

Standards of Business Conduct & Ethics for Third Parties



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Plexxikon



Standards of Business Conduct & Ethics for Third Parties

INTRODUCTION

Daiichi Sankyo Inc. ("Daiichi Sankyo"), Luitpold Pharmaceuticals, Inc., and Plexxikon Inc. (collectively, the "Companies") are firmly committed to being corporate citizens whose foundations are based on integrity, honesty and ethical conduct. The Companies are committed to conducting our business in compliance with all applicable laws, regulations, guidelines and industry codes.

The Standards of Business Conduct and Ethics for Third Parties applies to groups of third-party organizations with whom the Companies contract to provide services or products for or on behalf of our Companies as well as vendors who contract with our affiliates, including Daiichi Sankyo Company, Ltd., and Daiichi Sankyo Europe GmbH, to conduct work related to US-marketed products. The Standards of Business Conduct and Ethics for Third Parties articulate our commitment and expectations of Third Parties with whom we do business. The Companies recognize that Third Parties have an important role in the Companies' success, and the Companies strive to conduct business only with Third Parties who share its commitment to the Standards of Business Conduct and Ethics for Third Parties. Therefore, the Companies encourage Third Parties to:

- Adopt and apply the Standards of Business Conduct and Ethics for Third Parties; and
- Have processes and/or systems in place to support operating in compliance with all applicable laws, regulations, guidelines and industry codes.

Luitpold Pharmaceuticals, Inc. will merge with its subsidiaries on December 31, 2018, and its name will change to American Regent, Inc. on January 1, 2019.

Standards of Business Conduct & Ethics for Third Parties

TABLE OF CONTENTS

COMPLIANCE AND ETHICS [1](#)

Business Integrity, Fair Competition and Confidentiality	1
Marketing and Promotional Practices	1
Interactions with Healthcare Professionals or Patients	1
Pharmaceutical Industry Laws	1
Privacy	2
Trade	2
Animal Welfare	2
Honest and Accurate Dealings	2

LABOR STANDARDS [3](#)

Freely Chosen Employment	3
Child Labor and Young Workers	3
Non-Discrimination	3
Fair Treatment	3
Wages, Benefits and Working Hours	3
Safe Conditions	3
Drug Use	3

ENVIRONMENT, HEALTH & SAFETY [4](#)

Environmental Authorizations	4
Waste and Emissions	4
Spills and Releases	4
Environmentally Responsible Practices	4
Emergency Protection	4
Process Safety	4
Workers Protection	4
Emergency Preparedness and Response	4
Hazard Information	4

MANAGEMENT SYSTEMS [5](#)

Commitment, Accountability and Risk Management	5
Legal Requirements	5
Reporting Concerns	5
Fraud Prevention and Reporting	5
Business Continuity	5

Standards of Business Conduct & Ethics for Third Parties

TABLE OF CONTENTS *continued*

QUALITY	6
Change Control	6
Quality / Delivery Performance	6
Quality System	6
Packaging / Labeling	6

DIVERSITY IN BUSINESS RELATIONSHIPS	7
Support for Diverse Sources	7
Support of Economic Development	7

US STANDARDS OF BUSINESS CONDUCT AND ETHICS FOR COMPANY EMPLOYEES	8
Conflict of Interest	8
Gifts, Entertainment, Hospitality, Gratuities and Other Favors	8

PROCEDURES	9
Training and Certification	9
Monitoring and Compliance	9
Documentation	10
Continuous Improvement	10

I. Compliance and Ethics

Third Parties must conduct their business in compliance with applicable laws, regulations, guidelines and industry codes, and in an ethical manner, including:

