

**MERCK & CO., INC.**

Kenilworth, N.J., U.S.A.



# MERCK BUSINESS PARTNER CODE OF CONDUCT

**"Our Values and Standards" for Business Partners**

Merck Business Partner Code of Conduct [Edition II] December 2015

Merck is committed to sustainability in all business activities and aims to apply and abide by the highest ethical, social and environmental standards. We recognize that our business partners play an important role in our overall success.

Accordingly, Merck strives to conduct business with individuals and organizations who share our commitment to high ethical standards and who operate in a socially and environmentally responsible manner.

To reinforce the standards to which we are committed, Merck developed this Business Partner Code of Conduct founded upon the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles, the 10 Principles of the United Nations Global Compact, and *Our Values and Standards*.

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# EXPECTATIONS

Merck sets high standards for conducting business ethically and in accordance with the law. We expect the same commitment from our business partners. This Business Partner Code of Conduct presents basic principles for business partners in dealings with Merck. We consider these principles in business partner selection and monitor business partners for compliance with these principles.

## BUSINESS PARTNERS ARE EXPECTED TO...

- Firmly adhere to ethical principles and business practices for labor, environment, health and safety, and management systems.
- Integrate, communicate and apply these principles.
- Operate in full compliance with all applicable laws, rules and regulations.
- Integrate the principles into a continual improvement approach that advances performance over time.

## KEY POINTS:

Business partners include individuals or organizations that provide services, raw materials, active ingredients, components, finished goods or other products to Merck and its operating subsidiaries, affiliates and divisions.

These principles are not intended to replace, supersede or conflict with any applicable legal or regulatory requirement or contractual obligation with Merck and its operating subsidiaries, affiliates and divisions.

It is up to each business partner to determine how to meet and demonstrate compliance with the principles and standards as stated in this Business Partner Code of Conduct. Where specified in contracts, Merck shall retain audit and inspection rights to verify compliance.

As part of an initial screen in selecting new business partners, Merck seeks assurance of compliance with this Business Partner Code of Conduct by requiring partners to complete a self-assessment questionnaire. Merck may seek further assurance of compliance by requesting an on-site visit.

Further guidance on how to meet these expectations may be obtained from the following links:  
<http://pscinitiative.org>  
<https://www.unglobalcompact.org>

At Merck, our values and standards have always formed the basis of our success. We believe that society and business are best served by responsible business behaviors and practices. Fundamental to this belief is the understanding that a business must, at a minimum, operate in full compliance with all applicable laws, rules and regulations. We remain mindful of differences in culture and the challenges associated with interpreting and applying these principles globally, but believe that what is expected is universal.

We believe in developing mutually beneficial relationships with our business partners, founded on trust and respect.

We conduct business with integrity; we comply with all applicable laws, rules and regulations of the countries in which we operate.

We seek to have a positive impact on the lives of our employees, their families and the communities in which we operate.

We expect companies in our business partner network to do the same.

# LABOR & HUMAN RIGHTS

Business partners shall uphold the human rights of workers and treat workers with dignity and respect.

## FREELY-CHOSEN EMPLOYMENT

Business partners shall not: (i) use any form of forced or involuntary labor, including bonded labor, prison labor or indentured labor; or (ii) engage in or support any form of slavery or human trafficking. All work must be voluntary and workers shall be free to leave or terminate their employment at any time. No unreasonable restrictions shall be placed on a worker's freedom of movement.

## CHILD LABOR & YOUNG WORKERS

Business partners shall not use child labor. The employment of young workers under the age of 18 shall only be allowed: (i) for non-hazardous work; and (ii) if the individual is above a country's legal age for employment or the age established for completing compulsory education.

## EMPLOYMENT PRACTICES

Business partners shall only use recruiters (agencies) that comply with local labor laws. Partners and recruiters acting on their behalf shall not: (i) withhold or prevent a worker from accessing his or her identity or immigration documents, such as passports, work permits or drivers' licenses; or (ii) charge workers recruitment or placement fees, or require workers to make deposits or participate in savings programs (unless legally required). When required by Merck, if the partner has workers who are not nationals of the country in which they perform work, the partner shall provide return transportation (or pay the cost of the return transportation) at the conclusion of the worker's period of employment.

## EMPLOYEE DISCLOSURES

Business partners must not use misleading or fraudulent recruitment practices and shall disclose to workers all information regarding key terms and conditions of their employment, including wages and benefits, the location of the work, the living conditions, housing and associated costs (if housing is provided or arranged) and any significant costs to be charged (if applicable). If required by law or if requested by Merck, partners must provide written agreements to workers in their native language that include all minimum information required by law.



## FAIR TREATMENT

Business partners shall provide a workplace free of harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion, or verbal abuses of workers. Partners shall also provide a workplace free of harassment and discrimination. Discrimination for reasons such as race, color, gender, age, religion, national origin, ancestry, ethnicity, disability, sexual orientation, gender identity, gender expression, genetic information, citizenship status, marital status, military/veteran status or any other characteristic protected by applicable law will not be tolerated.

