Risk Management

The Daiichi Sankyo Group defines “risks” as those factors that may prevent it from achieving its goals and targets and that can be predicted in advance. We take appropriate measures against risks inherent in our corporate activities through retaining, reducing, avoiding, and transferring these risks; should risks materialize, we promote risk management to minimize impacts on people, society, and the Group itself.

For details on our risk management system, crisis management, and BCP (Business Continuity Plan), please click here

Risk Management Promotion System

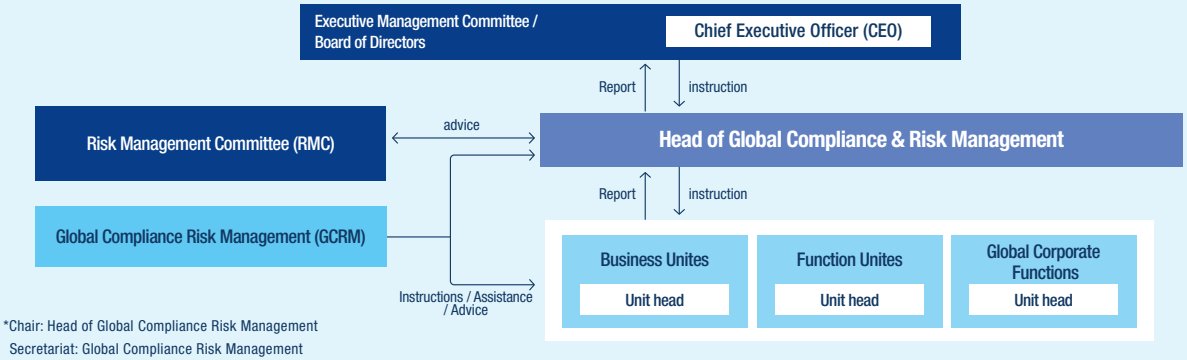
Our Group is overseen by the Head of Global Compliance and Risk Management (GCRM), who oversees the Group’s risk management activities. Within this structure, the Heads of each Unit and Function conduct risk identification, risk assessment, and countermeasure implementation, promoting autonomous risk management. GCRM handles operational affairs for the entire Group while providing necessary instructions, support, and advice to each Unit and Function.

The significant risks of our Group are determined by the Executive Management Committee (EMC) and the Board of Directors. For each significant risk, each designated Head of Unit or Function (risk owners) is responsible for implementing countermeasures and monitoring them periodically. When signs of potential material risks are detected within a Unit or Function, the respective Head promptly reports them to the CEO and the Head of GCRM.

In FY2024, we enhanced the Daiichi Sankyo Group’s Risk Management by implementing improvements based on interviews with senior management and industry practice reviews. As part of this initiative, we established the Risk Management Committee (RMC) to facilitate discussions on risks at the EMC level. The RMC consists of core members and additional flex members invited based on the agenda, and it engages in in-depth discussions on various risks. The Risk Management team invites external specialists as necessary to ensure that discussions benefit from up-to-date expertise on relevant topics.

Additionally, the Risk Management team has established a process through which Risk Coordinators, designated by each Unit or Function, support the Head of Unit or Function and promote the risk management processes. Furthermore, we have introduced a recurring PESTLE analysis to monitor external factors and changes, establishing a systematic approach that enables us to respond promptly to emerging risks.

Risk Management System Chart



Response to Emerging Risks

We also monitor emerging risks (new risks that may affect the company over the next few years and are still under evaluation due to their high uncertainty and dynamic nature). Depending on discussions at the RMC and EMC, the assessment of an individual emerging risk may be changed to a material risk or a unit-level risk. We monitor the following risk as the emerging risk.

Areas	Risk Summary	Status of Risk Management
Risks Related to the Utilization of AI	**1.Decline in competitiveness due to delays in applying AI and digital transformation** Amid rapid advances in AI technology research and development and digital transformation (hereinafter “DX”) worldwide, the utilization of AI, particularly generative AI, is becoming indispensable, especially in drug discovery research and development processes. If we fail to respond to these technological innovations in AI, we may lose our competitive advantage in research and development, which could adversely affect the performance of our Group. **2. Response to AI-related regulations** Regulations governing the use of AI technology are becoming increasingly stringent worldwide. In particular, inadequate response to new regulations such as the EU AI Act in the EU could result in fines or restrictions on business activities. Additionally, inadequate AI governance frameworks could lead to incidents that adversely affect patient health or safety. Furthermore, this could result in a decline in the Group's social credibility or claims for compensation, which could negatively impact business performance.	In response to these various risk scenarios, the Group is continuing to build a framework aimed at accelerating research and development through technological innovation using AI and promoting DX based on the utilization of AI throughout the company. In addition to complying with AI-related regulations, we are also working to establish an AI governance system (formulating a global AI governance policy, establishing global guidelines for AI development and operation according to risk classification, etc.).

