



We are Otsuka.



Code of Ethics and Professional Conduct



Otsuka America Pharmaceutical, Inc. (OAPI)

Otsuka Pharmaceutical Development &
Commercialization, Inc. (OPDC)



People creating new products for better health

Dear Valued Colleague,

We are innovators. The word innovation brings to mind science and research, creativity and technology, big ideas and smart solutions. Every day, in every location, we strive to create industry-leading solutions, while remaining mindful that each of our actions must have sound footing. We innovate with integrity, never losing sight of the trust others have placed in us.

We recognize that providing solutions for patients and their families is at the very core of what we do. We believe that the creation of healthier lives begins with our own fair, open, and honest community. We treat one another with dignity and respect. As a caring corporate citizen, we take responsibility for our actions in the local, national, and international communities where we operate.

Our Code of Ethics and Professional Conduct represents our commitment to conducting business with integrity at all times. It provides an overview of the important policies, procedures, work practices—all collectively referred to in our Code as "standards"—as well as the laws and regulations that apply to our business. It also provides many tools to assist you, including helpful questions and answers for common issues that arise and ready references to applicable policies and SOPs. We expect you to read and follow the Code and to commit to conducting business in accordance with high ethical standards.

Don't ever underestimate the role you play in our success. In every action you take, in every decision you make, you represent our heritage and our Company. Together, we continue to make a difference in people's lives. We are Otsuka.



Kabir Nath
President & CEO NAPB, OAI

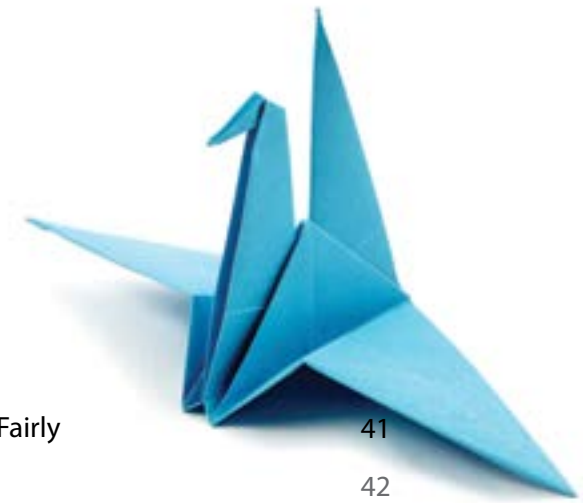


William H. Carson, MD
President & CEO, OPDC

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1

Sharing a Commitment

Our Code embodies our uncompromising commitment to high standards of integrity, ethical conduct, and professionalism.

- 1.1 Our Code
- 1.2 Otsuka's Compliance Program
- 1.3 Ethical Decision-Making
- 1.4 Speaking Up
- 1.5 Non-Retaliation Policy
- 1.6 Violations of Our Code or Standards

1.1 Our Code

We have a long, rich history of combining a commitment to caring with a passion for innovating, to develop new products for better health worldwide. Our Code of Ethics and Professional Conduct (“Code”) is our credo. It frames the way we do business and articulates the ethical values we all share.

Your Responsibility

The decisions you make on the job every day help to define the kind of Company we are. Our Code is designed to provide you with an overview of the standards that apply to our business, help you understand what is expected of you, and direct you to the people and resources available to help you make the right choices.

- You have a responsibility to read and comply with our Otsuka Group Global Code of Business Ethics (GCOBE) in addition to this U.S. regional Code. In the event of any conflict between the GCOBE and this U.S. regional Code and associated policies, you should decide which sets forth higher standards of conduct. If one requires higher standards than the other, that Code should guide your behavior. Simply put, we must consistently follow the most stringent rules. If you are in doubt, seek guidance from your supervisor, E&C, or Legal Affairs.
- You have a responsibility to read and comply with our U.S. regional Code and standards and to be familiar with the laws and regulations governing the life sciences industry.

Our U.S. regional Code applies equally to all employees of OAPI and OPDC. We also hold third parties (e.g., contractors, vendors, suppliers, CROs, etc.) who act on our behalf to the same high standards.

Know the Standards, Laws, and Regulations Where You Work

As a global Company operating in a highly regulated industry, each of us has a responsibility to follow the standards, laws, and regulations of the states and the countries in which we work.

Be aware that they can change and vary by location or by job function. The laws of some countries even extend to conduct beyond their borders. It’s important that you know and comply with the requirements that apply to the work you do and ask for guidance if you’re ever unsure of the proper course of action.

Your commitment to an ethical culture not only helps us comply with the law, it also helps to promote the kind of workplace—and sustain the kind of success—we all want.

Supervisors Have an Added Responsibility

Supervisors play a critical role in promoting an ethical culture. If you are a supervisor, be a leader and inspire your colleagues. Always work with integrity and ensure that employees understand their obligation to do the same. Create the kind of workplace where everyone feels comfortable coming forward with questions and concerns without fear of reprisal. For more information about supervisors’ responsibilities under the Code, refer to Otsuka’s Supervisors’ Guide, Leading with Integrity.

Find Out More



For additional resources, explore our policies and procedures on the Otsuka Document Portal.

When you see “Otsuka” or “Company” or “we” or “our” in this Code, it means all employees of Otsuka America Pharmaceutical, Inc. (OAPI), Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC).

1.2 Otsuka's Compliance Program

Our comprehensive compliance program reflects the commitment we make to conducting business honestly, ethically, and in compliance with the laws and regulations where we operate.

Ethics & Compliance (E&C)

E&C's mission is to promote an organizational culture integrating ethical conduct, integrity, and compliance into innovative, quality solutions for better health. E&C oversees the development and implementation of our comprehensive compliance program, which includes training, auditing, and monitoring, policies and procedures, compliance committees, ongoing communications and advice, and internal investigations.

Led by the Chief Compliance Officer, E&C is a dedicated resource available to support all Otsuka employees in maintaining an ethical culture. To submit general questions to E&C for advice about policies, procedures, or practices, email: E&CHelpline@otsuka-us.com. (Please do not submit confidential concerns or information using this email address — use the Integrity Line instead.)

Additional details regarding Otsuka's compliance program can be found on our [website](#).

Find Out More



For additional resources, explore our policies and procedures on the Otsuka Document Portal.



Q&A

What if...

There is a conflict between the Code and the local law where you work?

Always abide by the laws of the United States unless the local law is stricter. If you have any doubts about whether an action might violate either local law or U.S. law, contact Legal Affairs or E&C for guidance.



1.3 Ethical Decision-Making

Each of us has a responsibility to read, understand, and follow our Code and standards and to be familiar with the laws and regulations that apply to our jobs. Together, they lay the foundation for ethical decision-making, regardless of where we work or what we do.

When the Answer Isn't Clear

The Code explores many—but not all—ethical situations you may face on the job, so apply good judgment, make decisions that are consistent with our values, and, if the right course of action is ever unclear, ask for help.



Ethics Decision Tree

A decision tree can be a useful tool when you're faced with a difficult decision.



Find Out More



For additional resources, explore our policies and procedures on the Otsuka Document Portal.

1.4 Speaking Up

We also have a responsibility to speak up if we have a question or if we see or suspect activity that potentially violates our Code, our standards, any law or regulation. Speaking up may not be easy, but it's always the right thing to do.

Why Speak Up?

Sometimes if you suspect illegal or unethical conduct, it may seem easier to say nothing, but a violation, left unreported, can put our Company, patients, and others at risk. That's why speaking up is not just the right thing to do—it's required under our Code. All colleagues have a duty to report potential misconduct to the Company. Don't be a bystander.

By promptly sharing [good faith](#) concerns, you allow the Company to address your concerns.

Speak up when:

- You are unsure about how to navigate a situation properly and need advice
- You believe that you or someone acting on behalf of the Company has done, is doing, or may be about to do something that violates our Code, our standards, the law, or regulations
- You make a mistake (it's better to self-report than to be the subject of a report)

Resources for Reporting

You have many resources available to address your concerns or questions. In most cases, your supervisor is in the best position to help you, but if you are not comfortable talking about an issue with your supervisor or are not satisfied with his or her response, you may contact the Chief Compliance Officer, E&C, Human Resources (HR), Legal Affairs, or the Integrity Line.

See [Where to Go for Help](#) for contact information.

The Integrity Line

The Integrity Line can be accessed via phone or Web, is available anytime, day or night, and offers you the option of reporting your concerns anonymously. When you contact the Integrity Line, a third-party vendor documents your concern in detail and forwards the information to our Company for follow-up. Reports made to the Integrity Line are never recorded or traced.

