

VENDOR CODE OF CONDUCT

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1. Introduction

Bionical Emas is a Contract Research Organisation that combines Clinical Development, Clinical Trial Supply (“CTS”) and Early Access Programs (“EAP”). This Vendor Code of Conduct (“Code”) mandates the principles, guidelines, and expectations for conducting business with Bionical Emas. It applies to all “Vendors” of Bionical Emas, which includes all suppliers and sub-contractors, such as (without limitation) distributors, wholesalers, in-country service providers. The Code applies not only to Vendors of Bionical Emas, but their vendors, affiliates, associates, subcontractors, agents, and staff/workers, and as such all are collectively captured by the references to “Vendors” in this Code. All Vendors engaged in providing products and services to Bionical Emas are expected to act in accordance with the Code, and they are expected to uphold similar requirements in their organisation and across their supply chains.

Vendors are expected to understand the requirements of this Code and operate in accordance with the expectations outlined in it. Vendors shall comply, at a minimum with and adhere to all applicable laws and regulations of the countries they operate in, with environmental laws and regulations, and with industry-specific requirements and quality regulations of the pharmaceutical and clinical research industry, this includes the Good Practice guidelines, “GxP”, where the “x” stands for the various fields that can include good clinical, laboratory, distribution, manufacturing, and other practices. If there is a conflict between any applicable laws or regulations, GxP, the commercial agreement (or any other contractual documents) between Bionical Emas and a Vendor, and this Code, the Vendor shall, unless otherwise agreed in writing between the Vendor and Bionical Emas, meet the most stringent standard. The Vendor shall notify Bionical Emas immediately in writing on becoming aware of any such conflict.

Bionical Emas has the right to modify this Code from time to time. The current version of the Code is displayed on the Bionical Emas website, <https://bionicalemas.com/vendor-code-of-conduct/>.

2. Subcontractors and Associates

Vendors are liable to Bionical Emas for the non-performance, or breach of the standards set out in this Code, of their staff/workers, affiliates, agents, associates and/or subcontractors. Vendors must adhere to the following requirements, prior to subcontracting:

- Inform Bionical Emas in writing of their planned use of any third party,
- Carry out thorough due diligence checks in accordance with their own processes.
- Obtain written approval from Bionical Emas to subcontract goods/services.
- Put in place fully executed agreements with their agents, associates and/or subcontractors (and where applicable affiliates) prior to commencing activities.

3. Ethics and Business Conduct

Vendors are expected to behave ethically and with integrity in all business transactions, and as such they shall uphold the following standards for business practices:

3.1. Anti-bribery & Anti-corruption

All types of bribery or corruption are prohibited, including but not limited to extortion, fraud, embezzlement, money laundering, the payment of bribes, kickbacks, facilitation payments, illegal political contributions, or other illegal or illicit payments or consideration for any reason, including the waiver of penalties or fines or the receipt of any other items of value, whether provided directly or through a third party such as a distributor, customs broker, or other agent. Vendors shall implement robust anti-bribery, anti-fraud and anti-corruption prevention and reporting programmes, in line with industry-specific requirements of the pharmaceutical and clinical research industry, and never less than the applicable legal requirements and regulations.

3.2. Debarment

Vendors must not be debarred or proposed for debarment, nor at any time use the services of any person or entity debarred or proposed for debarment. Vendors must prohibit the employment or engagement of any person or entity excluded, debarred, suspended, or otherwise declared ineligible from performing a clinical research study by any government department, agency or government programme, including U.S. federal healthcare or procurement or non-procurement programmes or anyone who has been convicted or is under investigation for an offence relating to healthcare fraud and/or clinical research misconduct but has not yet been excluded, debarred, suspended, or declared ineligible.

3.3. Economic Sanctions and Terrorist Financing

Economic and trade sanctions are restrictive measures taken by a country, or group of countries (e.g., the European Union), or an international organization (e.g., the United Nations), which target one or more countries, organizations, entities and/or individuals. Vendors must ensure, as a matter of principle, that not only must they comply with economic and trade sanctions (and ensure that their staff must not do anything that is not permissible under applicable law) but also those they deal with in any manner within their supply chain.

