


# DifGen

## Code of Conduct

# A MESSAGE FROM OUR FOUNDERS AND CO-CEOS

Welcome to the DifGen Pharmaceuticals Code of Conduct.



At DifGen, our mission is to be the trusted partner you can rely on whether you are a patient, customer, employee, or shareholder. We excel in advanced drug delivery through innovative research, state-of-the-art infrastructure, and comprehensive manufacturing. Our global partnerships drive high-quality healthcare solutions and medical advancements. We take pride in our commitment to manufacturing safe, effective medicines that meet strict regulatory standards, and this means we must always strive to live up to our values and principles.

Wherever we may work and whatever our role may be, at we hold ourselves to the same high standards, both legally and ethically. Every employee is personally responsible and accountable for helping our company maintain the reputation we have built together.

**DifGen's Code of Conduct ("Code of Conduct")** outlines what is expected of each of us, and the behaviors and ethics our customers and patients can expect from us. Given its importance to all of us and the way we do business, we trust you will read this Code of Conduct with due care and attention and take full personal ownership. Recognize that breaches of this Code of Conduct will be taken seriously and may lead to disciplinary action, up to and including termination of employment.

If you have any questions or are unsure about a particular policy or compliance issue, we urge you to speak up. Similarly, if you believe this Code of Conduct has been broken by anyone at DifGen, we encourage you to speak out with the full knowledge that you will be protected from retaliation of any kind.

As employees of DifGen, embodying the principles of our Code of Conduct is not only critical to the continuing success of our company and reputation - it's simply the right thing to do.

**Ramandeep Singh Jaj, MBA, Founder and Co-CEO**

**Santhanakrishnan Srinivasan, Ph.D., MBA, Founder and Co-CEO**



# Our Mission

At DifGen, our mission is to be the trusted partner you can rely on whether you are a patient, customer, employee, or shareholder.



# Our Values

## Innovate

Adept and excelling in integrity, quality, execution, commitment, and compassion to make a meaningful impact in healthcare.

## Evolve

Prioritize continuous improvement to adeptly navigate the evolving pharmaceutical regulatory and commercial landscape, staying ahead of the competition.

## Excel

Drive growth through unparalleled quality, execution, and compassion to significantly impact health.



## Diversity and Inclusion

Diversity and inclusion are integral to our culture. We celebrate the unique backgrounds, experiences, and perspectives of our team members. By fostering an inclusive environment, we enrich our workplace, drive innovation, and enhance our ability to serve diverse patient populations.



## Collaborative Environment

We understand that the best solutions come from working together. Our collaborative culture promotes open communication, teamwork, and mutual respect. We offer robust career development programs, mentorship opportunities, and ongoing training to help you grow your career. Whether you are starting out or a seasoned professional, we are invested in your success. Our global reach provides exciting opportunities for internal transfers, cross-site collaboration, and international assignments, allowing our employees to explore new challenges and roles within the company.



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# OUR GUIDING PRINCIPLES

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## 1 **We Innovate**

We are adept and excel in integrity, quality, execution, commitment, and compassion to make a meaningful impact in healthcare.

## 2 **We Evolve**

We Prioritize continuous improvement to adeptly navigate the evolving pharmaceutical regulatory and commercial landscape, staying ahead of the competition.

## 3 **We Excel**

We drive growth through unparalleled quality, execution and compassion to significantly impact health

## 4 **We Lead by Example**

We are committed to ethical and quality behaviors which are aligned with DifGen corporate values. These behaviors are modelled by executives and leaders at all levels and are understood and demonstrated by all employees in everything they do.

## 5 **We Empower our Employees**

We commit to creating and sustaining an environment in which all employees are encouraged, empowered, and accountable, without fear of retribution or punishment, to identify and speak up when something must be improved or corrected. Leaders support a variety of reporting channels



# INTRODUCTION TO THE DIFGEN CODE OF CONDUCT

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## The Importance of this Code of Conduct

To achieve outstanding business results, fully help patients, serve our industry partners, our various customers and each other, we must conduct all aspects of our business ethically and in compliance with various laws and standards.

This Code of Conduct is our guide and binds all of us to principles of integrity required by the company and expected among those working in the pharmaceutical industry.

