

PASSION FOR HEALTH

**SUSTAINABILITY
REPORT 2021**

Contents

Introduction	Passion for Health	4
	CEO Message	10
	2020 at a Glance	12
	About Us	14
	Our Vision & Mission	15
	Company History	16
	Business Model	17
	Business Performance	18
Sustainability Highlights	Materiality Assessment	22
	Highlight 1. Building a Sustainable Supply Chain	24
	Highlight 2. Strengthening Product Responsibility and Safety	30
	Highlight 3. Strengthening Environmental Management	38
Sustainability Management	Talent Management	46
	Protecting Human Rights	52
	Health and Safety Management	54
	Social Contributions	58
Corporate Governance	Governance Structure	64
	Risk Management	67
	Ethics and Compliance Management	70
Appendix	Financial Data	78
	Non-Financial Data [Environmental Performance]	82
	Non-Financial Data [Social Performance]	84
	GRI Standards Index	88
	SASB Standards	90
	Sustainability Initiatives	91
	Awards and Associations	93
	Independent Assurance Statement	94



PASSION FOR HEALTH



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About This Report

Report Overview

Samsung Bioepis is committed to pursuing sustainability management with a focus on ESG (Environment, Social, and Governance). We plan to share our yearly achievements and activities transparently through our annual report, and enhance the effectiveness of our sustainability management by gathering our various stakeholders' opinions and reflecting them.

Reporting Period

This report covers our activities and performance from January 1, 2020 to December 31, 2020, and for some key issues, our activities and performance in the third quarter of 2021 are included. Quantitative performance data for the latest three years, from 2018 to 2020, are presented to provide trend analysis.

Reporting Principles

This report is prepared in accordance with the Core Options of the Global Reporting Initiative (GRI) Standards. It also reflects our activities and achievements that are aligned with the the Sustainability Accounting Standards Board (SASB) and the Ten Principles of the United Nations (UN) Global Compact.

Reporting Scope

This report covers the sustainability management activities and performance. Financial performance information has been prepared based upon consolidated K-IFRS accounting standards. Both our financial information and non-financial information are reported for the fiscal year based on the financial disclosure standards while data on our energy use and greenhouse gas emissions are reported based on the results of emission verification.

Report Verification

To enhance the internal and external reliability of information included in the report, Samsung Bioepis commissioned third-party verification to the British Standards Institution (BSI), an international standards organization to ensure reliability and fairness in the reporting process, data and other contents. Detailed assurance statements are included in the Appendix.

Company name	Samsung Bioepis Co., Ltd.
Location	76, Songdogoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea
Dept. for Inquiries	ESG Secretariat
E-mail	epis.esg@samsung.com
Website	https://www.samsungbioepis.com

PASSION FOR ENVIRONMENT

Samsung Bioepis is engaged in various environmental management activities at each step of value chain, with an aim to minimize our environmental impact over the product life cycle.

We take great care in managing the waste, air pollutants, and hazardous chemicals that are produced at our worksites, and constantly monitor climate change trends and impacts as a way to take an effective response to global warming.

Going forward, we will continue to make a concerted effort to protect the health of our planet as well as for the health and happiness of humanity.



INTERACTION WITH SOCIETY

Our diverse social contribution activities are carried out under the vision of "Enabling People! Together Towards the Future!". Samsung Bioepis is doing its part to make a meaningful difference in the lives of our communities where we live and work. Part of our activities include 'Youth Bio Class' and other activities such as fundraising for social contribution that are focused on fostering the next generation and supporting our communities.

We are committed to fulfilling our social responsibility for improving the lives of people in our communities as well as across the world.



REFORMATION OF GOVERNANCE

Samsung Bioepis' Board of Directors seeks to support the company's sustainable growth and enhance stakeholder value with fair and rational decision-making process.

The Board is composed of directors with diverse backgrounds and expertise.

Transparent management helps Samsung Bioepis to realize one of its corporate core values - Honest.



CEO Message



Dear Stakeholders,

We are pleased to share our very first sustainability report. This report reflects our commitment to examine our sustainability efforts and our determination in taking our actions to the next level. Since our establishment in 2012, Samsung Bioepis has been dedicated to improving access to high-quality biologic medicines at affordable prices and has rapidly grown to become a leading player in the biopharmaceutical sector through innovations in product development, a firm commitment to quality, extensive global network and marketing through our partnerships and our seasoned professionals.

At the center of our priorities and vision are the patients around the world without viable treatment options. This is why we are working to help create a healthier and more sustainable future for all and reshaping the way we work to incorporate Environmental, Social and Governance (ESG) values and goals. Samsung Bioepis has strengthened its supply chain sustainability through carefully-chosen partners and smooth communication. We have constantly enhanced our product stability based on our unmatched research and development expertise and strict quality control process. In a recognition of our ongoing efforts, Samsung Bioepis was acknowledged as Authorized Economic Operator (AEO) by the Korea Customs Service in January 2020.

To be part of addressing environmental impacts that we all face, Samsung Bioepis has been putting more efforts to reduce energy consumption, while improving energy and resource efficiency. Our new headquarters, which opened in early 2021, are equipped with energy-saving materials from specially coated glass to highly energy-efficient LED lights.

Taking wider responsibility as a company, Samsung Bioepis maintains and focuses on policies and practices that encompass our social responsibility. Samsung Bioepis is firmly committed to recruiting and retaining the talented people that will enable us to improve the health of patients worldwide. We seek to foster a healthy environment where all of our colleagues can reach their full potential. We do this by providing a comprehensive employee benefits program and learning opportunities as well as ensuring health and safety for our colleagues and stakeholders.

In addition, Samsung Bioepis is committed to making a meaningful difference in the lives of our communities where we live and work. Samsung Bioepis' various programs such as cooperation between industry and academia are focused on supporting and fostering the next generation of talented people. Building on these efforts, Samsung Bioepis' employees give back to their communities through volunteer service and charitable donations.

Meanwhile, as part of our commitment to conducting business on an ethical basis, Samsung Bioepis operates risk management processes and works in full compliance with applicable laws and regulations. For our governance structure, Samsung Bioepis' Board of Directors are composed of directors with diverse backgrounds and expertise. The general meeting of shareholders appointed a female director as one other director in 2020 and appointed a female director as one inside director in 2021 to expand gender diversity and bolster female leadership.

Going forward, Samsung Bioepis will continue to establish a long-term sustainable business plan and operate business by emphasizing the importance of ESG values. Underscoring our commitment, we have recently formed a dedicated ESG team. The team will explore and implement key initiatives that will navigate our transition towards a sustainable business from 2022 onwards.

Samsung Bioepis remains committed to developing and expanding a broad and industry-leading portfolio to stay competitive and propel our growth. We are further committed to being a socially responsible and sustainable company by listening to our stakeholders' voices and understanding what their expectations are. Samsung Bioepis has taken a first significant step to evolve sustainability efforts and will continue to make such efforts that help address important issues that matter to our business, our stakeholders and society.

Sincerely,

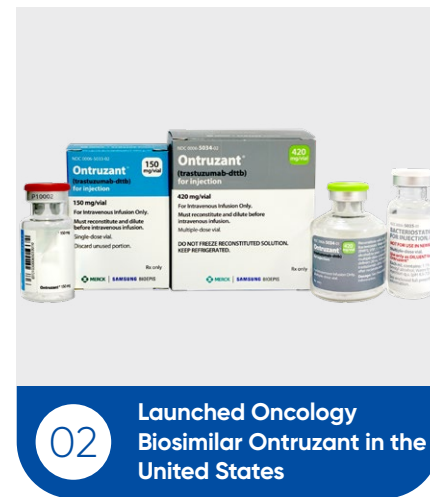
Christopher Hansung KO
President and Chief Executive Officer

2020 at a Glance



01 Obtained Authorized Economic Operator (AEO) Certification

Samsung Bioepis obtained Authorized Economic Operator (AEO) certification from the Korea Customs Service in January 2020. AEO certification is the international certificate recognized by the World Customs Organization (WCO) which allows certified companies to enjoy benefits such as shorter customs clearance time for five years and simplified customs procedures. AEO certification allowed Samsung Bioepis to strengthen its global supply chain management capabilities.



02 Launched Oncology Biosimilar Ontruzant in the United States

Samsung Bioepis launched its first oncology biosimilar Ontruzant (SB3, trastuzumab biosimilar) in the United States in April 2020. Ontruzant, marketed and distributed by commercial partner Organon, is used for treatment of patients with breast cancer or metastatic gastric cancer. Ontruzant's sales are growing in the United States based on the affordable price and sales experience gained from Europe.



03 Initiated Phase 3 Clinical Trial for SB15

Samsung Bioepis initiated Phase 3 clinical trial for SB15, the company's proposed aflibercept biosimilar in July 2020. The company plans to conduct the Phase 3 clinical trial on 446 patients with neovascular age-related macular degeneration in 10 countries.



04 Won Two Awards at Prestigious Red Dot Award 2020

Samsung Bioepis won two awards from the prestigious international award, the 'Red Dot Award 2020' for 'Brand Design & Identity' and 'Packaging Design' in August 2020. The awards were in recognition for the company's patient-centric design. On top of that, in November, Samsung Bioepis also received an award for brand design at the Good Design Selection Korea.



05 Launched Oncology Biosimilar Ontruzant in Brazil

Samsung Bioepis launched its oncology biosimilar Ontruzant in Brazil, Latin America's largest pharmaceutical market, in August 2020. This oncology biosimilar is supplied in Brazil through a Productive Development Partnership (PDP)¹⁾ with the Brazilian government, local research organization, and local partners. Through PDP, the company is expected to generate steady sales revenue from the Brazilian market which has high potentials for growth.



06 Received European Commission Approval for Aybintio

Samsung Bioepis received marketing authorization for its oncology biosimilar Aybintio (SB8, bevacizumab biosimilar) from the European Commission (EC) in August 2020, becoming the first South Korean company to gain approval for a bevacizumab biosimilar. The approval provides a new biologic treatment option for patients suffering from colorectal cancer or non-small cell lung cancer.



07 EMA and FDA Initiated Review of Regulatory Filings for SB11

The Marketing Authorization Application (MAA) for SB11 (ranibizumab biosimilar), Samsung Bioepis' first ophthalmology biosimilar, was accepted for review by the European Medicines Agency (EMA) in October 2020, and the Biologics License Application (BLA) was accepted by the U.S. Food and Drug Administration (FDA) in November 2020. SB11 is the sixth biosimilar developed by Samsung Bioepis.



08 Initiated Phase 1 Clinical Trial for SB16

Samsung Bioepis initiated Phase 1 clinical trial for SB16, the company's proposed denosumab biosimilar, in November 2020. Its Phase 3 clinical trial was initiated a month after the Phase 1 trial. Samsung Bioepis plans to run the clinical trials smoothly and expand treatment options for patients with osteoporosis.



09 Won Biosimilar Initiative of the Year at the Global Generics & Biosimilars Award

Samsung Bioepis won a prestigious Biosimilar Initiative of the Year at the 'Global Generics & Biosimilars Awards 2020'. The award was in recognition of the company's outstanding achievements and setting new milestones to prove its leadership in biosimilar industry over the past year.

¹⁾PDP (Productive Development Partnership): A policy enacted by the Brazilian government to support the market entry of overseas companies and to promote the development of Brazil's own bio-industry.

About Us

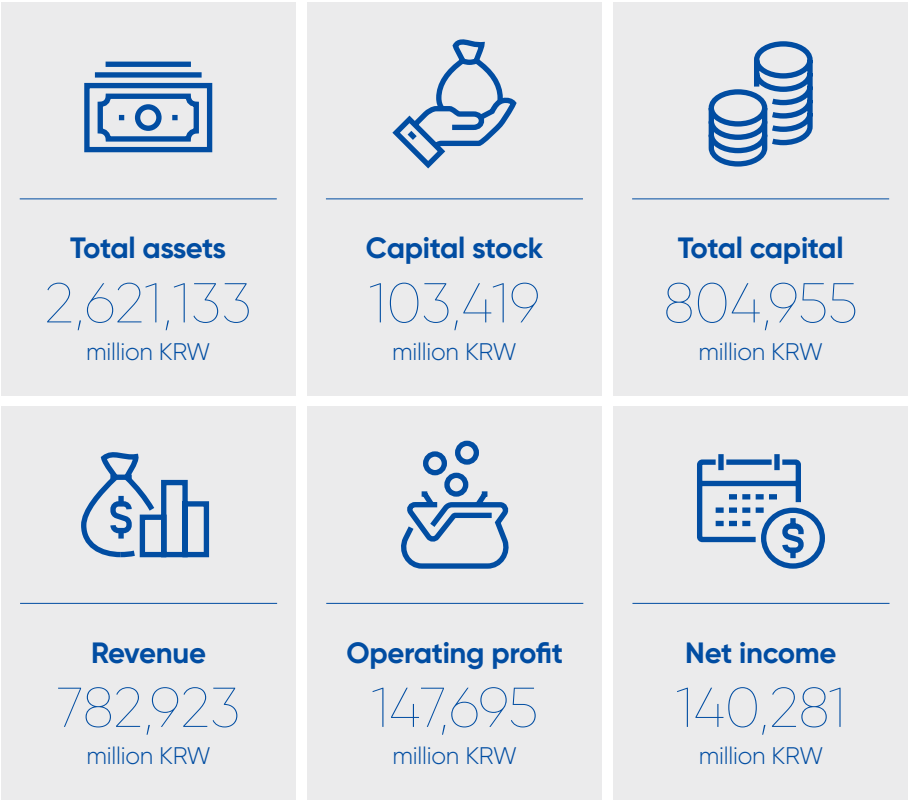
Established in 2012, Samsung Bioepis is a biopharmaceutical company dedicated to enhancing access to high-quality biologic medicines to more patients at affordable prices. Through innovative research and development platforms, combined with optimized supply chain capability and extensive marketing partnerships, we have developed a broad and industry-leading portfolio of 10 biosimilars, and among them, five products are approved and launched in multiple countries around the world, as of September 2021. Samsung Bioepis will continue to drive innovations and find smarter, faster ways of getting high-quality biologic medicines to patients in need.

(As of September 2021)

Company name	Samsung Bioepis Co., Ltd.
CEO	Christopher Hansung Ko
Founded	February 28, 2012
Industry	Biopharmaceutical R&D
Headquarters	76 Songdogoyuk-ro, Yeonsu-gu (Songdo-dong) Incheon, Republic of Korea
Overseas subsidiaries	UK, Switzerland, The Netherlands, Poland, Australia, Hong Kong, Taiwan, Brazil, US, Israel
No. of employees	940

2020 Performance

(As of December 2020)



Our Vision & Mission

At Samsung Bioepis, with our united passion for health and vision for improving the lives of patients, we are relentless in our efforts to enhance access to high-quality biologic medicines to more patients at an affordable price. Our long-term vision is to become one of the leading biopharmaceutical companies that can help address the unmet needs of patients without viable treatment options.

Our advanced development platform allows us to speed up the development of high-quality biosimilars, by implementing rigorous quality control at each step of the development process and through continuous innovation across research and development, clinical development, and regulatory review and approval process. We have come a long way since our founding in 2012 and now, we are one of the world-leading biosimilar companies, with five of our biosimilars available around the world.

We embed 'process innovation' at every stage of the development process, and we have established world-class commercialization and manufacturing partnerships to meet the demands of healthcare systems across the globe. While our focus remains on the development of high-quality biosimilars, we are now taking our first steps into novel biologic development. We are also looking to enhance the patient experience, including through the development of ergonomic autoinjector devices and extended storage conditions for our products.

Our Vision, Mission and Core Values



Company History

Since our establishment in 2012, we have developed the industry's most rapidly advancing biosimilar medicines portfolio and have become a leader in biosimilar industry.

2012



- Samsung Bioepis established and opened first R&D Center

2013-2015



- Infliximab and etanercept biosimilars approved by Korea's Ministry of Food and Drug Safety (MFDS)

2016-2018



- Infliximab and etanercept biosimilars approved by the European Commission (EC)
- Infliximab biosimilar approved by the U.S. Food and Drug Administration (FDA)
- Adalimumab and trastuzumab biosimilars approved by the EC and MFDS

2019



- Trastuzumab, etanercept and adalimumab biosimilars approved by the FDA

2020



- Bevacizumab biosimilar approved by the EC

2021



- Samsung Bioepis moves into the new headquarters located in Songdo, Korea
- Bevacizumab biosimilar approved by MFDS
- Ranibizumab biosimilar approved by the EC and the FDA

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Business Model

Business Areas

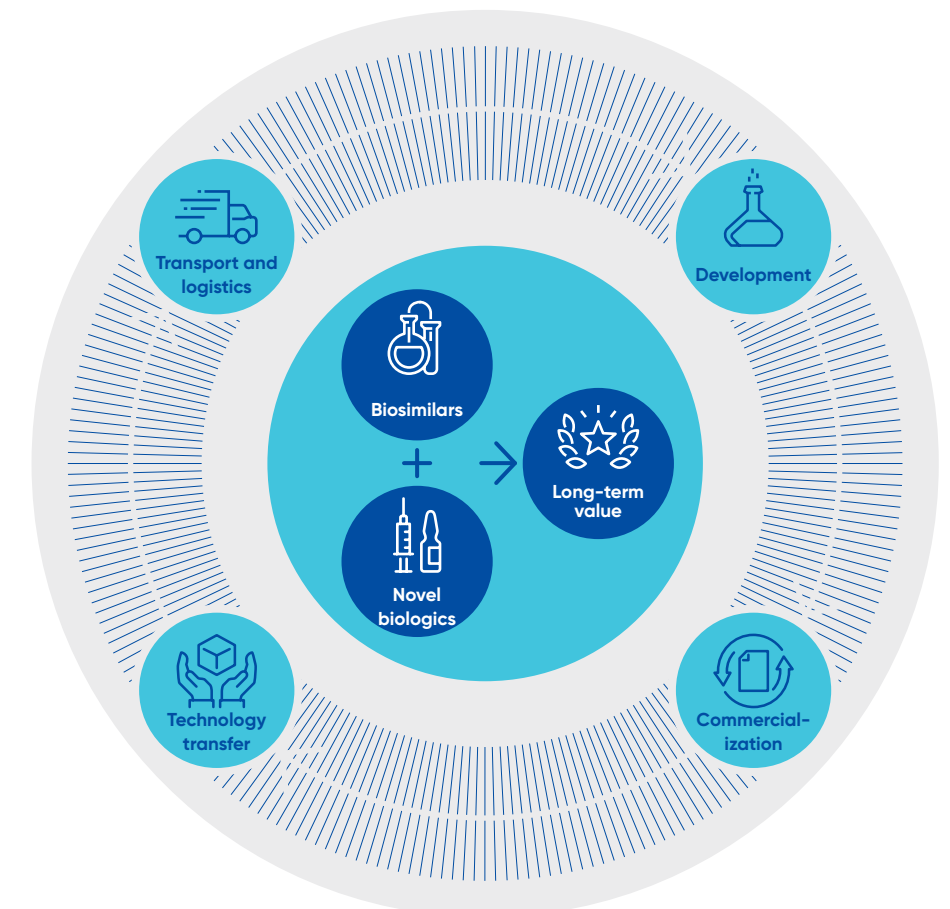
Our core business lies in the development and commercialization of biosimilar products. We are working to expand into novel biologics business in the long term for sustainable growth.

Main Product Lines

We apply our R&D process to six therapeutic areas: oncology, immunology, ophthalmology, hematology, gastroenterology and endocrinology. So far, we have three immunology products and two oncology products launched across multiple regions around the world, and we are preparing to launch products in other therapeutic areas as well.

Product Development, Manufacturing, Distribution and Sales

Samsung Bioepis is committed to working in close cooperation with global contract research organizations (CROs) and contract manufacturing organizations (CMOs) in our development and manufacturing process. Our supply chain, spanning Europe, North America and Asia, ensures stable production and timely supply of biological medicines to patients around the world. We have established a worldwide sales network through extensive global commercialization partnerships in various markets such as Korea, Europe, the United States, Australia, Canada, the Middle East and Brazil.



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Business Performance

(As of September 2021)



Americas

- We have four biosimilars (infliximab, etanercept, adalimumab, trastuzumab) approved in the US and two of them (infliximab, trastuzumab) are currently available.
- Since launch, the uptake of our infliximab biosimilar is increasing, partly due to the Department of Veteran Affairs tender which was secured in 2018.
- We have three biosimilars (infliximab, etanercept, adalimumab) launched in Canada.
- Three biosimilars (infliximab, etanercept and trastuzumab) are approved in Brazil and two of them (etanercept, trastuzumab) are currently available. Our etanercept biosimilar was the first anti-TNF biosimilar to become available in Brazil in 2019.