Integrity Line
1-800-363-5670

<https://tnw.reportlineweb.com/custom/Otsuka-us>

24 hours a day, 7 days a week.
You DO NOT have to give your name.

After You Report

Regardless of the resource you use, your concern will be handled professionally, discreetly, and in accordance with our Company's internal investigation procedures and applicable legal and regulatory requirements. The information you provide will be shared only with those individuals with a need to know.

Find Out More



For additional resources, explore our policies and procedures on the Otsuka Document Portal.

**Ethics is why you do what you do
when no one is watching.**

1.5 Non-Retaliation Policy

Otsuka strictly prohibits retaliation against anyone who makes a good faith report about a known or suspected violation of our Code or standards or any law or regulation.

Where to Go for Help

If you suspect that you have been subject to retaliation or if you're aware of retaliatory conduct by others, immediately contact HR, E&C, Legal Affairs, or the Integrity Line. Anyone who engages in retaliatory behavior will face disciplinary action that may include termination of employment.

When employees raise observed or suspected violations of our Code or standards or any law or regulation, supervisors have a responsibility to listen to their concerns and to never respond in a retaliatory manner. Supervisors also have an obligation to report and prevent retaliation by others.

Find Out More



Search the [Employee Handbook](#) and the SOP Viewer using the keyword: Retaliation

For additional resources, explore our policies and procedures on the Otsuka Document Portal.

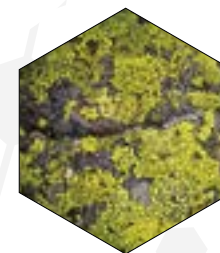


Q&A

What if...

You report a concern and an investigation finds there was nothing wrong?

Any time you report a concern in good faith, you're doing the right thing. "Good faith" doesn't mean that you have to be right. It means you honestly believe that something is wrong and are not making a complaint for improper purposes. Regardless of whether or not the reported concern is substantiated, we do not allow retaliation for any reports made in good faith. We may not be able to share the specifics of an investigation with you, as we respect the privacy of both the person raising the concern and the person about whom the report is being raised. We do, however, treat all reports seriously, fairly, and promptly.



1.6 Violations of Our Code or Standards

We are committed to compliance with our Code and standards. Anyone who violates them in spirit, intent, or letter may be subject to disciplinary action and corrective action, up to and including termination of employment.

Corrective Action and Internal Investigations

Allegations of misconduct are evaluated and investigated on a case-by-case basis. Any investigative activity will be conducted without regard to the potential wrongdoer's length of service, position, or relationship with the Company and will be handled in the most discrete manner possible. Under certain circumstances and if the facts warrant, we may report violations to the government or other third parties, or we may report matters to law enforcement authorities for possible prosecution.

As an employee, you are obligated to cooperate in any internal investigations. As an organization, we strive to maintain your confidentiality to the extent reasonably possible given our business and legal obligations.

Follow not only what's written
in our Code, but also the spirit of
our Code...



If You Are a Supervisor

Supervisors are responsible for ensuring that employees know and understand what is required of them and for creating an environment that promotes ethical conduct. Supervisors can face disciplinary action if they ignore reports of misconduct or fail to address them effectively and appropriately.

Consequences of Misconduct

If misconduct is confirmed, the Company will determine the appropriate disciplinary action or actions that may include (and not necessarily in sequential order) coaching, written warning, suspension, termination, referral for criminal prosecution, or reimbursement to Otsuka for any losses or damages resulting from the misconduct. Any action taken as a result of an investigation is based on the individual facts of the matter.

Compliance is critical to our Company's reputation, our continued success, and the safety of our employees, patients, and customers. Follow not only what's written in our Code, but also the spirit of our Code, and keep in mind that no one, at any level, has the authority to tell you to do something unethical or illegal.

Failure to comply with our Code or standards, applicable laws or regulations, or failure to report potential violations or concerns to the Company may result in disciplinary action.

Find Out More



Search the [Employee Handbook](#) using the keywords: Corrective Action, Discipline

For additional resources, explore our policies and procedures on the Otsuka Document Portal.



2



Maintaining an Ethical and Respectful Workplace

Our success is driven by dedicated employees who are committed to high standards of behavior day after day, year after year.

- 2.1 A Commitment to Diversity
- 2.2 Preventing Harassment and Discrimination
- 2.3 Alcohol and Drugs
- 2.4 Health and Safety

2.1 A Commitment to Diversity

The unique blending of individual skills, backgrounds, experiences, and cultures—and a highly collaborative spirit—creates a powerful team, a superior work experience, and a distinct advantage in driving innovation and improving patient care.

What That Means For You...

Each of Us Is Valued Here

We are proud of our diverse workforce. Each of us has unique experiences and perspectives that together drive the creativity and ingenuity that marks our Company's success. Each of us shares the responsibility to treat every person with respect and dignity; it's a fundamental aspect of how we work and who we are as a Company.

We apply the principles of equal employment opportunity and nondiscrimination to all employment decisions, including those related to recruitment, hiring, training, and promotion. Our affirmative action program helps to promote opportunities for individuals in certain protected classes and further supports our commitment to a fair, equitable, and diverse workplace.

We make reasonable accommodations, when requested, for qualified individuals with disabilities, in accordance with the law.

Find Out More



Search the [Employee Handbook](#) using the keywords: Diversity, Equal Opportunity, Reasonable Accommodation

For additional resources, explore our policies and procedures on the Otsuka Document Portal.



“

...work up the courage and make every effort to break through the thunderclouds of unfairness.

”

Masahito Otsuka

2.2 Preventing Harassment and Discrimination

We are committed to maintaining a respectful workplace that is free of unlawful discrimination and harassment, including sexual harassment.

What That Means For You...

We Insist on a Professional Atmosphere

We do not tolerate [discrimination](#) or [harassment](#) based on an individual's race, color, religion, sexual orientation, age, gender identity or gender expression, national origin, citizenship, ancestry, marital status, disability, genetic information, veteran status, or other characteristics protected by applicable laws.

We expect leaders to set the tone for ethical and professional behavior. If you observe any inappropriate behavior among teams or in meetings —such as unprofessional conduct or comments — we expect you to address the situation in the moment and to escalate. Each of us is responsible for promoting a work environment that fosters mutual respect, openness, and individual integrity.

Our policy prohibiting harassment and discrimination applies to all executives, supervisors, employees, job applicants, independent contractors, and suppliers. It applies to employees working at the office, in the field, or at Company functions away from the office.

Recognize and Report Inappropriate Behavior When You See It

Celebrate each individual's contributions and treat all colleagues with respect. If you experience or witness any incident of discrimination or harassment, immediately report it.



What kinds of activities can create a disrespectful or harassing work environment?

Physical activities such as unwanted hugging, touching, standing too close, or blocking someone's path

Verbal activities such as making derogatory statements, crude jokes, comments, or slurs—even a comment or joke that you may think is innocent can be unwelcome or offensive to others

Visual activities such as displaying obscene pictures, cartoons, or posters

Find Out More



Search the [Employee Handbook](#) using the keywords: Harassment, Discrimination

For additional resources, explore our policies and procedures on the Otsuka Document Portal.

2.3 Alcohol and Drugs

We share a commitment to a drug-free workplace, one that will allow each of us to achieve the high levels of professional performance we expect and ensure a safe working environment for everyone.

What That Means For You...

Comply with Company Standards

Being under the influence of alcohol or illegal drugs can impair your job performance and the job performance of those around you, as well as create an unsafe work environment. That's why our standards prohibit employees and third parties working for Otsuka from performing work or driving a vehicle for Company business while under the influence of alcohol or an illegal or unauthorized drug (including a prescription medication that's not prescribed to them).

Possessing, using, selling, or offering illegal or unauthorized drugs while working, while on Company premises, or while driving a vehicle for Company business are also strictly prohibited.

You are also prohibited from consuming alcoholic beverages at work or possessing open alcoholic beverage containers on Company premises, unless you are attending a Company-sanctioned event at which alcohol is being served. If you choose to drink alcoholic beverages at Company functions, do so responsibly. Failure to use good judgment can lead to disciplinary action up to and including termination.

Safeguarding Our Employees

In order to ensure the safety of all employees, we may require you to submit to drug and/or alcohol testing while you're employed at Otsuka under any of the following conditions:

- You are involved in an on-the-job accident or in an accident involving a Company-provided vehicle and there was personal injury or damage to Company property

- It is part of a follow-up program for treatment for drug abuse
- There is a reasonable suspicion that you're in violation of our standards regarding alcohol and drugs, or there are reports from witnesses of unsafe or threatening behavior

Find Out More



Search the [Employee Handbook](#) using the keywords: Alcohol, Drugs

Q&A

What if...