## Integrity is a Shared Responsibility

Concerning this Code of Conduct, as a company and as individuals, acting with integrity means:

- Complying with this Code of Conduct and related policies and with the legal and regulatory requirements that apply to our job activities;
- Being honest and using good judgment while conducting business; and
- Seeking advice when unsure about what to do in situations that seem to pose ethical issues.





## **Framework and Scope**

The purpose of this Code of Conduct is to define a framework for our employees worldwide on the conduct of business within our standards of ethical values, and in compliance with regulatory and legal obligations and internal policies. It is not intended to be a comprehensive manual of all company policies or responsibilities under law that apply to your role in DifGen. It should, however, provide and reinforce the core values and principles to help you avoid, resolve, or report ethical and legal issues. This Code of Conduct is supplemented by specific policies and procedures, which set out in more detail DifGen's expectations and your obligations as an employee. Where expectations are not explicitly stated, employees are expected to adhere to the spirit of this Code of Conduct.

This Code of Conduct applies to all employees around the world; it describes policies that apply to all of us in every country where we operate. As DifGen is a global company, the laws and regulatory requirements of one country may apply to activities in another country. For example, many requirements of the U.S. Food and Drug Administration (FDA) must be followed by DifGen operations outside of the U.S. In addition, we must also be aware of, and abide by, the legal standards, country laws and regulatory requirements applicable to our business. This means that some employees must adhere to additional, country-specific requirements. You are expected to seek guidance from your Country Manager or the Global Legal department if questions arise regarding the impact and relevance of different countries' laws on our local activities.

## **What if Someone Violates this Code of Conduct?**

DifGen holds each and every employee, regardless of their position in the organization, accountable for any violations of this Code of Conduct. Confirmed violations may result in disciplinary action, including termination of employment and, at times, legal prosecution. Failure to cooperate in a compliance investigation may also lead to disciplinary action including termination. As with all disciplinary matters, principles of fairness and equity are applied.

## **Periodic Certification**

Periodically, all employees will be asked to acknowledge that this Code of Conduct has been provided to them, and that they have read and understood the Code.

# SPEAKING UP

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## What is Expected of Me?

1. You are expected to speak up when you have concerns about a violation of the Code or the law, even if you are unsure the concerns are valid.
2. Always speak up if you suspect someone may have violated the law, as failure to promptly report the violation can itself be illegal.
3. Each employee has a responsibility to cooperate fully with DifGen's investigations of compliance concerns.

## What Should I Expect?

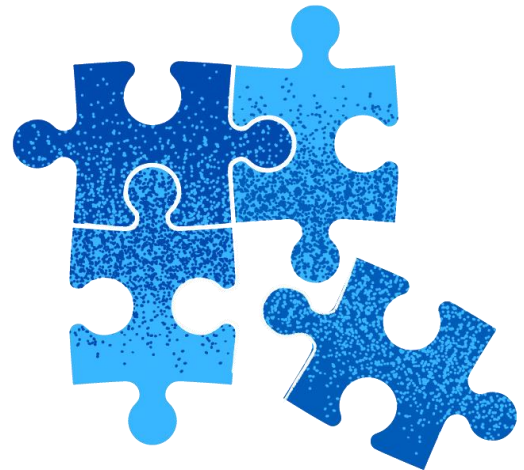
DifGen takes all reports of non-compliance seriously. As such, DifGen employees should expect that all reports are investigated appropriately.

## Expectations of Managers

All those who manage people—including your direct manager, senior management and executives have a special responsibility to lead the way.

We expect all people leaders to:

- Act as role models
- Champion a culture of ethics and speaking up
- Recognize and reward behavior that exemplifies our Core Values and our Code of Conduct
- Assist in enforcing the Code of Conduct
- Treat those employees who speak up with respect
- Report any violations or potential violations of the Code in a timely manner



## Could Raising a Concern Affect My Job?

DifGen does not tolerate any form of retaliation against employees who report concerns or issues in good faith. Employees who engage in retaliation will be subject to disciplinary action up to and including termination of employment. In addition, DifGen will not condone frivolous, malicious or vexatious complaints and any employee who makes such a complaint will be subject to disciplinary action. Victims of such frivolous allegations or complaints will receive appropriate advice, support and assistance.