# LABOR & HUMAN RIGHTS

Business partners shall uphold the human rights of workers and treat workers with dignity and respect.



## WAGES, BENEFITS & WORKING HOURS

Business partners shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits. Partners shall clearly and promptly communicate with the worker: (i) the basis on which he or she is compensated; and (ii) whether overtime may be required and the wages to be paid for such overtime.

## FREEDOM OF ASSOCIATION

Open communication and direct engagement with workers (and/or designated union officials, if applicable) to resolve workplace and compensation issues is encouraged. Partners shall respect the rights of workers, as set forth in local laws, to associate freely, join or not join labor unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

## PRIVACY & DATA PROTECTION

Business partners shall respect individuals in a manner consistent with the rights to privacy and data protection. They shall at all times use information about people appropriately for necessary business purposes and protect it from misuse in order to prevent harm to individuals such as discrimination, stigmatization or other damage to reputation and personal dignity, impact on physical integrity, fraud, financial loss or identity theft.

## COMMERCIAL SEX ACTS

For workers that conduct business for or on behalf of Merck, or work on Merck projects or products, business partners shall prohibit those workers from engaging in commercial sex acts (e.g., solicitation of prostitutes) while on partner/company business, including meetings with internal colleagues, customers or other external business partners.

# HEALTH, SAFETY & ENVIRONMENT

Business partners shall provide a safe and healthy working environment.



## WORKER PROTECTION

Business partners shall protect workers from overexposure to chemical, biological and physical hazards and physically demanding tasks in the workplace and in any company-provided living quarters.

## PROCESS SAFETY

Business partners shall have programs in place to prevent or mitigate catastrophic incidents associated with operations and processes. Programs shall be commensurate with the facility risks.

## EMERGENCY PREPAREDNESS & RESPONSE

Business partners shall identify and assess emergency situations in the workplace and any company-provided living quarters, and minimize their impact through prevention and by implementing emergency plans and response procedures.

## HAZARD INFORMATION

Safety information relating to hazardous materials, including pharmaceutical compounds and pharmaceutical intermediate materials shall be available to educate, train and protect workers from hazards.

## HOUSING STANDARDS

Business partners that provide housing or living accommodations for workers will ensure that local (in-country) housing and safety standards are met.

## ENVIRONMENTAL SUSTAINABILITY

Business partners are expected to conserve natural resources and engage in activities aimed at reducing water usage, energy consumption and greenhouse gas emissions. Partners shall have systems in place to quantify the amount of water used, energy consumed, and greenhouse gases emitted by their operations.

Business partners shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Partners are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle.

## ENVIRONMENTAL AUTHORIZATIONS

Business partners shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

## WASTE & EMISSIONS

Business partners shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment.

## SPILLS & RELEASES

Business partners shall have systems in place to prevent and mitigate accidental spills and releases into the environment.



# MANAGEMENT SYSTEMS

Business partners shall use management systems to facilitate continual improvement and compliance with the expectations of these principles.



## **COMMITMENT & ACCOUNTABILITY**

Business partners shall demonstrate commitment to the concepts described in this document by allocating appropriate resources.

## **LEGAL & CUSTOMER REQUIREMENTS**

Business partners shall identify and comply with applicable laws, regulations and standards and relevant customer requirements, and address identified gaps in a responsible and timely fashion.

## **RISK ASSESSMENT & RISK MANAGEMENT**

Business partners shall have mechanisms to assess and manage risks in all areas addressed by this document.

## **DOCUMENTATION**

Business partners shall maintain documentation necessary to demonstrate conformance with these expectations, and compliance with applicable regulations.

## **SUPPLIER SELECTION & MONITORING**

Business partners shall apply the principles outlined in this document when selecting their own partners and suppliers. Partners shall have or put in place systems to monitor their supplier and subcontractor compliance.

## **TRAINING & COMPETENCY**

Business partners shall have a training program that provides management and workers with the knowledge and skills needed to address the expectations set forth in this document. Partners will also ensure that management and workers have the necessary qualifications, resources and authority to meet these expectations.

## **BUSINESS CONTINUITY**

Business partners are responsible for the development and implementation of appropriate business continuity plans for operations supporting Merck business.

## **CONTINUAL IMPROVEMENT**

Business partners are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal and/or external assessments, inspections and management reviews.

# ETHICAL BUSINESS PRACTICES

Business partners shall conduct their business and operations in an ethical manner and act with integrity.

## **BUSINESS INTEGRITY**

Business partners shall not offer, pay, ask for or accept anything of value – or give the appearance that they do – in order to improperly influence decisions or actions with respect to any Merck business or government activities. Partners shall maintain processes and procedures to prevent and detect corrupt activities.

## **FAIR COMPETITION**

Business partners shall conduct their business consistent with fair and vigorous competition and in compliance with applicable antitrust laws. Partners shall employ fair business practices including accurate and truthful advertising.

## **ACCURACY OF BUSINESS RECORDS**

All financial books and records must conform to generally accepted accounting principles. Records must be complete and accurate in all material respects. Records must be legible, transparent and reflect actual transactions and payments. Partners will not use any “off the books” or similar funds.