Europe

- We launched our first biosimilar in Europe in 2016, and now have five biosimilars (infliximab, etanercept, adalimumab, trastuzumab, bevacizumab) available in Europe.
- In Europe, our immunology biosimilars have been used to treat approx. 240,000¹⁾ patients.

¹⁾Third Quarter 2021 Financial Results and Business Update, Biogen (2021.10)

Global Sales Growth

In countries outside Korea, Samsung Bioepis maintains an extensive sales and marketing network through our global commercialization partnerships with Biogen and Organon. Globally, in 2019, annual product sales exceeded 990 million USD (approximately 1.1 trillion KRW). In 2020, through close cooperation in the midst of COVID-19 pandemic with our partners Biogen and Organon, we achieved sales of 1,119 million USD (approximately 1.3 trillion KRW).

Sales continued to grow steadily in the September 2021, amounting to 921 million USD. Cumulatively, as of the September 2021, sales in Europe of three TNF inhibitor biologics (Benepali, Imraldi and Flixabi) came to 3,246 million USD (approximately 3.8 trillion KRW) and are steadily increasing. In addition to the stable growth of existing products, we expect to see a continued rise in global sales with the following launch of a new ophthalmology biosimilar.

Product sales performance of global commercialization partners

(Unit: million USD)

Partner	Products and Regions	2019	2020
Biogen	· Europe: three anti-TNF biosimilars - Benepali (SB4, stanercept biosimilar) - Imraldi (SB5, adalimumab biosimilar) - Flixabi (SB2, infliximab biosimilar)	738	795
	· Ex-Europe/Korea: three anti-TNF biosimilars - Brenzys (SB4, etanercept biosimilar) - Hadlima (SB5, adalimumab biosimilar) - Renflexis (SB2, infliximab biosimilar)	252	324
Total		990	1,119

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Asia

- We have partnership agreements with 3SBio and CBC Group/ AffaMed Therapeutics in China.
- We have five approved biosimilars (infliximab, etanercept, adalimumab, trastuzumab, bevacizumab) available in Korea.
- Two biosimilars (etanercept, adalimumab) is approved in Israel and etanercept is currently available.
- Two biosimilars (etanercept, trastuzumab) are approved in Taiwan.
- Our adalimumab biosimilar is approved in Saudi Arabia.
- Our etanercept biosimilar is approved in Ukraine.



Oceania

- Four biosimilars (infliximab, etanercept, adalimumab, trastuzumab) are launched in Australia.
- Our etanercept biosimilar is approved in New Zealand.

Global Commercial Partnership

At Samsung Bioepis, we aim to ensure 100% supply continuity for patients. We achieve this by efficiently managing manufacturing and storage sites and working with renowned Contract Manufacturing Organizations (CMOs) across Europe, North America and Asia. Our manufacturing strategy is established during early stage development in order to ensure commercial supply continuity. Across our portfolio, we have implemented a dual sourcing strategy at all stages of manufacturing, which includes securing additional capacity from a second CMO. At all stages, we closely monitor inventory levels to accommodate market dynamics and fluctuation in demand.

Also, we established an extensive sales and marketing network through our global commercialization partnerships with Biogen and Organon. Biogen is a biotech pioneer with over 40 years of experience of developing, manufacturing and commercializing advanced biologic medicines, that is underpinned by a reliable supply chain record. Organon, a global healthcare company formed through a spinoff

from Merck, also known as MSD outside of the US and Canada, works with customers and operates in more than 140 countries to increase patient access to treatments.

In China, we have established partnerships with 3SBio and CBC Group/AffaMed Therapeutics for the clinical development, regulatory registration and commercialization of our products. Through the Productive Development Partnership (PDP) we have with Bionovis and Bio-Manguinhos, we have been supplying our etanercept and trastuzumab biosimilar to Brazil's Ministry of Health while also contributing to the development of the local biopharmaceutical industry by transferring manufacturing technology to our local partners.

We will continue to pursue the global growth of our biosimilar business through strong partnerships with the most capable global CMOs and commercialization partners.

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Sustainability Highlights

- 22 — Materiality Assessment
- 24 — Highlight 1. Building a Sustainable Supply Chain
- 30 — Highlight 2. Strengthening Product Responsibility and Safety
- 38 — Highlight 3. Strengthening Environmental Management

Materiality Assessment

Materiality Assessment Process

For this report, we conducted a materiality assessment to determine the content to be included and to identify key sustainability management issues that could affect the overall business environment. In forming a sustainability issue pool, we analyzed best practices from leading companies in our industry, global assessment metrics, and other external ESG requirements. We also reviewed media reports pertaining to our company's sustainability. The final issues selected for the report were determined through an assessment of business impact and stakeholder interest pertaining to the issue pool we formed through this analysis.

We aim for this report to contribute to the development of Samsung Bioepis as a leading company in sustainability management by transparently disclosing our efforts and performance on the selected issues.

01
STEP

Assemble sustainability management issue pool

	Industry benchmarking	· Survey of industry-specific sustainability issues and trends · 15 Global biopharmaceutical companies
	Analysis of global assessment metrics	· Global standards and initiatives pertaining to sustainability issues · GRI Standards, DJSI, ISO 26000, KCGS, UNGC, UNSDGs · Industry-specific standards · SASB, PSCI
	Analysis of external ESG requirements	· ESG assessment items of potential clients
	Media research	· Survey of news articles from 2020 · 1,013 relevant articles out of 1,253 articles in total
42 sustainability management issues identified		

02
STEP

Materiality assessment

	Analysis of stakeholder interest	· Analysis of external ESG requirements and scoring of media research results · Weighing of issues through internal interviews
	Analysis of business impact	· Analysis of global assessment metrics, scoring of industry benchmarking results · Weighing of issues through internal interviews
Issues scored according to materiality		

03
STEP

Determine reporting issues and content

	Internal/external review	· Review of Samsung Bioepis management and supervising departments · Consulting by external sustainability experts
Three core reporting issues, seven important reporting issues selected		

Materiality Assessment Results

The results of the materiality assessment identified the following areas as core sustainability management issues for Samsung Bioepis in 2021: sustainable supply chain selection and evaluation; strengthening product responsibility and safety; and strengthening environmental management system. Our management policies and activities on these core issues are reported in the Sustainability Highlights chapter, and all other related issues are included throughout the report.



Rank	Sustainability reporting issues	Report pages
CORE	1 Sustainable supply chain selection and evaluation	24-29
	2 Strengthening product responsibility and safety	30-37
	3 Strengthening Environmental Management Systems	38-43
	4 Enhancing integrated risk management systems	67-69
IMPORTANT	5 Compliance with standards for clinical trials and animal testing	33
	6 Practicing ethical management	70-75
	7 Employee health and safety management	54-57
	8 Enhancing resource efficiency for a circular economy	43
	9 Prohibition of discrimination and respect for diversity	48
	10 Reducing energy consumption and enhancing efficiency	40-41

Stakeholder Communication

When it comes to sustainability management activities, Samsung Bioepis places high value on stakeholder communication. We have established a customized communication channel for each stakeholder group, including governments, customers, employees, suppliers, and local communities.

Samsung Bioepis will strive to create shared value with the society, and fulfill our environmental responsibilities by reflecting stakeholder opinions in our business activities and building solid, trusting relationships through close and continuous communication.

Stakeholder communication channels

Stakeholder group	Communication channel	Communication Issues
Customers	Website, Customer Service Center, Media outlets	Status of product development, product information
Employees	In-house Bulletin Board, Internal Communications Channel 'EPISIN', Labor-Management Council, Counseling Center, Reporting channels (Compliance, Audit Team)	Company news, organizational culture, benefits, HR system, employee and department profiles, industry news, company events, etc.
Suppliers	Regular business meetings	Fair trade, market trends/status, co-prosperity
Community	Volunteering, CSR activities	Contributing to local economies, nurturing young scholars, social contributions
Schools	Research Note competition at universities	Nurturing industry talents
Governments	Public hearings, Meetings, Seminars, Newsletters, Local government websites	Government policy changes, law/regulation (tax) compliance, industry trends, local government trends
Industry associations	Participation in meetings and other events	Expanding the industry ecosystem

COOPERATION FOR SUSTAINABILITY

Building a Sustainable
Supply Chain

IMPORTANCE

Amid growing global interest in supply chain-related environmental and human rights issues, sustainability management is becoming ever more important in the rapidly globalized pharmaceutical supply chain. Supply chain issues are pointed to more frequently as major business risks, and there is increasing demand from a range of stakeholders, including customers and investors, for broader supply chain disclosures.

APPROACH

Samsung Bioepis selects suppliers according to strict criteria aimed at building and operating a responsible supply chain, and they are managed through a transparent registration system. For CMOs in particular, we carefully select companies that have obtained international standard (ISO) certification for their environmental management, energy management, and occupational health and safety management systems, verifying that they systematically practice environmental and safety management. Going a step further, we are reviewing the introduction of a policy for the preferential use of eco-friendly transportation as a way of governing the environmental impact of our supply chain. We are also discussing the use of additional ESG evaluation items in our processes for supplier selection, regular evaluations, and contract renewal.

PERFORMANCE

- Distribution of 2016 Supplier Code of Conduct
- CMO ISO Certifications Obtention Rate



80%

ISO 14001
Environmental
Management System



70%

ISO 45001
Occupational Health and
Management System



40%

ISO 50001
Energy
Management System



Supply Chain Operation and Management

Supply Chain Operation

Our Supply Chain Philosophy

At Samsung Bioepis, we work closely with our partners in all processes from product development to distribution as part of our efforts to provide high-quality biopharmaceuticals to the people who need them. We build transparent and equitable business relationships by adhering to fair trade principles and laws, and we provide active, win-win support to our partners to bolster their own competitiveness. Also, by expanding our cooperative efforts to the areas of sustainability and the environment, we are working to strengthen the sustainability of the overall supply chain and to fulfill our social responsibilities.

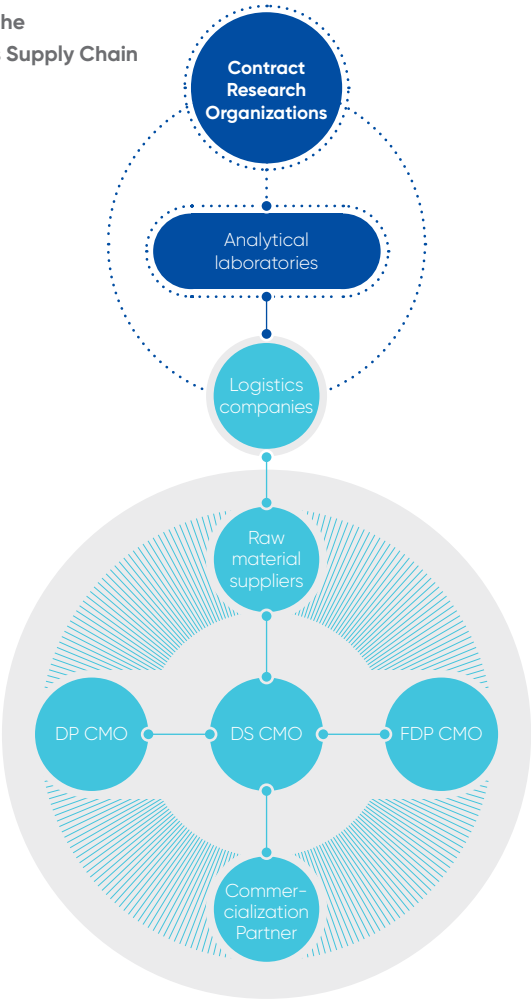
Supply Chain Management

Samsung Bioepis Suppliers

Our partners include raw material suppliers, contract research organizations, contract manufacturing organizations (CMOs), logistics companies (transport, storage), and commercialization partners. Partners from whom annual purchases exceed 1 billion KRW, including CMOs (DS¹/DP²/ FDP³), logistics companies and raw material suppliers, are designated as key suppliers, and to these partners we apply active selection and management processes.

¹Drug Substance
²Drug Product
³Finished Drug Product

Key Suppliers in the Samsung Bioepis Supply Chain



Supplier Selection

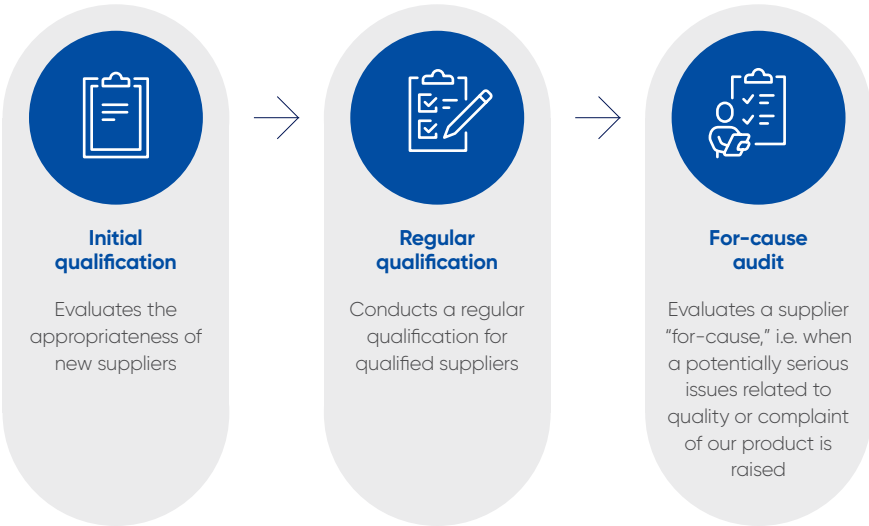
Samsung Bioepis selects suppliers according to strict criteria, and maintains a fair and transparent supplier registration system. In the case of CMOs in particular, to ensure that the biopharmaceuticals they manufacture are part of a responsibly managed supply chain, we carefully select companies that have obtained international standard (ISO) certification for environmental management, safety and health management and energy management systems. Of the ten domestic and overseas CMOs with which we currently do business, eight companies have ISO certifications for environmental management systems, seven companies for occupational health and safety management systems, and four companies for energy management systems.

ISO certifications obtained by CMO suppliers			
(As of September 2021)			
Certification type	Environmental management system (ISO 14001:2015)	Occupational health & safety management system (ISO 45001:2018)	Energy management system (ISO 50001:2018)
Obtation Rate (Among 10 suppliers)	80%	70%	40%

Supplier Evaluations

When sourcing from CMOs for clinical or commercial purposes, we conduct supplier evaluations to minimize risk in these relationships while boosting the competitiveness of our partners. Led by the Quality Team, supplier qualification covers not only quality management systems, but also facilities, equipment, manufacturing management systems and more. We meet regularly with key partners such as CMOs and logistics companies to share the results of these evaluations and discuss steps for improvement. Going forward, we plan to add ESG evaluation items to the processes for supplier selection, and contract renewal.

Supplier qualification process



Supply Chain Operation and Management

Reinforcing Supplier Communication

We are working to reinforce mutual communication with our key CMOs and commercialization partners by meeting with them on a regular basis. At these meetings, we determine the required production quantity for each product based on inventory status and analyses of the market environment, and we discuss related plans. To strengthen our collaboration with CMOs in particular, we regularly engage with them and perform *Health Check Surveys*. By applying new work processes and revising contract terms, we are addressing operational inefficiencies and working together to improve the efficiency of our production operations overall. Also, with our commercialization partners, we are strengthening our collaboration by meeting regularly through regular working-level meetings and decision-making committees.

Supplier communication channels

Communication channel	Description
Supply Roundtable	A consultation body that establishes and reviews optimized production plans by aligning the interests of the parties to ensure continuity of suppliers in the market.
Business Review Meeting	A quarterly business review meeting for facilitating rapid response measures and for discussing issues that are urgent or that need to be raised to higher-level meetings.
Partnership Decision Meetings	A communication forum where decisions are made to achieve shared goals. Held upon mutual agreement, it is the highest-level quarterly or biannual meeting.
Health Check Survey	Reviews improvements to optimize CMO operations and maintain optimal partnerships.

Supplier Code of Conduct

In 2016, Samsung Bioepis published a Third-Party Code of Conduct requiring the compliance of all suppliers. The Code of Conduct represents our determination to adhere to high ethical standards in our business, and mandates compliance with legal and ethical standards, respect for customers and employees, consideration for the environment, health and safety, and compliance with management systems. We encourage all suppliers to adhere to the Code of Conduct so that they can take part in efforts by Samsung Bioepis to protect and improve the health and well-being of people around the world.

 Third-Party Code of Conduct for Samsung Bioepis Suppliers 

Promoting Improvements to Supply Chain Sustainability

Strengthening Supplier Competency

Samsung Bioepis aims to achieve shared growth throughout the supply chain by providing multi-faceted support to our partners to strengthen their business competitiveness. As part of these efforts, in 2020, we created opportunities for our small and medium-sized partners who developed low dead space syringes (dubbed as "K-Syringes") to export by providing active support for the production of prototypes and securing Emergency Use Authorization from the U.S. FDA. Furthermore, from 2021, we have joined with Korean small and medium-sized enterprises to pursue the localization of pharmaceutical packaging materials such as drug substance (DS) pallet boxes and shippers to improve supply stability in the midst of COVID-19 pandemic. By localizing packaging materials, we expect to reduce costs as well as boost sales for our partners and strengthen their technological capabilities. Moreover, to enhance sustainability in our supply chain, we plan to make a policy that prioritizes environmental-friendly transportation and develop materials that are reusable and eco-friendly with our packaging suppliers.

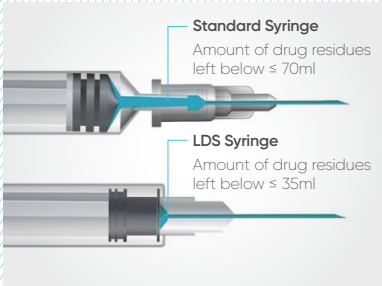
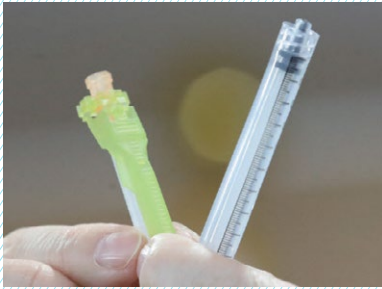
[CASE]

FDA approval of syringes for COVID-19 vaccines accelerated through our partnership

Low dead space (LDS) syringes – often dubbed as "K-Syringes" in Korea – are widely being used to inoculate COVID-19 vaccines around the world as these special syringes are designed to minimize the amount of a vaccine left in the syringe after injection. In the midst of the global race to develop and inoculate COVID-19 vaccines, South Korea's collaboration between large and small companies and government support has been a key driver to mass-produce and export LDS syringes. Samsung Bioepis played a part in supporting Poonglim Pharmatech – our partner company and manufacturer of the syringes, and steering the process to gain approval of the syringes from the U.S. Food and Drug Administration (FDA). Demand for these syringes soared as the syringes enhance the efficiency of COVID-19 vaccines by 20% by minimizing drug residues left in the syringe after use. With the use of LDS syringes developed by Poonglim Pharmatech, a single vial of Pfizer's COVID-19 vaccine could draw six doses, compared to five doses with a standard syringe

Despite a spike in global demand for the syringes from several vaccine manufacturing companies, the syringe manufacturer faced setbacks to receive FDA approval, which typically takes a few months. As our partner company needed help to manage regulatory procedures, we provided our full support to enable our partner company to gain U.S. FDA approval for their syringe. Our collaborative efforts culminated in obtaining emergency use authorization for the syringe by the U.S. FDA on February 17, 2021, just in a month after filing for approval. With the approval, the syringes are widely being used to inoculate COVID-19 vaccines globally. Our cooperation with our partner company is being touted as one of the key success stories of well-established partnership and growth between large and small companies.

Source:
2021.02.18 The Republic of Korea Cheong Wa Dae
Speeches & Remarks
(Link: <http://english1.president.go.kr/BriefingSpeeches/Speeches/945>)



PASSION FOR CREATION

Strengthening Product Responsibility and Safety

IMPORTANCE

Though the global economy continues to see weakness and low growth, demand continues to increase for highly effective, low-cost biosimilars. While biologics are now considered the gold-standard treatment across many conditions, cost continues to be a significant barrier to access. At Samsung Bioepis, we are confident that biosimilars will continue to positively impact all stakeholders across the world over the coming years with governments implementing infrastructures for biosimilars.

APPROACH

By increasing market competition, biosimilars have become an important lever for the innovation of next generation biologics. While our focus remains on the development of high-quality biosimilars, we are now taking our first steps into novel biologic development. We are also looking to enhance the patient experience, including the development of ergonomic autoinjector devices and extended storage conditions for our products.