Vendors must ensure compliance with all national and international laws and regulations prohibiting the provision of resources and support to individuals and organizations associated with terrorism. Vendors must not be designated on any list of sanctioned parties.

3.4. Gifts, Travel & Entertainment

Vendors must not provide lavish or otherwise inappropriate gifts, fees, favours, other compensation, including travel and entertainment, which are intended to influence, or may appear to influence, a business decision. The offering of gifts, travel and entertainment may create an inappropriate obligation or expectation or appearance of an improper exchange. It can also raise issues even if no benefit was provided.

3.5. Accurate Record-keeping

Vendors must maintain an environment of transparency and keep accurate books and records, including but not limited to their financial records and performance, to demonstrate to Bionical Emas compliance with all applicable laws, regulations, and accounting practices.

3.6. Conflicts of Interest

Vendors must avoid improprieties and conflicts of interest or the appearance of either. A conflict of interest may exist when a Vendor is involved in an activity that affects – or could appear to affect – professional judgement and objectivity. If a conflict of interest arises, or is suspected may arise, the Vendor must inform Bionical Emas in writing immediately.

3.7. Fair Competition

Vendors must engage only in fair business practices ensuring compliance with all applicable competition and/or anti-trust laws, including but not limited to those relating to teaming and information sharing with competitors, price fixing, and rigging bids.

3.8. Privacy & Data Protection

Vendors must adopt and maintain processes to provide protections and security for personal, proprietary, and confidential information, including information that they access, receive or process on behalf of Bionical Emas. Vendors must ensure that there is no unauthorised access of the information. Vendors must comply with all applicable privacy, data protection and information security laws and regulations. Vendors must notify Bionical Emas within one working day if they become aware of any of unauthorised or unlawful processing/use, sharing, disclosure, transfer, loss, damage/corruption, or destruction of confidential data (including personal data).

3.9. Mobile Devices, Electronic Media, Internet & E-mail Use

Where a Vendor has access to Bionical Emas' electronic environment (including, without limitation, email, voicemail, intranet, internet, or software), the Vendor shall use these tools for business purposes only and use these tools in compliance with industry-accepted information technology security requirements, such as ISO27001. Vendors must not interface with Bionical Emas' electronic systems without first implementing appropriate cybersecurity safeguards on their own systems.

3.10. Intellectual Property

Vendors shall implement safeguards to prevent improper use of intellectual property, including (including but not limited to trademarks) of Bionical Emas or its clients or other Bionical Emas partners or stakeholders, including issuing statements in advertising, media publications, or endorsements, without the prior written consent of Bionical Emas.

4. Labour and Human Rights

4.1. Vendors must be committed to upholding the human rights of workers and to treat them with dignity and respect. Vendors shall comply with all internationally recognised human rights, and at a minimum, as those expressed in the International Bill of Human Rights and the International Labour Organisation's Declaration on Fundamental Principles and Rights at Work. Worker shall mean any individual person engaged by Vendor. Slavery, Human Trafficking, Forced & Child Labour

Vendors must never use slavery, forced or involuntary labour (including bonded, indentured, or prison labour), human trafficking or child labour in any form. Bionical Emas will not knowingly work with Vendors who engage in these practices or who permit those in their supply chain to engage in these practices. Vendors must fully comply with all applicable anti-slavery and human trafficking laws, statutes, regulations, and codes of practice. Bionical Emas' Modern Slavery Statement is available on its website and the standards set out there in form part of this Code's requirements for Vendors.

4.2. Freedom of Association

Vendors are expected to respect the rights of workers, as set forth in local laws, to associate freely, to seek representation, and to form and join trade unions. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation, or harassment.