# How do I report a concern?

## Channels for reporting

There are several channels for speaking up:

- **Your Direct Manager/Supervisor.**
- **Human Resources by emailing [hrm@DifGen.com](mailto:hrm@DifGen.com) or calling (954) 430-3340**
- **Global Legal directly by emailing [legal@DifGen.com](mailto:legal@DifGen.com) or calling (954) 430-3340**



## WORKING TOGETHER

### Human Rights

Human rights are rights inherent to all human beings, regardless of race, religion, national origin, age, color, gender, sexual orientation, marital status, citizenship status, disability, or any other status protected under applicable laws. DifGen holds all employees and business partners accountable to just, fair and equitable conduct and prohibits any unfair treatment or discrimination on the basis of any of these universally protected grounds.

### Equal Employment Opportunity

DifGen is committed to providing equal opportunity on the basis of individual qualifications and job performance and will act fairly and respectfully in all aspects of the hiring, promotion, development opportunities and termination processes, and throughout the employment relationship.

### Respectful Workplace

DifGen has an expectation of professional behavior by all employees in relation to interactions with colleagues, customers and other business contacts. Our respectful workplace is integrated within DifGen's core values.

### Freedom from Workplace Harassment, Discrimination and Violence

DifGen promotes and values a work environment free of discrimination, harassment, sexual harassment and retaliation, as defined by applicable laws. Workplace harassment, bullying or violence of any kind, including hostile physical contact, intimidation or threat that causes others to feel unsafe, will not be tolerated and may result in disciplinary actions up to and including termination of employment. Our Leaders must maintain a work environment that is free of discrimination, harassment, sexual harassment, and retaliation, and must report any such conduct of which they become aware.

### Employment Law

DifGen is committed to upholding applicable employment laws in the countries where we conduct business. We also comply with applicable labor standards including, but not limited to, freely chosen employment, freedom of association, living wages, working hours, discrimination, child labor, and working conditions.

How Noncompliance May Appear

**Samantha, a financial analyst, is excluded from presenting the financial projection she created, as her management felt a man would be better suited to present to the all-male executive team attending the client presentation.**

**Robert repeatedly asks Cindy to go out for dinner after work, even though Cindy has told him it makes her feel uncomfortable. He won't take 'no' for an answer.**



# SAFE AND HEALTHY WORKPLACE & RESPECTING THE ENVIRONMENT

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## Meeting Safety and Environmental Standards

All employees have an obligation to fellow staff members and to the general public to ensure work conditions meet our safety and environmental standards. We strive to continuously improve our safety and environmental record by:

- Complying with all applicable safety, health and environmental policies and procedures;
- Attending all relevant safety training and utilizing all necessary personal protective equipment to perform work in a safe manner;
- Promptly reporting all environmental, health and safety issues including unsafe conditions, near misses, workplace injuries and illnesses;
- Cooperating with investigation of health and safety or environmental incidents, and with identification and execution of corrective actions; and
- Practicing environmentally responsible purchasing.

## Refraining from Substance Abuse

DifGen is committed to delivering services and products in a safe and conscientious manner. Performance of one's role under the influence of alcohol or drugs is prohibited.

## Reporting Concerns

If you become aware of any actual or potential safety or environmental hazard or concern, immediately notify your direct manager. All direct managers must report all injuries (including near misses) and environmental hazards (e.g., spills).

How Noncompliance May Appear

**I've noticed some practices that we do in my area that don't seem safe. To whom should I speak to? I'm new here, and don't want to be considered a troublemaker.**





## QUALITY STANDARDS

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Ensuring quality and compliance is everyone's responsibility; it is embedded in our Quality Culture, core values, and vision. We remain clear that Quality is at the core of everything we do. Essential to these commitments are three principal drivers:

1. Our excellence comes from robust integration of people, processes and Products
2. We strive to maintain patient safety and maximize patient benefit in all our endeavors
3. We provide drugs of exemplary quality with consistency and reliability and serve

As part of our quality standards, we are fully committed to ensuring our products are in full compliance with our rigorous internal standards, all applicable regulations, and GxP<sup>1</sup>. This commitment applies equally to products produced in our facilities and to those supplied by third party manufacturers.

<sup>1</sup>GxP collectively denotes Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Pharmacovigilance Practice (GVP) regulations.