You have a question or concern about substance dependency or abuse?

Use the resources of the confidential Employee Assistance Program (EAP). Information about EAP can be found on the Company intranet. We encourage you to seek guidance by contacting the EAP or your healthcare professional.

2.4 Health and Safety

Safety is everyone's responsibility. We are each responsible for taking the necessary precautions to protect ourselves, our guests, and our work environment.

What That Means For You...

Observe Safe Work Practices

Take an active role in ensuring your own safety by complying with all workplace safety rules and procedures, including those issued by the Occupational Safety and Health Administration (OSHA). Health and safety concerns, near-misses, and injuries should be reported immediately in accordance with our standards.

Physical Security

If you have a Company-issued ID badge, keep it visible at all times while on Company business. Direct all visitors to enter through approved security points. Visitors must wear badges prominently and are not permitted to take photographs without prior written approval from OAPI Administrative Services. Promptly report any suspicious activity to OAPI Administrative Services.

Zero-Tolerance for Workplace Violence

Violence in any form is not tolerated. Report all threats, incidents of violent behavior, or any unauthorized persons that you observe in your work environment by calling the Crisis Management Hotline at x6666, or by notifying your supervisor, another member of management, or HR. If a situation occurs that could result in immediate danger, ensure your personal safety by following emergency procedures and, if necessary, removing yourself from the area.

Company policy prohibits you from possessing a [deadly weapon](#) while on Company premises or while conducting Company business.

Find Out More



Search the [Employee Handbook](#) and the SOP Viewer using the keywords: Health, Safety, Injuries, Violence

Speak Up About Any Potential Risks

- Health or safety concerns
- Work-related injuries or illness
 - Suspicious activity
- Unauthorized persons in the workplace
- Workplace threats or violence

Be aware that you will never face disciplinary action for reporting a good-faith health or safety concern that you believe presents a danger to yourself or others in the workplace.

Q&A

What if...

You see someone taking pictures in the workplace?

Ask, "May I help you?" and follow up with, "What are the pictures for?" Report any suspicious activity to OAPI Administrative Services.

2.5 Respect for Privacy

People inside and outside of our Company trust us to protect their personal information. We have an obligation to protect, respect, and maintain the privacy of this data in accordance with our Company standards and the law.

What That Means For You...

Be a Good Steward

As part of your job responsibilities, you may come into contact with personal information, including [personally identifiable information \(PII\)](#) about your fellow employees, [healthcare professionals \(HCPs\)](#), patients, clinical trial participants, distributors, suppliers, and other third parties. You have an obligation to safeguard any information to which you have access. In particular, safeguard information relating to PII or Protected Health Information (PHI) against inadvertent or unauthorized disclosure, and take reasonable precautions to prevent it from coming into the hands of unintended recipients. Comply with all requirements related to its collection, use, transmission, and retention.

The personal information you learn about others as part of your job responsibilities should be considered [confidential information](#) and used or disclosed only for legitimate business purposes. Share it only with those who are authorized to receive it and have a need for it in order to do their job.

Limit the amount of information you share to what is required to accomplish the task. Make sure that the person who receives the information knows it is confidential and understands any restrictions related to its use, dissemination, or transmission. Be careful when sending or storing information via phone, email, text, social media, cloud, or other means—ensure that information is securely stored, as appropriate, depending on the sensitivity of the data.



Examples of Personal Information:

- Full name (if not common)
- Vehicle plate number
- Driver's license number
- Credit card number
- Date of birth
- National Identification Number (in the United States, a Social Security Number)
- IP Address (in some cases)
- Digital identity
- Face, fingerprints, or handwriting
- Birthplace
- Email address

Personal information is any information that can be used to distinguish or trace an individual's identity.

Find Out More



Search the SOP Viewer using the keywords: Data Privacy, Personal Information





3



Driving Product Excellence

We understand that the purpose of industry laws and regulations is to protect patient safety, so we honor and follow them—in doing so, we also achieve our mission of creating new products for better health worldwide.

- 3.1 Industry Laws and Regulations
- 3.2 Ethical Research
- 3.3 Product Quality and Safety

3.1 Industry Laws and Regulations

The products we discover, design, develop, manufacture, and distribute touch millions of lives around the world. We understand the critical obligation we have to comply with all industry laws and regulations to ensure the quality of our products and protect patient safety.

What That Means For You...

We Are Subject to Many Requirements

The federal, state, and local requirements that relate to our industry are substantial and sweeping, but all are aimed at a single objective—to protect the health and safety of patients and consumers.

We recognize the duty we have to abide by these requirements and follow all laws and regulations governing research, development, manufacturing, promotion, sales, and distribution of our products in the countries where we operate. Ensuring product quality and safety is paramount.

Some of the U.S. laws that apply to our operations include the Food, Drug, and Cosmetic Act (FDCA), the False Claims Act (FCA), the Foreign Corrupt Practices Act (FCPA), the Patient Protection and Affordable Care Act (PPACA), the Anti-Kickback Statute (AKS), and the Health Insurance Portability and Accountability Act (HIPAA). Our internal standards help to ensure compliance not only with these laws, but with all applicable laws and regulations.

In addition to legal and regulatory requirements, we also comply with industry codes (including PhRMA and AdvaMed) to ensure the integrity of relationships with third parties, such as [HCPs](#), HClIs, payers and advocacy groups.



Know the Requirements that Apply to Your Job

Your understanding of—and compliance with—federal, state, and local requirements helps us maintain the reputation for trust we have built within the marketplace. Refer to our internal standards to ensure compliance with all of the requirements that apply to your role and responsibilities.

If you are working outside the United States, always abide by the laws of the United States unless the laws of any locale in which you work are stricter. If you have any doubts about whether any action might violate either local law or U.S. law, contact Legal Affairs for guidance.

Report Suspected Violations

Non-compliance with our standards can compromise patient safety, subject us to substantial civil and criminal penalties and individual liability, and damage the trust we have earned through ethical business dealings.

If you see or suspect violations, speak up. Your voice matters. We take concerns seriously and promptly investigate them. By speaking up, you help our Company do the right thing. A failure to speak up about violations can result in disciplinary action.

Find Out More



Search the SOP Viewer using the keywords: FDCA, FCA, HIPAA, PPACA, AKS

...help us maintain the reputation for trust we have built within the marketplace.

3.2 Ethical Research

We are committed to innovative, high-quality research, conducted with the highest ethical standards and in accordance with all applicable laws, regulations, guidelines, and industry codes.

What That Means For You...

Safety Is Our Highest Priority

Ensure the rights, safety, and well-being of all research subjects in clinical trials and protect them from exposure to unnecessary risks:

- Inform all participants of the nature and purpose of the research and obtain their informed consent.
- Conduct all clinical trials under the supervision of an Independent Review Board (IRB) and in accordance with Good Clinical Practices (GCP) and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines.
- Carefully record and store all information from clinical trials in compliance with data protection laws.
- Produce clean, auditable data to support regulatory approval of new medicines, new indications, and new formulations.

Independent proposals for research grants must be scientifically reviewed in accordance with external laws and regulations and all internal standards.

Promote Animal Welfare

As a Company, we continually strive to adopt new testing methods that do not require the use of animals.

When the use of laboratory animals is scientifically necessary, we ensure that

research is conducted ethically, responsibly, and humanely in accordance with the law and our standards.

Ensure the rights, safety, and well-being of all research subjects...

We Are Committed to Transparency

As a Company focused on innovation, we recognize that access to clinical trial data is valuable for the advancement of public health and science and that greater transparency of clinical trial data promotes better health worldwide. We are committed to sharing clinical trial data and results through clinical trial registries in public databases, such as www.clinicaltrials.gov, through publication in peer-reviewed journals, as well as in accordance with evolving industry requirements to advance clinical trial data transparency.

Our goal is to strike the necessary balance between advancing science for public health and fostering innovation with the need to protect the privacy of individual patients, who have made a selfless contribution to the advancement of medicine.

Find Out More



Search the SOP Viewer using the keywords: GCP, Research, Clinical Trials, Audits, Non-compliance, Deviations, Corrective Action Preventive Action (CAPA), Regulatory, Safety, Data Management



3.3 Product Quality and Safety

Our continued success depends on our ability to provide quality products that are both safe and effective. We have a responsibility to continually monitor our products to ensure they meet our high standards and to take appropriate action if they do not.

What That Means For You...

Take Personal Responsibility for the Work You Do

Wherever you work at Otsuka, whatever your duties, you should carry out your work precisely, accurately, and in conformance with appropriate standards.