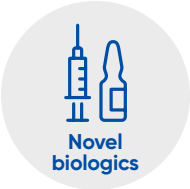
PERFORMANCE

Product development



6/10

Six products approved in ten pipelines
(As of September 2021)



1

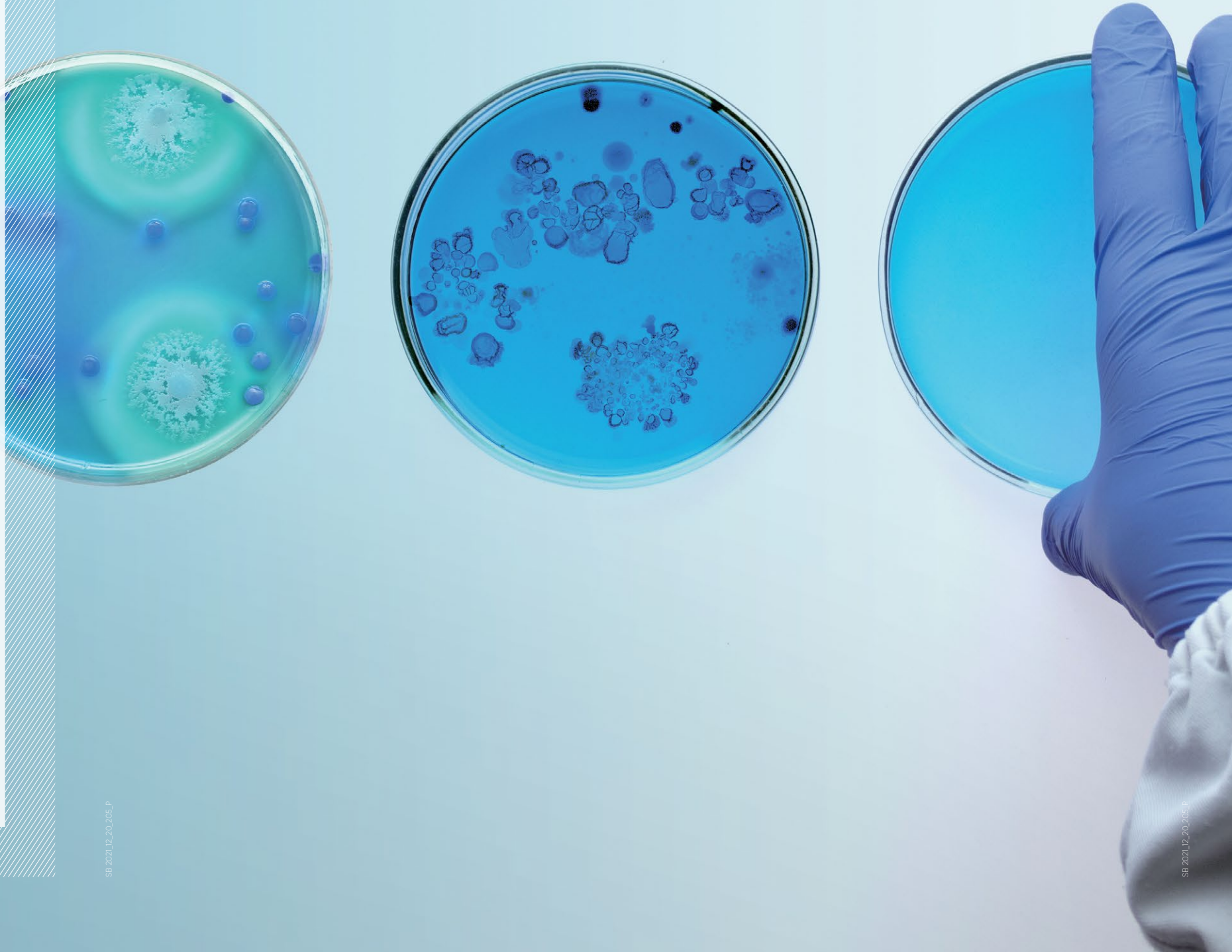
One in development
(As of September 2021)

R&D Investment



180.6

billion KRW
(As of December 2020)



Research & Development

R&D Overview

R&D Investment

Our world-class competitive edge in R&D includes a diverse range of pipelines, advanced development platforms, optimized clinical development and operational capabilities and manufacturing technology, and our outstanding R&D personnel. As a biopharmaceutical R&D company, we have been steadily expanding our R&D investment, involving a substantial amount of 180.6 billion KRW in 2020, approximately 23% of Samsung Bioepis sales that year. As a result, we have a total of 10 biosimilar products in our pipelines, which include five biosimilar products for which we have obtained regulatory approval. With the announcement of a large-scale investment plan in the biopharmaceutical area by Samsung in August 2021, we look forward to the continued growth of R&D investment.

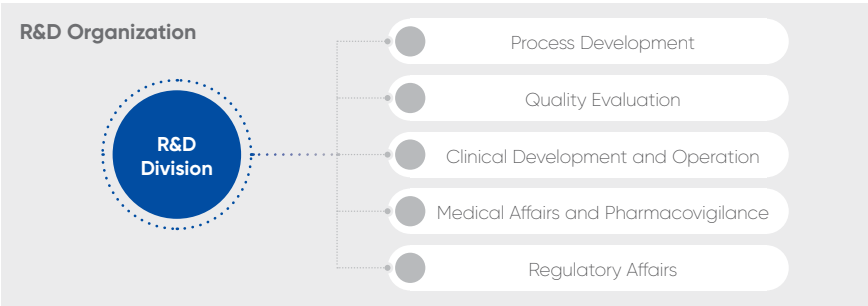
R&D Investment

(Unit: 100 million KRW)

Category	2018	2019	2020
R&D Expenditure	1,059	1,524	1,806
R&D to Sales Ratio (R&D Expenditure/Total SalesX100)	29%	20%	23%

R&D Expertise in Human Resource

The R&D department of Samsung Bioepis consists of five teams and two groups under Development Division 1 and 2. As of September 2021, we have a total of 569 dedicated R&D personnel, including 108 Ph.Ds, 229 with Master's degrees and 232 others. In addition to hiring new and experienced employees in various fields, we have recruited outstanding personnel from global pharmaceutical companies who contribute their professional experiences and passion.



R&D Personnel

(As of September 2021, Unit: persons)

Category	Doctorate	Master's	Other	Total
Personnel	108	229	232	569

Building an Advanced R&D Platform

Through process innovation, we have built an advanced development platform that enables extensive analysis, risk management and strict quality control at each step of the development process, from the preclinical stage to large-scale production.

Strengthening of R&D Capabilities

With this platform, we have been able to successfully produce high-quality biosimilars in a short period of time while minimizing risk at each stage. Going forward, we plan to further strengthen our R&D capabilities through continuous innovation in our development platform.

Clinical Development and Real-World Experience Studies

At Samsung Bioepis, we continue to generate clinical and real-world data, in order to demonstrate the similarity of our biosimilar medicines with the reference molecules in terms of efficacy and safety, as well as pharmacokinetic and pharmacodynamic profiles.

These studies have been conducted in a timely manner while maintaining stringent quality standards, allowing Samsung Bioepis to make our high-quality biosimilar medicines available to patients worldwide immediately following loss of exclusivity. Most notably, in 2020, when the COVID-19 pandemic posed unprecedented challenges, we were able to successfully conduct eight clinical studies¹⁾ without interruption or termination.

As of September 2021, Samsung Bioepis has successfully conducted a total of 19 global clinical studies across approximately 500 sites in 30 countries. Meanwhile, a wealth of real-world evidence on our biosimilar medicines continues to be published, referencing the experience of more than 35,000 patients worldwide.

Compliance with Clinical Quality Standards

When conducting pre-clinical and clinical studies, Samsung Bioepis strictly adheres to all relevant laws and regulations, including international ethical and quality standards, such as International Conference on Harmonization Guideline for Good Clinical Practice (ICH GCP) and Good Laboratory Practice (GLP). Equally important, such laws and regulations have been thoroughly reflected in Samsung Bioepis' stringent and thoroughly tested standard operating procedures.

Furthermore, Samsung Bioepis' clinical studies are preceded by approvals from the regulatory authorities in all relevant countries as well as the independent ethics committees of the hospitals in which the clinical studies take place.

Ten Biosimilar Pipelines

Samsung Bioepis has ten biosimilar pipelines in six therapeutic areas: immunology, oncology, ophthalmology, hematology, gastroenterology and endocrinology. We have brought five biosimilars to market in Europe and other countries, including autoimmune disease treatments and oncology biologics. One ophthalmic disease treatment received approval in Europe in August 2021, and the other four are currently undergoing Phase 3 clinical trials. From this starting point, we plan to actively pursue the development of novel biologics that can help patients whose needs remain unmet, and we will continue to leverage our world-class R&D capabilities to expand our competitive biosimilar pipeline.

¹⁾ Phase 1 clinical trials (SB16, SB17, SB5B),
Phase 3 clinical trials (SB11, SB12, SB15, SB16, SB17)

R&D Performance

Research & Development

¹Phase 1 clinical trial waived for SB15

Biosimilar products in development pipeline			
(As of September 2021)			
Samsung Bioepis Code	Molecule	Therapeutic area	Phase
SB12	Eculizumab	Hematology	3
SB15 ¹	Aflibercept	Ophthalmology	3
SB16	Denosumab	Endocrinology	3
SB17	Ustekinumab	Immunology	3

Novel biologics in development pipeline			
(As of September 2021)			
Project code	Molecule	Therapeutic area	Phase
SB26/TAK-671	Ulinastatin-Fc Fusion Protein	Gastroenterology	1

Successfully Securing Regulatory Approval

Biosimilars must meet the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. The regulatory agencies including the Korean Ministry of Food and Drug Safety (MFDS), the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) apply very strict standards for assessment, review, and approval of biosimilar products. As of September 2021, Samsung Bioepis has obtained approval for six biosimilars by engaging strategically and proactively with regulatory bodies. We gained our first approval in 2016 for SB4 (etanercept biosimilar) and SB2 (infliximab biosimilar) in Europe. Within a few years, we gained approval for SB5 (adalimumab biosimilar), SB3 (trastuzumab biosimilar), and SB8 (bevacizumab biosimilar). In August 2021, we obtained approval for SB11 (ranibizumab biosimilar) in Europe.

Approved biosimilar products			
(As of September 2021)			
Approved biosimilar products	Molecule	Therapeutic area	Approved country
SB4	Etanercept	Immunology	FDA (US), EMA (Europe), HC (Canada), ANVISA (Brazil), TGA (Australia), Medsafe (New Zealand), MFDS (ROK), etc.
SB2	Infliximab	Immunology	FDA (US), EMA (Europe), HC (Canada), ANVISA (Brazil), TGA (Australia), MFDS (ROK), etc.
SB5	Adalimumab	Immunology	FDA (US), EMA (Europe), HC (Canada), TGA (Australia), MFDS (ROK), etc.
SB3	Trastuzumab	Oncology	FDA (US), EMA (Europe), ANVISA (Brazil), TGA (Australia), etc.
SB8	Bevacizumab	Oncology	EMA (Europe), MFDS (ROK)
SB11	Ranibizumab	Ophthalmology	FDA (US), EMA (Europe)

Quality Management

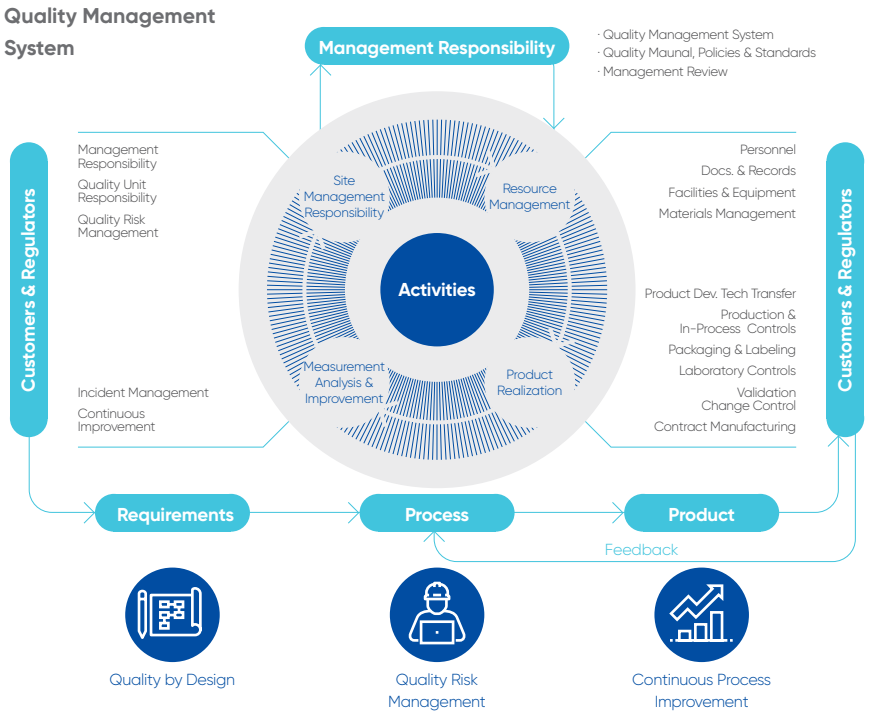
Quality Management System

Quality Assurance Process

Biopharmaceuticals, developed and supplied to improve patient health and extend lives, require thorough quality assurance in all processes, from development and manufacturing, to storage, distribution and sales. To ensure the timely delivery of safe, high-quality biosimilars, Samsung Bioepis maintains an enterprise-wide quality management system at the global level. We also provide systematic training to reinforce the quality assurance capabilities of our employees. Based on our strict quality control processes, we are doing our utmost to supply high-quality biosimilars to the people around the world who need them most.

Quality Assurance System

Samsung Bioepis has established an efficient Quality Assurance System encompassing general quality management and the standards of Current Good Manufacturing Practices (cGMP). The Quality Management System prevents quality risk by monitoring process performance and product quality, and when quality issues do arise, they are addressed promptly through clear decision-making. Furthermore, we are continuously innovating throughout the quality management process to ensure that it reflects the needs of stakeholders, including medical experts, and regulatory agencies such as the FDA and EMA throughout.



Quality Management

Quality assurance across the company is centered systematically around the Quality Team. As a dedicated department, the Quality Team establishes an annual quality management plan for enterprise-wide quality assurance, which is implemented in all processes, from product development to production and supply. To improve quality assurance, we conduct analyses, evaluations, and internal and external audits, while seeking and reflecting feedback from medical experts and regulatory agencies gathered through a variety of communication channels.



Quality Assurance Activities

Optimized process modeling and simulations

An important factor in biosimilar development is the scaling up of production. Even small changes in cell culture conditions such as temperature can have a big impact on the quality of biosimilars. Therefore scale-up must be accompanied by thorough quality management. Samsung Bioepis is taking proactive steps alongside scale-up, engaging in computer simulations and extensive testing. At each stage, an internal review committee meets to perform a separate evaluation of biosimilar quality. When commercial production begins, biosimilar quality is managed meticulously according to strict standards to minimize any variance between production batches.

More than 80 advanced analytical methods

The development of biosimilars requires a total understanding of the key quality elements of the reference molecules. Furthermore, it is necessary to fully understand in advance not only the biological and physicochemical characteristics of the drug, but also the pharmacological action of the drug when the target cell is found in the body. Samsung Bioepis uses more than 80 analytical methods to analyze and assess reference molecules in many different aspects. Moreover, to fully understand the potential variance in production batches that can occur due to the use of live cells as source materials, we obtain and analyze large quantities of reference molecules.

Reinforcing Quality Assurance Capabilities

¹⁾ GxP: an abbreviation for "Good Practices" as applied in various regulated industries, including pharmaceuticals and medical devices, where x represents the specific field, for example, M (Manufacturing, GMP), C (Clinical, GCP), etc.

Meticulous process design and risk management

Samsung Bioepis has quality designed in, meaning that all variables and parameters critical to the quality of the product are examined, challenged, and understood as to their impact on product quality. A properly designed process and control strategy should be suitable for scalability, transferability, validation, commercialization and continuous improvement throughout its lifecycle. Samsung Bioepis' Quality Risk Management (QRM) allows decisions about product safety and efficacy to be made more soundly on the basis of scientific evidence of the patient risk and criteria defining the acceptability of the product under sub-optimal conditions.

Tollgate System

The Tollgate System, as a quality management system, determines whether quality targets have been achieved at each inflection point in the development process, which helps in the development of higher quality drugs as they pass through each stage.

Robust Quality Trainings

We establish and manage a formal training program, to ensure that competencies and training requirements are identified for all roles. The programs cover the particular operations that the employee performs and GxP¹⁾ as they relate to the employee's functions.

Status of quality assurance training (As of September 2021)	
Training course	Training content
GxP Regulations	Overview of GxP regulations
Quality Management System	Quality assurance manual and policies, company quality standards
General Processes in Quality Assurance	Overall quality assurance processes
Department-specific Quality Assurance Processes (Teams/ Groups)	Quality assurance for specific departments

FUTURE FOR NEXT GENERATION

Strengthening
Environmental Management

IMPORTANCE

Awareness of environmental impact and corporate responsibility has been growing since the late 1980s, primarily in developed countries in industries with a high degree of environmental sensitivity. In the 21st century, as the seriousness of climate change and the need for global response to it becomes more apparent, environmental management has once again become a major part of corporate non-financial risk management. There has not only been a continuous strengthening of environmental policies and regulations globally, but also a growing demand for environmental responsibility among corporate stakeholders, including customers and investors.

APPROACH

At Samsung Bioepis, we have established environmental management principles and systems adhered to the green management philosophy, which we are practicing across the company. As an R&D company with low energy consumption, we are not subject to targets for Greenhouse Gas (GHG) emissions and energy consumption. Nonetheless, we are continuing our proactive efforts to save energy and reduce emissions. Furthermore, we have put in place a management system for water resources, waste, air pollutants and hazardous chemicals, and we are introducing eco-friendly packaging materials as part of building a circular economy and enhancing resource efficiency.

PERFORMANCE

Reducing greenhouse gas emissions



Using high-efficiency equipment

LED lighting
(90% of all lighting),
high-efficiency pumps,
high-efficiency heat pumps



Reducing energy consumption

Lights/HVAC¹⁾ turned off
outside of work hours,
cooling control system with
inverters



Developing eco-friendly packaging

Package size reduction,
use of paper trays,
no plastic coating



Promoting eco-friendly shipping

No PVC wrapping,
shipper boxes made of
recycled paper

¹⁾ Heating, ventilation, and air conditioning



Environmental Management

Strengthening Environmental Management System

Environmental Management Principles

Samsung Bioepis practices enterprise-wide environmental management based on the conviction that we should contribute to the preservation of the environment we live in. To respond effectively to climate change caused by global warming, we are continuously monitoring climate change trends and their effects, while working to reduce our greenhouse gas (GHG) emissions and our consumption of energy and resources. Furthermore, to minimize our impact on the environment throughout the production process, we engage in a wide range of environmental management efforts at each stage of the value chain, while thoroughly managing water resources, waste, air pollutants and hazardous chemicals.

Environmental Management System

At Samsung Bioepis, an enterprise-wide environmental management plan is established and implemented by the Facility Management Group, a dedicated department. The environmental management plan covers the management of wastewater and waste in accordance with the law; the management of environmental facilities to reduce emissions of air pollutants and hazardous chemicals; goals and tasks for reducing GHG emissions, saving energy and reducing resource consumption; implementation and inspection; evaluation and improvement measures, and more. Additionally, we have established an emergency response system in preparation for unforeseen environmental accidents, and we regularly conduct environmental facility inspections and emergency response drills.

Environmental Management Organization



Reducing Greenhouse Gas Emissions

As a business, our focus on R&D entails lower energy consumption, and therefore Samsung Bioepis is not subject to targets for GHG emissions and energy consumption. Nonetheless, we are taking active steps to reduce our GHG emissions through the use of high-efficiency electrical and mechanical equipment and other energy-saving activities.

Our new building, completed in December 2020, uses exterior materials with strong insulation (special coated glass, etc.) to reduce energy consumption, and has high-efficiency LED lighting (90% of all lighting), high-efficiency pumps, high-efficiency heat pumps, and power factor capacitor (PFC) power supplies. The building also minimizes energy consumption by using inverter controls, and HVAC system with district heating and absorption chillers.

Responding to Climate Change

Minimizing Our Environmental Impact

To further reduce energy consumption, lighting and air conditioning is turned off during hours when employees are not in the office, and with the installation of electric car charging stations in the parking lot of our new building, we are encouraging the use of electric vehicles. In these ways and more, we are promoting GHG reductions and energy conservation in daily life.