### How Noncompliance May Appear

**Raul works on the production line. He notices that the finished product does not meet the DifGen Quality Standards. He doesn't alert anyone of his concern because he does not want his team to miss their deadline.**

# INTERACTIONS WITH HEALTHCARE PROFESSIONALS (HCPs)

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## Our Principles

- We are committed to ethical, transparent and responsible interactions with healthcare professionals globally, thereby ensuring scientific integrity and unbiased exchange of information.
- We never misrepresent information regarding our Company's product safety or influence the outcome of clinical trials inappropriately.
- We respect the independence and professionalism of Healthcare Professionals.
- We will comply with the applicable laws, regulations and other industry standards and our policies.

## General Rules to Follow when Interacting with HCPs

- Ensure interactions are primarily for the purpose of providing accurate, relevant, valid and up-to-date information about our products.
- Never promise or provide payments or other gifts to an HCP to induce them to purchase, prescribe or recommend our products.
- Ensure that payments to HCPs are appropriate for the services provided, are of fair market value and are for legitimate business purposes (e.g., for bona fide research or consultancy).
- Be aware that country-specific rules may apply to the giving of payments or gifts to HCPs. Marketing activities acceptable in other business sectors may be unacceptable when dealing with HCPs.

Violations of healthcare, fraud and abuse laws may result in severe corporate or individual penalties including large fines, jail sentences, and other country-specific legal ramifications.

## Disclosure of Payments

Throughout the world, there is a call for increased transparency regarding payments made by the pharmaceutical industry to HCPs. Therefore, payments or other items of value provided to HCPs must be tracked and disclosed as required by country-specific transparency rules. If you make any payments to an HCP, Healthcare Organization or Patient Association (e.g., for consulting, research, meals, travel etc.) contact the Global Business Ethics and Compliance Officer to ensure compliance with country-specific disclosure requirements.

How Noncompliance May Appear

**Laars pays his pharmacy client a cash rebate of 10% of the list price of an DifGen product, and disguises this under a 'consulting' contract with that client.**

**Kelsey, a marketing director, plans for an advisory board meeting and pays for three physicians and their spouses to meet at a lavish golf resort where the meeting will take place.**

# INTERACTIONS WITH BUSINESS PARTNERS

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## What is Expected of You

Create business partnerships (e.g., with suppliers and wholesalers) after reviewing the relevant background and qualifications of potential partners, and ensure quality and integrity are built into your selection criteria. To the extent possible, your due diligence should include:

- When business partners will represent DifGen, ensuring they know their obligations to follow applicable laws, regulations and DifGen policies;
- Using price, quality, reputation and service as the drivers for making supplier selection, not a conflict of interest (see 'Conflicts of Interest' section); and
- Ensuring that prospective business partners commit to proper interactions with government officials and HCPs.

Treat business partners with respect and integrity. Negotiate in good faith and honor agreements made with them.

## Business Entertainment and Gifts

The purpose of business entertainment and gifts is to build goodwill and strengthen relationships with customers, suppliers and other business partners, not to gain unfair advantage for DifGen or to obtain a personal benefit. Any business entertainment or gift must be consistent with reasonable customary business practices and therefore must not be in the form of cash or cash equivalents (e.g., gift certificates), give the impression of influencing business decisions or judgment, or violate any applicable law, regulation or known customer policy.

Business entertainment in the form of sporting or other social events with a business partner may be acceptable if the expense is moderate and in keeping with good business practices, as long as no explicit or implicit obligation is involved in such provision or acceptance.

These expectations apply both when either giving or receiving gifts and entertainment.

How Noncompliance May Appear

**Jake gets offered a 'fee' to provide a vendor with the lowest bid he has received on a contract so far.**

**Pradeep, a business development executive, has offered to pay for a weekend at a resort for a customer's wife to compensate her for the time her husband has spent over the past month evaluating DifGen's products.**



# INTERACTIONS WITH COMPETITORS

## ANTITRUST AND COMPETITION LAWS

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### Avoiding Anti-Competitive Violations

- Compete with others on the basis of innovation, efficacy, quality, service, performance and price.
- Do not communicate with competitors about competitive business matters such as prices, costs, discounts, customer suppliers, marketing plans, production capacities or any terms of conditions of sale that could create the appearance of improper agreements or understandings.
- Do not conspire with other bidders when competing for contracts.
- Do not enter into agreements that limit production capacities.

