

Sharing our progress in corporate culture reforms and actions to resolve issues with investors



IR Day 2025 Overview

Date	March 25, 2025	Location	Nihonbashi, Chuo-ku, Tokyo (streamed online)
Speakers	Mitsuo Sawai, Group CEO and COO / Shoji Yokota, Director, Senior Managing Executive Officer, and Group Chief Research & Development Officer / Masatoshi Ohara, Outside Director / Nawomi Todo, Outside Director / Masayuki Mitsuka, Outside Director / Motohiko Kimura, Senior Managing Executive Officer, Representative Director, President of Sawai Pharmaceutical Co.,Ltd. / Taku Nakaoka, Executive Officer, and Group Chief Financial Officer		

Note: Affiliations and positions are as of the date of the meeting.

The Sawai Group’s IR Day was held in March 2025 with the aim of further deepening dialogue with investors. On the day of the meeting, attending members of the Board of Directors explained in detail the status of the Board’s monitoring activities and the Group’s R&D capabilities enabling it to launch generic drugs which are the first or the sole item in their market category. Outside directors in attendance also engaged in a lively exchange of views on themes of importance of investors and future prospects through a question-and-answer session.

Here, we compile some topics of particular interest from the day’s Q&A session.

Q.1 Outside directors’ roles and actions after discovery of inappropriate testing

Investor: At what point were you informed and what was your reaction to the inappropriate testing that was discovered in 2023? Please also tell us what role the outside directors played in the subsequent formulation of measures to prevent recurrence, strengthening of monitoring, cooperation with the third-party committee, and holding

senior management accountable.

Ohara: We apologize for the great concern this incident has caused Sawai’s shareholders and investors.

The incident in question was first discovered in April 2023, and the Board of Directors received the first report of the occurrence on May 11, 2023. At that stage, it was said that a proper investigation would be carried out and another report would follow. Board meetings were subsequently held on May 22 and June 27, but as of May 22, there was no report on this investigation. The reason given was that

quality assessment had been made a top priority to determine if a product recall was necessary.

The quality assessment work was completed on June 19, and at the June 27 Board of Directors meeting, the director in charge at the time reported on developments so far and that a special investigation committee had been established. Since then, each Board meeting has involved discussions and reports on this matter.

Furthermore, as part of measures to prevent recurrence, we, the outside directors and Audit & Supervisory Board members have inspected the Daini Kyushu Factory, most recently on February 26, 2025, to confirm the status of quality assurance and quality control.

As for what measures were taken, we took two approaches to tackling this issue. One is how to establish a system to investigate the cause of the incident and prevent recurrence. The other is that there may have been a delay in reporting to the administrative authorities and, presumably, a delay in sharing information with the Board of Directors. These are two issues we have identified and pointed out.

The special investigation committee has made recommendations to investigate the causes and prevent recurrence, and my understanding is that the Company has properly established systems so misconduct is not repeated. However, building a system is not the end of the process; it is necessary to see that it is properly operated. In this regard, as an outside director, I have access to and review the minutes of the monthly Group Compliance Committee meetings.

Regarding the reform of the corporate culture that led to this misconduct, as outside directors, we have asked for closer communication with those working on site to improve openness, and also for changes in mindsets of those working at the factory. In this regard, education and study are not the only tools; we also hold town hall meetings to facilitate smooth communication and exchange of opinions between those actually working on the front lines and their supervisors and senior management, and we believe this is proving to be effective.

As for the second issue pointed out, which is the review of the system for reporting to the Board of Directors, in addition to regular reports, any other events are to be reported to the holdings company’s Board of Directors on an ad-hoc basis. A great deal of time has been spent among Sawai Group Holdings’ Board of Directors, and reports have been very thorough; I have also asked questions and offered my opinions. My feeling is that the Board of Directors will discuss what we as outside directors will do in response to the timely sharing of information.

Next is how Sawai fulfilled its responsibilities as a pharmaceutical supplier. I also serve as the Chairman of the Nomination, Remuneration, and Other Governance Committee, and the committee has held Sawai’s officers at the time of the incident clearly accountable by giving them

pay cuts. As mentioned just a moment ago, we outside directors will do our utmost to ensure that such a thing never occurs again, and if, for some reason, it does, we will do our best to deal with it as swiftly as possible.