Water Resource Management

We inspect the water quality of all our water supply facilities once a year in accordance with the Standard Operating Procedure (SOP) for water supply facilities, and we clean or replace any lines that exceed the inspection standards. Additionally, all testing in the development process, such as cell line development and purification, is conducted according to detailed plans to save water and prevent the unnecessary generation of wastewater.

To prevent the discharge of water pollutants, we maintain a wastewater treatment system with a capacity of 190 tons/day (daily throughput) that can treat any wastewater and/or emissions generated by our bio laboratory to legal standards. Also, in case the wastewater treatment system is disrupted, we have installed a wastewater storage tank with about two days' capacity, and have set up an emergency response system to enable emergency treatment through a contracted treatment company. Effluents generated are monitored daily and are managed to ensure that end-point water quality is within 30% of the legal standard (permissible discharge standard).

Waste Management

In accordance with waste treatment regulations, Samsung Bioepis separates and disposes of waste generated from offices and laboratories, thereby eliminating the risk of mixed emissions. We are working to increase the recycling rate and reduce waste by sorting office waste into recycling and general waste. Laboratory waste is handled by waste consignment companies to ensure that it is always disposed of legally. Where possible, laboratory supplies are recycled as well.

In addition, we are carrying out a number of recycling campaigns in which our employees participate to reduce waste and recycle more. Personal mugs are provided to new employees, who get discounts for using them at the in-house cafe. The company cafeteria does not provide disposable utensils. We also strongly encourage the use of Electronic Document Management System (EDMS) and electronic documents as part of our efforts to become a paperless company.

Status of waste treatment

Office waste	Separation of recycling/general waste → government pick-up and disposal
Lab waste	Separation of designated waste types (toxic waste materials, medical waste, etc.) → Disposal contracted to specialist treatment company (100% incinerated), quantities managed through the government portal, Allbaro system

Environmental Management

Air Pollution Management

From April 2021, Samsung Bioepis is measuring emissions of the air pollutants carbon monoxide (CO), sulfur oxides (SOx), nitrogen oxides (NOx) and particulate matter (PM) to respond effectively to climate change. Going forward, we plan to measure and manage emissions every half year. For nitrogen oxides (NOx), a major component of fine dust, we have installed low-NOx burners for all gas burner equipment that emits the substance, including three burners (ultra low NOx burners) and two gas absorption chillers (low NOx burners). For the chillers, we are considering the installation of ultra low NOx burners and exhaust reduction devices to further reduce NOx emissions.

Hazardous Chemical Management

When procuring, handling and disposing of chemicals, Samsung Bioepis strives to conduct and monitor the entire process safely and properly. First, when registering chemical substances in connection with the procurement system, the safety environment manager conducts a preliminary safety evaluation to determine whether the process can go forward. Furthermore, we monitor our handling of chemicals through monthly safety inspections and a full chemical inspection once every quarter. Waste chemicals are disposed of according to legal procedures through specialized treatment companies. To laboratory researchers handling chemicals, we also provide special health and safety training, management supervisor training and health check-ups on a regular basis.

Stepwise chemical management system



Making Our Products More Eco-Friendly

In line with the worldwide shift to eco-friendly packaging, Samsung Bioepis has developed and is using eco-friendly packaging materials in view of their positive impact from the development stage to production, logistics and disposal. Considering this impact, the size of packaging has been reduced, trays are now made of paper instead of plastic, and where paper is used, it is not coated with plastic, which makes it easier to recycle.

In the shipping process, we do not wrap pallets with PVC, a material that generates dioxins when incinerated. Instead, we use LDPE, which does not generate harmful substances. For shipper boxes, including refrigerated shipping, more than 75% of the paper we use is recycled paper. Furthermore, we only use paper materials certified by Forest Stewardship Council (FSC) or Programme for the Endorsement of Forest Certification (PEFC) that have been verified free of hazardous substances. Our efforts continued in 2020 with the in-house development of a simulator tool that can increase efficiency in packaging material development.

By developing eco-friendly packaging materials, we have not only been able to reduce the amount of waste in the production process, but with smaller packaging, also to reduce the amounts of energy consumed and pollutants generated in the logistics process. Other achievements include a reduction of packaging production costs and logistics expenses as well as a shorter product development period. Going forward, we plan to expand our use of eco-friendly packaging by improving existing materials and developing new ones.

[Packaging tray improvement status]



[Previous] Plastic trays

[Improved] Paper trays

Sustainability Management

46 — Talent Management

52 — Protecting Human Rights

54 — Health and Safety Management

58 — Social Contributions

Talent Management

MANAGEMENT APPROACH

Samsung Bioepis, as a company specializing in R&D, focuses on managing talent to enable all employees to perform to the best of their abilities and achieve results, in the belief that our personnel are our greatest asset. We actively support work-life balance by continuously improving our working conditions and working culture through labor-management consultations, internal communication and job satisfaction surveys. We respect the diversity of our employees and strictly prohibit discrimination. Our substantive and practical systems are leading the way in fostering talented women and protecting mothers and their children. We not only improve employee satisfaction with our systems for rational performance evaluations and fair compensation, but also support a variety of training programs for competency-building and career development to nurture outstanding bio-industry talent.

KEY PERFORMANCE



A healthy organizational culture combining expertise and insight



Respect for diversity and non-discrimination in a culture of respect for employees



Rational performance evaluations and fair compensation



Employee benefits in support of work-life balance



Healthy Organizational Culture

Improving Work Culture

Samsung Bioepis offers a flextime work arrangement so employees can maximize work efficiency while maintaining a work-life balance. Through our system based on a "Work Smart" ethos, individual employees can adjust their own work hours and plan their vacation time to suit their needs. Moreover, by empowering our employees with autonomy and responsibility, we are building a work culture with clear boundaries between work and rest.

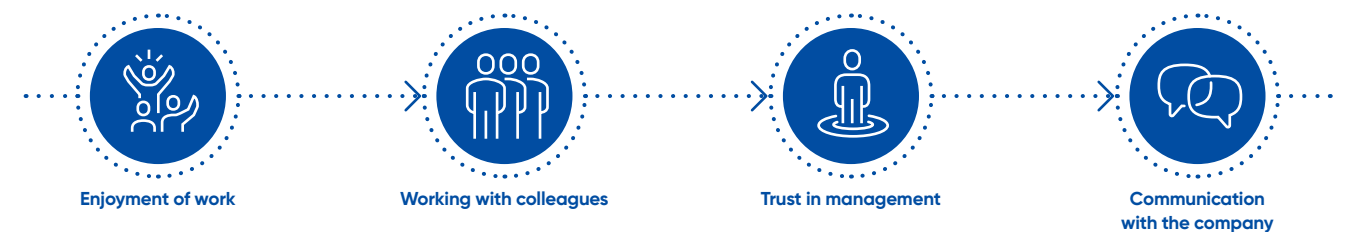
Supporting Work-Life Balance

We provide a variety of programs to help employees balance work and family by promoting immersion at work and harmony at home. Our mother-and-child protection policy supports employees through pregnancy, childbirth and childcare, while family care leave accommodates their needs when family members require major surgery or sick care. Starting in 2020, with the urgent need for childcare in the midst of the COVID-19 pandemic, we have encouraged the active use of family care leave. Moreover, to alleviate the burden of education and medical expenses, we provide tuition assistance for the children of employees and help with the costs of medical care for their children and spouses. We also contribute a set amount for medical expenses in the event of a serious illness in the employee's family to help prevent unexpected financial hardship.

Employee Job Satisfaction Survey

Our unique employee work satisfaction survey, the Samsung Culture Index (SCI), consists of 50 questions pertaining to enjoyment of work, working with colleagues, trust in management, and communication with the company. The survey's chief objective is to discover and improve the strengths and weaknesses of the company's organizational culture. Over 80% of current employees participate in SCI, which was implemented in 2016, and survey scores are rising every year. Based on the survey results, we are striving to build an even better organizational culture by implementing improvement measures at the department, division and company levels.

Components of the SCI work satisfaction survey



Promoting communication between labor and management

The Samsung Bioepis Labor-Management Council, dubbed "Compassionate Companionship," serves to represent employees, and works with management to find ways to improve our working conditions and organizational culture. Representing employees, the Council holds weekly meetings, monthly meetings, and quarterly meetings, working to build an organizational culture that is mutually beneficial to labor and management. The Council includes four employee representatives elected through a vote in which 75% of employees participated. We provide feedback to 100% of the opinions and concerns submitted by our employees and build a consensus with them by providing detailed explanations about what is to be improved and will be kept as it is. The management leads quarterly business briefings, quarterly meetings with each division, and meetings with each department to explain current management issues, listen to the opinions of employees, and find ways to strengthen trust between labor and management.

Labor-Management Council Activities



Expanding Intergenerational Communication

Because our average employee is 33 years old and 80% of all employees are in their 20s and 30s, we believe open communication between generations is key to a healthy organizational culture. This is why we designate a junior employee with under five years of experience as each department's Change Agent, or CA, who is in charge of organizational culture change. This system promotes innovation in our organizational culture.

Respect for Diversity and Prohibition of Discrimination

Respect for Diversity

Samsung Bioepis is working to promote our culture of respect for employees and all their forms of diversity throughout the company. Samsung Bioepis does not tolerate discrimination against employees on the basis of gender, race, age, disability or religion, and we seek to ensure that our culture enables all those of diverse backgrounds and cultural values to maximize their potential. Every year, all employees must attend mandatory training on sexual harassment prevention, workplace bullying and disability awareness. We strive to embody a culture of diversity and inclusion, for example, by including diversity training in our curriculum for new employees. Moreover, we guarantee equal pay for work of equal value, for all women and men, including young people and employees with disabilities. In particular, by properly recognizing the value of women's labor, we support women's social participation and their obtaining of economic opportunity.

Employee Diversity	(As of September 2021)
Ratio of female among total workforce	50%
Age of average employee	33 years old

Talented Women Leaders

Samsung Bioepis supports talented women in a variety of ways to ensure they can perform to the best of their abilities and develop into future leaders. Since 2019, to create a women-friendly culture, we have maintained a Women's Council consisting of four

representatives of the women employed by the company. It is separate from the legally required labor-management council, and holds regular meetings once a month. The Women's Council helps address any issues women may face at the company, and supplements our mother-and-child protection policy. Also, through multiple social media channels, we publicize our efforts to support women developing their talents and careers. This content includes leadership interviews with women in executive positions, and informs the public about our increasing gender diversity and our resolve to foster talent among women. As part of these efforts, we have appointed a female director as one of the inside directors in 2021.

Mother-and-Child Protection Policy

We go above and beyond the legal requirements for maternity protection by providing multiple programs to ensure that the careers of female employees are not interrupted by pregnancy, childbirth or childcare. From 2021, we started providing longer paid fertility leave to married women in need of fertility treatment. We also now began providing subsidies for fertility treatment, and extending the length of paid leave from one day to three in case an employee's spouse has suffered a miscarriage or stillbirth. In addition to giving employees childbirth bonuses and gifts, we operate a maternity care area where expecting mothers can rest, as well as an in-house daycare center for the benefit of working parents. To those participating in our mother-and-child protection policy, we provide phone consultations, (re) orientations and one-on-one meetings to ensure they have no difficulties in later returning to work.

[Our Story]

"When women have a seat at the table, this helps companies take entirely new directions and explore business opportunities that may not have occurred otherwise."

Kyung-Ah Kim, Senior Vice President, Development Division 2 Leader

Q How important is it for companies to have female leaders?

A Women can bring different perspectives that can benefit a company, especially in biopharmaceuticals as health conditions affect different demographics and genders. When women have a seat at the table, this helps companies take entirely new directions and explore business opportunities that may not have occurred otherwise. Those women who hold decision-making roles in a company help empower other female colleagues to bring forth a diversity of opinions and serve as invaluable mentors to them at the same time. By setting the example, these female leaders can inspire and create a more dynamic workforce in a company.

Q Please give us an overview of how Samsung Bioepis is leveling the playing field for female employees.

A Samsung Bioepis encourages a work-life balance as the happiness of our colleagues and their families is a priority. We have on-site daycare, supportive maternity and paternity leave programs, and children's education incentives. We also have a high number of female colleagues throughout our company compared to others in the industry which builds a culture of success for women. In addition, there are many opportunities for growth and internal promotion, which means that female colleagues can move up and develop a great career here.

Q What is your proudest achievement since starting at Samsung Bioepis, and how would you say your work here has helped other women?

A One of my proudest achievements has been my contribution to the development of our biosimilars and seeing them being approved and marketed to treat patients in need. Both for me and my colleagues, it is our passion and goal to deliver high-quality biologics to people who have limited options and realizing that our dream is achievable. Personally, as a woman, I feel particularly proud that our biosimilars can address the needs of patients who suffer from diseases that more often affect women. Also, as a senior colleague at Samsung Bioepis, I have been mentoring female colleagues so that they could build confidence and we could all learn from each other's experiences at the same time.

Fairness in Performance Evaluations and Compensation

Performance Evaluation System

We operate a standardized Management by Objectives (MBO) system that enables employees to set clear goals and perform their duties based on these goals. This performance evaluation process is managed through feedback from interim reviews. When evaluations are finalized, employees have the opportunity to appeal the results through a re-evaluation system. Moreover, to enhance fairness, we take steps to reinforce the competencies of our appraisers, including training and Standard Operating Procedures (SOP) for evaluation interviews. This has resulted in positive feedback from employees about evaluation competence. Going forward, we plan to further reinforce fairness in evaluations by supplementing them with follow-up surveys.

Compensation System

To ensure that the results of performance evaluations are reflected in compensation, the evaluations are the basis for our salary grading system, with salary raises and bonuses paid according to the calculated salary grades. We strive to ensure fair, performance-based compensation by using individual performance to determine performance bonuses and a variety of other incentives.

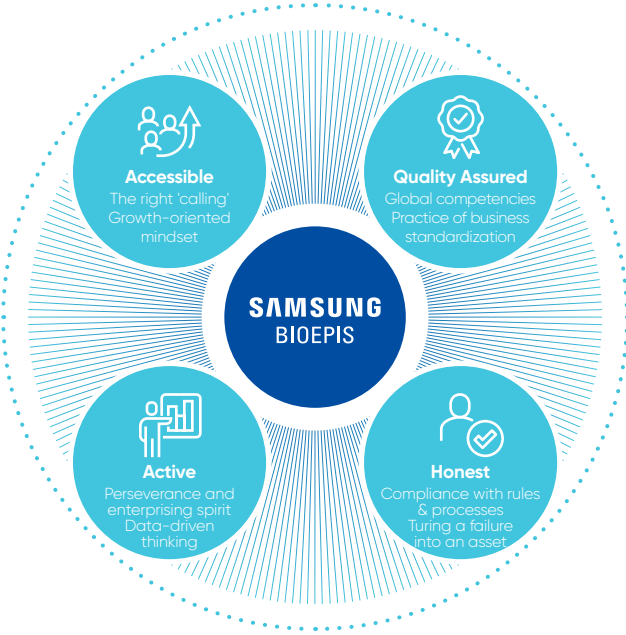


Talent Development

Employee Talent

At Samsung Bioepis, people of diverse backgrounds and competencies work together to research innovative biopharmaceutical manufacturing and supply methods. It is the place where many talented people from all over the world would like to work. The employees Samsung Bioepis aims to recruit are global talents who produce results through creativity, innovation and collaboration based on expertise in their respective fields. In a variety of ways, we seek to enable everyone to perform to the best of their abilities and develop into outstanding bio-industry professionals.

Samsung Bioepis Employee Profile

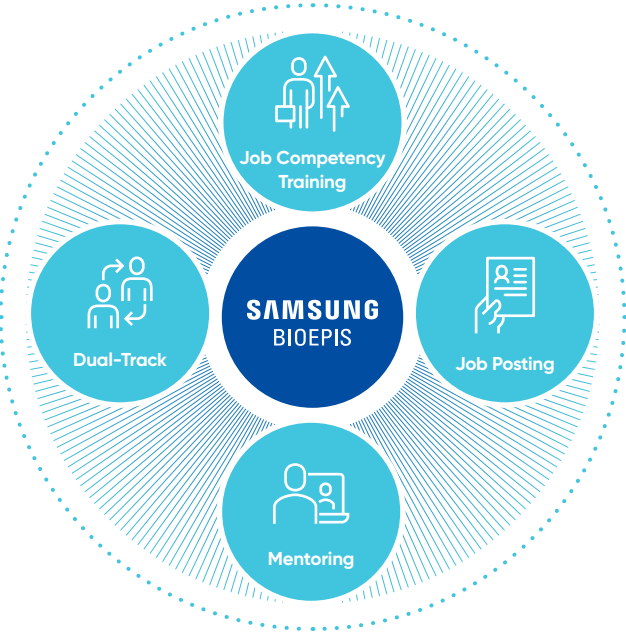


Employee Career Development

To support employee career advancement, Samsung Bioepis offers numerous on/offline training programs through our Human Resource Development System. Through the Job Competency Training System, we provide customized training tailored to the job competencies of each department.

The Training Lab in particular is unique to Samsung Bioepis, serving to continuously strengthen employee competencies in testing. Furthermore, our Job Posting System offers employees the opportunity to do the kinds of jobs that interest them. Our Dual Track Program systematically guarantees an R&D career track in addition to an executive track for R&D specialists. Moreover, we provide a mentoring program pairing newcomers with experienced employees to help employees adjust to their new roles more smoothly.

Employee Career Development Program



Leadership Development for Executives and Departmental Heads

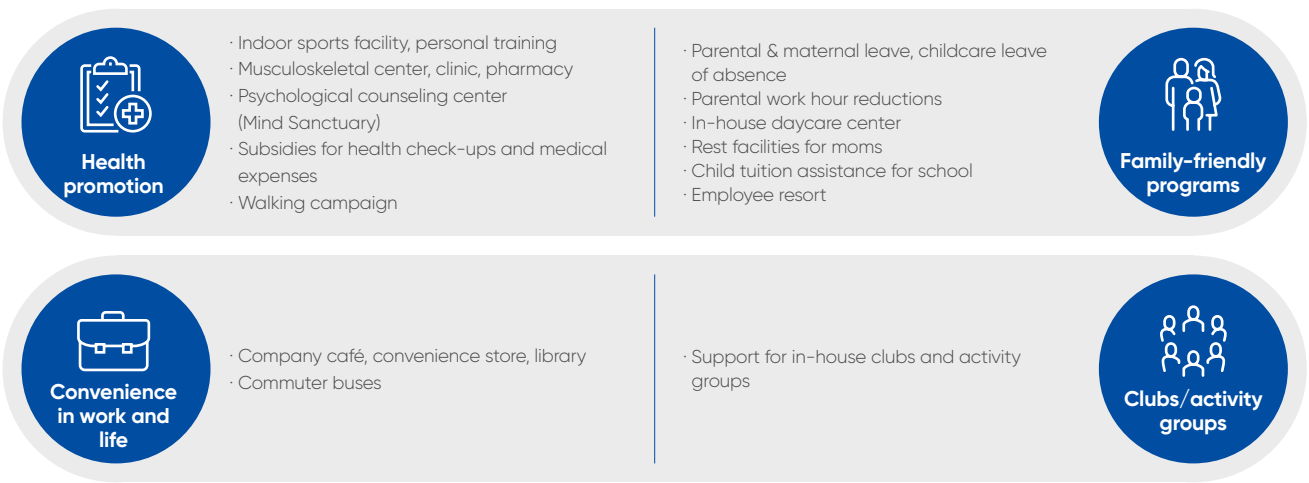
Each year, we provide executives and departmental heads with leadership reviews and individual consulting to support the development and reinforcement of their leadership skills. Moreover, departmental heads receive two days of leadership training every year, while annual leadership training is provided to departmental head candidates. We also operate a job rotation system that enables them to learn roles in a number of related departments, expand their competencies and grow as leaders.

Employee Benefits

Benefits System

Samsung Bioepis employees receive a number of benefits through our system, designed with their input, aimed at creating a healthy and pleasant working environment and encouraging work-life balance. We maintain state-of-the-art fitness facilities, a musculoskeletal center, affiliated clinics, and offer psychological counseling to promote employee health, both physically and mentally. We also provide family-friendly programs such as maternity and childcare leave, in-house daycare centers, tuition support for children's education, and an employee resort. For convenience in work and daily life, we also have an in-house cafeteria and buses for commuters, as well as a range of opportunities for self-development, including in-house clubs and activity groups.