### Examples of Unfair Competition

- Using bribes as a method to gain market share.
- Disparaging one of our competitors or its products.
- Interfering with our competitors' supply chain or customer contracts.
- Obtaining or attempting to obtain competitive business intelligence through unlawful or unethical means such as misrepresentation, deception, theft, espionage or bribery.
- Coercing a customer to buy from us.

It is important that we recognize the potential harm to DifGen's reputation and the severe monetary and criminal penalties that may result from breaching these laws.

If faced with a situation that may raise anti-competitive (i.e., antitrust) issues, contact the Global Legal department to determine the proper course of action.



#### How Noncompliance May Appear

**At the annual generic industry trade show, Lisa and a business development representative from a competitor whose company is the only one with ANDA approval for a product, talk over drinks and agree to split customers within a territory.**

**Two competing pharmaceutical companies arrange to set and keep their product prices artificially high.**

# INTERACTIONS WITH GOVERNMENT

## ANTI-CORRUPTION, TRADE COMPLIANCE

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### Anti-Corruption

DifGen conducts its business in many countries around the globe.

Many laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, specifically prohibit making any offer, promise, or gift of any value to an employee, agent or official of a federal government (foreign or domestic) to secure any concession, contract or favorable treatment. Bribes may include inappropriate gifts, kickbacks or unlawful payments. A government official is an individual, whether elected or appointed, who holds a legislative, administrative or judicial position of any kind. Depending on the jurisdiction, physicians and other HCPs may be considered as government officials. We will not tolerate attempts to improperly influence government officials in order to secure favorable treatment or to advance DifGen's interests.

### Doing Business with Government Officials

The sale of goods and services to governments is heavily regulated. When involved in sales transactions to governmental customers, DifGen employees must take all necessary steps to ensure the transactions comply with applicable laws and regulations, including the provision of gifts and government procurement contract obligations. For example, customs in one country regarding the giving and receiving of gifts may not be lawful in another country.

### Trade Issues

There may be legislation authorizing the imposition of trade and economic sanctions where DifGen conducts business. For example, the United States restricts or prohibits doing business with certain countries and parties. In all international business, DifGen employees must comply with those sanctions; any export restrictions need to be checked conscientiously, and legal advice taken as necessary, before business transactions are undertaken.

Contact the Global Legal department to ensure your planned export and import activities fully comply with applicable laws.

See Appendix for more information on country-specific laws.

How Noncompliance May Appear

**Ravi, a business development executive, offers to take a government employee out to lunch to smooth over some price contract talks.**

**Reza, a company executive, needs to meet a vendor in a country where a visa is required. He agrees to pay a 'facilitation fee' to speed up the process.**

**Barbara, a DifGen employee, arranges a contract with an Iranian pharmaceutical distributor without contacting the Global Legal department first.**

# CONFLICTS OF INTEREST

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All business decisions that DifGen employees make should be in the best interest of the Company – and not based on personal or other business interests. It is important to avoid even the appearance of conflicts of interest. The appearance of a conflict is what a reasonable person might view as a potential conflict. A conflict may arise because of your own actions or through family connections.

## Outside Employment or Business Interests

Having outside business interests or employment with an entity that does business with, or is a competitor, supplier or customer of DifGen, and/or which may interfere with your ability to perform your responsibilities, are considered to be conflicts of interest.

## Business Relationships

Conflicts of interest occur when you or an immediate family member has a substantial financial interest in a DifGen supplier, competitor, consultant or customer.

## Business Opportunities

DifGen employees must never take for themselves or divert a business opportunity in which DifGen has a financial interest, or that is discovered through the use of company information, position or property, for their own personal gain, either directly or indirectly.

## Business, Scientific, Political and Professional Organizations

DifGen supports employee participation in business, scientific, political and professional organizations as long as the affiliation does not conflict with DifGen interests; for example, the affiliation must not negatively impact your ability to perform all of your job responsibilities.

## Reporting Actual or Perceived Conflicts of Interest

DifGen requires employees to provide notice of actual or potential conflicts of interest as they arise. Provide notice to your direct manager and receive written approval from Global Legal before engaging in any activity that may invoke any conflict of interest situation.