Major Risks and Corresponding Responses

Areas	Risk Summary	Response (Including Countermeasures and Mitigation Action)
Research and Development & Alliances with Partner Companies	The potential of discontinuation of research and development, failure to obtain approval due to changes in approval review criteria, or changes or termination of contract terms related to collaborations in the development of new drug candidates. Investment may not be recovered due to changes in development plans and excess inventory may result in disposal costs. This includes Trastuzumab Deruxtecan (T-DXd/DS-8201: Anti-HER2 ADC, product name: ENHERTU®) and Datopotamab Deruxtecan (Dato-DXd/DS- 1062: Anti-TROP-2 ADC, product name: DATROWAY®) in partnership with AstraZeneca, as well as Patritumab Deruxtecan (HER3-DXd/U3-1402), Ivnatamab Deruxtecan (I-DXd/DS-7300), DS-6000 (R-DXd), and MK-6070 (DS3280) in partnership with Merck.	Continue a Joint Committee with each AstraZeneca and Merck, create a unified vision between the two companies for each area of collaboration, and use this vision to formulate and manage the progress of strategies; Ensure constant communication with pharmaceutical regulatory authorities in each country as a means of managing and reducing risks.
Pharmaceutical Side Effects and Quality Issues	Pharmaceutical products may be recalled or withdrawn from the market due to quality issues or unforeseen side effects; significant expenses may be incurred due to resulting allegations of injury and other matters of liability.	Consistent quality assurance through the enhancement of management systems compliant with GMP and GDP standards; Regular audits of group company facilities and business partners are conducted; Perform objective assessments, reviews, and analysis of safety management information (e.g., information on side effects) is globally collected; Share this information with health care professionals in an appropriate manner; Provide all employees with training in safety management information every year.
Overseas Business Expansion	Operations overseas may be impacted by a number of factors, including: political instability, changes in tariffs, sudden policy changes, deterioration of economic circumstances, contraventions of local laws and regulations, and worsening labor management relations.	Appoint risk coordinators in each unit, and collect and share information on a regular basis; When a problem occurs, follow the crisis initial response procedure, aiding prompt problem resolution. Collect timely information to understand the potential impact on the business, work out different scenarios, consider requests to the government through industry organizations in Japan, the U.S., and Europe, and examining the possibility of strengthening local production in the US.
Manufacturing and Procurement	Risks affecting manufacturing, procurement activities, and investigational products, including quality risks in contract manufacturing, may include damage to Group-owned facilities, impairment of public infrastructure, and technical issues.	Establish systems to rapidly restore operations in the event of an emergency and to ensure stable supplies of pharmaceuticals with assured quality for the continued provision of medical services; Continuously improve BCP by reviewing operations and organizational structure related to priority supply items, etc.; Periodically review list of priority supply items. Ensure distribution of manufacturing and logistics bases, and install private electricity generators; Strengthen IT foundations (e.g. infrastructure), such as by ensuring redundancy in core systems. Enhance the oversight of contracted manufacturing sites through risk management and promote the implementation of risk mitigation measures.
Environment & Safety	Some chemical substances used in the research and manufacturing of pharmaceuticals may potentially have adverse effects on human health and ecosystems. Climate change-induced weather disasters, global warming, and loss of biodiversity pose potential risks to the pharmaceutical supply chain, such as disruption, increased manufacturing costs, and restrictions on the use of natural resources.	Establish and ensure continuous monitoring of independent management standards that are more rigorous than those set by local authorities; Disclose information according to recommendations of the TCFD (Task Force on Climate-related Financial Disclosures), Risk assessment and disclosure in accordance with the TNFD (Taskforce on Nature-related Financial Disclosures).
Intellectual Property Rights	Third party claims of patent infringement or other intellectual property claims against the Group, which could interrupt the Group's business or result in legal action; the Group itself may initiate legal action if a third party is found to have infringed Group-owned intellectual property rights.	Maximize value and minimize risks for the creation and protection of intellectual property; Establish systems to identify, monitor and minimize the impact of intellectual property challenges disputes on business by working together with internal and external parties.
Litigation	Lawsuits may arise over pharmaceutical side effects, product liability, employment/labor issues, and fair trade-related litigations, among others.	Minimize legal risks and maximize business opportunities under applicable laws and regulations, contracts, and dispute prevention and resolution.
Laws and Regulations and Regulatory Trends to Limit Healthcare Expenses	Negative impact may arise from administrative measures related to drug price revisions, the healthcare system, and health insurance .	Monitor drug price policies in each country, collect timely information to understand the potential impact on the business, consider requests to the government through industry organizations in Japan, the U.S., and Europe and work out different scenarios.
Compliance Risk	Material violations of laws and regulations, including personal misconduct by directors and employees, have a significant adverse impact on our business performance, financial and reputational condition.	Ensure compliance with laws and regulations through education and awereness-raising activities. CEO's compliance message (twice a year), monitoring of business operations to detect any inappropriate activities as early as possible. Prevent and ensure early detection of compliance violations through the whistleblowing system (Global Hotline) available not only to executives and employees but also to business partners, and take strict action when they occur. Established Global Ethics & Compliance Committee.
Financial Market and Exchange Rate Fluctuations	Negative effects may result from stock market behavior, interest rate trends, or exchange rate fluctuations.	Reduce cross holdings; Implement mid-term reviews of pension fund asset allocations; Execute currency hedging transactions.
Information Security	Network infection, cyber-attacks, and other similar events may result in a system shutdown or leakage of confidential information.	Under the leadership of the CDXO*,promoting measures related to information security and cybersecurity, establishing policies and rules; Provide employees with continuous information security training; Establish security systems with defense functions, infringement detection, and countermeasure function; Strengthen information security and cybersecurity infrastructure and to improve operations; Implement security measures and management system designs for factories, manufacturing facilities, and systems (OT systems); Regular monitoring of personal information management practices.
Securing Talent	Increasingly competitive job markets may result in an inability to secure sufficient talent with the high levels of expertise required for various roles.	Strengthen planned recruitment activities and foster and secure talents through diverse approaches; Establishment and implementation of a globally unified HR system and human resource information system; Promote both One DS Culture and Inclusion & Diversity (I&D), and analyze and improve employee engagement through global engagement surveys, Maximize utilization of human resources globally.

*Chief Digital Transformation Officer