulations and any internal and external rules, documenting it with a written agreement.

*We pay reasonable amounts for any service fee request that Shionogi has received such as consultant or advisory etc., and record the service details in writing.

*We do not give, offer, promise, or accept any "bribe" from individuals or business organization regardless of public or private.

*We will comply with relevant laws such as the Unfair Competition Prevention Act and the "Shionogi Group Anti-corruption and Anti-bribery Policy" and domestic/overseas rules. We maintain fair and equitable relationships with all business partners, and strive to prevent corruption and bribery.

- Do you refuse in a resolute way any offering of profits from business partners?
- Do you clarify all terms and conditions in a contract etc., even if it's one-time business?
- Do you explain "Shionogi partner bribery prevention guidelines" to the business partners before starting the business?
- Have you taken money or entertainment in return for favors?
- Have you sent invitations in accordance with the regulations of the organization to key note speakers and chairpersons and pay appropriate honorarium?