How Noncompliance May Appear

**Tony's wife is an executive, with ownership interest, at a marketing firm that seeks to be a vendor for supplying materials for a new DifGen product. He is on the panel who will decide on the contract winner.**

**James, a Vice-President of Procurement, sits on the board of directors of an DifGen supplier. He has not disclosed this relationship to DifGen.**

**Moniqua, a Manager in Regulatory Affairs, hires her niece for a position in her department, bypassing the hiring process and not disclosing her family connection.**



# ACCURACY OF BUSINESS RECORDS, FRAUD AND LEGAL HOLDS

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DifGen must maintain an accurate record of all business transactions. These records are essential to managing our business and fulfilling our legal and ethical obligations to governments and our customers.

## What are Business Records?

Business records can be captured on paper, electronically (e.g., computer files, e-mail, audio or video recordings) or using other media. Included in business records are financial "books and records" involved in the preparation of financial statements relevant to audits and financial reviews. Financial records encompass bills and invoices, payroll, benefits, and other company data necessary to provide a complete picture of DifGen's financial state. Justified and reasonable business expenses must be charged to DifGen by following company policies.

## Accuracy and Timely Completion

All information must be entered in an honest and timely fashion and retained according to corporate schedules. Knowingly providing false, inaccurate or incomplete information is improper, and, in most situations, is illegal and may constitute fraud.

We have a responsibility to provide accurate, complete, timely and transparent disclosures in reports and documents we file with governmental and regulatory agencies. These requirements also apply to regulated "Good Practice" requirements (e.g., GMPs, GCPs, etc.), collectively referred to as GxP records.

## Reporting Fraud

If you become aware of a questionable accounting or record-keeping practice, you must report the concern promptly to your direct manager, to a member of the Executive Team, or to the Global Legal

## Legal Holds

If we receive a subpoena requesting business records, or if we become aware of actual or potential litigation or investigation, relevant employees will receive notification (i.e., a litigation hold notice) and be required to search their files, or submit to having their files searched, for the requested records. All employees are required to fully cooperate with both internal and external investigations. Upon receiving a litigation hold notice, no records – hard copies or electronic – may be deleted, destroyed, or altered.

How Noncompliance May Appear

**Eunice alters production data to cover up a GMP violation for a batch of product in order to meet production quotas.**

**Karmen, a Regulatory Affairs executive, submits reimbursement for personal items to the company**

# SAFEGUARDING DIFGEN INFORMATION

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Every employee must exercise diligence in maintaining the integrity of DifGen's proprietary and confidential information by:

- Maintaining the strict confidentiality of DifGen information entrusted to you;
- Obtaining confidentiality agreements before exchanging non-public, confidential, proprietary or sensitive information with any third party;
- Respecting the valid intellectual property rights of others; for example those outlined in DifGen third party contracts;
- Being mindful of sending information externally by convenient forms of communication like email; and
- Notifying IT immediately if your company assigned assets (e.g., computer, phone or other technical equipment) have been lost or compromised.

These obligations apply even after you leave DifGen. In addition, you may not disclose confidential information to an DifGen employee that you learned during previous employment (e.g., trade secrets).

## Some Examples of Proprietary and Confidential Information

- Intellectual property such as patents, trademarks, copyrights and trade secrets;
- Technical specifications, drawings and designs;
- Financial affairs, customer lists, pricing practices, bidding or marketing strategies; and
- Written and oral agreements between DifGen and others.

Additionally, your role may encompass developing proprietary information (i.e., intellectual property) for DifGen. When developing intellectual property for DifGen using DifGen's resources, it is expected that you do not do anything to compromise DifGen's ownership of or rights to that intellectual property. This includes refraining from selling it, using it for personal gain, or distributing it to unauthorized third parties.

How Noncompliance May Appear

**Daniel and Aron, company employees, are discussing confidential company information onboard an airplane, where they can be overheard.**

**Tony shares a list of DifGen customers with his brother-in-law who is starting up a small biotech company.**

**Chetan offers to share the results of a completed clinical trial with a former employee, Samantha, as it may help her in her new position.**

**Jordan stores copies of confidential sales data on his personal cell phone. He subsequently loses his phone on the subway.**

# USE OF COMPANY PROPERTY

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The electronic communication systems, along with DifGen’s physical assets, are in place to enable employees to perform their business-related activities.