- a. Business Integrity, Fair Competition and Confidentiality
 - i. The Companies are committed to conducting its business free from extortion, bribery and all unlawful, unethical or fraudulent activity. Therefore, Third Parties must not offer, give, promise or authorize any bribe, gift, loan, fee, reward or other advantages to any government official or employee, customer, any Company employee or any other person to obtain any business advantage or improperly influence any action or decision. Third Parties must conduct their business consistent with fair and vigorous competition and must comply with all applicable international laws and regulations, including the U.S. Foreign Corrupt Practices Act. Third Parties must maintain books and records in accordance with international accounting principles.
 - ii. Third Parties must ensure that non-public information obtained through the course of their relationship with the Companies are not used for the personal benefit of the Companies' business partners, their employees or other persons.
 - iii. Third Parties are required to keep all confidential, proprietary, and trade secret information in confidence at all times. Third Parties must not disclose such information to any unauthorized party, and use it only for the business of the Companies. Third Parties must not communicate externally about the Companies' prospects. Third Parties must not trade in, or provide others with, non-public information that could impact the securities price of the Companies or another entity. Third Parties must not disclose publicly any confidential or proprietary information related to any aspect of Company business.
- b. Marketing and Promotional Practices
 - i. All marketing and promotional materials and activities must conform to high ethical, medical, and scientific standards, and comply with all applicable laws, regulations, guidelines and industry codes. All such materials and activities must be reviewed by the applicable Company before use or dissemination.
- c. Interactions with Healthcare Professionals or Patients
 - i. When interacting with healthcare professionals or patients on behalf of the Companies, Third Parties must conduct such interactions in an ethical manner and in compliance with applicable laws, regulations, guidelines and industry codes.
- d. Pharmaceutical Industry Laws
 - i. Third Parties, their employees and any other individual involved with providing services to the Companies must be aware of and shall comply with applicable laws and regulations relating to the pharmaceutical industry, including, but not limited to, all applicable federal health care program and FDA requirements. Any suspected violation of these laws or requirements must be reported to the Chief Ethics and Compliance Officer of Daiichi Sankyo, Inc. or to the Daiichi Sankyo, Inc. Compliance Hotline: 1 (877) 48ALERT (1-877-482-5378) or <https://dsi.alertline.com>. The Luitpold Pharmaceuticals, Inc. Compliance Hotline is 1-800-398-1496 or <https://www.lighthouse-services.com/luitpold.com>. Suspected violations relating to Plexxikon Inc. must be reported to the Plexxikon Compliance Officer or to the Daiichi Sankyo Compliance Hotline (via the contact information listed above). Anyone who, in good faith, raises a concern about a possible compliance violation will not be subject to any form of retaliation. As appropriate to the circumstances, any such report must remain confidential and the identity of the individual must remain anonymous.
 - ii. Third Parties shall also comply with the good manufacturing practices, good clinical practices and good laboratory practices requirements of their respective countries.

The Companies are committed to conducting its business free from extortion, bribery and all unlawful, unethical or fraudulent activity.

I. Compliance and Ethics *continued*

Third Parties must conduct their business in compliance with applicable laws, regulations, guidelines and industry codes, and in an ethical manner, including:

- iii. Consistent with the above, Third Parties must not employ or otherwise allow any individual to provide services to the Companies who is excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. 1320a - 7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. In addition, Third Parties will not utilize in the performance of services for the Companies, either as employees or consultants, any individuals who are on the following lists:
 - HHS/OIG List of Excluded Individuals/Entities (LEIE)
 - General Services Administration's System for Award Management (SAM)
 - iv. The Companies comply with all state and federal laws regarding tracking and reporting in connection with payments or transfers of value to healthcare professionals. Third Parties will report to the Companies all such payments and transfers of values made on behalf of the Companies.
 - v. Third Parties must report any adverse events related to Daiichi Sankyo, Inc. products within twenty-four (24) hours of first becoming aware of an adverse event, to the Contact Center at 877-4-DS-PROD (877-437-7763). Adverse events associated with Luitpold Pharmaceuticals, Inc. products must be reported within twenty-four (24) hours to Luitpold's Pharmacovigilance Department at 800-734-9236 or via e-mail at pv@luitpold.com. Adverse events related to Plexxikon Inc. products must be reported within twenty-four (24) hours to Gideon Bollag, CEO, Plexxikon Inc. at 510-647-4062 or via email at gbollag@plexxikon.com. An adverse event includes any unintended experience associated with the use of a drug, any unanticipated exposure, overdose, abuse, misuse, medication error, product defect, or product quality complaint, and must be reported whether or not the event is considered to be drug related.
- e. Privacy
 - i. Third Parties must safeguard and make only proper use of confidential and/or personal information to ensure that the Companies', employees, consultants, and patient privacy rights are protected.
 - f. Trade
 - i. Third Parties must comply with all applicable import and export controls, sanctions, and other trade compliance laws of the country(ies) where the transaction(s) occur(s).
 - g. Animal Welfare
 - i. Animals must be treated humanely, 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 or discomfort. Alternatives to animal testing must be used whenever scientifically valid and acceptable to regulators.
 - h. Honest and Accurate Dealings
 - i. Third Parties must not make any false representation in connection with any Company transaction, including, but not limited to, oral misrepresentation of fact, the promotion or utilization of false documentation such as fraudulent or forged contracts, forged letters or destruction and/or other false or inaccurate records.