Main Benefit Programs



Protecting Human Rights

MANAGEMENT APPROACH

Samsung Bioepis is strengthening protections for the human rights of all stakeholders, including employees, based on human rights management principles that conform to human rights and labor-related international standards and guidelines. We strive to prevent human rights violations by identifying and addressing a range of human rights risks and providing employees with human rights training. Furthermore, our systematic grievance handling system provides support for a workplace in which each employee's human rights are respected.

KEY PERFORMANCE



Managing risks to human rights that could arise when doing business



Company-wide human rights training to prevent human rights violations



Grievance handling system to address related issues



Practicing Human Rights Management

Principles of Human Rights Management

As a global biopharmaceutical company, Samsung Bioepis respects the human rights of all stakeholders, including employees, in all business activities, and strives to practice human rights management. Based on international human rights principles and standards, we work to prevent human rights violations, respect diversity, prohibit discrimination, forced labor and child labor, and guarantee freedom of association. Through our annual employee work satisfaction survey, we are continually seeking to improve our organizational culture. We also practice human rights management by providing a hotline that employees can use at any time and by enforcing strict and impartial compliance regulations.

Managing Risk in Human Rights Management

At Samsung Bioepis, we work proactively to prevent human rights violations by identifying risks that could arise in the course of doing business. Our annual employee satisfaction survey (SCI, Samsung Culture Index) serves to preemptively identify and resolve employee grievances, and we maintain a hotline through which grievances can be communicated at any time or place. We also prevent violations of our employees' basic rights by providing psychological counseling and annual Happiness Care Index (HCI)¹⁾ questionnaires to identify mental health risks.

¹⁾ HCI (Happiness Care Index):
A mental health diagnosis conducted annually in connection with online education for employees. Six major categories (118 questions/environment, stress, anxiety, depression, sleep, job stress)

Human Rights Training for All Employees

To prevent human rights violations, we provide training every year in areas such as the prevention of sexual and workplace harassment, disability awareness and privacy protection. The training is mandatory, and unless there is a specific reason an employee cannot take part, such as a leave of absence or sick leave, the training is attended by all active employees.

Our Grievance Handling System

At Samsung Bioepis, we listen attentively to employee feedback received through our anonymous online bulletin board and via offline grievance channels, which include the Labor-Management Council, Change Agent, and counseling centers, and we work to address grievances immediately. Our company's primary grievance board, called 'Our Voice', is designed to ensure that the person in charge of the relevant department responds to submitted grievances within 24 hours. To address grievances submitted through other channels, such as the Labor-Management Council or Change Agent, we hold consultations between labor and management on a weekly, monthly and quarterly basis.

In 2020, we received a total of 508 grievances. In all cases, the person who submitted the grievance has either been notified of the actions taken, or in cases that could not be resolved immediately, has received an action roadmap by the required deadline. Since 2020, the COVID-19 pandemic has made it difficult to file grievances in person, so we are doing our best to handle employee grievances in a variety of ways, including virtual meetings.

Grievance process



Health and Safety Management

MANAGEMENT APPROACH

Samsung Bioepis gives special attention to health and safety management to ensure that all employees can work in a safe and healthy environment and achieve their dreams. We have an Occupational Health and Safety Committee as well as a dedicated department, and we establish a health and safety plan every year for the entire company. In addition to our regular safety inspections and risk assessments of worksite facilities and equipment, we are strengthening our safety culture by providing employees with a range of safety education and training programs. To promote our employees' physical and mental health, we maintain a health clinic, sports facilities, psychological counseling services, and programs to promote healthy diets.

KEY PERFORMANCE

-  A systemic management approach that **strengthens workplace health and safety**
-  A consistent effort to **strengthen employee health and safety**



Strengthening Workplace Health and Safety

Health and Safety Planning and Implementation

Samsung Bioepis devises comprehensive plans for health and safety that incorporate the relevant departments, budgets, goals and tasks, along with annual inspections of compliance with our health and safety management principles. The health and safety plan is implemented after approval from the Board of Directors and the Occupational Safety and Health Committee, a labor-management consultative body for health and safety.

Compliance with Health and Safety Management Principles

Samsung Bioepis strives first and foremost to protect the health of all stakeholders, including customers, employees and partners. To this end, we have established management principles that reflect our dedication to health and safety. We are continuously striving to build a better work environment, disseminate a culture of safety, comply with regulations and prevent accidents.

Health and safety management principles

- Samsung Bioepis prioritizes securing the safety and health of customers, employees, and community while we comply with rule & process to prevent accidents and practice compliance management.
- Recognizing that health and safety are of the utmost value and should not be compromised in any circumstances, Samsung Bioepis will :
 - Encourage executives to continuously demonstrate leadership and commitment to safety and health.
 - Communicate the values and objectives of safety and health management to ensure that they are put into action company-wide with all employees and suppliers.
 - Ensure all employees and suppliers actively comply with the rule & process to prevent accidents.
 - Ensure the elimination of hazards, and reduction of safety and health risks prior to any work.
 - Create safe, healthy and pleasant working environment and make effort for continuous improvement.
 - Help incorporate safety into a daily routine and instill a positive safety culture at work.

Occupational Health and Safety Committee

In compliance with Article 24 of the Occupational Safety and Health Act, Samsung Bioepis maintains an Occupational

Health and Safety Committee consisting of an equal number of representatives from labor and management (four from management and four employees) that meets once every quarter, seeking to ensure an accident-free workplace that guarantees the health and safety of employees. The Committee deliberates and decides on matters pertaining to health and safety such as goals and plans, safety training, employee health exams, work environment inspections, and the mitigation of potential risks. Committee activities are shared with employees as part of efforts to communicate the company's health and safety aims and to encourage active employee participation. We will continue to build on the Committee's activities as we work to provide a safe and pleasant work environment and promote employee health.

Occupational Safety and Health Committee activities in 2020

Date	Agenda	Result
Jan 2020	Health & safety goals and plans for key activities in 2020	
May 2020	COVID-19 response plan	Established situation-based plans
Sep 2020	Accident prevention & working environment inspection results	Accident prevention measures
Dec 2020	Health & safety goals and plans for key activities in 2021	

Dedicated Department For Health and Safety

At the core of implementing our company-wide health and safety plan is the Facility Management Group, the dedicated department in charge of health and safety. The Facility Management Group works to prevent industrial accidents and fires, and forms emergency response systems to protect employee lives and company property. Our efforts to promote the health of our employees, create a pleasant and safe working environment, ensure timely utility supplies and provide optimal office and lab conditions also contribute to stability in production. Alongside these measures, we conduct compliance evaluations on a regular basis to verify the implementation of the health and safety plan.

Health and Safety Organization

Facility Management Group	
Safety/environment duties	Facility duties
Safety management	Construction management
Environmental facility management (wastewater/air/waste)	Machinery management
Health management	Electric equipment management
Firefighting facility management	Laboratory management

Strengthening Workplace Health and Safety

General Health and Safety Regulations (ESH SOP)

Title	Scope
Samsung Bioepis Business Continuity Plan (BCP)	· Response procedures for each type of emergency (e.g. fire, power outage, gas outage, disease outbreak)
Health & safety management regulations	· Health & safety organization and systems · Health & safety management standards and procedures
Risk assessment and operation rules	· Discovery, appraisal and action regarding workplace risks
Biosafety management regulations and guidelines	· Definitions for testing and laboratories involving Living Modified Organisms (LMO) · LMO safety management organization and its roles · Standards and procedures for LMO testing and lab safety management
Waste treatment regulations	· Licensing, treatment standards and procedures for each type of waste
Contractor selection and construction management regulations	· Contractor selection procedures, including bidding and procurement · Construction safety standards and issuance of construction safety licenses

Safety Inspections

Samsung Bioepis conducts intensive inspections of facilities related to lab safety (fume hoods, laboratory safety showers, chemical storage, etc.), compressed gas, fire safety, and others according to a cycle (daily, weekly, monthly, yearly). The inspection results are recorded in the inspection system or in document form as a way of monitoring the suitability of the inspections and as a record of their execution. As part of maintaining a safe workplace, we also eliminate potential risk factors through detailed, multifaceted inspections conducted by a third party once a year.

Status of health and safety incidents (As of September 2021)	
Type	No. of cases
Safety accidents	1
Fire accidents	0
Legal violations	0

Risk Assessment System

We collect feedback at all times, maintaining a risk assessment system in which employees can participate directly. This enables us to identify and address potential risks in advance as we work to establish a safe workplace and a self-motivated safety culture.

Strengthening Safety Culture Competency

To build a culture of safety and strengthen relevant employee competencies, all Samsung Bioepis employees receive safety training. In addition to our mandatory orientation and periodic statutory training, we promote knowledge of safety management and foster safety awareness through targeted training sessions. These include special health and safety training for research staff; special training for managers and supervisors; and training on LMO. Furthermore, all employees take part in a fire drill once a year in which they receive training on first-response measures and evacuation in case of fire.

Safety training status

Parti- cipants	Type of training	Training interval/hours	Content	No. of trainees		
				2018	2019	2020
Empl-o- yees (All)	Orientation training	1 initial session/ 16 hours	· Company safety rules & standards · Accident & emergency response (e.g. using AED) · Stretching techniques to prevent musculoskeletal disorders	123	123	130
	Periodic training	4 sessions per year/ Office personnel: 3 hours, Research personnel: 6 hours	· Road safety · Lab & general safety accident case studies & prevention · Accident & emergency response (e.g. using AED) · Stretching techniques to prevent musculoskeletal issues · Avoiding unsafe practices & preventing human error · Lab safety management & understanding MSDS (Separate sessions for office staff & researchers)	711 per session	757 per session	858 per session
	Firefighting ¹⁾	1 session per year/ 3 hours	· First-response measures & evacuation · Using fire extinguishers	711	774	-
Resear- chers	Special health & safety training	1 session per year/ 16 hours	· Handling chemicals · Dangers & accident case studies · Precautions (e.g. using protective gear) · MSDS content & usage	66	57	43
	Manager & supervisor training	1 session per year/ 16 hours	· Safety training for lab team leaders · Understanding the Occupational Safety & Health Act · Research facility safety management · Occupational accident response & emergency procedures	11	14	13
	LMO training	1 session per year/ 2 hours	· Handling LMO safely · Explanation of LMO laws & regulations · Safety management at LMO research facilities	-	170	161

¹⁾ Fire drills are conducted annually but have been postponed since 2020 due to COVID-19

No. of employees who completed safety training

Date	Person
2020	1,115

Strengthening Employee Health and Safety

Workplace Safety Management

Samsung Bioepis is engaged in a wide variety of efforts to create a safe and healthy working environment. To laboratory personnel, we provide safety glasses, safety boots, gas masks chemical-resistant gloves and sleeves and other protective equipment. Moreover, we supply laboratory safety and emergency response equipment, including automated external defibrillators (AED), shower facilities, fume hoods, hazardous material storage facilities and emergency response supplies. Our laboratory floors are coated with aggregate to prevent slips, and we have installed wall guides to prevent collisions. The different types of waste generated at our laboratories are safely discarded in designated boxes, and we conduct monitoring along with a twice-annual survey of the working environment to ensure our laboratories are always safe.

Managing Employee Health and Well-being

We offer a unique range of facilities and programs to promote the physical and mental health of our employees. Our musculoskeletal center and affiliated clinics provide counseling and exercise therapy for musculoskeletal issues that could occur on the job, and we subsidize comprehensive health check-ups and flu vaccines. Moreover, at our psychological counseling center, the Mind Sanctuary, we promote mental health by providing employees with professional one-on-one counseling with a strict guarantee of confidentiality. Moreover, our state-of-the-art fitness facilities are available for use by over 70% of our employees, who have access to personal training by professionals. Near our offices, we also have the Epis Dulle-gil (walking trail) and a walking community called Epis Walks to support good health habits. To promote healthy diets, we offer the Well-Fit²⁾, Healthy Box³⁾ and EPIS UP & DOWN⁴⁾ programs. In the COVID-19 pandemic, all worksites have been taking thorough quarantine measures for employee safety.

²⁾ Provides four weeks of health breakfasts to help in managing body fat

³⁾ Provides a week of low-calorie packed lunches to help in managing body fat

⁴⁾ A healthy lunch program varying for each day of the week provides meals rich in protein, calcium and dietary fiber (UP), and low in fat and carbohydrates (DOWN)

Social Contribution

MANAGEMENT APPROACH

As part of the local community, Samsung Bioepis is strategically engaged in a wide range of social contribution activities aimed at addressing social issues and contributing to the creation of social value. With the voluntary participation of our employees, we are focusing on activities in three areas in particular: support for the community, nurturing future talent, and employee volunteering. We are working to nurture the talent of the future through our Youth Bio Class, which leverages the unique nature of our business, the University Research Notes Contest, and our industrial-academic cooperation programs. In the COVID-19 pandemic, which has brought hardship to marginalized people in our community, we have also been working to grow as a trusted and cherished corporate by providing them with support.

KEY PERFORMANCE



Employees working together with **the local community**



Nurturing the **talent (youth)** of the future to discover the best



Employee **volunteering** to care for our neighbors



Social Contribution Principles

Strategic Social Contributions

Under the CSR vision of "Enabling People! Together Towards the Future!" Samsung Bioepis has been carrying out a multitude of social contribution activities that leverage our unique business characteristics while attracting the voluntary participation of our employees. As exemplified by our flagship Youth Bio Class program, we provide support for the marginalized, work with academic institutions to nurture bio-industry talent, and provide opportunities for employee volunteering. Through our strategic social contribution activities, we contribute to developing local communities, nurturing future talent, and creating social value, while maintaining a strong and trusting relationship with local communities.

Samsung Bioepis Social Contribution Areas



Community Support

- Funding for study rooms
- Support for single mothers and children in need



Talent (Youth) Development

- Youth Bio Class
- University Research Notes Contest
- Industrial-academic collaboration with universities



Employee Volunteering

- Crowdfunding
- Holiday charity
- Sending Christmas presents

Social Contribution Activities

Community Support

Support for the Marginalized in Our Community

We continue to expand our social contributions in support of the marginalized and their development in the Incheon area, where our company is located. These activities include the creation of local study rooms, sponsorship for social daycare facilities, subsidies for the living and medical expenses of the marginalized, and support for single-parent homes. In 2020, we funded study rooms, supported underprivileged children, improved childcare facilities, and subsidized emergency medical expenses in the local community, which has experienced even greater hardship in the pandemic.



Delivery of donated items to commemorate the company's founding

Talent (Youth) Development

Youth Bio Class

As part of our efforts to nurture future talent, since 2019, the Youth Bio Class has served as Samsung Bioepis' principal social contribution program aimed at helping young people cultivate knowledge in bioscience. In the Youth Bio Class, employees with expertise in medicine, pharmaceuticals and life sciences teach basic bioscience to youth from low-income households. The program provides a variety of learning opportunities, such as in the vaccine's mechanism of action, the correct use of medicines, and the chance to try out bioscience jobs. Through engaging lessons and friendly interactions, we give hope to young people dreaming of careers in science by helping them pursue learning about relevant subjects and choose their career paths.



Youth Bio Class

Social Contribution Activities

University Research Notes Contest

Since 2015, we have signed agreements with Korea's leading universities – including KAIST, Chonnam National University, POSTECH, Sungkyunkwan University, and Yonsei University – to conduct our Research Notes Contest. Through this program, we not only enhance the research capabilities of university students, but also promote the world-class biopharmaceutical R&D achievements of Samsung Bioepis.



MOU signing ceremony for the organization of the Research Note Contest with the Sungkyunkwan University

Industrial-academic Collaboration with Universities

In May 2021, we signed an industrial-academic collaboration agreement with the Seoul National University College of Pharmacy to nurture up-and-coming talent for the biopharmaceutical industry. We provide custom field training programs for undergraduate and graduate students by setting up "clinical medicine track" curricula. Subsequently, in July, we signed an industrial-academic collaboration agreement with Yonsei University and now run a custom training system to nurture promising bio-industry talent there, too.



MOU signing ceremony for the Industrial-academic collaboration with the Seoul National University College of Pharmacy

Employee Volunteering

The employees of Samsung Bioepis share with their neighbors in the community by volunteering at fundraisers and charity events. They serve as instructors at the Youth Bio Class program, the company's flagship social program, and volunteer at charity events for the marginalized held for the company's founding anniversary and the holidays. With a social contribution participation rate of 90% among employees, in the COVID-19 pandemic, we delivered mask kits for our founding anniversary and hand-made gifts to the marginalized at the end of 2020. Moving forward, we will plan to organize a variety of untact social contribution activities suited to the circumstances of the pandemic.



Delivery of donated items for the Lunar New Year holiday



Received award in 2019 as an Outstanding Neighbor of Persons of National Merit

Accelerating the Development of Global Healthcare Industry

Samsung Bioepis supplies high-quality biosimilars to Brazil, Latin America's largest market, through the Productive Development Partnership (PDP). The PDP is operated by the Brazil's Ministry of Health with the aim of developing the local biopharmaceutical industry in a three-way partnership with Samsung Bioepis, the Brazilian pharmaceutical company Bionovis, and the research institute Bio-Manguinhos, which is affiliated with the Brazil's Ministry of Health. The objective of the PDP is to supply biosimilar products while transferring manufacturing technology during the stipulated period.

In close cooperation with the Brazilian government, local companies and research institutions, we have been supplying the autoimmune disease treatment Brenzys (SB4, etanercept biosimilar) since 2019; and the breast cancer medication Ontruzant (SB3, trastuzumab biosimilar) since 2020. This project marks the first time a Korean biopharmaceutical company has supplied the Brazilian market through the PDP. Moreover, by transferring manufacturing technology and supplying high-quality biopharmaceuticals, we are contributing to the development of Brazil's own biopharmaceutical industry and providing medical services to people who need them.



Enabling Access to Innovative Medicines for Patients

The rapid growth of the biosimilar market has led to greater adoption of biosimilars to treat patients in Europe, but the question remains how well patients and healthcare professionals know or understand biosimilars. In 2020, Samsung Bioepis launched a new whitepaper, entitled 'Education in Biosimilars', which has been developed following extensive research throughout the year to identify fundamental information gaps and unmet needs in the biosimilar space.

Samsung Bioepis commissioned an independent research to understand more than 250 key opinion leaders' perspectives – across healthcare professionals, medical academics, journalists, plus patient groups and drug policy experts – on the use of biosimilars across the five European countries of France, Germany, Italy, Spain and the UK.

To support the analysis, Samsung Bioepis also held three online virtual expert panel sessions throughout the summer of 2020 to gain professional insight into: experiences with biosimilars to date, perceptions of biosimilars compared to biologics and attitudes to biosimilars in Europe in general.

While the uptake of biosimilars is different between countries for many different reasons, the research reveals that the role and suitability of biosimilars is not as clearly understood by both healthcare professionals (HCPs) and patients, as the general impression would suggest.

Based on the results of the survey, we concluded that educational initiatives such as providing workshops for patients in specific disease areas, or online guidelines and animations for disease awareness and treatment information are required. In the whitepaper, along with the results of the study, we suggest ways to expand education on biosimilars through a variety of channels and methods.

Through more effective education, Samsung Bioepis plans to make high-quality biosimilars more accessible to patients and healthcare professionals.



Corporate Governance

- 64 Governance Structure
- 67 Risk Management
- 70 Ethics and Compliance Management

Governance

Board of Directors

Board Roles and Composition

The Board of Directors, as the highest decision-making body at Samsung Bioepis, establishes all important company policy, including matters stipulated by law and/or the Articles of Incorporation and matters delegated by the General Shareholders Meeting; and decides on matters pertaining to the company's overall management and operation. It also establishes and executes the company's strategic direction, annual budget and business plan; and monitors and evaluates the company's overall performance.

The Board consists of six members – two inside directors and four other directors who are not engaged in regular business – in accordance with Article 26 of the Articles of Incorporation, which stipulates that the Board consists of three to six members. Directors have terms of three years, and are appointed by approval of the General Shareholders Meeting. The appointed directors support the company's sustainable growth by making fair and rational decisions, and they work to enhance value for all stakeholders.