Do your part to ensure that, as a Company, we meet or exceed requirements and customer expectations. Remember, no one is better positioned than you to identify and recommend improvements in the way we do business—always look for new ways to deliver on our promise of safe, high-quality products.

Promptly Report Any Safety, Quality, or Performance Issues

It is mandatory that [adverse events \(AEs\)](#) and [product quality complaints \(PQCs\)](#) related to our products be reported within 24 hours of the first Otsuka colleague being notified of the complaint.

To ensure safety and quality, we track, investigate or assess, and report AEs and PQCs. The information we collect is shared with patients, medical professionals, and regulatory authorities as well as used to continually improve our products and minimize risks to consumers.

Be Alert to Counterfeiting and Tampering

Product that is fraudulently mislabeled or is tampered with can pose a serious

**...carry out your work precisely,
accurately, and in conformance with
appropriate standards.**

risk to patients and consumers and harm our reputation for quality and safety. Any event involving known or suspected counterfeiting of or tampering with our products should be reported immediately via the Product Quality Complaints number.

Product Quality Complaints:

1-800-438-9927

Adverse Events:

1-800-438-9927 (clinical & product AEs)

1-866-232-2557 (ABILIFY® & SPRYCEL®)

It is mandatory that AEs and PQCs related to our products be reported within 24 hours of receipt. Remember, reporting a safety or quality concern could help save someone's life.

Find Out More



Search the SOP Viewer using the keywords: Adverse Event, Product Quality Complaint



4



Conducting Business Ethically and Fairly

We know and comply with the laws and regulations that affect our business and strive, in every interaction, to operate with the highest standards of professional conduct.

- 4.1 Fair Competition
- 4.2 Bribery and Corruption
- 4.3 Insider Trading
- 4.4 International Trade
- 4.5 Money Laundering
- 4.6 Relationships with Third Parties
- 4.7 Relationships with the Government



4.1 Fair Competition

We compete fairly and strategically in the marketplace in full compliance with antitrust and fair competition laws.

What That Means For You...

Promote Fair Business Practices

Do your part to build positive business relationships and comply with the letter and spirit of laws designed to foster competition in the country (or countries) where you do business. Avoid conduct that might even suggest a violation of antitrust or competition laws. For example, avoid any activity that might create suspicion of conspiring with a competitor. Even seemingly innocent conversations can be easily misconstrued. It is best to excuse ourselves from conversations involving the sharing of confidential business practices and Company secrets and data.

Some practices are never acceptable. You must never enter into any understanding or agreement—written or verbal—with a competitor, customer, or supplier to:

- Raise, set, or hold (i.e., “fix”) prices on our products
- Split territories, markets, or customers
- Participate in any kind of bid rigging
- Prevent another company from entering the market
- Refuse to deal with a customer or supplier
- Restrict production, sales, or output
- “Tie” two products together so that customers—in order to buy a product they do want—must buy something they don't

Be aware that engaging in anti-competitive behavior can result in severe legal risk to you and to Otsuka.

Gather Competitive Information Legally and Ethically

Never acquire information through improper means or enlist someone else to do so on our behalf. If you find you're in possession of information that may have been obtained in an illegal or unethical manner, contact Legal Affairs immediately.

Find Out More



Search the SOP Viewer using the keywords: Antitrust, Competition

Q&A

What if...

An informal conversation with a competitor turns to a topic that potentially violates our standards or the law?

Make it clear that you will not participate in discussions regarding any competitive matters, announce why you are leaving to ensure there is no ambiguity about your intention, then promptly leave and report the incident to Legal Affairs or E&C.

4.2 Bribery and Corruption

We comply with anti-bribery and anti-corruption laws in all of the locations where we operate, not only because we have a legal obligation to do so, but also because it reflects our commitment to conducting business honestly and with integrity.

What That Means For You...

We Are Subject to the Laws of Multiple Countries

Virtually every country has laws that prohibit bribery and corruption, and the laws of many countries have a global reach. That's why it's critical that you understand and comply with the statutory, regulatory, and contractual provisions that govern the work you do. Violations of anti-bribery laws can result in lawsuits, substantial fines (for both Otsuka and you), and even jail time.

Avoid Even the Appearance of Something Improper

You may not offer or accept anything of value, either directly or indirectly, in order to obtain an improper advantage for yourself or for Otsuka. Wherever you conduct business and regardless of local custom or practice, comply with U.S. law.

In addition, you may not offer or provide anything of value in order to influence someone to prescribe, purchase, recommend, or use products that are reimbursed by federal healthcare programs like Medicare and Medicaid.

"Anything of value" can be:

- Donations to charities or political parties
- Cash equivalents, like a check, gift card, or money order
- Discounts
- Entertainment
- Favors
- Travel

In addition to our own actions, we, as a Company, are responsible for the acts of our suppliers and other third parties working on our behalf. To ensure our suppliers conduct business in accordance with relevant laws, codes, and regulations, we conduct due diligence on our vendors. We do not buy business under any circumstances. All fee-for-service agreements must be in writing and approved in advance through the appropriate channels.

To honor our commitment:

- Comply with our anti-fraud and anti-corruption policies
- Know who you are working with, the business practices they employ, and the reputation they have for operating honestly and ethically
- Speak up if you see or suspect anything improper
- Ask questions if you're unsure of the proper course of action

Facilitating Payments Are Prohibited

The laws of some countries allow for facilitating payments (sometimes referred to as "grease payments") to be made to government officials to expedite or to secure the performance of a routine governmental action. We prohibit facilitating payments even when permitted under local law.

Know Your Obligations

Be aware that anti-bribery legislation is especially strict when it comes to offering bribes to government officials. [HCPs](#) working in, on behalf of, or affiliated with a government healthcare facility, institution, university, or hospital are also considered government officials. At all times and in all places, make sure your business conduct is above reproach.

Find Out More



Search the SOP Viewer using the keywords: Bribery, Corruption, AKS, FCPA, U.K. Bribery Act, Fraud

4.3 Insider Trading

We do not trade in the securities of any publicly held company (including our business partners or customers) based on material, nonpublic information.

What That Means For You...

Recognize and Protect "Inside" Information

Material, nonpublic—or "inside"—information is information you know about or become aware of by virtue of being an employee of our Company. It is illegal to trade securities (e.g., stocks, bonds, options, etc.) of a public company when you are aware of "inside" information.

Information is "material" if a reasonable investor would consider it important in deciding whether or not to buy, sell, or hold securities. Information that could be deemed to be material includes potential mergers, acquisitions, or divestitures. Information is considered "nonpublic" up until the point at which it is widely communicated to the public (for example, through the issuance of a press release or public filings).

Neither you, nor any member of your family or household, may use or disclose

Examples of material, nonpublic information:

- Projections of future earnings or losses
- The gain or loss of a substantial customer or supplier
- Merger and acquisition proposals
- Changes in executive management
- New products or discovery announcements
- New projects contemplated
- Significant developments in litigation

any inside information you acquire about Otsuka or other companies during your relationship with Otsuka. If you're not sure if information is material or if it has been released to the public, seek help from Legal Affairs before taking any action. Anyone who acts on inside information can be subject to liability, including criminal liability.

"Tips" Are Also Illegal

Passing along a "tip" is also a form of insider trading. Inside information should be treated as confidential and not shared with anyone else. Avoid even the appearance of an improper transaction.

Find Out More



Search the SOP Viewer using the keywords: Insider Trading, Material Nonpublic Information, Securities Trading, Investments



4.4 International Trade

As a Company that conducts business around the world, we are subject to—and comply with—the international trade laws of the countries where we work.

What That Means For You...

We Follow the Rules

We are subject to export control, economic sanctions, import, customs, and other trade compliance laws that govern how our products move across international borders. These laws are complex and violating them can result in significant fines and penalties, as well as an inability to export our products.

If you are involved in the import or export of products, services, information, or technology for our Company:

- Follow all rules regarding classification, valuation, country of origin markings, documentation, declarations to local government agencies, and authorization of government licenses
- Know and abide by:
 - U.S. anti-boycott laws
 - U.S. restrictions on doing business with foreign countries
 - All applicable export control requirements
 - The trade laws and regulations associated with countries with which you do business

Compliance with our Company standards will help you meet the requirements of applicable laws, regulations, and restrictions that relate to the import or export of our products, wherever we operate in the world.



Did You Know...

Export control laws apply not only to shipments of our products, but also to where they are hand-carried during traveling. To find out more about export and import requirements, seek advice from Legal Affairs.

Find Out More



Search the SOP Viewer using the keywords: Export, Import, Economic Sanction, Boycott

4.5 Money Laundering

We comply with laws designed to deter money laundering and terrorist financing.

What That Means For You...