Third Parties must report any adverse events within twenty-four (24) hours of becoming aware:

- For Daiichi Sankyo, Inc. products, please contact the Daiichi Sankyo Inc. Contact Center at 877 4 DS PROD (877-437-7763)
- For Luitpold Pharmaceuticals, Inc. products, please contact Luitpold's Pharmacovigilance Department at 800-734-9236 or via e-mail at pv@luitpold.com
- For Plexxikon, Inc. products, please contact Gideon Bollag, CEO, Plexxikon Inc. at 510-647-4062 or via email at gbollag@plexxikon.com

II. Labor Standards

Third Parties must uphold the human rights of workers and treat them with respect and dignity, including:



a. Freely Chosen Employment

- i. Third Parties must not use forced, bonded, enslaved, indentured or involuntarily imprisoned labor, nor engage in human trafficking.

b. Child Labor and Young Workers

- i. Third Parties must not use child labor. Young workers below the age of 18 may only engage in nonhazardous work. All employees of Third Parties must be above a country's legal age for employment or the age established for completing compulsory education.

c. Non-Discrimination

- i. Third Parties must provide a workplace that is free of harassment and discrimination. Discrimination for reasons such as gender, race, color, religion,

political affiliation, national origin, age, physical or mental disability, pregnancy, citizenship, status as a covered veteran, marital status, sexual orientation, ancestry, culture, ethnicity, genetic information, gender identity and expression, or any other characteristic protected by law is prohibited.

d. Fair Treatment

- i. Third Parties must provide a workplace free of harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of worker, and with no threat of any such treatment.

e. Wages, Benefits and Working Hours

- i. Third Parties must pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits. Third Parties must also communicate with workers, in a timely manner, the basis on which they are being compensated, whether overtime is required, and the wages to be paid for such overtime.

f. Safe Conditions

- i. Third Parties must provide a safe and hygienic working environment for workers and provide appropriate safety equipment and training.

g. Drug Use

- i. Third Parties will not permit the use, purchase, sale, transfer, or possession of illegal drugs or the illegal use of legal drugs while providing services to the Companies. Third Parties will not permit being impaired or under the influence of any drugs or alcohol during work time while providing services to the Companies.

Third Parties must not use forced, bonded, enslaved, indentured or involuntarily imprisoned labor, nor engage in human trafficking.

III. Environment, Health & Safety

Third Parties must operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Third Parties are encouraged to conserve natural resources, avoid the use of hazardous material where possible, and engage in activities that reuse and recycle. The environmental elements include:

a. Environmental Authorizations

- i. Third Parties must comply with all applicable environmental laws, regulations, guidelines and industry codes. All required environmental permits, licenses, information registrations and restrictions must be obtained, and their operational and reporting requirements must be followed.

b. Waste and Emissions

- i. Third Parties must have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any generation and disposal of waste, emissions to air and discharges to water with the potential to adversely impact human health or the environment must be appropriately minimized, and properly managed, controlled or treated prior to release into the environment.

c. Spills and Releases

- i. Third Parties must have systems in place to prevent and mitigate accidental spills and releases to the environment.

d. Environmentally Responsible Practices

- i. Third Parties must conserve natural resources, avoid the use of hazardous materials where possible, and reuse or recycle appropriate materials.

Third Parties must comply with all applicable health and safety laws and regulations by providing a safe and healthy working environment, including any living quarters that are provided by the Third Party. Other important health and safety requirements include:

e. Emergency Protection

- i. Third Parties must protect employees from overexposure to chemical, biological and physical hazards in the workplace.

f. Process Safety

- i. Third Parties must have programs to prevent or mitigate catastrophic releases of chemicals.

g. Workers Protection

- i. Third Parties must protect workers from exposure to chemical, biological and physical hazards and physically demanding tasks in the workplace, including any company-provided living quarters.

h. Emergency Preparedness and Response

- i. Third Parties must identify and assess emergency situations in the workplace and minimize their impact by implementing emergency plans and response procedures.

i. Hazard Information

- i. Safety information relating to hazardous materials including pharmaceutical compounds and pharmaceutical intermediate materials must be available to educate, train and protect employees from hazards.



Third Parties must comply with all applicable health and safety laws and regulations by providing a safe and healthy working environment, including any living quarters that are provided by the Third Party.