Use of company systems for personal use should be limited, and under no circumstance should they be used to facilitate illegal or illicit activities. Communications between employees on electronic systems should be conducted professionally. In some situations, these communications may be subject to disclosure to a third party.

All employees must use DifGen’s physical assets responsibly. This includes conserving DifGen funds, to the extent possible, by ensuring that inappropriate expenditures are not incurred.

## Precautions and Rules Governing the Proper Use of Company Systems

- Return your company-issued equipment immediately when requested.
- Although you may use DifGen equipment to a limited extent for non-business matters, you are not guaranteed personal privacy on DifGen’s electronic communication systems.
- DifGen assets may not be utilized for the distribution of inappropriate communication (e.g., hoax emails or pornography) or communications that may embarrass, harass or offend others.
- Double check that the recipients are correct before sending out any electronic communication.
- Do not use electronic communication devices in an unsafe or illegal manner (e.g., while driving, on an airplane, in restricted areas of hospitals).



How Noncompliance May Appear

**Maya lends her password to her husband so he can check their banking information on her work computer.**

**Kiran passes along an email with a racially based joke to his coworkers.**

**Pravinder, a research scientist, downloads “free” software, without authorization, to assist with a new clinical trial.**

# SOCIAL MEDIA AND EXTERNAL COMMUNICATION TO THE MEDIA AND GENERAL PUBLIC

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## Social Media

- Only company-designated personnel may publish content to speak on behalf of DifGen on social media, and such publications must be done solely on official DifGen social media accounts. Employees are encouraged to engage with content published on the company's official LinkedIn profile including "liking", "commenting" and "sharing" content.
- DifGen encourages employees to use their best judgment when discussing DifGen in any form of social media, as anything stated on social media may have unintended consequences for both the employee and DifGen.
- DifGen expects that your conduct online is consistent with this Code of Conduct and our Global Corporate Communications and Social Media Policy.
- Protect DifGen's confidential and proprietary information by refraining from discussions of such matters on social media.
- Do not use company logos or trademarks without explicit permission from an authorized executive.
- Never claim to be speaking on behalf of DifGen or express an official company position without pre-authorization.
- DifGen encourages employees to direct all comments, questions or feedback about DifGen to the appropriate internal channels rather than broadcast them on social media.
- Report any discoveries of inappropriate information that is related to DifGen, on any social medium.

## The Media

- Reporters, media representatives and the general public may try to solicit information directly from you.
- All media calls/requests are to be referred to the EVP, Head of Global Operations or a designated back-up contact immediately upon receipt of a request. Other than as above, only the Co-CEOs, are permitted to speak with media unless authorized by the above parties.

# DATA PRIVACY

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DifGen may collect personal identifiable information (PII) from many different individuals, including customers, patients, clinical trial subjects, healthcare professionals and employees. DifGen is dedicated to collecting and keeping only personal identifiable information needed for our business purposes and to have safeguards in place to protect such information.

## What is expected from you

- Follow local laws regarding data privacy (e.g., in some countries you must give notice and/or obtain consent when collecting, processing, transferring or storing personal information).
- Collect personal information only for legitimate business purposes and maintain it only for as long as necessary to fulfill those purposes and meet our legal obligations.
- Ensure that personal information is protected at every stage, from collecting and processing it, to storing and transferring it.
- Use personal information only for the purpose for which it was collected.
- Obtain written consent before collecting, using or disclosing personal information.
- Share personal information only with individuals who have legitimate need for it and who will protect it properly. Any external individual or organization with whom this information is shared must be bound by a written confidentiality agreement.

The definition of personal identifiable information varies by country, but generally it encompasses any personal identifying information (e.g., name, birth date, gender, address, health card number, etc.) and sensitive identifying information (e.g., religion, race, health status, marital status, telephone number, social security number, credit card number, etc.).



