

PharmaEngine, Inc.

Procedure for Risk Management

- Article 1 The Company integrates its business operations and risk management, advocating a system that emphasizes risk management. Based on the outcomes of risk management, it serves as a basis for formulating business strategies. Therefore, this Procedure for Risk Management (hereinafter the "Procedure") is established. The Procedure is formulated in accordance with the laws and regulations of the competent authority and the Company's operational strategies.
- Article 2 The Procedure serves as the highest guiding principle for risk management of the Company and applies to all levels of management and organizational units of the Company. All regulations related to risk management shall be subject to the Procedure.
- **Article 3** The risks referred to in the Procedure include the following risks:
 - 1. Market business risk: Refers to the risk of loss resulting from fluctuations in the value of financial assets and liabilities (including on- and off-balance sheet assets and liabilities) due to market business risk factors (interest rates, exchange rates, stock prices, and commodity prices).
 - 2. Credit risk: Refers to the risk of loss resulting from customers, suppliers, and counterparties failing to fulfill agreements or obligations.
 - 3. Liquidity risk: Refers to the risk of being unable to realize assets or obtain sufficient funds, leading to the inability to meet obligations as they come due (funding liquidity risk) or facing market price fluctuations due to changes in overall economic conditions (market liquidity risk).
 - Operational risk: Refers to the risk of direct or indirect losses resulting from improper or erroneous internal personnel actions, systems, or external events.
 - 5. Legal risk: Refers to the potential risk of loss resulting from non-compliance with relevant regulations, non-legal-binding contracts, unauthorized actions, clause omissions, or inadequate procedures, resulting in the invalidation of contracts.
- Article 4 To establish a good and proper risk management system, the Company, in addition to complying with relevant regulations, shall follow the Procedure in the organizational structure, responsibilities, risk identification, measurement, monitoring, reporting, and information disclosure aspects when handling risk



management. The aim is to ensure that the Company manages the risks it may encounter during its operations within acceptable levels, with the goal of achieving sustainable business operations.

- Article 5 The risk management of the Company shall not only focus on risks undertaken by individual units but also considers the potential effects resulting from the aggregation of various risks from the perspective of the overall operation of the company. This information should be used to formulate relevant operational, financial, and operational procedures for the company.
- **Article 6** Each department of the Company shall conduct risk assessment and implement relevant risk management based on all kinds of actual and potential risk situations.
- Article 7 Market business risk: Market business risk refers to the risk of loss in financial instrument items on the balance sheet, such as interest rates, exchange rates, equity securities, and commodity price fluctuations, due to changes in market prices.

When the Company formulates relevant market business management measures, it should take into consideration:

- 1. Authorization, structure, processes, and operation related to market business risk management.
- 2. The scope of permissible operations and transactions.
- 3. Methods for measuring market business risk.
- 4. Levels for determining market business risk limits and measures for handling breaches of these limits.
- Article 8 Credit risk: Refers to the risk of loss resulting from the counterparty, with whom the company engages in transactions, failing to fulfill its corporate obligations due to financial deterioration or other factors.

 When the Company formulates relevant credit management measures,

supplier management measures related to procurement and sales, credit management measures, and authorization limit management for financial transactions, endorsements, guarantees, and entities to which the Company may loan funds shall be taken into consideration.

Article 9 Liquidity risk: Liquidity risk includes market liquidity risk and funding liquidity risk. Market liquidity risk refers to the risk of significant market fluctuations when processing or offsetting positions due to insufficient market depth or disorder; funding liquidity risk refers to the risk of being unable to liquidate assets or obtain sufficient funds to meet obligations as they come due.



When the Company formulates relevant liquidity and cash management measures, the following shall be taken into consideration based on the operation nature:

- 1. Authorization, processes, and operation related to funding liquidity.
- 2. Control measures related to market liquidity.
- Article 10 Operational risk: Operational risk refers to the risk of loss resulting from improper or erroneous internal personnel actions, systems, or external events. When the Company formulates relevant internal control systems and management procedures, it should consider:
 - 1. Authorization, processes, and operation related to operational risk management. All operational planning, etc., shall comply with the provisions of the internal control system, relevant management procedures, and operational procedure manuals.
 - 2. Operational risk management contents.
 - 3. Internal control system and related management procedures.
- **Article 11** Legal risk: Legal risk refers to the risk of non-compliance with government regulations, leading to illegal actions, and the potential losses due to non-legal-binding contracts, clause omissions, or inadequate procedures, resulting in the invalidation of contracts.