IV. Management Systems

Third Parties must use management processes that help facilitate continual improvement and ensure compliance with these Standards of Business Conduct and Ethics for Third Parties, including:

- a. Commitment, Accountability and Risk Management
 - i. Third Parties must demonstrate commitment to the concepts described in these Standards of Business Conduct and Ethics for Third Parties by allocating appropriate resources.
 - ii. Third Parties must have mechanisms to monitor and manage risks in all areas addressed by these Standards of Business Conduct and Ethics for Third Parties.
- b. Legal Requirements
 - i. Third Parties must identify and comply with applicable laws and regulations, standards, relevant customer requirements, and must follow applicable guidelines and industry codes.
- c. Reporting Concerns
 - i. All employees of Third Parties must be encouraged to report concerns or potential illegal activities in the workplace without fear of retaliation, if permitted by local laws and regulations. Third Parties must investigate and take appropriate corrective action, if necessary, without retaliation against the individual who reports the concern or activity.
- d. Fraud Prevention and Reporting
 - i. Third Parties must have robust fraud prevention and reporting programs. Third Parties must report promptly to the Companies any potential fraud involving Company business, regardless of materiality.
- e. Business Continuity
 - i. Third Parties must develop and implement appropriate business continuity plans for operations supporting Company business. These plans must be designed and kept current to promptly recover and restore partially or completely interrupted critical functions to minimize disruption to Company business and protect the Companies' reputation.



All employees of Third Parties must be encouraged to report concerns or potential illegal activities in the workplace without fear of retaliation, if permitted by local laws and regulations. Third Parties must investigate and take appropriate corrective action, if necessary, without retaliation against the individual who reports the concern or activity.

V. Quality

a. Change Control

- i. Third Parties (including sub-suppliers) must not make any changes in specification, part design, material, manufacturing process, manufacturing location, or registration status, for any goods that the Companies will purchase, without prior written approval from the Company.

b. Quality / Delivery Performance

- i. Third Parties must ensure on-time delivery in accordance with the Companies' requirements.
- ii. Third Parties must monitor product quality performance and demonstrate continuous improvement measured by decreased internal defects, customer complaints and defects shipped. Third parties must have the capability to respond in a timely manner to all complaints issued by the Companies and their affiliates.

c. Quality System

- i. Third Parties must have a quality system and product registration process compliant with all applicable government regulations in the countries in which their products are produced and/or distributed.

d. Packaging / Labeling

- i. Products must be properly identified with appropriate label information, ensuring no misidentification will occur and allowing for complete traceability.



Third Parties must monitor product quality performance and demonstrate continuous improvement measured by decreased internal defects, customer complaints and defects shipped. Third parties must have the capability to respond in a timely manner to all complaints issued by the Companies and their affiliates.

VI. Diversity in Business Relationships

The Companies are advocates of the development of sustainable business relationships with companies that are historically underrepresented in the business world, and we seek to do business with Third Parties that share these objectives.

a. Support for Diverse Sources

- i. The Companies recognize that diverse talents and perspectives are vital to achieve success, particularly as our company reaches out to serve the needs of all of our customers. The Companies seek to obtain high quality goods, services and materials from companies that are owned by individuals who are minorities, women, veterans, disabled, and/or lesbian, gay, bisexual or transgender, or others who represent global diversity. Third Parties must do the same.

b. Support of Economic Development

- i. Third Parties shall make good faith efforts to develop partnerships with qualified small businesses and companies in distressed communities with high unemployment rates and low median household incomes, in order to encourage economic development to make a positive difference.



The Companies recognize that diverse talents and perspectives are vital to achieve success, particularly as our company reaches out to serve the needs of all of our customers.

VII. US Standards of Business Conduct and Ethics for Company Employees

In addition to the principles herein, the Companies have Standards of Business Conduct and Ethics for their own employees, which sets forth the fundamental principles that all Company employees are required to follow in their work. Accordingly, Third Parties who interact with Company employees must understand and comply with certain principles relating to conflicts of interest and acceptance of entertainment and gifts.

a. Conflict of Interest

- i. The Companies require their employees to avoid situations that present, or create the appearance of, a potential conflict of interest. A conflict of interest exists when an employee's private interests, including personal, social and financial, interfere in any way with the employee's performance of her or his responsibilities in conducting Company business.

b. Gifts, Entertainment, Hospitality, Gratuities and Other Favors

- i. Third Parties and their employees may never accept a gift that might influence, or be perceived to influence, their business decisions. Accepting gifts, entertainment, hospitality, gratuities or other favors from entities with which the Companies do business is generally not acceptable because it may pose a conflict of interest by implying an obligation on behalf of the Companies.