Watch for Red Flags

Money laundering is a process by which individuals or organizations work to hide or disguise the proceeds of criminal activity (such as terrorism, drug dealing, etc.) through a series of otherwise legitimate business transactions.

Take steps to prevent the inadvertent use of our business for this purpose. Immediately report any suspicious or unusual transactions or activities such as:

- Large payments in cash
- Requests to transfer funds to or from countries or entities that are not related to the transaction or the customer
- Unusual fund transfers to or from foreign countries

Find Out More



Search the SOP Viewer using the keyword: Fraud



...report any suspicious or unusual transactions or activities...

4.6 Relationships with Third Parties

We hold our suppliers to the same high standards to which we hold ourselves and communicate our expectation that they conduct business ethically, in compliance with the law, and in a manner that's consistent with our Code.

What That Means For You...

Select Suppliers Based on Objective Criteria

We encourage fair and open competition and the selection of suppliers based on due diligence considering such factors as quality, service, price, delivery, experience, capability, and reliability. Remember, all decisions should reflect Otsuka's best interest. Follow the procurement and sourcing procedures defined by our standards and ask questions if you're ever unsure of what's required.

Suppliers Must Honor Their Obligations

We require that suppliers abide by our Suppliers' Code which outlines key responsibilities, including:

- Ensuring the quality of the products and services they provide to us
- Ensuring the cost of their products and services is reasonable
- Protecting [confidential information](#) and Otsuka assets
- Complying with applicable anti-bribery, anti-corruption, and other laws

Otsuka can be held responsible for the actions of any suppliers with which we contract. If your job involves working with suppliers, partner with our strategic sourcing department to ensure consistency with Company standards and pricing/financial terms.



Monitor contractual agreements to ensure suppliers are meeting their obligations and speak up about any conduct that appears to be inconsistent with our high standards.

We Must Honor Our Obligations

Treat our suppliers with fairness and respect by honoring our commitments, ensuring timely payment, giving clear guidance as to scope of services, and protecting their confidential and [proprietary information](#).

Find Out More



Search the SOP Viewer using the keywords: Suppliers, Vendors, Third Parties.

**We require that suppliers abide by
our Suppliers' Code...**

4.7 Relationships with the Government

As a global Company, we interact with individuals from government entities in the United States and around the world and understand our obligation not only to meet our legal obligations but also to conduct business fairly, honestly, and transparently.

What That Means For You...

Follow the Rules

If you are involved in sales to the government (including U.S. or non-U.S. government agencies and government-owned businesses), make sure you are aware of any unique requirements that apply to this market. Promote procurement integrity by competing fairly and ethically throughout the bidding and negotiating processes.

Never:

- Seek confidential or source selection information before a contract is awarded
- Discuss employment or business opportunities with government procurement officials
- Provide a fee, payment, kickback, gift, or anything of value to any person

Make sure all representations, reports, data, and other statements that you submit on behalf of our Company are accurate and truthful.

If you are responsible for administering a government contract for Otsuka, understand and abide by the relevant statutory, regulatory, and contractual provisions of the work and avoid even the appearance of anything improper. Help us to be a responsible partner—comply with all security requirements associated with the contract and protect information from unauthorized disclosure.

Cooperate with Government Requests

Government representatives could potentially visit an Otsuka site or its employees as part of an inquiry, to issue a subpoena, or to execute a search or arrest warrant. If you are contacted, read or listen carefully to the request, then direct the individual to the proper resource.

For	Contact
GMP inspections or matters	Quality Management representative within E&C
GCP inspections or matters	Clinical Quality Management representative within E&C
Subpoenas, search or arrest warrants, visits from law enforcement	Legal Affairs
FDA or other agency inquiries related to product filings and Risk Evaluation and Mitigation Strategies (REMS)	Regulatory Affairs

We comply and cooperate with government requests for information or facility visits related to government inspections or investigations. If you are responsible for responding to a government request, be honest and accurate. Lying to a federal official is a crime. Never conceal, destroy, or alter documents, make misleading statements, or interfere with a government inspection or investigation.

Find Out More



Search the SOP Viewer using the keywords: Inspection, Investigation, Government Procurement

If you are responsible for responding to a government request, be honest and accurate.

4.8 Interactions with Healthcare Professionals

In our interactions with HCPs, HCIs, and advocacy groups, we follow not only the letter, but the spirit of the law, building on the reputation we've earned as a Company that operates ethically and honestly everywhere we conduct business.

What That Means For You...

Know Our Standards

We are committed to developing and marketing our products in a way that allows patients to live longer, healthier, and more productive lives. To protect the safety of patients and consumers and prevent fraud, waste, and abuse, we abide by codes from industry organizations such as PhRMA and AdvaMed that foster compliance with laws and professional ethical standards for interactions with [HCPs](#).

Remember that what is acceptable elsewhere in the commercial marketplace may not be acceptable when interacting with HCPs.

Maintain High Standards

We want our continued success to be based on the merits of the products we bring to the marketplace, never on unethical or illegal business practices. Be sure that any interaction:

- Is based on integrity and high ethical standards
- Achieves a legitimate business purpose, such as fostering education, research, or scientific advancement
- Doesn't interfere, or give the appearance of interfering, with someone's independent judgment — you shouldn't offer or give anything of value to an



HCP in order to induce or influence him or her to prescribe, use, purchase, lease, or recommend our products or to reward such use.

Find Out More



Search the SOP Viewer using the keywords: PhRMA, AdvaMed, Interactions, HCPs

Be sure that any interaction is based on integrity and high ethical standards.



4.9 Product Promotion

We are dedicated to open and transparent communication about our products—we work to ensure that all promotional materials and communications are honest, accurate, and balanced.

What That Means For You...

Follow the Law

Promote drugs and medical devices in accordance with FDA and other legal requirements for labeling (including information related to indications, patient population or age range, dosing strength, and phase of disease state or treatment).

Don't Mislead or Omit Important Facts

Know our standards regarding promotional activities. All advertising, promotional labeling, and statements must:

- Be consistent with all legal and regulatory requirements
- Be accurate, truthful, and not misleading
- Provide fair and balanced information
- Only make claims that are properly substantiated
- Never promote off-label use

To Whom Are We Promoting?

When providing promotional materials to [HCPs](#) or HCLs, we must ensure that they have a reasonable on-label use for the product. Product promotion for uses that are outside of the approved indications or to a population for which the product is not indicated or intended for use is prohibited.



Approval by Promotional Review Committee (PRC)

All promotional materials distributed to HCPs or to the public must be approved in advance by our PRC. Once approved, the materials may not be altered or modified in any way. This includes highlighting, underlining, editing, or changing the order in which the information appears.

Find Out More



Search the SOP Viewer using the keywords: Product Promotion, Advertising, Labeling, PRC

Provide fair and balanced information.





5

Safeguarding Our Reputation and Assets

It is paramount that we lead with integrity in all that we do.

- 5.1 Confidential and Proprietary Information
- 5.2 Protecting Otsuka Assets
- 5.3 Accurate Recordkeeping
- 5.4 Records Management
- 5.5 Avoiding Conflicts of Interest
- 5.6 Gifts and Entertainment
- 5.7 Communicating about Otsuka
- 5.8 Social Media



5.1 Confidential and Proprietary Information

We are committed to protecting confidential information about our Company, our employees, the companies with which we work, and the consumers and patients whom we serve.

What That Means For You...

Information Is a Critical Asset

Our manufacturing methods, our business plans, the research we do, the forecasts, budgets, and marketing strategies we develop—in fact, our entire knowledge base and work product are critical assets that give us a competitive advantage in the industry. Each of us has a responsibility to protect confidential and [proprietary information](#) since unauthorized disclosure can put our Company at risk. Unauthorized disclosure can also potentially violate data privacy, copyright, patent, trademark, and trade secret laws.

Know the Kind of Information that Needs Safeguarding

Protect:

- Proprietary information. Information that makes our Company unique such as [R&D information](#), [intellectual property \(IP\)](#), and non-public financial information
- Personal Information. Any information that could be used to identify our customers, patients, or fellow employees such as telephone numbers, birth dates, social security numbers, or other [PII](#)

Do Your Part to Protect Information



Before sharing confidential or proprietary information, be sure you are authorized to do so and that you disclose it only to those who have both a right and a business need for the information. Companies or individuals outside of Otsuka must sign a nondisclosure agreement before gaining access to our confidential or proprietary information.

Limit the information shared to only what is required. Make sure that the person receiving the information knows that it is confidential and understands any restrictions related to its use or dissemination.

Be a good steward of [confidential information](#) and observe good security measures when it's in your possession. Never use confidential information for personal benefit, never discuss it in public places, and never disclose it to others (including family members and friends) or to anyone else within the Company who doesn't have a need to know it.