4.3. Diversity, Equity, & Inclusion

Vendors are expected to provide a working environment that recognises and supports diversity, equity, and inclusion. Vendors shall not discriminate in hiring, compensation, training, advancement or promotion, termination, retirement, or any employment practice based on race, colour, national origin, gender, gender identity, sexual orientation, religion, age, marital or pregnancy status, disability, or any other characteristic other than the worker's ability to perform the job subject to any accommodations required or permitted by law.

4.4. Wages and remuneration

Vendors should provide wages and benefits that meet or exceed the requirements of local law. In addition, Vendors are strongly encouraged to commit to paying a living wage, which will be higher than the legally mandated minimum wage and where applicable overtime premiums. All other types of legally mandated benefits must be provided as required by law, including, as applicable, paid leave, pension, statutory insurance, health benefits, maternity leave, parental leave, family care leave, and childcare benefits.

4.5. Working environment

Vendors should provide safe, clean, and orderly working conditions, and respect workers' rights to rest and honour days off. Vendors must ensure a worker's working hours comply with applicable law.

Vendors shall not engage any person under the age of 18 in any work that involves a substantial risk of harm to their health or safety if adequate protections are not taken. Vendors shall comply with all applicable health and safety laws, and any other relevant laws where they operate.

5. Environmental Stewardship

Vendors are expected to operate in an environmentally responsible manner to minimise adverse impacts on the environment, and they shall encourage their supply base to do the same. Vendors shall comply with all applicable legal requirements for environmental protection and have all necessary licenses, permits and authorisations in place. Where appropriate to the size and nature of their operations, Vendors and their supply base shall have policies and management systems to identify, track, manage, and mitigate the environmental impact of their operations, and take steps to continuously improve environmental performance, reduce pollution, emissions, and waste. Vendors are

encouraged to conserve energy and natural resources, to avoid the use of hazardous materials where possible, and to engage in activities that reuse and recycle materials. Vendors shall ensure products do not contain restricted or banned materials, substances, and chemicals. Vendors shall raise awareness through the provision of training to employees and other workers in environmental matters.

6. Quality

Vendors must meet the specifications mutually agreed upon in the applicable agreement between Bionical Emas and the Vendor. To the extent applicable to GxP Vendors, such Vendors must meet certain established minimum quality requirements as set out below and are also expected to establish controls with their supply base to ensure quality requirements are met. Some of the provisions below may not be applicable to non-GxP Vendors.

6.1. Quality Management System

The Vendor shall implement and maintain an appropriate system of processes and procedures which aims to ensure the quality of products or services; a common example is the ISO 9001 series.

6.2. Product Integrity

The Vendor must at all times comply with all applicable guidance, legislation and regulations and have the appropriate licenses, authorisations, and approvals in place to undertake the required activities relating to the products. Additionally, it is imperative that Vendors have stringent controls in place to prevent falsified medicines or illegally traded products from entering the pharmaceutical supply chain and appropriate measures in place to detect falsified medicines or illegally traded products within the supply chain. Vendors must immediately inform Bionical Emas if there is any suspicion of falsified medicines or illegally traded products anywhere in the supply chain and shall provide Bionical Emas with all reasonable assistance in the investigation of the same.

6.3. Continuous improvement

Vendors shall have a process for timely correction of any deficiencies or violations identified by an internal or external audit, assessment, inspection, investigation, or review. The Vendor shall engage with problem solving and continuous improvement when its customers' signal their experience does not meet their expectation.

6.4. Training

Vendors shall ensure workers and any third party engaged by it are fully trained and proficient in carrying out the role for which they are engaged, and that they understand and comply with the requirements of this Code. Vendors shall keep a record of all training completed, and to make this information available to Bionical Emas on request.

6.5. Audits

Vendors shall perform periodic evaluations, “audits,” of their facilities and operations to ensure compliance with this Code and the law. Vendors will permit Bionical Emas, and third parties designated by Bionical Emas to periodically evaluate Vendor’s facilities and operations, and those of their subcontractors, associates, affiliates, or agents (or any other third party engaged by it). Vendors shall ensure that their own contractual terms with such parties aforementioned permit this, and that they have in place and comply with procedures for the conduct of these audits.

