PharmaEngine, Inc.

Risk Management Strategies for New Drug Development

1. Risk Management in the Development of New Drugs

The development of new drugs is a high-investment, long-term, and high-risk work. According to the study, the development of an innovative new drug, from initial compound selection to its ultimate market launch, often takes more than a decade of research and development time. Considering the cost of failed development projects, the average cost of researching and developing a successful new drug is approximately US$1 billion. Due to the extremely high risks involved in new drug development, conducting proper risk assessment and control becomes crucial to the increase of the success rate for new drug research and development.

The management for research and development risks in the Company include the evaluation and introduction for new projects, project management execution, quality management, process development control, pharmacology and toxicology research management, clinical research management, regulatory inspection and registration management, project outcome management, promotion of new product outcomes, and document maintenance and preservation operation.

2. Risk Identification

The Company categorizes potential risks in business operation into nine categories, including “new drug development” and “accidents and disasters.” The Company assesses the “probability of occurrence” and “impact level” for each risk category and identifies the annual significant risk as new drug development risk. The relevant business departments then develop corresponding plans, which are regularly monitored by the designated personnel to track the results of the development response plan. This allows for timely adjustments and improvements as needed.

Risk Item	Potential Risk	Probably of Occurrence	Degree of Impact
New Drug R&D	The timeliness, stringency and innovation of the R&D process do not meet the requirements for drug approval in various countries	Medium	High
Accidents/Disasters	Earthquake/fire/flood/blackout	Low	High
Cyber Security	System error	Medium	Medium
	Confidential information leakage	Low	High
	Confidential information leakage	Medium	High
Legal Compliance	Infringement of the intellectual property rights of others, doubts about the safety of listed drugs	Medium	High
Tax/Finance	Huge changes in interest rates and exchange rates	Medium	Medium
Personnel	Talen loss/poor health of employees/occupational hazards	Low	Medium
Operation Management	Poor corporate image	Low	High
Politics & Society	Significant changes in government regulations and economic crisis	Low	High
Business	Unstable supply of medicine/improper management of outsourced suppliers/counterfeit drugs	Low	High

3. Allocation of Risk Management Responsibilities

The risk management responsibilities of each major department in the Company are as follows:

Department	Risk Responsibility
President & CEO Office	Responsible for leading the Company's operating and 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 & Regulatory Affairs	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 reports, etc. Regulatory Affairs: Assist new project assessment and 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.
Corporate Development	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 investment cases and maintaining relationship with investors. 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 & Administration	Responsible for the Company's financial, accounting, administrative, general procurement, and computer systems and cyber security related issues. 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.