In the office, file sensitive documents and computer media in locked cabinets. Make sure to physically secure all laptops in a locked cabinet or with security cables and lock your workstation when you step away. And keep your user ID and passwords private.

Protect the Confidential Information of Others

You also have an obligation to protect the confidential information of others (including suppliers and other third parties) that has been entrusted to us. This includes pricing, strategies, and practices shared by our Company and our suppliers—this information should never be shared outside Otsuka, even if a non disclosure agreement is not in place.

Don't share confidential information you have learned from previous employers, and don't share confidential information about Otsuka with future employers. Your obligation to protect confidential information applies even if you stop working at Otsuka.



Find Out More



Search the SOP Viewer using the keywords: Confidential Information, Proprietary Information

Did You Know...

We have standards that protect our IP. Before it is shared externally, IP is evaluated to determine whether new patent applications are possible, whether past or future activity infringes on another party's IP rights and whether there is any conflict between R&D information and previous Otsuka publications or patents. We require preapproval of any potential publication involving Otsuka R&D information. To find out more about how we protect Otsuka's IP rights as well as the rights of other IP holders, check the SOP Viewer.



5.2 Protecting Otsuka Assets

In addition to our information assets, our physical and technology resources represent critical Company assets, and we work to safeguard them from theft, loss, waste, and abuse.

What That Means For You...

Use Company Assets for Company Business

As a general rule, Company assets, including equipment, facilities, computer files, and programs, should only be used for the advancement of our business and not for personal use. Use them as they are intended, protect them as you would your own, and report any instances of misuse or fraud.

Certain assets such as phones and copiers may occasionally be used for non-business purposes, but your use should be reasonable and infrequent and never interfere with your job.

Protect our Technology and Systems

Viruses and downtime can significantly impact our operations. Help us to keep our systems running smoothly—never install unauthorized applications, software, hardware, or storage devices on your Company-issued computer, iPad or mobile devices or phones, and don't access our network through unauthorized applications or devices. Protect your password(s) and ensure the physical security of information or hardware that is assigned to you. Note also that Otsuka forbids the unauthorized duplication of software.

// Technologies are the indispensable assets of a company... //

Masahito Otsuka

Keep in mind that information you create, send, receive, download, or store during the course of your employment is Company property, and we reserve the right to monitor, review, and disclose information as we deem appropriate, subject to applicable laws and regulations. You should have no expectation of privacy when using Company resources.

Use Electronic Communications Appropriately

Make sure your use of the Company intranet and Internet access complies with our standards and that personal use is limited. Take care to never violate a law, harass others, divulge [confidential information](#), or interfere with network users, services, or equipment. Immediately report any security concerns to the Crisis Management Hotline (x6666), to your supervisor, E&C, or the Otsuka helpdesk: 1-877-40TSUKA.

Safeguard the Otsuka Brand

The Otsuka Brand represents a rich heritage and a dedicated workforce. Each of us has a duty to protect it and the reputation it embodies by following the [applicable standards](#) and reporting any misuse by either internal or external parties.

Find Out More



Search the SOP Viewer using the keywords: Company Assets, Fraud

5.3 Accurate Recordkeeping

Data integrity is crucial to the successful operation of our business, so we follow all applicable laws as well as internal standards in our everyday transactions.

What That Means For You...

Be Accurate, Complete, and Honest

Information recorded in our Company books and records is used every day to make important business decisions. Some information we maintain is also submitted to government and regulatory agencies. Make sure that anything you record or produce is complete and accurate and fully discloses the true nature of the business transaction.

If you are responsible for creating or maintaining our [business records](#), remember that all transactions must be authorized and recorded in compliance with our standards, applicable laws and regulations, and generally accepted accounting standards. Falsifying records and accounts or misrepresenting or omitting facts or information could constitute fraud and result in severe penalties. It can also lead to disciplinary action, up to and including termination of employment.

Ultimately, data accuracy is more than a legal responsibility; it's about operating our business with integrity. If you become aware of any omission, inaccuracy, or false entry, report it promptly.



“Business records” include paper or electronic materials. Here are a few examples:

- Strategic and business plans
- Timesheets
- Contracts
- Bills
- Invoices
- Ledgers
- Vouchers
- Clinical data
- Emails
- Regulatory filings
- Voicemail
- Sales call records
- Sample disbursements
- Expense reports and required receipts
- Production and quality data
- Compensation records
- Performance evaluations
- Research results
- Training records
- Clinical safety/pharmacovigilance records
- Text messages

Find Out More



Search the [Employee Handbook](#) and the SOP Viewer using the keywords: Books and Records, Business Records, Financial Integrity, Time, Reporting, Schedule

5.4 Records Management

We have adopted good records management practices that not only allow us to meet our legal, tax, and regulatory requirements but also to protect our intellectual property and safely dispose of information that's no longer needed.

What That Means For You...

Follow our Records and Retention Standards

In today's business environment, we create, send, receive, and store records—including email, text, and voicemail messages. Each of us has a responsibility to retain these records in accordance with applicable legal, financial, and regulatory retention requirements and to store them in locations approved for that purpose. We also have a responsibility to dispose of Company records that have satisfied their retention requirements, as directed by our standards.

Note that requirements for creation, maintenance, access rights, storage, retention, and disposal can vary depending on your business unit and location. Make sure you are familiar with the specific standards that apply to you and the work you do.

We Expect Third Parties to Follow Our Standards

Otsuka suppliers are also required to abide by our [records management](#) standards. Do your part to ensure that they understand and comply with this obligation.

Check for "Legal Hold" Restrictions Before Disposing

Some records may have a [legal hold](#) placed on them which means they may be relevant to a subpoena, litigation, investigation, or audit and should not be modified or disposed of until Legal Affairs releases them. Comply with requests to hold documents until you are notified that they can be released.

Be aware that destroying, discarding, withholding, or altering records that are pertinent to an audit, litigation, or governmental investigation is a crime.

Find Out More



Search the SOP Viewer using the keywords: Records Management, CMC Data, Legal Hold

Did You Know...

As a Company operating in a highly regulated industry, certain records and documentation must be stored for specified periods of time and access to certain records may be limited. To find out more about retention and disposal requirements for your business group, contact your Functional Area Records Coordinator.



5.5 Avoiding Conflicts of Interest

We do what's right for Otsuka, avoiding conflicts of interest that could create—or appear to create—a conflict between our personal interests and the interests of the Company.

What That Means For You...

Put Otsuka's Interests First

As an employee, you are responsible for a wide range of business decisions every day. In every case, it's critical that you weigh all of the relevant criteria, use good judgment, and make decisions based on what's best for the Company. A conflict of interest can compromise your objectivity.

Avoid Activities that Might Affect Your Objectivity

While it's not possible to list every situation that could present a potential conflict, there are certain areas where conflicts typically arise. Familiarizing yourself with these areas may help you to better identify and resolve conflicts before they cause harm.

- Personal Relationships. Potential conflicts can arise if you hire, manage, or conduct business with close personal friends or relatives.
- Investments. A conflict can also arise if you or a family member holds a financial interest in—or exercises control over—one of our suppliers, customers, or competitors.
- Outside Activities. Board directorships or advisory roles with companies, universities, or other organizations may pose a conflict if they interfere with your job at Otsuka.
- A Second Job. Work outside of Otsuka can pose a potential conflict if it competes with the work you do for us or interferes with the time, talent, and energy you bring to your job.
- Personal Benefits. You should not use your position at Otsuka to gain a personal benefit or any type of compensation for yourself or your friends or relatives.

- Gifts. Gift-giving and receiving can also pose a conflict when doing so influences—or appears to influence—your decision-making. Make sure you know, understand, and comply with our standards regarding conflicts of interest, anti-bribery, and corruption.

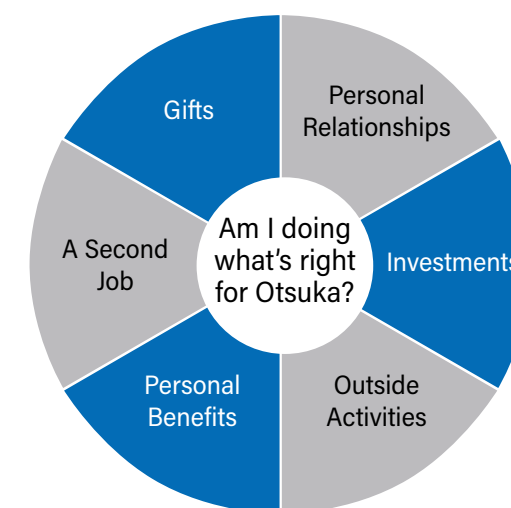
Transparency Is the Key

Disclose any actual or potential conflicts of interest to the General Counsel for discussion and resolution. Remember, even the appearance of a conflict should be avoided. When addressed promptly, many conflicts can be resolved in a way that's acceptable to both you and the Company.