Q.2 Monitoring by the Board of Directors and fostering corporate culture

Investor: What kind of monitoring does the Board of Directors do? I’d like to particularly ask Director Mitsuka, what do you think needs to be done and monitored in the future to foster culture, based on your experience?

Mitsuka: I would like to divide my explanation into two parts: monitoring at what we call the “management level,” and, especially in the area of culture, understanding and monitoring what is happening in the field.

First of all, in the formulation of the medium-term business plan, we imposed quite demanding requirements for monitoring in light of the aforementioned incident. Specifically, we asked that KPIs be established not only for financial indicators but also for non-financial indicators: for example, KPIs for manufacturing and quality information management, as a company, and more detailed KPIs for divisions.

In fact, many KPIs are not disclosed externally because of issues related to product quality, but the KPIs formulated in the new plan are shared internally, and the Senior Vice President of the Reliability Assurance Division has explained to us at Board meetings how the Company is progressing in accordance with the KPIs.

To give a sense of the Group’s KPIs, let me give an example in the area of quality. The worst-case scenario here would be a product recall, but the Group determines the severity of quality deviation, whether it falls into Class I, Class II, or Class III, before reaching that scenario. In addition, there had previously been a lack of corrective action and preventive action (CAPA) to address such deviations, and there were many cases where we knew we had to take action, but we did not have enough people to do so. Now, we are monitoring how well that is being handled on average as a KPI.

Secondly, as for fostering culture and what issues are currently present in the field, there are three major issues that need to be remedied, in my opinion.

The first is about the pressure to increase production. When I read the records and exchanges when the inappropriate testing was in its earliest stages, it was all about boosting production as a top priority, with a tendency to justify production increases because the market wants it. I also think that the Group needed to address the rapidly growing market. It should be noted that even today, the pressure to increase production continues to remain in the

policy of building new plants and supporting increased production while ensuring quality.

The Group's corporate commitment to ensuring quality as a vital mission, not just production volumes and sales, have been set out as KPIs. Now, it is necessary to pass these down to the senior vice president of each division, or to their subordinate or even further down the line as officers constantly assess whether these KPIs are moving toward improvement over the medium to long term.

The second issue is how we approach the pressure to ensure zero quality irregularities or issues. I think we, as a Group, need to explore what the proper approach should be in the culture of our workplaces.

Third is the issue of securing personnel. Just giving a command is unlikely to solve this kind of concern. What I personally think is particularly important is not simply to increase headcount, but to secure talent at a level that can provide guidance in the field—people who can answer questions from operators in the field, and of course the skill level is important.

Also, though you may never be able to completely eliminate the reticence that a line worker will have to consult with their busy supervisor despite a tough situation in the field, I believe it is important to establish a system facilitating open consultation.

To relieve the pressure to totally eliminate problems, it is important to first instill the idea that low-level problems can happen, and then let them handle these so that they do not lead to major problems.

In fact, the system for handling production problems was originally established by GMP, and it is based on the premise that deviations can occur, and when deviations do occur, it is stipulated that this should be done and that CAPA should be performed. It will be important to keep an eye on these issues in the long run as to how to control them so that they do not pop up again.

Deviations have also occurred as reported by the Reliability Assurance Division. In the short term, there has been an increase. We believe that this is due to increased sensitivity, and we are now in the process of monitoring how accurately these deviations are being handled over the long term. In a year or two, we hope to see a reduction in the number of items ending in recall.

In addition, the Group's large factories are dispersed throughout Japan, and we are very careful to watch for information barriers between the headquarters and production sites, and to make sure that they are not being unilaterally given unreasonable expectations.

Looking at the exchanges at the earliest stages of the inappropriate testing in question, there were instances where the problem was actually in the field, and emails sent to the headquarters went unanswered. Therefore, during my recent visit to the Daini Kyushu Factory, I have been able to review in detail through documents how the

factory is communicating with the headquarters as part of the ongoing project for inspection based on certification of approval.

At least from what the general manager said, I could see that the headquarters was willing to take ownership and cooperate to solve the problems at that factory. As a member of the Board of Directors, I would like to make sure that this is the case at all factories going forward.