The Companies require their employees to avoid situations that present, or create the appearance of, a potential conflict of interest. A conflict of interest exists when an employee's private interests, including personal, social and financial, interfere in any way with the employee's performance of her or his responsibilities in conducting Company business.

VIII. Procedures

a. Training and Certification

- i. Third Parties must communicate and provide training on these Standards of Business Conduct and Ethics for Third Parties to applicable employees. Third Parties must have a training program that ensures an appropriate level of knowledge, skills and abilities in management and workers to address these expectations.
- ii. Where required, each Third Party covered by the Standards of Business Conduct and Ethics for Third Parties must have an authorized representative certify that he or she read and understood the Standards of Business Conduct and Ethics for Third Parties and commits the Third Party to these standards.
- iii. In accordance with Daiichi Sankyo, Inc.'s Corporate Integrity Agreement (CIA), the applicable Company shall also provide a copy of the Standards of Business Conduct to each entity employing Third Party Personnel (as defined in the CIA) and must request such entity to: (a) make a copy of the Standards of Business Conduct and a description of the Companies' Compliance Program available to its Third Party Personnel; or (b) represent to the applicable Company that it has and enforces a substantively comparable code of conduct and compliance program for its Third Party Personnel.

b. Monitoring and Compliance

- i. The Companies may audit compliance with the Standards of Business Conduct and Ethics for Third Parties and appoint a third party to conduct an audit. Any violations will be reported to the Third Party's management for their attention and, if appropriate, corrective action. Third Parties must notify the applicable Company's Compliance Department of any reported violations within 48 hours. Third Parties will keep the applicable Company's Compliance Department apprised of the investigation of such reported violations and any resulting corrective actions, including providing all supporting documentation. It is the intention of the Companies to discontinue their relationship with any individual and/or Third Party who does not comply with this Standards of Business Conduct and Ethics for Third Parties or, upon discovery of noncompliance, does not commit to a specific plan to achieve compliance.



Third Parties must communicate and provide training on these Standards of Business Conduct and Ethics for Third Parties to applicable employees.

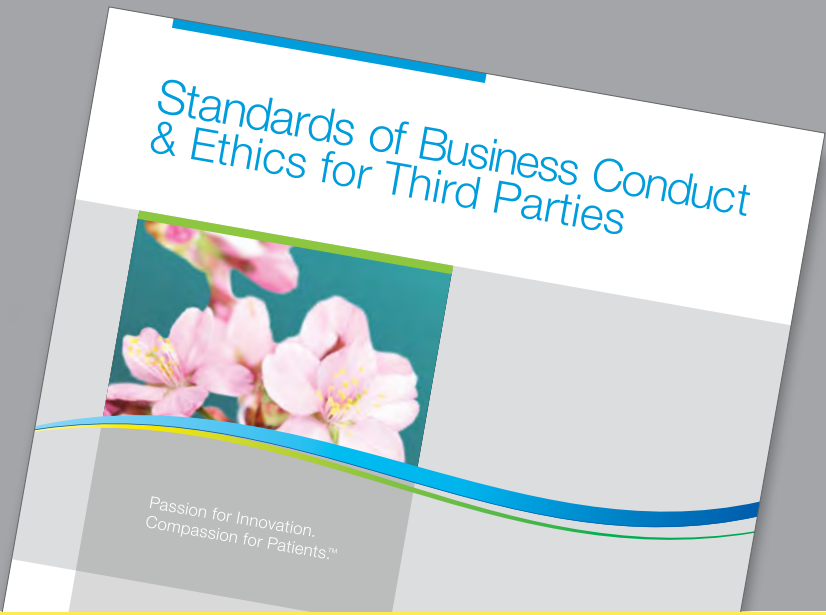
VIII. Procedures *continued*

c. Documentation

- i. Third Parties must maintain documentation that demonstrates compliance with these Standards of Business Conduct and Ethics for Third Parties and applicable laws, regulations, guidelines and industry codes.

d. Continuous Improvement

- i. Third Parties shall continuously improve their internal control environment by establishing objectives, implementing plans and taking appropriate corrective actions for any deficiencies identified by internal or external assessments, inspections, or management reviews.



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