Find Out More



Search the [Employee Handbook](#) and the SOP Viewer using the keywords: Conflicts of Interest, Investments, Gifts, Business Relationships, Outside Employment



Remember, even the appearance of a conflict should be avoided.

5.6 Gifts and Entertainment

We recognize that under the right circumstances, gifts and entertainment can create goodwill and build business relationships, but we are sensitive to the fact that they can also create the perception of a conflict of interest and, in some instances, violate the law. We do not engage in any activity that could raise concerns about our personal integrity.

What That Means For You...

Understand the Rules

You are prohibited from offering or accepting gifts, or entertainment of more than modest value (\$100) to or from anyone who conducts or seeks to conduct business with our Company.

There are significant legal restrictions that apply to offers of gifts or entertainment to [HCPs](#) and to government officials. Do not offer anything of value to individuals (or their related institutions) in these roles without obtaining approval in advance from Legal Affairs.

Be aware that it is never appropriate, under any circumstances, to solicit a gift or entertainment.

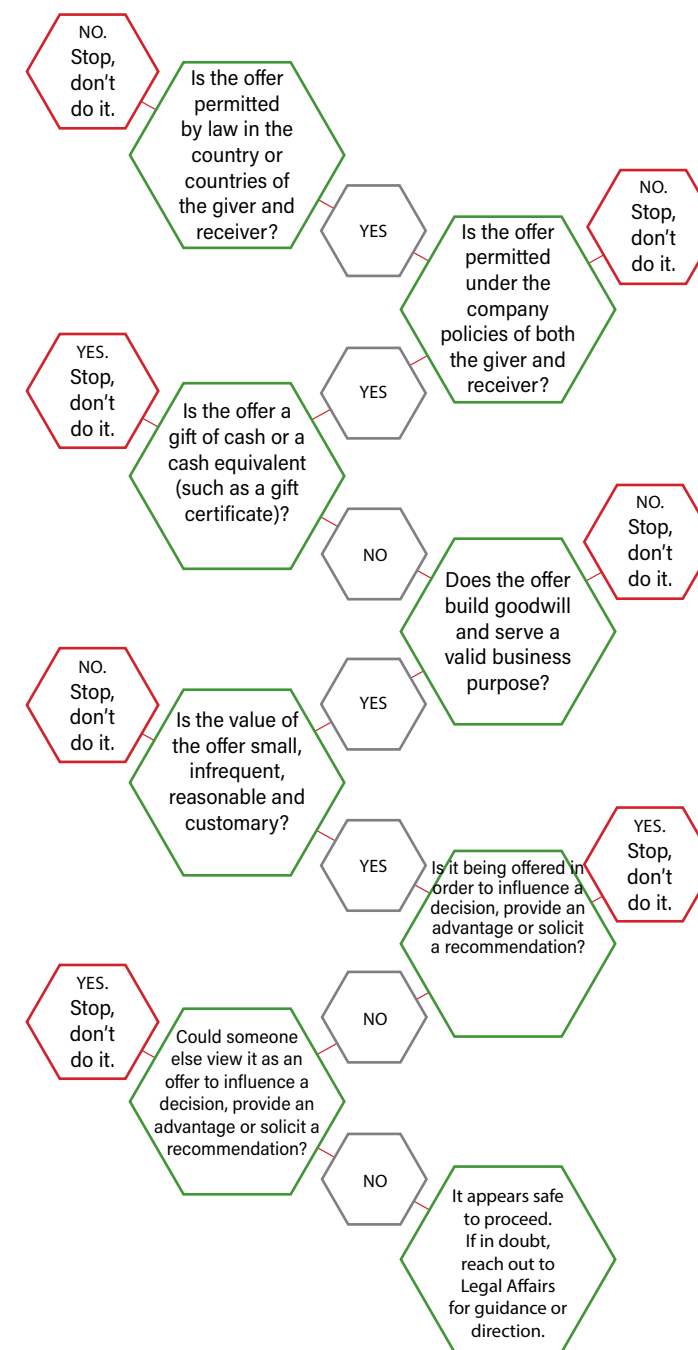
For offers of gifts and entertainment contemplated for non-HCPs and non-government officials, consider the following decision tree.

Find Out More



Search the SOP Viewer using the keywords: Gifts, Entertainment, Conflict of Interest

Before Proceeding, Ask Yourself:



There are significant legal restrictions that apply to offers of gifts or entertainment to HCPs and to government officials.

5.7 Communicating about Otsuka

We ensure that communications about our Company are accurate, complete, and timely and that confidential information is protected from unauthorized disclosure.

What That Means For You...

Direct Questions to the Proper Resource

We want to ensure that accurate information is conveyed to the public, to regulatory authorities, and to others, so we have designated individuals to serve as our official spokespersons.

If you are approached for information and you are not a designated spokesperson for our Company, do not make any statements or answer questions on our Company's behalf. Advise that you are not authorized to answer questions for Otsuka, then obtain the name of the person making the request and notify the appropriate internal contact.

For	Contact
Questions from the media	Corporate Communications
Questions from regulatory agencies	Regulatory Affairs
Questions regarding financial performance	Corporate Communications
Questions regarding legal issues	Legal Affairs
Questions from government representatives	E&C
Inspections	QM or CQM



You Are a Representative of Our Company

Remember that whatever you say in your interactions with others not only reflects on you and on our Company, but also impacts how others view Otsuka. When you are speaking on Otsuka's behalf (for example, representing Otsuka through a speaking engagement or releasing a publication that relates to our Company), pre-clearance is required. If you are speaking at a conference in an individual capacity, you must obtain pre-clearance approval from your manager, Corporate Communications, and the General Counsel and can never use or share [confidential information](#). Any materials you plan to use must also be approved in advance by Corporate Communications and the General Counsel.

When attending trade conferences, medical congresses, or other business venues, honor your obligation to protect our confidential information and the confidential information of the companies with which we do business.

Did You Know...

Communications about our Company must be approved in advance before they can be circulated externally. To find out more about communicating on behalf of Otsuka, contact OtsukaCommunications@otsuka-us.com.

Otsuka, noun [Oats' ~ kuh]

Find Out More



Search the SOP Viewer using the keywords: Communications, Social Media

5.8 Social Media

We are careful when we communicate with others about our Company online and use online tools in a manner that is consistent with our standards and in compliance with the law.

What That Means For You...

Use Good Judgment

Social media offers a great forum for the exchange of ideas, but it also introduces certain risks and carries with it certain responsibilities. We rely on you to use good judgment in your social networking activities whether you access the Internet on your Company-issued or personal devices.

Remember, only specifically authorized employees can use social media to speak on behalf of our Company in an official capacity.

That means if you write anything related to our business, and you are not a designated spokesperson for our Company, you must identify yourself as an employee of our Company and state that your views are your own and not Otsuka's. To comply with our Code, our Company policies, and the law, you must be careful not to post any content that would:

- Be discriminatory, harassing, intimidating, or offensive
- Violate copyright or trademark rights
- Violate another individual's right to personal privacy
- Disclose [confidential information](#) about our Company or third parties who conduct business with—or on behalf of—our Company

Note that you are not restricted from posting comments about the terms or conditions of your employment at Otsuka, as long as you follow the guidelines in our Social Media Policy.



You May Be Seen as a Representative of Our Company

Although you are solely responsible for the content you publish on blogs, wikis, or any form of user-generated media, please be aware that social media postings that adversely impact our Company could result in disciplinary action.

Find Out More



Search the SOP Viewer using the keyword: Social Media

Only specifically authorized employees can use social media to speak on behalf of our Company in an official capacity.





6



Focusing on Our Communities

We are good corporate citizens and value our place in the global community, working inside and outside of our corporate walls to make a difference.

- 6.1 Protecting the Environment
- 6.2 Promoting Human Rights
- 6.3 Political Involvement
- 6.4 Charitable Activities and Donations



6.1 Protecting the Environment

We respect the environment and are committed to minimizing the negative impact of our operations and promoting the sustainable use of natural resources.

What That Means For You...

Help Us Build on Our Commitment

Our responsibility to protect the environment is among our top priorities. Comply with Company programs, policies, and procedures designed to meet applicable Environmental Health and Safety (EHS) standards and take an active role in identifying new ways to help reduce our overall footprint.