Q.3 Human resource retention initiatives

Investor: I have a question regarding personnel retention. I believe it was mentioned in the Integrated Report 2024 that the working environment is unavoidably challenging and that there is turnover, especially among young employees. What are your thoughts on retention?

Mitsuka: To your point, it has been two years since I joined the Sawai Group, and when I first visited various sites, I was surprised to hear that there was a lot of turnover in the workforce. What is particularly noticeable when visiting a production site is that physical strength is required there, such as when handling heavy items.

Reviewing the data through December 2024 shows an annualized resignation rate of 3.94% overall, and 4.21% at the Manufacturing Division. My impression was that this was a high retirement rate for a new drug manufacturer versus my general perception at around 2% to 3%. However, since employees who have resigned account for about 10% in the entire manufacturing industry in Japan, Sawai's figure of about 4% is not particularly high when viewed through the lens of the manufacturing industry as a whole. Since approximately 70% of Sawai's workforce is in production, and the Manufacturing Division has a large number of part-time workers, the figure of 4.21% for the Manufacturing Division and 3.94% for the Group as a whole is not particularly high, but rather normal.

However, as we consider increases in factory capacity utilization rates in order to further boost production, this resignation rate will undoubtedly become a bottleneck in securing and training human resources, and I believe that how to improve this situation is an issue that should be addressed.

Fortunately, compared to the previous fiscal year's data, the numbers have improved slightly. In fiscal 2023, the annualized resignation rate was 4.1% for the Group overall, while in fiscal 2024, the annualized rate through December was 3.94%, a slight improvement. As a member of the Board of Directors, I can confirm that the most recent trend is in the right direction. However, when we look into resignation details, we find that many, especially in the Manufacturing Division, resigned due to job changes and



poor health, and we surmise that the workplace must be a considerably busy and stressful one.

In any case, Sawai produces so many items that the kiln where medicine is made changes items every two days. In addition, in order to log all factory data, a manufacturing test support system ensures that a record is kept of what and how much was weighed, one by one. I saw the work site myself, and there was a considerable amount of going back to the previous stage and redoing work. My feeling was that, for those who were not used to such a practice, the stress of having to ensure zero issues must be even greater than the physical exhaustion.

Therefore, I see one of the major challenges in health management as how to reduce the stress of those working in the Manufacturing Division. I also feel that it is an urgent and important management issue to have each and every person in the Manufacturing Division work in a healthy, happy and energetic manner in order to make the generic drug business a sustainable and healthy business. I would like to keep an eye on resignation rate figures while taking such details into account.

Q.4 Discussion on increasing the number of female leaders

Investor: Ms. Todo, you commented that cultivating female directors and executive officers from within is an important issue. We would like to know the context behind your awareness of this issue.

We would also like to know what kind of discussions are taking place in the Board of Directors regarding increasing the number of female executives and other diverse leaders.

Todo: Since I took office, I have said that it is my goal and dream to sit on the Board of Directors with female directors from within the company. As a sign of my intent to make this a reality, I held a roundtable discussion with female employees together with the now-Chairman Sawai shortly after assuming my position, and the discussion was published

in the company newsletter.

Despite this, the goal of appointing a female director from within the Company has not yet been achieved. Though it may not be appropriate for me to speak on the issue considering I am in this very same position, recruiting female directors from outside Sawai will not help it realize the active engagement of women. I believe it only makes sense to find such a person within the Company.

However, I cannot say that there are many female employees at Sawai today who are in management positions or who wish to be in management positions. It has long been my view that active engagement by women can only be realized in a company where all employees, not just women, are actively engaged. I believe that Sawai's female employees understand this concept, as I have expressed it at each conversation I have had with them and at our Board of Directors meetings.

To put it simply, I believe that a company cannot be a place where all employees can be actively engaged, especially in management positions, without the active engagement of women, and other minorities. In other words, to conceptualize an environment in which women can be actively engaged will lead to a corporate attitude that conceptualizes facilitative working environments for all employees.

I am aware that this concept is understood and that Sawai is taking actions in this area. Furthermore, I understand that through the implementation of unconscious bias training for all employees, Sawai has achieved results such as broadening the understanding of what constitutes a facilitative working environment.