Board Profile (As of September 2021)

Type	Name	Position	Key Experience	Term
Inside Directors	Christopher Hansung Ko	CEO	Samsung Bioepis,CEO	9 years 7 month
	Kyung-Ah Kim	Senior Vice President	Samsung Bioepis, Head of Development Division 2	1 month
Other Directors	Ian Henshaw	Senior Vice President	Biogen Inc, Senior Vice President	2 years 11 months
	John Rim	CEO	Samsung Biologics, CEO	2 years 4 month
	Peter Puype	Vice President	Biogen Inc, Vice President	2 years 4 month
	Robin C. Kramer	Vice President	Biogen Inc, Vice President	1 year

Shareholder Composition (As of September 2021)

Shareholder	Shares	Equity	Relation
Samsung Biologics	10,341,853	50%+1 Share	Affiliate
Biogen	10,341,852	50%-1 Share	Partner
Total	20,683,705	100%	-

Operation of the Board

Board meetings are held at least once every quarter, unless otherwise determined by the Board. The Board is also convened periodically either by the CEO himself or at the discretion of the CEO upon written request from the directors. The Chairman of the Board sends a notice (in Korean and English) stating the date, place and purpose of the meeting to all directors via post, fax or e-mail at least seven days prior to the date of the meeting. Each notice is accompanied by copies of relevant reports and materials so the directors may review and examine the meeting agenda in advance. However, with the written consent of all directors, the Board may convene without this notice procedure.

All Board resolutions require ratification by a majority vote of the directors present at a meeting in which there is quorum. No director, the Chairman of the Board included, has the authority at a Board meeting to break a tie vote. Directors may participate in Board meetings and resolutions via videoconferencing or teleconferencing platforms through which all meeting attendees can see and hear each other simultaneously.

In 2020, the Board held seven meetings to deliberate and decide on major management issues such as the approvals of a transaction with an affiliate; the approval of a concurrent appointment for an other director; and the approval of management plans for 2021. Board attendance in 2020 was 100%.

Board Meetings (As of September 2021)

Date	Agendas & Resolutions	Attendance
January 8, 2020	· Establishment of Investigations Committee	100%
February 6, 2020	· Approval of Financial Statement for the 8th term · Convening of Annual General Shareholders	100%
June 24, 2020	· Convening of Extraordinary General Meeting	100%
July 23, 2020	· Borrowing of bank loan · 2020 transaction with Samsung Biologics · Convening of Extraordinary General Meeting	100%
September 22, 2020	· Securing of bank loan	100%
October 14, 2020	· Convening of General Shareholders Meeting for appointment of other director (Robin C. Kramer) · Approved an other director John Rim's concurrent appointment as Samsung Biologics inside director	100%
December 9, 2020	· Approved 2021 business plan · Approved 2021 relocation of HQ to new offices · Convening of Extraordinary General Meeting	100%
February 24, 2021	· Approved financial statement for the 9th term · 2021 health and safety plan · 2021 transaction with Samsung Electronics · 2021 funding plan · Convening of regular General Shareholders Meeting	100%
March 24, 2021	· Reappointment of CEO	100%
July 14, 2021	· Transaction with Samsung Biologics	100%
September 29, 2021	· Convening of General Shareholders Meeting for appointment of inside director (Kyung-Ah Kim)	100%

Independence, Expertise and Diversity

To uphold the autonomy of the Board, the majority of the Samsung Bioepis Board of Directors is consisted of other directors rather than inside directors. The Chairman of the Board serves as a mediator who listens to feedback from inside directors and other directors alike to enable the Board to more impartially oversee the management of the company.

The rapidly changing business environment requires continuous decision-making by the Board, which is why the expertise and diversity of each director is so important. Samsung Bioepis has appointed an executive overseeing development as an inside director; and as other directors, several executives in charge of commercial, SCM (logistics) and accounting from global biopharmaceutical developer and manufacturer Biogen. This Board, consisting of members of diverse backgrounds, is therefore able to discuss matters from a variety of perspectives and supervise and advise management objectively and with expertise.

In appointing directors, Samsung Bioepis holds steadfast to the principle of prohibiting discrimination based on attributes not limited to gender, race, nationality, ethnicity and place of origin. The current Board consists of directors with diverse backgrounds (in terms of gender, race, nationality, etc.), experience, expertise and competencies. We are strengthening gender diversity by appointing a female director as other director in 2020 and appointing a female director as an inside director in 2021.

Inside Director Evaluations and Compensation

Inside directors receive a base annual salary and bonuses determined according to the compensation limits approved by the General Shareholders Meeting. The 2020 General Shareholders Meeting approved a director compensation limit of 5.6 billion KRW, which is a 500 million KRW decrease from the limit of 6.1 billion KRW the previous year. To reinforce performance-based compensation for inside directors, we are implementing the long-term performance incentive program applied across Samsung Group.

Committees under the Board of Directors

To enhance operational efficiency, the Board of Directors has established the Management Committee in accordance with Article 34, Paragraph 3 of the Articles of Incorporation. The Management Committee consists of two inside directors who have been delegated authority by the Board to make timely decisions on general management matters.

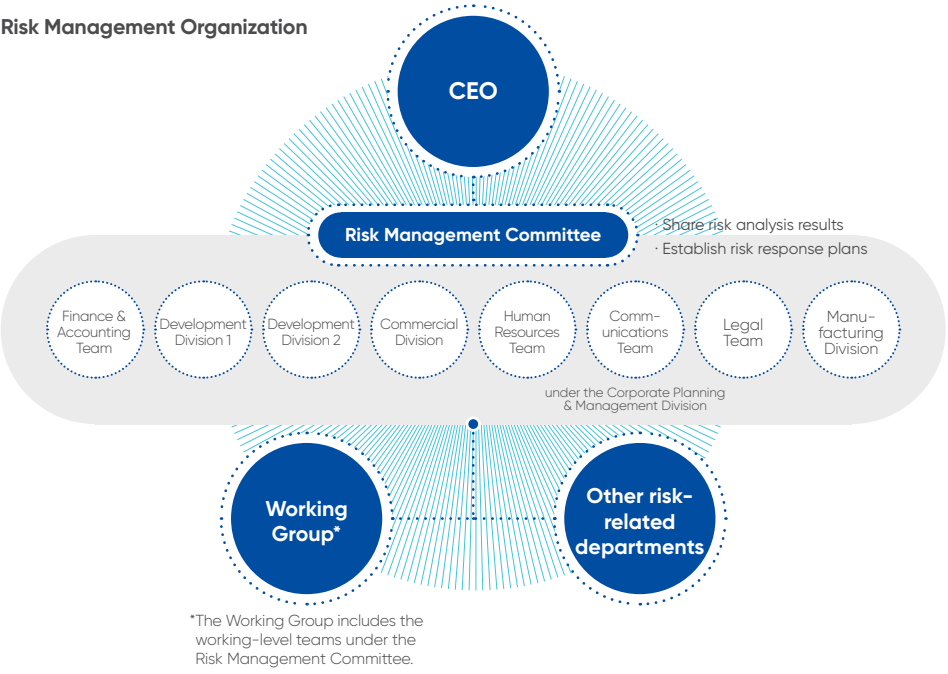
All directors are notified of resolutions made by the Management Committee, and each director may, if deemed necessary, request that the Chairman of the Board reconvene the Board to vote again on the Committee's resolutions. The Management Committee did not meet in 2020, and has itself been put on the Board agenda in a process aimed at strengthening management supervision. Also, to reinforce the increasingly important practice of ESG management, we inaugurated a dedicated ESG organization.

Risk Management

Risk Management System

The Samsung Bioepis Risk Management Committee serves to facilitate a timely response to risks. When risks arise, the Committee is immediately convened by the chairperson and works to perform a risk analysis and establish a detailed risk response plan within 72 hours (so-called golden hour). The Risk Management Committee operates directly under the CEO. The working-level organizations under the Committee, in turn, include the Finance & Accounting Team, Development Divisions, Commercial Division, Corporate Planning & Management Division, Legal Team and Manufacturing Division.

Risk Management Organization



Types of management risk

Financial risks	Non-financial risks
· Exchange/interest rate risk	· Global supply chain risk
· Liquidity risk	· Climate change risk
· Disclosures/financial statement risk	· Privacy risk
· Tax affairs (Finance) Accounting risk	· Reputational risk

Financial Risk Management

Exchange Rate and Interest Rate Risk

Samsung Bioepis generates most of its sales overseas, and therefore exchange rate volatility can impact revenues and profits. Moreover, with a significant portion of the company's financial liabilities subject to variable interest rates, profits can be affected by interest rate fluctuations at any time. Led by the relevant departments, we conduct periodic monitoring and assessments while managing exchange and interest rate risk, and we internally review these risks on a regular basis.

Non-financial Risk Management

Liquidity Risk

As we increase our borrowing to boost our R&D capabilities and build product pipelines, sudden changes in market conditions could lead to liquidity issues. To manage liquidity appropriately, we manage liquidity risk through regular cash flow forecasting and adjustments.

Disclosure Risk

In addition to the annual audit report, we make regular disclosures (of the status of large corporate entities) and ad hoc disclosures (of important matters such as unlisted companies) in a timely manner as required by the Fair Trade Commission (FTC). It should be noted that Samsung Bioepis has never incurred a fine for violating FTC disclosure regulations.

Tax Risk

We do our utmost to comply with the tax laws of Korea and all the countries where we operate, and we make sure to fulfill our tax filing and payment obligations. Our tax affairs manager keeps up to date on tax laws and procedures, reviews the impact of unusual situations and the appropriate steps to take, and shares these findings with the relevant departments. When laws or forms are revised, we immediately upgrade our systems to reflect the changes in our work processes. At all times, we maintain information channels that provide timely updates on important trends and ensure prompt, proactive responses. Every year, we evaluate the operations of our internal accounting management system for each type of tax activity, including whether new or revised tax laws are identified and reported to management in a timely manner, as well as whether the appropriate approval processes are used for tax filings and accounting entries.

Global Supply Chain Risk

The current disruption in the global supply chain for raw and subsidiary materials could expand and impact production. Also, with rising demand for outsourcing to global CMOs due to the COVID-19, there is a possibility that products may not be supplied on time. Samsung Bioepis ensures that products are delivered in a timely manner to patients who need treatment by ensuring stable production through a global supply chain spanning Europe, North America and Asia.

Climate Change Risk

In line with the Paris Agreement, climate regulations are being strengthened. Amid a global pandemic and abnormal climate events in the United States and elsewhere, there is a high likelihood that Korea will experience climate change risk in the coming years. Samsung Bioepis is therefore establishing response scenarios for each type of natural disaster and is boosting investment in facilities for natural disaster prevention and recovery.

Furthermore, with growing demand from our customers around the world for managing GHG emissions and energy consumption, we are working to plan and implement additional measures in response to this demand.

Privacy Risk

Globally, corporations increasingly have a responsibility to protect human rights and individual privacy. In the process of drug development and clinical trials, Samsung Bioepis collects personal information from employees and patients. In doing so, we ensure that the rights of employees and patients are protected by identifying compliance risk factors in terms of privacy protection in Korea and abroad while transparently disclosing our procedures for handling personal information.

Response to COVID-19



Reputational Risk

Since its establishment in 2012, Samsung Bioepis has received regulatory approval for six products and is developing and/or conducting clinical trials for five other products. As we develop and receive regulatory approval for more biopharmaceuticals, our status in the industry is rising. However, the reputation of the company is vulnerable to damage from potential legal violations or failures to take sufficient steps in terms of ESG. Accordingly, Samsung Bioepis will seek to lead the way in ESG management, and will further ramp up efforts to comply with all of its legal obligations.

[Special Page]

COVID-19 Response

Here at Samsung Bioepis, we have planned and taken necessary and progressive precautions to ensure the physical safety and mental wellbeing of our employees and our local community. This has been done in order to prevent the spread of COVID-19 whilst also ensuring patients continue to have access to the treatments they need. We pledge to keep our colleagues and community safe and will continue to monitor the situation and make amends to the way we run our business until we can safely return to the ordinary, together.

Company-wide Crisis Management

Our dedicated COVID-19 task force was established towards the end of January 2020. A number of measures were taken by our task force in order to prevent the spread of the virus. All of our workspace are disinfected every day, and hand sanitizers and disinfectants are placed on each floor, and we monitor the temperature of our employees throughout the day, with thermal imaging cameras placed at all entrances to the campus. We encouraged employees to conduct social distancing, by minimizing face-to-face meetings and replacing them with virtual meetings, and minimizing the non-essential travel. For employees who need to take care of their children at home because of COVID-19, they can take the family care leave without limitations. Through these efforts, the company did not have to implement any shut-downs so far as of September 2021, since the initiation of COVID-19 quarantine measures.

Supply Chain Management

To ensure the continued supply of our medicines to patients in need, Samsung Bioepis has closely collaborated with our manufacturing partners across the world to implement strict prevention and response measures against COVID-19.

Spearheaded by our SCM team, Samsung Bioepis has gone the extra mile to ensure supply continuity of our medicines to patients in need and manage supply chain efficiently in the midst of COVID-19. The team has assessed the potential impact of COVID-19 on supply chain, and has come up with a response strategy, while closely monitoring the situation around the clock. In addition, we have further strengthened our communication with our key stakeholders, patients and healthcare professionals through various channels including corporate social media as a way to share our firm commitment to ensure our business continuity as well as product continuity amid the pandemic. Throughout this pandemic, Samsung Bioepis has ensured there is no major supply disruption, and will continue to put efforts to secure supply continuity.

Support for Our Community

In celebration of our anniversary in February 2021, our colleagues made mask kits and donated to 13,000 local elementary students. Even in the face of COVID-19, we ran our 'Youth Bio Class' virtually to keep providing learning opportunities and our colleagues hosted the class to around 300 local students.

Compliance

Compliance System

Compliance Principles

Compliance with the law is essential to corporate sustainability and is a fundamental management principle of Samsung Bioepis. Amid rapid shifts in the business environment in Korea and overseas, and as business regulations become stricter, we are aware that legal violations can directly damage the company's reputation and lead to business losses. Moreover, we believe that ethical and compliance management, above all, are prerequisites to the fulfilling of our social roles and responsibilities as a global biopharmaceutical developer and vendor. We are working constantly at Samsung Bioepis to enhance our compliance management system as part of efforts to ensure we practice ethical and compliance management. We have a range of systems and programs in place, led by our compliance organization, that serve to prevent, monitor, inspect, and follow up on a variety of legal risks. We also strive to instill in our employees a vigilant sense and culture of legal compliance. This practice of strict ethical and compliance management will enable us to protect the company and employees, grow together with our partners, and fulfill our corporate social responsibilities.

Employee Code of Conduct

The Samsung Bioepis' Code of Conduct, enacted in 2016, sets out the manner by which we, as a company and as individual officers and employees, endeavor to conduct our business and must be strictly followed by all officers and employees affiliated with Samsung Bioepis. Based on the shared Samsung Values employees must adhere to, the Code of Conduct stipulates the management principles of: complying with laws and ethics; maintaining a clean organizational culture; respecting customers, shareholders and employees; prioritizing the environment, health and safety; and fulfilling our social responsibilities as a global corporate citizen. As stakeholders in a global biopharmaceutical leader built on ethical foundations, Samsung Bioepis employees will continue to follow the company Code of Conduct and engage in sound decision-making and execution across all operations.

[Samsung Bioepis Code of Conduct]

01

Compliance with Legal and Ethical Standards

02

Maintenance of a Organizational Culture

03

Respect of Customers, Shareholders and Employees

04

Care for the Environment, Health and Safety

05

Practice Social Responsibility as a Corporate Citizens

Samsung Bioepis Code of Conduct (CoC)

Compliance Organization

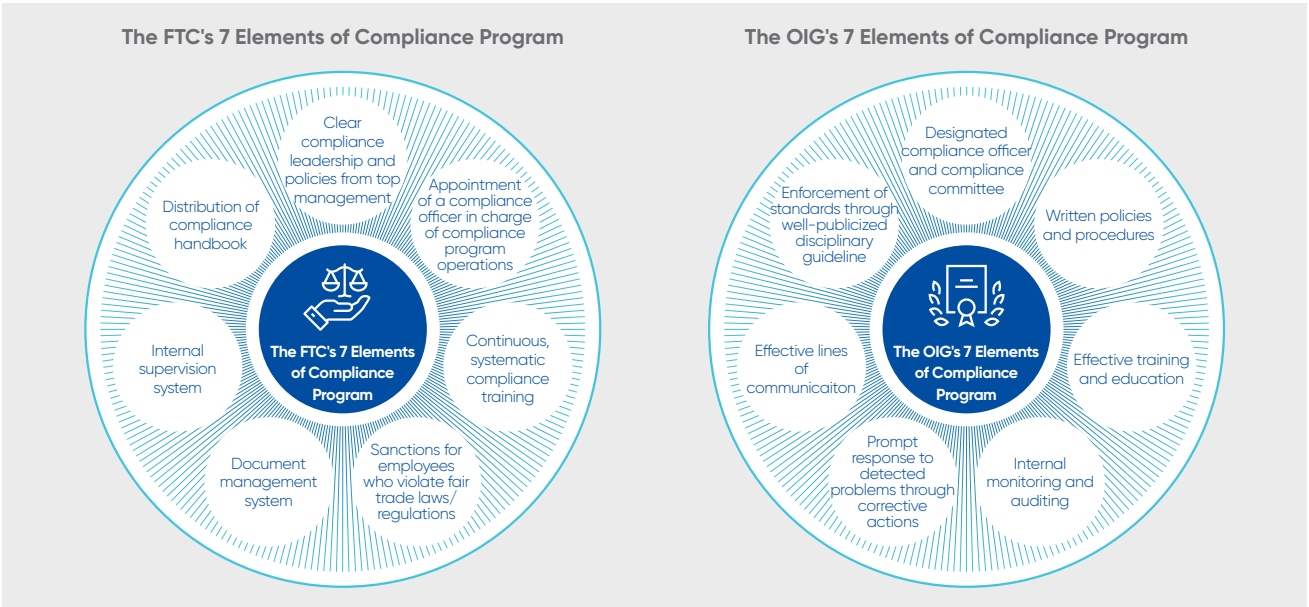
The Samsung Bioepis compliance organization consists of the Compliance Committee, which is empowered to make decisions, and the Compliance Team, which is a dedicated working-level organization. The Compliance Committee, launched in 2014, serves to review and decide on key agendas in order to facilitate efficient responses to compliance-related issues, and to promote interdepartmental collaboration. The Chief Compliance Officer may confer on and establish company-wide responses to matters discussed at the Committee, and the Compliance Team and relevant functions will take implementation actions. The Compliance Committee convenes twice a year (May and October), and as necessary on an ad hoc basis. The Compliance Team, meanwhile, operates compliance programs, fosters experts, and works with relevant departments to support any ethical or compliance activities necessary to the company's operations in a variety of areas, including fair trade, anti-corruption, human rights, environment/safety, and intellectual property rights.

Structure of compliance organization

Compliance Committee		Compliance Team	
Chairman	CEO	Leader	Head of legal department
Chief Compliance Officer	Executive appointed by the Chairman	Compliance Team Manager	Member of legal department
Members	Executives	Manager of operational department	Head of operational department
Secretary	Compliance Team Leader (working-level organization)		

Compliance Program

In 2014, Samsung Bioepis adopted a Compliance Program (CP) tasked with ensuring compliance with all laws and regulations across all company operations. The Samsung Bioepis Compliance Program conforms to the seven elements for compliance program operations stipulated by Korea's Fair Trade Commission (FTC) and the Seven Elements of a Compliance Program recommended by the Office of the Inspector General (OIG), an oversight body at the US Department of Health & Human Services. Currently, major activities being carried out through the Compliance Program include the drafting of compliance manuals; employee training; monitoring; investigation and response; employee sanctions and rewards; Compliance Program Management System (CPMS) operations; document and information management; reviews of major policies; and operational performance evaluations.

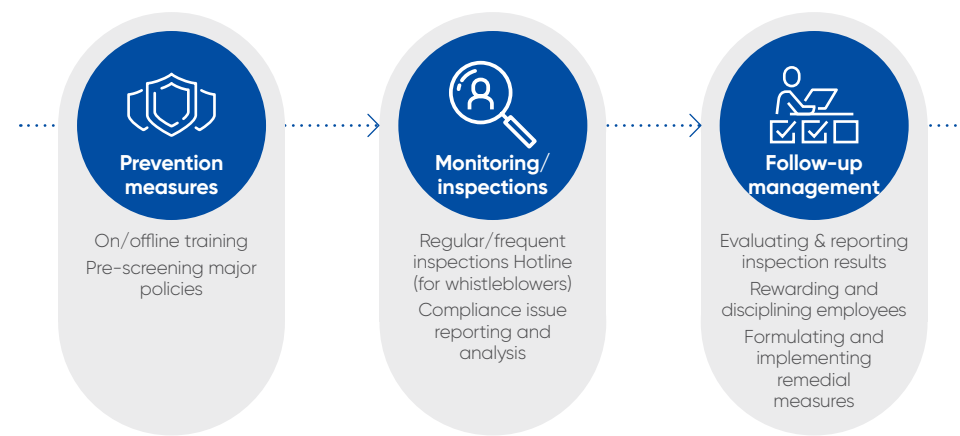


Compliance risk management

Compliance Risk Management Process

At Samsung Bioepis, our efforts are focused on protecting the company and its employees by preempting or minimizing risk through strict legal compliance. Compliance risk is managed systematically through a process of prevention, monitoring/inspection, and follow-up management. We preempt risks through employee training and by pre-screening major policies. Risk factors are mitigated via monitoring, regular/frequent inspections, accepting and handling whistleblower reports, and compliance issue reporting and analysis. Moreover, we spare no effort in our follow-up management activities, such as evaluating and reporting the results of inspections; rewarding and disciplining employees; and formulating and implementing remedial measures.