A few simple acts can have a significant environmental impact:

- Recycle whenever possible
- Reduce your personal consumption of water and energy
- Conserve paper by limiting printing
- Report any actual or potential environmental hazard
- Turn off your office lights when you leave



Find Out More



Search the SOP Viewer using the keywords: Environment, Sustainability

...take an active role in identifying new ways to help reduce our overall footprint.



6.2 Promoting Human Rights

We believe all human beings, everywhere in the world, have the right to be treated with dignity and respect.

What That Means For You...

Honor Our Commitment

We show respect for human dignity and the rights of the individual by supporting the principles set forth in the United Nations Declaration of Human Rights and complying with employment laws in the markets where we operate.

We prohibit the employment of underage children or forced labor, as well as any form of physical punishment or abuse.



Find Out More



Search the SOP Viewer using the keyword: Human Rights



6.3 Political Involvement

We encourage free expression and participation in civic and political activities.

What That Means For You...

Participate Responsibly as an Individual

We support your participation as a private citizen in the political process and respect your desire to address the needs of the communities where you live and work.

Make sure that any activities in which you engage are lawful and appropriate and don't create a conflict between your personal interests and those of Otsuka. Also be sure to make it clear that your views and actions are your own and not those of our Company. Activities should be conducted on your own time and at your own expense—never use Otsuka funds, facilities, or the Company name in connection with your activities unless authorized to do so.

Know the Rules Regarding Political Contributions

You have the right to make personal contributions to a political party, campaign, or candidate from your own funds, subject to applicable legal limits, but do not make any contributions on behalf of Otsuka or have any expectation of being reimbursed for the contributions you make.

Government Affairs Is Our Company Liaison

Government Affairs has the responsibility for coordinating our activities with government officials and policy makers. Do not communicate with public officials about Otsuka-related issues or speak on our Company's behalf, and never offer or give anything of value to members of Congress, the Executive Branch, or their staffs.

Find Out More



Search the SOP Viewer using the keywords: Political Involvement, Contributions

Did You Know...

There are complex federal and state restrictions that regulate the kinds of political contributions we can offer as a Company. For more information about Otsuka's political initiatives or about legislation affecting our industry, contact Government Affairs.



6.4 Charitable Activities and Donations

We are committed to making a positive impact on our community.

What That Means For You...

You Make a Difference

We support your involvement in volunteer service and celebrate the many ways that you and your colleagues build and sustain community. It's important, however, that your personal activities don't conflict with your business responsibilities. Volunteer and charitable pursuits should be done outside of work hours, using your own resources, and shouldn't interfere with the work you do at Otsuka.

We Make a Difference

As a Company, we leverage our people, skills, expertise, and financial resources to broaden knowledge, improve health, and enhance the quality of life for neighbors near the office and around the world. We work with local and national advocacy groups and community organizations to promote positive change.

While we encourage all employees to get involved, these Company-sponsored activities are strictly voluntary and have no bearing on your performance evaluation or your employment with us.

Product Donations and Assistance Programs

When there is a demonstrated public health need, we endeavor to respond with product donations or financial support. We also have Patient Assistance Programs associated with some of our products that provide assistance to those with financial hardships.

We comply with all rules and regulations regarding drug donation and only donate our products to reputable organizations or well-defined government programs, where we can be confident that our products are directed to—and benefit—the intended recipients.

Find Out More



Search the SOP Viewer using the keywords: Charitable Activities, Donations, Grants

Examples of charitable activities that Otsuka may support include community health fairs, charity "walks," patient education initiatives, and tier-level sponsorships of fundraising events. To find out more about how we support community, contact OtsukaCommunications@otsuka-us.com.



Our Big Venture Company – Closing Thoughts

Our reputation is a priceless asset, one that has been built over many years. The responsibility to uphold it rests with each one of us.

You are key to the success of our Company. Each one of us, every day, in every decision has the opportunity to build on our culture of integrity.

With your help and your commitment, we will continue to innovate, to shape change in the industry, and to enhance the health and well-being of patients around the world.



Use the Code to guide your daily behavior. It should be viewed as a Company policy, and as with other Company policies, compliance with it is considered a condition of employment. Our Code, however, is not a contract, nor does it in any way alter the at-will employment status of employees in the United States.

Our Code may be amended from time to time. The version on our Company intranet will always reflect the latest revisions and updates.

// One's personal worth is determined by how many people he or she has made happy. //

Masahito Otsuka

Glossary

Adverse Event (AE): Any untoward medicinal occurrence in a patient or clinical study subject which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not it is considered causally related to the medicinal product.

Business records: Any information captured in physical or electronic media that is created or maintained as part of Otsuka's business.

Confidential information: Information our Company has or acquires that is kept private and not made available to the public. It includes: proprietary information about our Company (or companies with which we conduct business); personally identifiable information (PII) about our employees, consumers, and patients, and information shared by our Company and our suppliers about pricing, terms, and conditions.

Deadly weapon: An instrument designed to cause death or serious injury including, but not necessarily limited to, firearms of any kind, loaded or unloaded, air rifles or pistols, swords, and knives or similar implements.

Discrimination: Treating someone or a group of people less favorably as a result of the individual's race, color, religion, gender, sexual orientation, age, gender identity or gender expression, national origin, citizenship, ancestry, marital status, disability, genetic information, veteran status, or other characteristic protected by applicable laws.

Good faith: Absence of any intent to defraud, act maliciously, or take unfair advantage; honesty, fairness and lawfulness of purpose.

GxP: Good Clinical Practices (GCP), Laboratory Practices (GLP), and Manufacturing Practices (GMP), as well as Quality System Regulation (QSR) are collectively referred to as GxP.

Harassment: Any action that inappropriately or unreasonably creates an intimidating, hostile, uncomfortable, or offensive work environment or unreasonably interferes with an individual's ability to perform the duties or responsibilities of his or her employment.

Healthcare Professional (HCP): Someone who possesses a relevant healthcare degree or is a Pharmacy and Therapeutics (P&T) committee member or is licensed to prescribe, administer, dispense, or purchase prescription pharmaceuticals or medical devices for human use.

Intellectual Property (IP): Intangible property that has commercial value and is the result of creative effort including copyrighted property, patents, trademarks, business methods, and industrial processes.

Legal hold: A notice that advises an employee or third-party contractor or supplier not to dispose of certain records as they may be required for a legal proceeding, investigation, or audit.

Personally Identifiable Information (PII): Any information which can be used to distinguish or trace an individual's identity, such as their name, Social Security Number, biometric records, alone or when combined with other personal information which is linked or linkable to a specific individual, such as date and place of birth or mother's maiden name. Personal information commonly includes (but is not limited to): full name (if not common), national identification number (in the United States, a Social Security Number), IP address (in some cases), vehicle registration number, driver's license number, face, fingerprints or handwriting, credit card number, digital identity, maiden name, or genetic information.

Product Quality Complaint (PQC): Information provided by a healthcare professional, consumer, patient, medical representative, Competent Authority, alliance/collaborating company, affiliate, or other third party that alleges a deficiency relating to the identity, quality, labeling, durability, reliability, efficacy, or performance of a medicinal product or a suspected counterfeit product.

Proprietary Information: Information that a company owns that represents the work it does. It includes research findings, techniques, product specifications, nonpublic financial information, marketing data—all of the information that makes a company unique. All proprietary information is considered confidential information.

R&D Information: Any research or clinical trial results and protocols for new clinical trials.

Records Management: The appropriate process for creating, retaining, and discarding of business records.

Workplace Violence: Any act or threat of physical violence, harassment, intimidation or other threatening behavior occurring in the work environment or in places where we conduct Otsuka business. It can include verbal abuse, physical assaults and even homicide. It can be committed by anyone, inside or outside of our Company, and it can impact anyone including employees, clients, customers, and visitors to our facilities.

Where to Go for Help



RESOURCE	CONTACT INFORMATION
Crisis Management Hotline	x6666
HR Helpdesk	x1111 or 855-687-8524 hrhelp@otsuka-us.com
IT Helpdesk	x3333 or 1-877-4OTSUKA otsuka@service-now.com
E&C Helpline	OAPI-E&CHelpline@otsuka-us.com For general questions to E&C for advice about policies, procedures, or practices. Please do not submit confidential concerns or information using this email address – use the Integrity Line instead.
Integrity Line	1-800-363-5670 or https://tnw.reportlineweb.com/custom/Otsuka-us 24 hours a day, 7 days a week. You DO NOT have to give your name. Otsuka adheres to a non-retaliation policy.
Legal Affairs	x5445 or 240-683-5445
Government Affairs	OAPI-GovtAffairsAdvocacyTeam@otsuka-us.com