In addition to complying with government regulations, the Company, when entering into contracts, shall let the corporate development department - intellectual property and contracts division review the contract details and provide legal advice, or engage external legal consultants for review before signing to manage legal-related risks.

- Article 12 The Company shall establish a risk management system in accordance with the following measures and incorporate it into the internal control operational procedures for management. The contents are as follows:
 - 1. The Company shall establish a risk management organizational structure responsible for overseeing, planning, and executing related risk management affairs. This structure includes the general manager's office, the audit office, the project management department, the corporate development department, and the finance and administration department. The functions and responsibilities of each department are as follows:

Department	Risk Management Responsibility
President &	Responsible for leading the Company's operating and
CEO Office	business directions, through internal control and budget



	system planning with business performance audit, while
	participate in R&D planning and consultation.
	Its risk management responsibilities are mainly business
	decision-making risk, IP risk and product quality risk.
Audit	In charge of the internal auditing process of the
	Company.
	Its risk management responsibilities are mainly internal
	control and internal audit related risk.
	Clinical Development: Responsible for planning and
	implementing of clinical trials, includes trial proposal
	preparation and submission, the selection of test center
	and the host, the selection of CRO, trials followed by
	ICH-GCP guidance, progress reports, test drug adverse
	reaction reports, statistical analysis reports and test
Clinical &	reports, etc.
Regulatory	Regulatory Affairs: Assist new project assessment and
Affairs	submission regarding regulation requirements,
	responsible for product inspection and registration, and
	establish a good relationship with pharmacological
	organizations.
	Its risk management responsibilities are mainly the
	clinical trials, product inspection, and registration risk
	management of R&D projects.
	Responsible for the planning and recommendation of
	the Company's operation and development, the
	evaluation and introduction of the project, the planning
	and implementation of the external and foreign
Camanata	investment cases and maintaining relationship with
Corporate	investors.
Development	Its risk management responsibilities mainly include the
	risk assessment of competitors in the development of
	new drugs, the risk assessment of newly introduced
	projects, and the risk assessment and management of
	sales markets after product launch.
Finance 0	Responsible for the Company's financial, accounting,
Finance &	administrative, general procurement, and computer
Administration	systems and cyber security related issues.
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	Its risk management responsibilities are mainly related
	to the management of financial matters, response
	strategy implementation, operations, and information
	security evaluation.
Research & Development	Responsible for the relevancy of preclinical trials, the
	evaluation of the new project and manufacturing, also
	the project's overall planning and execution controlling.
	Its risk management responsibilities are mainly for
	preclinical animal pharmacology, toxicology and
	pharmacokinetics test related research, external R&D
	resources management, project planning and execution
	related risk management, and risk management of new
	drug R&D, manufacturing, and analysis.
Marketing & Sales	Responsible for the Company's product marketing
	strategy and rollout.
	Its risk management responsibilities are mainly product-
	related marketing or sales and account-related risk
	assessment management.

- 2. The basis for the company's risk control mechanism includes Corporate Governance Best Practice Principles and related regulations, internal control systems, management procedures, operational procedure manuals, and guidelines. The levels for drafting and approval shall be carried out in accordance with the Company's relevant regulations.
- 3. The execution of the company's risk control operations includes procedures for setting risk limits, measurement and monitoring, handling breaches of limit, exception management, risk reporting in accordance with the relevant contents of the risk control mechanism.
- 4. The Company's risk management information system includes procedures for checking the scope of risks, control functions, and the accuracy and completeness of information sources. These procedures shall be carried out in accordance with the internal control system, management procedures, or operational procedure manuals, and other relevant regulations.
- 5. The Company should conduct regular or irregular performance evaluations of the risk management as described above, carried out independently by internal audit personnel. The reporting process shall be independent of administrative operations and the risk management system. External audit



personnel may be engaged to perform the assessment.

- Article 13 Risk management is the responsibility of each department, and all units of the Company shall identify, monitor, report, and disclose specific risk sources. They should also confirm and classify these risks for further measurement and management.
 - Each department of the Company shall, based on their business activities, effectively manage all relevant risks and sources after careful consideration, and risk management shall be implemented in accordance with this Procedure.
- **Article 14** The Company shall disclose relevant risk management information in accordance with the regulations of the competent authority.
- **Article 15** The Procedure shall be implemented after being approved by the board of directors. The same shall apply when amendments are made.

This Procedure was formulated on August 13, 2014.