Compliance risk management process



[CASE]

Review process for managing external disclosure risk

In complying with each country's guidelines on providing prescription drug information, Samsung Bioepis has established a process for pre-disclosure compliance review that serves to prevent leaks of trade secrets, and protects intellectual property rights. The main subjects of review are materials for external distribution in a range of formats, including printed materials like brochures, magazines and magazine ads; presentation slide decks; videos; promo items; websites; mobile apps; and e-mail notifications. To prevent and manage compliance risks arising from public disclosures, we conduct reviews of external announcements in three stages: preliminary e-mail review; parallel approval in progress; and final compliance approval.

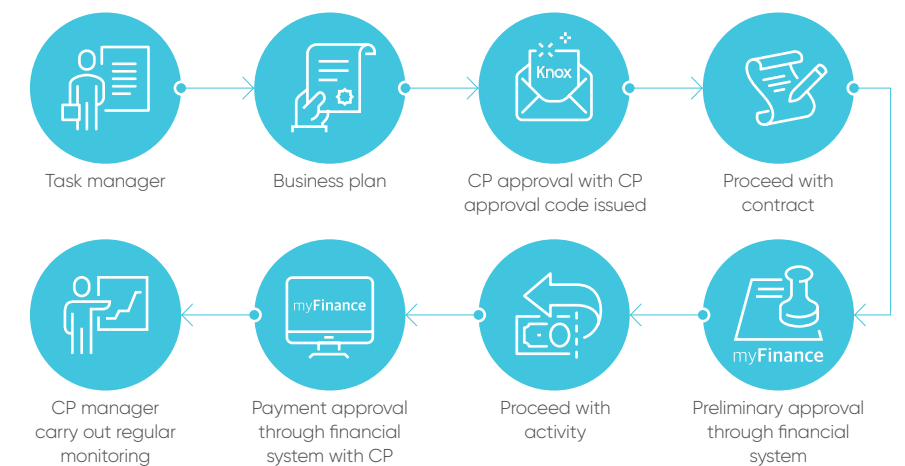
[CASE]

Systemizing review and control for "economic benefits for medical personnel" initiative

To preemptively mitigate compliance risk, Samsung Bioepis has been strengthening preliminary reviews of major company policies. In 2020, for our "economic benefits for medical personnel"¹⁾ initiative, we upgraded the company-wide financial system to enable preliminary review and control. Through the upgraded system, we began applying the new review process from March 2021.

With this upgrade to our financial system, it is now possible to exercise internal control over each work phase. In accounting, budgets and payments can be managed smoothly thanks to a function that designates accounts as needing separate management or management in the approval/settlement phase. This means we now have a system in place for advance controls on the provision of economic benefits to medical personnel through a four-stage review.

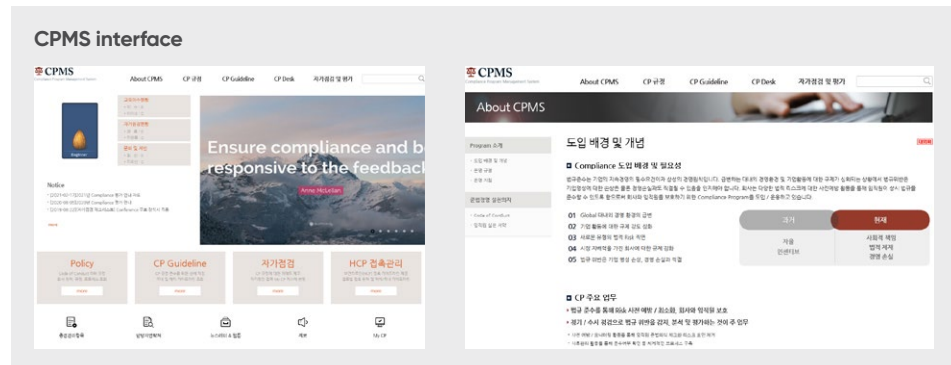
By systemizing compliance review and control and applying a unified review process, we have not only improved employee work accuracy and efficiency, but also created a framework for minimizing risk. We will continue working to raise our compliance management standards by rigorously applying the legally stipulated guidelines to our systems and processes.



¹⁾Projects that include the provision of economic benefit, as each country permits, for items such as lecture fees, consulting fees, academic group subsidies, and product briefings for health care professionals (HCPs), health care organizations (HCOs), and patient organizations (POs).

Compliance Program Management System (CPMS)

To efficiently manage compliance, Samsung Bioepis operates a robust compliance management system embedded in our IT system. Our CPMS provides explanations of the need for and concept of compliance, the relevant regulations, guidelines and codes of conduct; as well as content on making inquiries and reports, and performing self-inspections and appraisals. CPMS is used to communicate policies, internal regulations and processes pertaining to personal information, anti-corruption, public disclosures, fair trade, trade controls, and document preservation to enable employees to cross-check information at any time and practice compliance accordingly.



Channels for Reporting Violations

To improve operational transparency and establish a sound corporate culture, Samsung Bioepis provides channels for the reporting of illegal and unethical acts including: the acceptance or solicitation of bribes; violations of internal regulations pertaining to gifts and entertainment; unreasonable instructions and treatment; and security violations such as the leaking of confidential and/or internal information. Whistleblowers are guaranteed strict anonymity and protection from disadvantages. We investigate, corroborate and verify the details of any report submitted, then in conjunction with the applicable department, the matter is settled through disciplinary action and/or reward according to our internal regulations. We accept reports via e-mail hotline or the internal CPMS, and an external reporting channel (K-Whistle) is adopted in October 2021.

Channels for reporting violations

Internal		External
Hotline (e-mail)	CPMS	K-Whistle
· Main submission e-mail cp.hotline@samsung.com	· CPMS > CP Desk > Report · Bioepis service link > compliance management > CP reports	· Access website via PC (www.kbei.org) or mobile APP/QR code > access external website > submit report

Building a Compliance Culture

¹⁾Topics vary from year to year; training provided in 2020 on HCP/HCO regulations, the Improper Solicitation and Graft Act, the Personal Information Protection Act, and public disclosures.

²⁾Compliance regulations and guidelines provided for the 51 countries where the company operates.

³⁾Includes employees tallied at beginning of reporting year, and employees who resigned or took leave during the reporting year

* All training in 2020 was conducted online due to COVID-19.

Compliance Training

To minimize the risk of legal violations and to instill the practices of ethical and compliance management, Samsung Bioepis continuously conducts company-wide compliance training programs that reflect trends in regulation and the areas specific to the biopharmaceutical industry. We conduct at least four sessions/year of regular online training¹⁾ for all employees, with in-depth training provided by individual departments according to the nature of their work. Compliance training for new hires (entry-level and experienced) is also provided monthly. Moreover, compliance guidelines²⁾ essential to operating the CPMS are available at all times for employees to use in their work.

Compliance training sessions completed

(Unit: sessions/person)

Training format (No. of employees ³⁾)		2018 (837)	2019 (870)	2020 (892)
Offline	Sessions	1	-	-
	Persons(cumulative)	837	-	-
Online	Sessions	3	4	4
	Persons(cumulative)	2,580	3,560	3,680
Training hours/employee		4	4	4

(Unit: sessions/person)

Training format (No. of employees)		2018 (23)	2019 (20)	2020 (28)
Online	Sessions	1	1	1
	Persons(cumulative)	21	19	21

Strengthening our Compliance Culture

Every year since 2014, Samsung Bioepis employees have issued a public declaration of their commitment to compliance. This commitment is made in an annual compliance declaration ceremony on Law Day, a Korean public observance on April 25, and it includes an annual message from our CEO on ethical and compliance management. Furthermore, all employees take an annual pledge via the CPMS to abide by the Code of Conduct. Another way we strengthen our compliance culture is the regularly published Compliance Newsletter, which is distributed at least four times a year. It includes the latest trends in ethics and compliance management, explanations of the Improper Solicitation and Graft Act, and the results of annual regular training. In 2019 and 2020, in lieu of the compliance declaration, employee awareness of compliance was raised through publication of the Compliance Newsletter.

Pledge taken by employees

Year	2019	2020
No. of employees taking pledge	703 persons	884 persons

CEO's Compliance Message

CEO's Compliance Message

Dear Employees,

Samsung Bioepis has grown dramatically since its founding in 2012. Having become a world-class product company, currently with the largest number of biosimilar products, the sales growth and profits we have generated will soon become apparent.

As an R&D company, we prioritized efficiency, but now as a product company, we must be deliberate in adopting an approach not only of efficiency, but also of transparency and control.

Looking at other startup companies that grew beyond deficits to become product companies with full-fledged sales and profits, and then became the focus of intervention and investigation by regulators within a year or two, we can see that we must in short order adopt a compliance system of our own.

The results of an early May survey conducted on our company's compliance program present many implications.

We now face risks that are difficult to foresee, and especially in times such as these, I urge all Episons to remain true to the fundamentals.

This year marks an important period for us with the world's attention on our company.

Let us all work together for another leap forward by Samsung Bioepis as a trusted and respected company. Thank you.

May 2018

Christopher Hansung KO
President and Chief Executive Officer

2020 Compliance Newsletter



Appendix

78	Financial Data
82	Non-Financial Data [Environmental Performance]
84	Non-Financial Data [Social Performance]
88	GRI Standards Index
90	SASB Standards
91	Sustainability Initiatives
93	Awards and Associations
94	Independent Assurance Statement

Financial Data

Consolidated Statement of Financial Position

(As of December 2020, Unit: million KRW)

Category	2018	2019	2020
Assets			
I. Current assets	1,332,992	1,677,877	1,582,668
Cash and cash equivalents	177,612	155,187	97,727
Short-term financial instruments	145,691	-	-
Trade and other current receivables	170,324	316,586	186,941
Current tax assets	9,168	8,765	12,480
Inventories	799,093	1,100,124	1,216,521
Other current assets	31,105	97,215	68,999
II. Non-current assets	564,199	824,353	1,035,335
Long-term financial instruments	8	2,902	3,385
Other receivables	7,710	5,481	5,506
Tangible assets	86,589	90,056	219,963
Intangible assets	461,502	511,411	592,034
Right-of-use assets	-	5,085	1,262
Deferred tax assets	-	195,085	199,304
Other non-current assets	8,390	14,332	13,881
Total assets	1,897,191	2,502,229	2,618,003
Liabilities			
I. Current liabilities	1,229,279	1,611,430	1,277,932
Long-term trade and other payables	435,070	491,720	290,971
Short-term borrowings	349,448	539,758	566,850
Deferred income	331,889	535,784	409,891
Current portion of debent	111,579	-	-
Current lease liabilities	-	4,597	784
Current income tax liabilities	-	34,474	6,839
Withholdings	1,294	5,098	2,596
II. Non-current liabilities	265,777	224,917	537,461
Long-term borrowings	222,086	81,250	390,140
Non-current lease liabilities	-	483	381
Other payables	2,654	10,901	7,022
Lon-term deferred income	31,921	123,108	129,444
Defined benefit liabilities	9,116	9,175	10,475
Total liabilities	1,495,056	1,836,348	1,815,393
Equity			
I. Equity of parent company	402,134	665,882	802,609
Capital stock	103,419	103,419	103,419
Capital surplus	930,267	930,267	930,267
Accumulated other comprehensive income	(6,697)	(6,369)	(7,604)
Deficit	(624,853)	(361,435)	(223,472)
II. Non-controlling interests			
Total equity	402,134	665,882	802,609
Total liabilities and equity	1,897,191	2,502,229	2,618,003

Consolidated Statement of Comprehensive Income

(As of December 2020, Unit: million KRW)

Category	2018	2019	2020
I. Sales	368,734	765,859	777,374
II. Cost of sales	176,509	274,557	281,870
III. Gross profit	192,224	491,303	495,504
IV. Selling and administrative expenses	294,941	368,512	350,457
V. Operating profit	(102,717)	122,791	145,047
VI. Non-operating profit (loss)	47,861	(17,161)	(2,880)
Other income	177,010	829	1,104
Other expenses	(103,606)	(108)	(142)
Financial income	34,065	94,254	87,380
Financial expenses	(59,608)	(112,137)	(91,222)
VII. Income before tax	(54,856)	105,630	142,167
VIII. Income tax expense (profit)	101	(157,789)	4,204
IX. Profit for the year	(54,957)	263,418	137,963
X. Other comprehensive income	(1,629)	329	(1,235)
Other comprehensive income not reclassified as profit or loss			
Remeasurement of net defined benefit	(1,579)	270	(1,162)
Other comprehensive income reclassified as profit or loss			
Profit (loss) on overseas operations	(50)	58	(73)
XI. Comprehensive income	(56,585)	263,747	136,728

Financial Data

Consolidated Statement of Changes in Equity

(As of December 2020, Unit: million KRW)

Category	Capital stock	Capital surplus	Accumulated other comprehensive income	Deficit	Non-controlling interest	Total
2018.01.01 (Beginning equity)	103,419	930,267	(5,069)	(569,885)	-	458,731
Comprehensive income						
Profit for the year	-	-	-	(54,957)	-	(54,957)
Remeasurement of net defined benefit	-	-	(1,579)	-	-	(1,579)
Profit (loss) on overseas operations	-	-	(50)	-	-	(50)
Total comprehensive income	-	-	(1,629)	(54,957)	-	(56,585)
2018.12.31 (Equity at end of term)	103,419	930,267	(6,697)	(624,853)	-	402,134
2019.01.01 (Beginning equity)	103,419	930,267	(6,697)	(624,853)	-	402,134
Comprehensive income						
Profit for the year	-	-	-	263,418	-	263,418
Remeasurement of net defined benefit	-	-	270	-	-	270
Profit (loss) on overseas operations	-	-	58	-	-	58
Total comprehensive income	-	-	329	263,418	-	263,747
2019.12.31 (Equity at end of term)	103,419	930,267	(6,369)	(361,435)	-	665,882
2020.01.01 (Beginning equity)	103,419	930,267	(6,369)	(361,435)	-	665,882
Comprehensive income						
Profit for the year	-	-	-	137,963	-	137,963
Remeasurement of net defined benefit	-	-	(1,162)	-	-	(1,162)
Profit (loss) on overseas operations	-	-	(72,742)	-	-	(72,742)
Total comprehensive income	-	-	(1,235)	137,963	-	136,728
2020.12.31(Equity at end of term)	103,419	930,267	(7,604)	(223,472)	-	802,609

Domestic Income Tax Payment

(As of December 2020)

Category	Sales	Operating profit	Income tax paid
Domestic income tax payment	774,219	147,695	9,844

Consolidated Cash Flow Statement

(As of December 2020, Unit: million KRW)

Category	2018	2019	2020
I. Cash flow from operating activities	(24,159)	(5,536)	(154,943)
1. Cash generated from operations	(9,211)	15,637	(93,629)
(1) Net income	(54,957)	263,418	137,963
(2) Adjustments	179,582	(86,702)	74,276
(3) Changes in assets and liabilities	(133,837)	(161,079)	(305,868)
2. Interest received	2,350	4,358	723
3. Interest paid	(19,819)	(25,123)	(22,010)
4. Income tax refunded	2,520	(408)	(40,026)
II. Cash flow from investing activities	(213,299)	52,104	(242,026)
1. Cash inflows from investing activities	2,978	170,186	3,623
Proceeds from disposal of tangible assets	46,707	20,177	25
Decrease in guarantee deposits	2,931	4,319	3,598
Decrease in short-term financial instruments	-	145,691	-
2. Cash outflows from investing activities	(216,277)	(118,083)	(245,649)
Acquisition of tangible assets	15,128	31,469	118,585
Acquisition of intangible assets	51,268	81,559	122,921
Increase in guarantee deposits	2,165	2,160	3,660
Increase in long-term financial instruments	147,715	2,894	482
III. Cash flow from financial activities	326,042	(67,699)	341,787
1. Cash inflows from financial activities	647,419	395,045	834,568
Short-term borrowings	510,064	363,795	478,802
Long-term borrowings	137,355	31,250	355,766
2. Cash outflows from financial activities	(321,377)	(462,745)	(492,782)
Repayment of short-term borrowings	289,235	346,741	487,626
Redemption of debenture	32,142	111,810	-
Repayment of lease liabilities	-	4,194	5,156
IV. Increase (decrease) in cash	88,583	(21,132)	(55,182)
V. Cash at beginning of year	89,660	177,612	155,187
VI. Change in cash due to changes in foreign exchange rates	(631,760)	(1,293)	(2,278)
VII. Cash at end of year	177,612	155,187	97,727

Non-Financial Data [Environmental Performance]

Energy Consumption

Category	Unit	2018	2019	2020
Gas		23.09	25.77	23.67
Electricity	TJ	108.32	112.04	109.43
Total energy consumption		131.41	137.81	133.10
Energy consumption per unit area	TJ/1,000 m ²	6.61	6.93	6.70

* Energy consumption for 2018-2020 combines figures for Songdo and Suwon business sites.

* Calculated according to Korea Energy Agency conversion factor

- Gas: GJ=1.029*0.001 toe/Nm³ * 41.868 GJ/toe

- Electricity: GJ=0.229*0.001 toe/kWH * 41.868 GJ/toe

GHG Emissions

Category	Unit	2018	2019	2020
Scope 1: Direct emissions		1,168	1,303	1,197
Scope 2: Indirect emissions	tCO ₂ eq	5,190	5,368	5,243
Total GHG emissions		6,358	6,671	6,440

* GHG emissions for 2018-2020 combine figures for Songdo and Suwon business sites.

* Derived according to Korea Energy Agency tonne of oil equivalent and emissions calculator (2017 country-specific emission factor)

Water Consumption

Category	Unit	2018	2019	2020
Total water consumption	Ton	41,682	44,322	37,672

* Water consumption for 2018-2020 combines figures for Songdo and Suwon business sites.

Water Discharge

Category	Unit	2018	2019	2020
Total wastewater emitted	Ton	7,989	7,282	8,769

* Wastewater emissions for 2018-2020 combines figures for Songdo and Suwon business sites.

Management of Water Pollutants

Category	Unit	2018	2019	2020
Total organic carbons (TOC)		24.5	20.7	21.6
Suspended solids (SS)		13.2	11.8	8.4
Total nitrogen (T-N)	mg/L	11.2	11.7	12.2
Total phosphorus (T-P)		0.3	0.3	0.2

* Emissions standards: TOC under 75 mg/L, SS under 120 mg/L, T-N under 60 mg/L, T-P under 8 mg/L

* In 2020, treated effluents from Samsung Bioepis were mixed with those of Samsung Biologics, and therefore the reported discharge concentrations are from Samsung Biologics.

Waste Management

Category	Unit	2018	2019	2020
Generated waste	General waste	15.5	11.6	23.6
	Designated waste ¹⁾	97.0	80.9	90.2
	Total waste generated	112.5	92.5	113.8
Treated waste	Incinerated (outsourced)	112.5	92.5	113.8

¹⁾ Designated waste: Medical waste and other designated waste (approved drugs)

* Waste management performance for 2018-2020 combines figures for Songdo and Suwon business sites.

* Waste amounts exclude office waste disposed of by local governments using required weight-based bags (landfill).

Environmental Regulatory Violations

Category	Unit	2018	2019	2020
Total amount of fines	100 million KRW	0	0	0
No. of lawsuits filed		0	0	0
No. of non-monetary sanctions	Cases	0	0	0

Occupational Health and Safety

Category	Unit	2018	2019	2020
Accident rate ²⁾	%	0	0	0.11

²⁾ Calculation method: (One person injured in 2020/946 persons (average no. of employees in 2020) x 100

* No. of deaths from workplace accidents in three years: Zero

Non-Financial Data [Social Performance]

Employee Profile

Category		Unit	2018	2019	2020
Total employees	Total		828	871	920
	Male		436	449	475
	Female		392	422	445
By employment type: Regular & Fixed-term	Total		774	823	869
	Male		404	420	441
	Female		370	403	428
By employment type: Contract	Total		5	7	6
	Male		3	5	6
	Female		2	2	-
Under 30	Total	Persons	270	285	298
	Male		97	94	99
	Female		173	191	199
30's and 40's	Total		547	572	603
	Male		330	344	360
	Female		217	228	243
50's and older	Total		11	14	19
	Male		9	11	16
	Female		2	3	3
Female in management	No. of Female in junior management		11	13	20
	No. of Female in middle management		148	155	158
	No. of Female executives		3	3	5

* The location of Samsung Bioepis in Songdo, Incheon is part of the Incheon Free Economic Zone, which grants foreign-invested companies an exemption from the mandatory hiring of disabled persons, senior citizens and persons of national merit, which applies also to our company. As of December 2020, Samsung Bioepis employed four people with disabilities.