## **PROTECTING INFORMATION**

Business partners shall protect Merck’s intellectual property and confidential information, including any personal information collected, stored or processed for or from Merck, and act to prevent its loss, misuse, theft, improper access, disclosure or alteration. This includes protecting against any unauthorized communication and/or publication of information acquired from or on behalf of Merck. Unless expressly authorized by Merck, partners shall not share Merck’s intellectual property, confidential information or other information that they possess or acquire with respect to Merck’s business.

## **CLINICAL TRIALS**

Business partners involved in clinical trials on behalf of Merck will ensure compliance with all applicable regulatory requirements in the countries where clinical trials are conducted and where Merck’s products are marketed, registered and distributed. Partners must respect and adhere to relevant guidance on Good Clinical Practice (GCP) issued by national and local regulatory authorities, as well as guidance published by the International Conference on Harmonization - Good Clinical Practices (ICH-GCP), and they must follow the ethical principles that have their origin in the Declaration of Helsinki. Clinical trial business partners must provide full visibility to Merck of any subcontracted clinical trial activities.

## **ANIMAL WELFARE**

Animals shall be treated respectfully, with pain and stress minimized. Animal testing should be performed after consideration to replace animals, reduce the numbers of animals used or refine procedures to minimize distress. Alternatives should be used whenever scientifically valid and acceptable to regulators.

## **PRODUCT QUALITY**

Business partners involved in the supply, manufacturing, packaging, testing, storage and distribution of materials/products on behalf of Merck will ensure compliance with applicable Quality regulations and Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) requirements for the markets in which the products are registered and distributed. Documentation or data relevant to activities performed, including without limitation any GMP documentation, must be original, accurate, legible, controlled, retrievable, and safe from intentional or unintentional manipulation or loss. Partners will comply with all record retention requirements set by local regulators, as well as those specified in any Quality Agreement with Merck.

# ETHICAL BUSINESS PRACTICES

## RESPONSIBLE SOURCING OF MINERALS

Business partners that engage in manufacturing or are in Merck's direct materials supply chain shall maintain processes and procedures to ensure the responsible sourcing of minerals. Partners shall endeavor to avoid the purchase of minerals (e.g., tin, tantalum, tungsten and gold) that directly or indirectly finance or benefit armed groups or perpetrators of serious human rights abuses. When requested by Merck, partners shall provide information that shows the source and origin of minerals used by the partner.

## TRADE COMPLIANCE

Business partners must comply with all applicable import and export controls, sanctions and other trade compliance laws of applicable country(ies) where transaction(s) occur.

## CONFLICT OF INTEREST

Business partners should avoid interactions with any Merck employee that might conflict, or appear to conflict, with that employee acting in the best interests of Merck. For example, partners should not employ or otherwise make payments to any Merck employee during the course of any transaction between the partner and Merck, other than pursuant to the Merck contract. If a partner or any of its employees have a relationship with a Merck employee that might represent a conflict of interest, the business partner should disclose this fact to Merck.

## MARKETING & PROMOTIONAL PRACTICES

All marketing and promotional materials and activities must conform to high ethical, medical and scientific standards, and comply with all applicable laws and regulations. When engaged with health care professionals, patients or animal health care professionals, all partners must adhere to relevant industry standards of conduct that apply to them, such as the European Federation of Pharmaceutical Industries & Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).



## GIFTS, MEALS, ENTERTAINMENT

Business partners should not provide any gift, meal or entertainment to a Merck employee in any situation in which it might influence, or appear to influence, any of the employee's decisions in relation to the business partner.

## COOPERATION WITH GOVERNMENT AGENCIES

Business partners will cooperate with investigating government agencies charged with enforcing compliance as and to the extent required by local laws (including, where permitted, by providing reasonable access to facilities and workers). When required, partners will notify the relevant authority if they receive credible information that a worker, contractor or subcontractor has violated local laws.

## IDENTIFICATION OF CONCERNS

Business partners shall encourage all workers to report concerns or suspected illegal activities without threat of reprisal, intimidation or harassment, and shall investigate and take corrective action if needed. Partners shall provide workers with information on how to confidentially report concerns, and shall ensure that reporting workers are protected from retaliation. Anonymous reporting channels should be provided where permitted by law.

## RAISING CONCERNS

Business partners who believe that a Merck employee, or anyone acting on behalf of Merck, has engaged in illegal or otherwise improper conduct, should report the matter promptly to Merck. Any individual or organization, who knows or suspects that a Merck business partner, or anyone acting on their behalf, has engaged in activities that violate Merck's Business Partner Code of Conduct, should report the concern to the Merck through its AdviceLine.

### **To contact the AdviceLine:**

- Go online: <http://www.theadvice.com>
- Call: +1 (877) 319-0273

The AdviceLine, available 24 hours a day, is staffed by an outside organization, so you can remain anonymous when you call. The operator will not provide advice directly, but will relay the information to our company's Office of Ethics and give you a case number and a call-back date. Although questions and concerns raised to the AdviceLine are sent to the Office of Ethics for review, no identifying information is forwarded without your consent.