How Noncompliance May Appear

**Michael, a Manager in Regulatory Affairs, posts a list of his employees' birth dates (including year) on the company bulletin board as a reminder to wish his employees a happy birthday.**



# U.S. Specific Laws and Industry Codes

## Anti-Kickback Laws (Federal and State)

The federal Anti-Kickback Statute and similar state laws prohibit payments, in any form, intended to reward past prescribing or to induce someone to purchase, prescribe or recommend a product that is reimbursable under a U.S. federal healthcare program. Exceptions, called Safe Harbors, are provided for discounts and certain other **arrangements, if specific requirements are met.**

## Exclusion of individuals from U.S. healthcare programs

The U.S. government has the authority to exclude individuals and entities who have engaged in fraud or abuse from participating in Medicare, Medicaid or other healthcare programs or to receive federal contracts or assistance pursuant to sections 1128 and 1156 of the Social Security Act. As a result we need to check the U.S. employees and contractors of DifGen against the List of Excluded Individuals and Entities (LEIE). This list **is maintained by the Office of Inspector General (OIG)** in the U.S., and includes persons who have been excluded, debarred, or suspended ("ineligible individuals") from U.S. government health care programs such as Medicare and Medicaid. If we employ such individuals, we ourselves could be liable to civil penalties.

## Food, Drug and Cosmetic Act (FDCA)

The ultimate purpose of the Federal Food, Drug, and Cosmetic Act (FDCA) is to protect consumer health. Under the FDCA, the Food and Drug Administration (FDA) regulates several areas of prescription drug development and marketing, including clinical studies, **manufacturing, market approval, safety and efficacy**, and advertising and promotion.

## Anti-Trust Laws

The set of federal and state laws that prohibit collusion **and price fixing, market allocation and other anti-competitive behaviors.**

## Physician Payment Sunshine Act

The Physician Payment Sunshine Provisions of H.R. 3590 § 6002 were signed as federal law as part of the Patient Protection and Affordable Care Act (PPACA). The law requires pharmaceutical manufacturers to annually report and publicly disclose to the Open Payment Program, via the Centers for Medicare and Medicaid Services (CMS), payments and other transfers of value provided to US physicians and teaching hospitals.

## The Federal False Claims Act (FCA) and State False Claims Laws

The federal FCA and similar state laws make it a crime to deliberately submit a false claim for reimbursement to the US government or do anything to cause, assist or encourage customers to submit false claims to these programs. Pharmaceutical sales and marketing activities that might violate the federal FCA include (but are not limited to) submitting false claims for government payment, fraudulently reporting false pricing information to government agencies and similar activities.

## The Foreign Corrupt Practices Act (FCPA)

**The FCPA prohibits corrupt payments to foreign officials**

for the purpose of obtaining or keeping business.

## The Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers

**These are guidelines provided by the Office of Inspector**

General (OIG) of the Department of Health and Human Services (DHHS) for pharmaceutical manufacturers to consider when developing, implementing, or evaluating a compliance program. The guidance is intended to assist with the development and implementation of internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal healthcare programs.

This summary is intended to be a guide to some country-specific laws, regulations and industry codes that relate to this Code of Conduct. This list is not exhaustive, and lists only those laws, regulations and codes that apply where most DifGen business is conducted. Where laws are stricter than this Code of Conduct, those laws must be followed. There are other country-specific laws outside the regions listed above. If you have any questions about those laws, please contact the Global Legal department.

# Ex-U.S. Specific Laws

## **UK Bribery Act**

The UK Bribery Act applies to British nationals or someone who is ordinarily resident in the UK, a body incorporated in the UK, or a Scottish partnership to bribe anywhere in the world. The 4 key offenses are (a) offering, promising, or giving of a bribe to another person, (b) requesting, agreeing to receive, or accepting a bribe (c) bribery of a foreign (non-UK) public official and (d) failure by commercial organizations to prevent bribery committed by their associated persons to obtain or retain business, or an advantage in the conduct of business.

## **India's Prevention of Corruption Act, 1988**

The Law was enacted to combat corruption in government agencies and public sector businesses in India. The Act does not use the term corruption or bribe but instead uses the phrase "undue advantage". Undue advantage is defined as any benefit which is given to a public servant. The bribe can be monetary or non-monetary, such as gifts etc. The benefit which is given should be something other than the public servant's lawful salary or any other lawful payment owed to the public servant.



# DifGen

## DIFGEN CODE OF CONDUCT

DifGen Code of Conduct  
February 1, 2025

The code can be found electronically at  
<https://www1.DifGen.com/global/ethics>