New Hires

Category		Unit	2018	2019	2020
By gender	Total	Persons	123	123	130
	Male		60	54	58
	Female		63	69	72
By age	Total	Persons	123	123	130
	Under 30		50	56	73
	30's and 40's		71	66	55
	50's and older		2	1	2

Employee Turnover Rate

Category		Unit	2018	2019	2020
Turnover Rate	Total ¹⁾	%	9.30	5.51	7.72
By gender	Male	Persons	34	24	26
	Female		43	24	45

¹⁾ Calculation method: No. of regular employees resigning compared to total employees in the given year

Parental Leave Users and Returners²⁾

Category		Unit	2018	2019	2020
Employees who used childcare leave	Total		16	21	34
	Male	Persons	4	4	4
	Female		12	17	30
Employees who returned to work after childcare leave	Return rate	%	76	100	87
	Total		13	19	27
	Male	Persons	4	3	1
Employees who served for over 12 months after returning from childcare leave	Female		9	16	26
	Continued employment rate	%	79	93	80
	Total		15	14	16
	Male	Persons	1	4	2
	Female		14	10	14

²⁾ Based on the number of employees entitled to parental leave (No. of employees with children under 12 years old: 179 men, 88 women) who took leave in 2020

Employee Compensation

Category		Unit	2018	2019	2020
Ratio of basic salary and remuneration of Female to Male ³⁾		%	93	93	92

³⁾ Calculation method: Women's average base pay / men's average base pay * 100

Performance Appraisal

Category	Unit	2018	2019	2020
Performance appraisal rate		100	100	100
Management by Objectives (MBO) ⁽⁴⁾	%	88.6	99.7	99.5
Multi-source performance assessment		6.2	7.2	58.5
Formal comparative ranking of employees within one employee category		93.8	94.1	95.2

⁴⁾ Systematically uses measurable targets set in consultation with immediate supervisor

Non-Financial Data [Social Performance]

Training Overview

Category	Unit	2018	2019	2020
Total training hours	Hours	121,770	113,884	112,676
Total no. of training participants ¹⁾	Persons	56,713	50,219	69,247

¹⁾ Calculation method: Based on no. of regular employees who completed training

Status of Training Programs

Category		Unit	2018	2019	2020
General training ²⁾	Training hours	Hours	112,403	109,291	111,544
	No. of participants	Persons	52,352	48,509	69,152
Ethical management training ³⁾	Training hours	Hours	1	1	1
	No. of participants	Persons	670	793	885
Sexual harassment prevention training ⁴⁾	Training hours	Hours	1	1	1
	No. of participants	Persons	760	800	840
Information security training	Training hours	Hours	-	0.50	0.50
	No. of participants	Persons	-	860	917
Human rights training	Training hours	Hours	4	4	4
	No. of participants	Persons	828	871	920

²⁾ Includes job/leadership training for office positions

³⁾ Ethical management training provided to 932 persons in 2020 (96% completion rate)

⁴⁾ Sexual harassment prevention training provided to 963 persons in 2020 (100% completion rate)

Incidents of Discrimination and Corrective Actions Taken

Category	Unit	2018	2019	2020
Cases reported	Cases	0	0	0
Corrective action taken		0	0	0

⁵⁾ Cases of discrimination by sex, race, age, social status, etc.

Grievance Reporting and Handling

Category	Unit	2018	2019	2020
No. of human rights-related grievances either submitted through official reporting channels or discovered, and resolved	Cases	0	0	0
No. of labor practice-related grievances either submitted through official reporting channels or discovered, and resolved		0	0	0

Information Security Violations and Response

Category	Unit	2018	2019	2020
No. of legal violations	Cases	0	0	0
Fines related to legal violations	1,000 KRW	0	0	0

GRI Standards Index

Universal Standards(GRI 100)

Classification	Disclosure	Indicators	Report pages
Organizational Profile	102-1	Name of the organization	14
	102-2	Activities, brands, products, and services	15, 18, 33-34
	102-3	Location of headquarters	2, 14
	102-4	Location of operations	2, 14
	102-5	Ownership and legal form	14
	102-6	Markets served	18-19, 34
	102-7	Scale of the organization	14
	102-8	Information on employees and other workers	84-85
	102-9	Supply chain	26
	102-10	Significant changes to the organization and its supply chain	No material change to the organization or supply chain during the reporting period
	102-11	Precautionary Principle or approach	67
	102-12	External initiatives	90-92
	102-13	Membership of associations	93
Strategy	102-14	Statement from senior decision-maker	10-11
	102-15	Key impacts, risks, and opportunities	67-69
Ethics and Integrity	102-16	Values, principles, standards, and norms of behavior	53, 70
	102-17	Mechanisms for advice and concerns about ethics	53, 74-75
Governance	102-18	Governance structure	64-66
	102-21	Consulting stakeholders on economic, environmental, and social topics	23
	102-22	Composition of the highest governance body and its committees	64-66
	102-23	Chair of the highest governance body	64
	102-24	Nominating and selecting the highest governance body	64-65
	102-29	Identifying and managing economic, environmental, and social impacts	66
	102-31	Review of economic, environmental, and social topics	65
	102-33	Communicating critical concerns	23
Stakeholder Engagement	102-34	Nature and total number of critical concerns	22-23
	102-40	List of stakeholder groups	23
	102-42	Identifying and selecting stakeholders	23
	102-43	Approach to stakeholder engagement	22-23
	102-44	Key topics and concerns raised	23
	102-45	Entities included in the consolidated financial statements	78-81
	102-46	Defining report content and topic Boundaries	23
	102-47	List of material topics	23
Reporting Practice	102-50	Reporting period	2
	102-51	Date of the most recent report	2
	102-52	Reporting cycle	2
	102-53	Contact point for questions regarding the report	2
	102-54	Claims of reporting in accordance with the GRI Standards	2
	102-55	GRI content index	88-89
	102-56	External assurance	94-96
Management Approach	103-1	Explanation of the material topic and its Boundary	24, 30, 38
	103-2	The management approach and its components	24, 30, 38

Economic Performance(GRI 200)

Classification	Disclosure	Indicators	Report pages
Economic Performance	201-1	Direct economic value generated and distributed	14, 18, 78-81
	201-2	Financial implications and other risks and opportunities due to climate change	68
Indirect Economic Impacts	203-1	Infrastructure investments and services supported	59-60
	203-2	Significant indirect economic impacts	61
Anti-corruption	205-2	Communication and training about anti-corruption policies and procedures	75
	205-3	Confirmed incidents of corruption and actions taken	No cases of corruption confirmed or related corrective action taken during the reporting period.
Anti-competitive Behavior	206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	No legal actions for anti-competitive behavior, anti-trust and monopoly practices taken during the reporting period

Environmental Performance(GRI 300)

Classification	Disclosure	Indicators	Report pages
Energy	302-1	Energy consumption within the organization	82
Water	303-4	Water discharge	82
Emissions	305-1	Direct (Scope 1) GHG emissions	82
	305-2	Indirect (Scope 2) GHG emissions	82
Effluents and Waste	306-3	Waste generated	83
Environmental Compliance	307-1	Non-compliance with environmental laws and regulations	83

Social Performance(GRI 400)

Classification	Disclosure	Indicators	Report pages
Employment	401-1	New employee hires and employee turnover	84-85
	401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	51
	401-3	Parental leave	85
	403-3	Occupational health services	47, 57
	403-4	Worker participation, consultation, and communication on occupational health and safety	55-56
Occupational Health and Safety	403-5	Worker training on occupational health and safety	57
	403-6	Promotion of worker health	57
	403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	55-56
	403-9	Work-related injuries	56
Training and Education	404-3	Percentage of employees receiving regular performance and career development reviews	85
Diversity and Equal Opportunity	405-1	Diversity of governance bodies and employees	84
	405-2	Ratio of basic salary and remuneration of women to men	85
Non-discrimination	406-1	Incidents of discrimination and corrective actions taken	89
Human Rights Assessment	412-2	Employee training on human rights policies or procedures	53, 86
Local Communities	413-1	Operations with local community engagement, impact assessments, and development programs	59
Customer Privacy	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	87
Socioeconomic Compliance	419-1	Non-compliance with laws and regulations in the social and economic area	No violations of laws or regulations in the social or economic area during the reporting period

SASB Standards

Samsung Bioepis shares the sustainability management goals of the Sustainability Accounting Standards Board (SASB), and in 2021 has begun voluntary efforts to comply with the standards for the healthcare and biotechnology & pharmaceuticals industries.

Code	Topic	Accounting Metric	Main Activities
HC-BP-210a.1.	Safety of Clinical Trial Participants	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	In accordance with the ICH-GCP guidelines on clinical trials, we regularly monitor results in the clinical trial process, and we maintain systems for responding to potential adverse events by continuously monitoring for adverse events among trial participants.
HC-BP-250a.1	Drug Safety	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Samsung Bioepis products are not listed on the FDA's MedWatch Safety Alerts for Human Medical Products.
HC-BP-260a.1	Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	We have a traceability monitoring system in place in accordance with the regulations of the EU FMD, US DSCSA and other national regulations to ensure the serialization of packaging and to prevent counterfeiting/forgery.
HC-BP-270a.1	Ethical Marketing	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Samsung Bioepis incurred no monetary losses in 2020 as a result of legal proceedings associated with false marketing claims.
HC-BP-330a.1	Employee Recruitment, Development & Retention	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	Samsung Bioepis recognizes the right of employees to freedom of association and collective bargaining, and seeks to provide fair and rational leadership and assessments. We support them in choosing from a variety of career paths while developing training programs to enable their growth as experts and providing ample time for learning.
HC-BP-510a.1	Business Ethics	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Samsung Bioepis incurred no monetary losses in 2020 as a result of legal proceedings associated with corruption or bribery.

Sustainability Initiatives

The Ten Principles of the UNGC

Samsung Bioepis supports the aims of the United Nations Global Compact (UNGC) as a global sustainability management initiative, and in 2021 is voluntarily adhering to each of the Ten Principles of the UNGC regarding human rights, labor, the environment and anti-corruption.

Category	Principle	Main Activities	Report pages
Human Rights	1	Businesses should support and respect the protection of internationally proclaimed human rights; and	
	2	make sure that they are not complicit in human rights abuses.	
Labor	3	Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;	Samsung Bioepis adheres to human-centered management principles throughout the company to prevent human rights violations in the course of our business activities. We prohibit forced labor and child labor, and employees are selected and evaluated in a fair and reasonable manner. 53
	4	the elimination of all forms of forced and compulsory labour;	Samsung Bioepis recognizes freedom of association and the right to collective bargaining, and operates a number of grievance channels so that employee grievances can be addressed immediately.
	5	the effective abolition of child labour; and	
	6	the elimination of discrimination in respect of employment and occupation.	48
Envi-ronment	7	Businesses should support a precautionary approach to environmental challenges;	Samsung Bioepis practices enterprise-wide environmental management based on a philosophy of green management. Though as an R&D company with low energy consumption, we are not subject to GHG or energy target management, we continue our efforts to proactively respond to climate change, and we maintain management systems for water resources, waste, air pollutants and harmful chemical substances. We are also boosting our efforts to introduce eco-friendly packaging materials as part of building a circular economy and improving resource efficiency. 38, 68
	8	undertake initiatives to promote greater environmental responsibility; and	40-43
	9	encourage the development and diffusion of environmentally friendly technologies.	43
Anti-Corruption	10	Businesses should work against corruption in all its forms, including extortion and bribery.	At Samsung Bioepis, we are continuously strengthening our compliance management system. We maintain a range of systems and programs centered on the compliance organization to prevent a variety of legal risks, conduct monitoring/inspections, and take follow-up measures. We are also working to internalize a culture of compliance to ensure that employees comply with the law at all times. 70-75

Sustainability Initiatives

UN SDGs

Samsung Bioepis shares the aims of the United Nations Sustainable Development Goals (UN SDGs), and in 2021 is voluntarily supporting their attainment. We are currently engaged in activities related to 10 of the 17 goals, and plan to gradually expand the scope of our activities going forward.

Goals		Main Activities	Report pages
Goal 3	Ensure healthy lives and promote well-being for all at all ages	Strengthening Product Responsibility and Safety, Social Contributions	30-37, 58-61
Goal 4	Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all	Talent Management, Social Contributions	48, 50, 59
Goal 5	Achieve gender equality and empower all women and girls	Talent Management	48
Goal 6	Ensure availability and sustainable management of water and sanitation for all	Strengthening Environmental Management	41
Goal 7	Ensure access to affordable, reliable, sustainable and modern energy for all	Strengthening Product Responsibility and Safety, Talent Management, Protecting Human Rights	32-34, 46-51, 52-53, 54-57
Goal 9	Build resilient infrastructure, promote inclusive and sustainable industrialization, and foster innovation	Strengthening Product Responsibility and Safety	30-37
Goal 12	Ensure sustainable consumption and production patterns	Strengthening Environmental Management	43
Goal 13	Take urgent action to combat climate change and its impacts by regulating emissions and promoting developments in renewable energy	Strengthening Environmental Management	40-41
Goal 15	Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	Strengthening Environmental Management	41-43
Goal 16	Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels	Ethical Management	70-75

Awards and Associations

Awards and Recognition

Year/month	Organization	Award Event	Award Name
2021.04	iF International Forum Design	iF Product Award	· Communication - Corporate Identity/Branding · Packaging - Medicine/Pharmaceutics
2020.11	Ministry of Trade, Industry and Energy	Good Design Selection	· Brand Design Category
2020.11	Informa	Global Generics & Biosimilars Awards 2020	· Biosimilar Initiative of the Year
2020.08	Red Dot	Red Dot Design Award	· Packaging Design · Brand Design & Identity
2020.07	IMAPAC	Asia-Pacific Bioprocessing Excellence Award 2020	· Bioprocessing Excellence in Korea
2020.01	Korea Customs Service	Certified as Authorized Economic Operator	· Certified as Authorized Economic Operator

Industry Associations

Korea Biotechnology Industry Organization (KoreaBIO)
Korea Biomedicine Industry Association (KoBIA)
Biosimilars Forum
Medicines for Europe

Independent Assurance Statement



To: The Stakeholders of Samsung Bioepis

Introduction and objectives of work

BSI Group Korea (hereinafter "the Assurer") was asked to verify Samsung Bioepis's '2021 Sustainability Report (hereinafter "the Report"). This assurance statement applies only to the relevant information contained in the scope of the assurance. Samsung Bioepis is solely responsible for all information and assertion contained in the report. The responsibility of the assurer is to provide an independent assurance statement with expert opinions to Samsung Bioepis's executives by applying the verification methodology and to provide this information to all stakeholders of Samsung Bioepis.

Assurance Standards and Levels

This assurance was based on the AA1000AS v3 (2020) Assurance Standard and confirmed that the report is prepared in accordance with the Core Option of GRI Standards. The assurance level was based on the Type 1 that confirmed compliance with the four principles of AA1000 AP (2018) in accordance with the AA1000 AS.

Scope of Assurance

- The scope of assurance applied to this report is as follows;
- Based on the period from January 1st to December 31st, 2020 included in the report
 - Appropriateness and consistency of processes and systems for data collection, analysis and review
 - Major assertions included in the report such as sustainability management policies, strategies, objectives, business and performance
 - Information related to material issues determined as a result of materiality assessment
 - The following items were not included in this assurance
 - Financial information, SASB, UNGC and UN SDGs included in the report appendix
 - Other related additional information such as the website presented in the report

Methodology

- As part of its independent assurance, the assurer has used the methodology developed to collect relevant evidence to comply with the verification criteria and to reduce errors in the reporting, and has performed the following activities;
- To determine verification priorities, review of materiality issue analysis process and verification of the results;
 - System review for sustainability strategy process and implementation;
 - Review the evidence to support the material issues through interviews with senior managers with responsibility for them;
 - Verification of data generation, collection and reporting for each performance index

Assurance Opinion

- On the basis of our methodology and the activities described above, it is our opinion that
- The information and data included in Samsung Bioepis's Sustainability Report are accurate and reliable and the assurer cannot point out any substantial aspects of material with mistake or misstatement.
 - The report was prepared according to the Core option of the GRI Standards

The assurance opinion on the four principles presented by the AA1000 AP (2018) is as follows.

AA1000 AP (2018)

Inclusivity: Stakeholder Engagement and Opinion

Samsung Bioepis has a stakeholder engagement process in which key stakeholders such as Customers, employees, government and local governments, business partners, academia, local communities and associations participate. It was confirmed that key stakeholders' expectations and various opinions are collected and the drawn agenda is reflected in decision-making on sustainability management.

Materiality: Identification and reporting of material sustainability topics

Samsung Bioepis identified global issues including the UN SDGs (Sustainable Development Goals) and issues raised by international organizations and non-profit organizations, and conducted industry issue analysis, media research, and stakeholder survey to derive economic, social, and environmental material reporting issues related to sustainability management, and determined priorities by measuring social interest and evaluating business impact, and reported a total of 3 material sustainability management topics.

Responsiveness: Responding to material sustainability topics and related impacts

Samsung Bioepis established and implemented plans for each topic to appropriately respond to identified material topics in a way that reflects stakeholders' expectations, and detailed response activities and performance on material topics were disclosed in the Sustainability Commitment in the report.

Impact: Impact of an organization's activities and material sustainability topics on the organization and stakeholders

Samsung Bioepis implemented the process to identify and evaluate the impact on organizations and stakeholders related to material topics. Samsung Bioepis has implemented strategies and detailed targets by reflecting the impacts derived by corporate governance and product, social and environmental sectors, which are indicators of the mid to long term strategy and roadmap.

Key areas for ongoing development

- To the extent that the results of the verification are not affected, the following comments were made.
- It is recommended to establish a system to collect and manage performance data for each area of economy, society, and environment on a regular basis to manage performance against targets on a regular basis, and to integrate it with the internal audit process for data reliability management.
 - Samsung Bioepis has selected 3 material issues according to the materiality assessment process and is making efforts to faithfully include them in the report. In addition, we recommend that future reports provide wider information in relation to response to climate change, employee health and health management, energy consumption reduction and efficiency improvement identified as material issues.
 - It is expected that more effective ESG management will be possible if high-level policies and goals for sustainability management are established at the Samsung Bioepis board of directors, and the structure of responsibility for operation strategy establishment and performance reporting is clearly allocated.

Independent Assurance Statement

Statement of independence and competence

The assurer is an independent professional services company that specializes in Quality, Health, Safety, Social and Environmental management with almost 120 years of history in providing independent assurance services. No member of the assurance team has a business relationship with Samsung Bioepis. We have conducted this verification independently, and there has been no conflict of interest. All assurers who participated in the assurance have qualifications as AA1000AS assurer, have a lot of assurance experience, and understand the BSI Group's assurance standard methodology.

Evaluation against GRI 'In Accordance' Criteria

The assurer confirmed that this report was prepared in accordance with the GRI Standards Core Option and the disclosures related to the following Universal Standards and Topic-specific Standards Indicators based on the data provided by Samsung Bioepis.

[Universal Standards]

Organizational Profile (102-1~13)/ Strategy (102-14, 102-15)/ Ethics and Integrity (102-16~17), Governance (102-18/21~24/29/31/33/34)/ Stakeholder Engagement (102-40, 102-42~44)/ Reporting practice (102-45~47, 102-50~56)/ Management Approach (103-1&2)

[Topic-specific Standards]

- Economic: 201-1, 201-2, 203-1, 203-2, 205-2, 205-3, 206-1
- Environmental: 302-1, 303-4, 305-1, 305-2, 306-3, 307-1
- Social: 404-1~3, 403-3~7, 403-9, 404-3, 405-1~2, 406-1, 412-2, 413-1, 418-1, 419-1

16 Nov 2021



K. S. Song
BSI Group Korea, Managing Director



PASSION FOR HEALTH

Samsung Bioepis Sustainability Report 2021



The FSC™ (Forest Stewardship Council™) label means the wood used to make the product is from FSC-certified forests, developed and managed in consideration of their social, economic, and environmental impact.

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