6.6. Regulatory inspections

Vendors shall promptly notify Bionical Emas of regulatory inspections and regulatory issues, such as but not limited to, warning letters, Food and Drug Administration Form 483 observations, letters of non-compliance, seizures and injunctions including observations relating to goods and services delivered to, or on behalf of Bionical Emas. Vendors shall ensure that they:

- Have in place and comply with procedures for the conduct of inspections.
- Notify Bionical Emas of inspections within one working day of receipt of the notice.
- Allow Bionical Emas (and/or any applicable Bionical Emas client) and/or a designated third party to be present at such regulatory inspections.
- Accept and consent that Bionical Emas may be asked to disclose contractual and other documents to the regulatory inspectors and applicable stakeholders, which relate to Vendors and their subcontractors.
- Update Bionical Emas with a written summary of the inspection outcome, within one working day of the inspection
- Update Bionical Emas with a written summary of the inspection outcome, within one working day of receipt.

Vendors agree to provide their full cooperation to Bionical Emas and/or to attend a regulatory inspection of Bionical Emas (or its clients), where the inspection’s remit relates to or could relate to the Vendor’s contracted goods or services.

7. Business Continuity

Vendors are expected to manage business continuity risk and ensure the availability and continuity of critical services during a crisis. Depending on the relevant applicability and nature of their respective businesses, Vendors should have plans in place for their business and services to continue with minimal interruption in the event of a crisis event. Vendors shall regularly test the plans for effectiveness, will share these plans and test results if requested by Bionical Emas.

8. Code Compliance

This Code sets forth expectations for current and future Vendors. All new and existing Vendors are expected to meet these minimum expectations and to aspire to make continuous improvements to their businesses as noted herein across ethical, labour, and human rights, diversity, equality and inclusion, environmental stewardship, business continuity and governance areas. Any facts or circumstances which are likely to lead to a vendor's inability to meet the requirements and expectations of this Code should be immediately reported in writing to Bionical Emas.

Bionical Emas may engage in activities to confirm a Vendor's conformance to the Code, including on-site assessments of facilities, use of questionnaires, review of available information, or other measures necessary.

In accordance with the commercial agreement terms in place between Bionical Emas and Vendors, and by Vendor's continued provision of goods and/or services after the notification of this Code, the Vendor is bound to comply with this Code for the duration of their relationship with Bionical Emas. Vendors are required to ensure that their affiliates, associates, subcontractors, agents, and staff/workers (collectively referred to as Vendors) comply with the Code, and shall monitor their compliance, immediately notifying Bionical Emas in writing of any violations (actual or suspected) in their supply chain. Vendors are expected to have and maintain appropriate insurance to cover any breaches of the provisions of this Code.

Vendors shall not retaliate or take disciplinary actions against any member of the collective Vendor group who has reported in good faith, violations of this Code, or who has sought advice regarding this code.

If a Vendor is found to be in violation of the requirements of this Code, the Vendor is expected to immediately or as soon as is practicable remedy any such violation in a timely and sensitive manner. Failure by a Vendor to do so may lead Bionical Emas to carry out the activities below:

- Audit of the applicable Vendor, with a requirement that the Vendor produces a remediation plan within 14 days or being requested, that will lead to Code compliance.
- Suspend some or all contracted activities, until the audit remediation plan is completed to the satisfaction of Bionical Emas.
- Terminate some or all contracted activities, with no further liability to the Vendor for the terminated services.

Any facts or circumstances which are likely to lead to a vendor's inability to meet the requirements and expectations of this Code should be reported immediately to Bionical Emas.

In the spirit of the standards reflected here, we encourage anyone to report any conduct known or believed to be in violation of this Code by e-mail to legal@bionicalemas.com.

REVISION HISTORY

Version	CRAN Number	Reason for Change	Date of Issue
1	New document– no CRAN required.	To set out standards which all Bionical Emas' vendors must adhere.	1 May 2023