

Internal control systems

SanBio is committed to management transparency and thorough implementation of compliance-based management. Therefore, SanBio endeavors to build an organization that is swiftly responsive to changes in the management environment, while maintaining exemplary corporate governance. The current state of internal control system development at SanBio is as follows:

1. System to assure compliance with laws, regulations, and the company's articles of association

(a) A Code of Conduct has been established for compliance with statutory laws, the SanBio articles of association, and social norms. Companywide recognition is awarded for the improvement and maintenance of compliance awareness.

(b) A scheme for internal reporting to auditors has been created by implementing the Company's Whistleblower Protection Regulations, ensuring early detection and prevention of problems, as well as swift and effective action on any problems detected.

(c) The Company is committed to avoiding involvement with any antisocial force. If any unreasonable demand is made to the company, it will be reported to the Manager of Management Administration Department and refused categorically, in accordance with the company's Regulations on Dealing with Anti-Social Forces and in coordination with the police.

2. System for storage and management of information pertaining to the execution of the duties of the directors

(a) Information pertaining to the execution of duties by the directors is to be stored and managed appropriately by the Management Administration Department.

(b) The directors and auditors shall be able to access such documents, etc., at all times.

3. System for management of risks on potential losses

(a) Risk management and countermeasures are implemented by the relevant business departments. Deliberation into any issues that arise will be held swiftly when necessary, by the Executive Committee and the Board of Directors, to prevent and mitigate the various risks involved in business activities.

(b) Should an emergency occur, an emergency response headquarters shall be set up for precise and swift action to address the risk, including communication of relevant information within the organization and to external parties.

4. System to assure efficient execution of duties by directors

(a) The decision-making and supervision functions of the Board of Directors are separated from the execution function of the Executive Committee.

(b) Regulations are established for the Board of Directors, assigning responsibilities and job jurisdictions to clarify and define the duties, authorities, and responsibilities of the directors.

(c) In addition to the monthly meeting of the Board of Directors, extraordinary meetings are held as needed.

5. System to allocate responsibilities between SanBio and its subsidiaries

(a) The Management Administration Department is to take charge of management of subsidiaries in compliance with the Regulations on Management of Subsidiaries. In accordance with the Regulations on Job Jurisdiction in the Corporate Group, SanBio makes the most important decisions arising at subsidiaries, excluding transactions that cause conflict of interest between the parent company and subsidiary, and matters that should be resolved at the subsidiary, such as key personnel appointments.

(b) The Board of Directors has authority to ratify or modify the corporate group's management plans. The Management Administration Department reports progress status on such plans at the monthly meeting of the Board of Directors.

(c) On the basis of the Regulations on Internal Audit, the Management Administration Department conducts internal audits for the company and its subsidiaries on a quarterly basis. The audit findings are reported to the Representative Director and President. Internal audit for the Management Administration Department will be conducted by the Representative Director and Chairman. If nonconformities or other deficiencies are identified, the internal auditor issues improvement instructions to the relevant business department, and that department is tasked to develop an improvement plan and submit it to the internal auditor. The internal auditor is to conduct a follow-up audit within three months from the date of improvement implementation.

6. Matters related to employees, when the auditors request the assistance of such employees

(a) The Board of Directors appoints staff to assist the auditors in the performance of auditing duties upon request from the auditors.

7. Matters related to the independence of employees assisting the auditors

(a) Employees who have been requested to assist the auditors in the performance of auditing duties shall not be required to receive instructions or orders from the directors or other superior officers.

(b) The appointment and job evaluation of such employees shall require the consent of the auditors.

8. System for report by directors and employees to the auditors

(a) The auditors attend the meetings of the Board of Directors, as well as important Executive Committee meetings, and are able to request reports on job performance from the directors and employees.

(b) Should a director or employee discover evidences of violation of statutory law or evidences of activities threatening harm to the company, the director or employee is to report promptly to the auditors.

9. Other systems that assure effective implementation of auditing

(a) The Board of Auditors is to include outside auditors who are neutral in position and without interests in the SanBio Group, in accordance with statutory law, to assure transparency and fairness.

(b) The auditors are to engage in regular exchange of views with the Representative Directors to foster mutual communication.

(c) The auditors are to engage in regular exchange of information with the company's accounting auditor and internal auditors, to foster coordination of activities.

(d) Should the auditors decide it necessary for performing their duties, the auditors shall be able to consult attorneys, certified public accountants and other specialists, with the company bearing the necessary expenses.

Risk management and compliance

All business departments are in charge of risk management and resolution of risks in their own business operations. Should a risk emerge or be likely to emerge, deliberations are to be conducted promptly by the Executive Committee and the Board of Directors.

Additionally, in order to secure the knowledge and expertise of specialists, executive management has access to an advisory group consisting not only of the founding scientist Professor Hideyuki Okano of Keio University, but also a former science director of the US National Institute on Aging (NIH), a former director of the US Food and Drug Administration, a pioneer in research on mesenchymal stem cells, and other experts. Based on the specific expertise of these advisers, they are classified into "founding scientists," "scientific advisors," and "senior advisors." The Group's key technology, regenerative medicines via allogeneic cell implantation, is a highly innovative regenerative technology and boasts significant advantages over other regenerative medicines in safety, efficacy, cost, and wide applicability. However, the rapid pace of innovation in this sector, and the possibility of unexpected side effects from these new approaches, mean that risks are always present. In order to address these risks, the company has organized a network formed by the founding scientist, scientific advisors, and senior advisors supplying the company with cutting-edge scientific knowledge and clinical experience.

By managing business risks and preparing countermeasures, the company endeavors to protect and maximize corporate value consistent with compliance with statutory law and internal regulations, careful review by the Board of Directors and the Executive Committee, and coordination with outside specialists, such as contract attorneys, patent attorneys, certified public accountants, and other external advisors.

Furthermore, to protect the personal information of patients and employees and to prevent leakage of the company's corporate information, Regulations on Information System Management and Information Security Control have been established. Clinical trial data and personnel-related documents are being stored in locked cabinets, and data access is being managed by defining access levels and establishing control procedures, to assure information efficiency and confidentiality.