



Arcera Third Party Code

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Affected Site/s

This Framework applies to the following site/s (see also chapter on scope):

This Procedure applies to Arcera, all locations and divisions, and all its subsidiaries and legal entities.

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1. Introduction

The Arcera Third Party Code expresses the minimum standards in key areas of ethics, human rights, labour, health, safety, environment, and related management systems to which we expect our third party business partners (“Partners”) to commit in the context of their business relationship with Arcera and throughout its term and any extension thereof.

Arcera acknowledges both the United Nations Guiding Principles on Business and Human Rights (UNGPs) (“Ruggie Framework”) and the OECD Due Diligence Guidance for Responsible Business, and recognises the fundamental conventions of the International Labour Organization (ILO): elimination of forced and compulsory labour (Conventions 29 and 105), abolition of child labour (Conventions 138 and 182), elimination of discrimination in respect of employment and occupation (Conventions 100 and 111), freedom of association and collective bargaining (Conventions 87 and 98).

In cases where Partners involve affiliated companies or permitted subcontractors in the provision of goods or services to Arcera, Partners shall implement adequate procedures to ensure that such affiliates or subcontractors follow these minimum standards.

2. Ethics

Partners shall conduct their business ethically and act with integrity. This commitment includes:

2.1. Anti-bribery and corruption

All forms of bribery, corruption, extortion, embezzlement, money-laundering, tax evasion, and terrorism financing, insider trading and market manipulation are prohibited, and Partner shall act in full compliance with related applicable laws. Partners shall not pay or accept bribes or participate in other illegal inducements or illegal payments in business or government relationships, either directly or through the use of intermediaries. Partners shall prohibit “facilitation” or “grease” payments, meaning payments to secure or expedite the performance of a routine or necessary action to which the payer has legal or other entitlement. Partners shall ensure they, their Affiliates and permitted subcontractors have adequate systems in place to prevent bribery and comply with applicable laws, money-laundering, tax evasion and terrorism financing.

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2.2. Sanctions

Partners shall perform their obligations to Arcera in full compliance with applicable Sanctions and shall obtain any necessary permits under applicable Sanctions. Partner shall not do, or omit to do, anything that would cause Arcera to be in breach of Sanctions. Partner represents that it is neither classified as, nor controlled by, a Sanctioned Person.

The terms "Sanctions" refers to all applicable sanctions, embargoes, export and/or import controls and/or trade, economic or financial restrictive measures, laws and regulations, including, without limitations, any sectoral and/or territorial sanctions, or any other type of sanctions limitations, in each case as may be applicable to the Partner and/or their Affiliates, permitted subcontractors, agents, representatives or other intermediaries involved in the performance of the relevant agreement. "Sanctioned Person" means an individual, entity, organization, its Affiliate/s, its representatives, its permitted subcontractors or its agents designated as a restricted party by the Sanctions (e.g. such as a "Specially Designated National" or "blocked person") or any individual, entity or organization being included in the consolidated list of sanctioned parties or asset freeze targets designated by the applicable Sanctions.

2.3. Fair competition

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

2.4. Animal welfare

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

2.5. Data protection and security

Partners shall establish adequate safeguard and security measures for personal data and the information they, and any third party acting on their behalf, process. Partners shall make only proper use of confidential information to ensure that company, worker, patient, subject and donor privacy rights are protected. Partners shall comply with applicable privacy and data protection laws and ensure the protection, confidentiality, security, and lawful processing of personal data.

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Partners must establish an appropriate organizational framework, along with effective processes and protocols, to safeguard the confidentiality, integrity, and availability of personal data. This is to prevent any accidental or unauthorized instances of loss, damage, modification, disclosure, utilization, or unauthorized access. In case of an actual or suspected data breach Partners shall notify Arcera immediately by sending an email to and assist Arcera in investigating and responding to the data breach and/or any request from the data subjects or respective data protection authorities.

Partners shall maintain sufficient policies and procedures that focus on both technical and organizational security measures. They are also expected to take reasonable measures to stay updated and periodically verify their compliance with these protocols.

Partner, when acting as a data processor, shall disclose or transfer personal data to third parties only with the prior written consent of Arcera, when legitimate grounds to do so have been established and reasonable and appropriate measures have been taken to ensure the adequate protection of that personal data, in compliance with applicable laws. Partners must have adequate safeguards, rules, and procedures to ensure that they remain in compliance with all applicable laws that govern cross-border data transmissions, where applicable.

2.6. Confidentiality and intellectual property

Partners shall not misappropriate or infringe valid intellectual property rights or confidential information of third parties, including Arcera. To this end, all information shall be safeguarded against accidental or unauthorized access, use, alteration, loss, or destruction.

2.7. Patient safety and access to information

Partners shall ensure that adequate management systems are in place to minimize the risk of adversely impacting on the rights of patients, subjects, and donors, including their rights to health and to access information directly.

2.8. Conflicts of interest

Partners shall take reasonable care to identify, avoid, and manage any conflicts of interest, including those involving Arcera employees— whether arising from business relationships, family links or other personal connections with Arcera employees or their relatives. Partners are required to promptly notify all affected parties, including Arcera, if any actual, potential, or perceived conflict of interest arises, and must disclose the nature of the conflict and the measures proposed to address it.

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2.9. Clinical trials

Clinical trials shall be conducted in adherence with international guidelines, national and local laws and regulations as well as the strictest medical, scientific and ethical principles.

3. Human Rights and Labor

Partners shall commit to upholding the human and employment rights of workers and to treat them with dignity and respect. This commitment includes:

3.1. Freely chosen employment

Partners shall not use forced, bonded or indentured labor or involuntary prison labor. No worker shall pay for a job or be denied freedom of movement.

3.2. Child labor and young workers

Partners shall not use child labor. The employment of young workers below the age of 18 shall only occur in non-hazardous work and when young workers are above a country's legal age for employment, or the age established for completing compulsory education.

3.3. Non-discrimination

Partners shall provide a workplace free from discrimination. There shall be no discrimination for reasons such as race, color, age, pregnancy, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status.

3.4. Fair treatment

Partners shall provide a workplace free of harassment, harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers and no threat of any such treatment.

3.5. Wages, benefits and working hours

Partners shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits. Partners shall communicate with workers on the basis on which they are being compensated in a timely manner.

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Partners are also expected to communicate with workers whether overtime is required and the wages to be paid for such overtime. Overtime shall be consistent with applicable laws and national and international standards.

3.6. Freedom of association and right to collective bargaining

Partners shall encourage open communication and direct engagement with workers to resolve workplace and compensation issues. 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 and participate in collective bargaining. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation, or harassment.

4. Health and Safety

Partners shall provide a safe and healthy working environment, including - where applicable - for any company-provided living quarters. Health and Safety measures shall extend to contractors and subcontractors on Partner sites. This commitment includes:

4.1. Worker protection

Partners shall protect workers from over-exposure to chemical, biological, physical hazards, and physically demanding tasks in the workplace and in any company provided living quarters. Partners shall ensure appropriate housekeeping and provide workers with access to potable water.

4.2. Process safety

Partners shall have management processes in place to identify the risks from chemical and biological processes and to prevent or respond to catastrophic release of chemical or biological agents.

4.3. Emergency preparedness and response

Partners shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

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4.4. 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.

5. Environment

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. This commitment includes:

5.1. Environmental authorizations and reporting

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.

5.2. Waste and emissions

Partners shall have systems in place to ensure the safe handling, movement, storage, disposal, 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 measured, managed, controlled, and treated prior to release into the environment. This includes managing releases of active pharmaceuticals into the environment (PiE).

5.3. Spills and releases

Partners shall have systems in place to prevent and mitigate accidental spills and releases to the environment and adverse impacts on the local community.

5.4. Resource use

Partners shall take measures to improve efficiency and reduce the consumption of resources.

5.5. Sustainable sourcing and traceability

Partners shall carry out due diligence on the source of critical raw materials to promote legal and sustainable sourcing.

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5.6. Greenhouse gas emissions

Partners are encouraged to quantify, disclose and take action to reduce greenhouse gas emissions and support their respective partners to do the same.

6. Management Systems

Partners shall use management systems to maintain business continuity, facilitate continual improvement and compliance with the expectations of this Code. This commitment includes:

6.1. Commitment and accountability

Partners shall demonstrate commitment to the concepts described in this document by allocating appropriate resources and identifying senior responsible person.

6.2. Legal and customer requirements

Partners shall identify and comply with applicable laws, regulations, standards, and relevant customer requirements.

6.3. Risk management

Partners shall have mechanisms to determine and manage risks in all areas addressed by this Code.

6.4. Documentation

Partners shall maintain the documentation necessary to demonstrate conformance with this Code and compliance with applicable regulations.

6.5. Training and competency

Partners shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address the expectations in this Code.

6.6. Continual improvement

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

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6.7. Identification of concerns

Partners shall encourage their employees and their respective business partners to report concerns, illegal activities or breaches of the principles set forth in this Code without threat of or actual reprisal, intimidation, or harassment. Partners shall investigate and take corrective action if needed.

6.8. Communication

Partners shall have effective systems to communicate the principles in this Code to employees and their respective business partners.

7. Reporting

All incidents of noncompliance relevant to any agreement with the Arcera Group, including but not limited to incidents in the areas of occupational safety, hygiene, dangerous goods, narcotics, Human Rights and Ethics, must be reported immediately (and in any case within 24 hours of knowledge of such incident), either directly to Arcera or through the Arcera Speak-Up Line (<https://arcera.ipm.eu.starcompliance.com/#landing>).