

Samsung Bioepis Sustainability Report 2025

PASSION for HEALTH

SAMSUNG
BIOEPIS

About this Report

Reporting Scope

This report covers the sustainability management activities and performance of Samsung Bioepis' domestic operations. Financial data were prepared in accordance with the consolidated Korean International Financial Reporting Standards (K-IFRS). Both financial and non-financial data were prepared for the fiscal year in line with the disclosure standards, and data on energy consumption and Greenhouse Gas (GHG) emissions were reported based on the results of GHG emissions verification.

Reporting Cycle and Period

Following our first report in 2021, we have published sustainability reports each year since 2023. This report outlines Samsung Bioepis' economic, social, and environmental achievements and activities during the period from January 1, 2024 to December 31, 2024, and this extends to April 2025 for some significant performance. For quantitative performance, three-year data are presented from 2022 to 2024 to help understand their yearly trajectory.

Reporting Standards

This report aligns with the Global Reporting Initiative (GRI) Standards 2021. This report was also prepared in consideration such as the Sustainability Accounting Standards Board (SASB), the Task Force on Climate-related Financial Disclosure (TCFD), the European Sustainability Reporting Standards (ESRS), the principles of UN Global Compact (UNGC), and others.

Assurance

To ensure the international and external credibility and impartiality of the reporting process and the information disclosed, this report received thirdparty assurance by Korea Management Registrar Inc. as an independent assurance provider. The detailed assurance report is on page 55.

Inquiry

For further information on Samsung Bioepis, please visit our website.
Additionally, for inquiries about this report, contact us.
E-mail: epis.esg@samsung.com
Web Page: www.samsungbioepis.com

Forward-looking Statement Disclaimer

This report may include forward-looking statements that relate to the future and the present as well as the past. Forward-looking statements can be identified by the use of words such as "anticipate", "pursue", "goal", "strategy", "estimate" and similar expressions. It is worth noting that this report may contain statements related to Samsung Bioepis' ESG activity plans regarding the Company's future business strategy. While Samsung Bioepis believes that expectations reflected in these forward-looking statements are reasonable, we cannot guarantee these expectations will actually materialize. Forward-looking statements are intended to assist readers in understanding Samsung Bioepis' ESG approach, strategy, and expected operational environment and may not fit other purposes such as investment. Furthermore, forward-looking statements are subject to assumptions, inherent risks, and uncertainties, many of which are associated with factors that are beyond our control or cannot be accurately estimated. As such, investors are cautioned not to place undue reliance on these forward-looking statements, recognizing that actual results may differ from what was expressed or implied in these forward-looking statements. Except as required by applicable laws or regulatory responsibilities, Samsung Bioepis assumes no obligation to update any forward-looking statements as a result of new information, future events or other developments.

Cover Story

Connection lines, connecting life.
The graphic reflecting the DNA structure that symbolizes the connection between life and technology is expressed with Samsung Bioepis's corporate will to continue to lead a better life through innovative R&D.



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Message from Our CEO

Samsung Bioepis has remained committed to building a differentiated competitive position in the biosimilar sector over the past 13 years.

We are in the process of preparing for a second leap forward to meet unmet patient needs through open innovation and discovery of novel therapies.



Dear stakeholders,

At Samsung Bioepis, we put patients' lives first and strive to improve lives through innovation and by expanding access to high-quality treatments. Additionally, we are committed to fulfilling our responsibilities as a conscientious corporate citizen by adhering to ESG management principles.

Contributing to the health of humanity

The COVID-19 pandemic and climate challenges further highlight the vital role of the biopharmaceutical industry in safeguarding global health and human life. Samsung Bioepis is fully committed to leading this industry by driving cutting-edge R&D innovation and strengthening global partnerships across the entire value chain—from foundational research to manufacturing and commercialization. We are also continuing our proactive investments to address unmet medical needs for patients across various therapeutic areas, and aiming to make difference in patients' lives. Beyond simply providing medicines, we operate with a strong sense of mission, ensuring that our business activities and products contribute meaningfully to improving human health and enhancing patients' quality of life.

Fulfilling our corporate social responsibility

We believe that sustainable growth is made possible when we uphold our responsibilities towards the environment and society. Samsung Bioepis has been certified to international standards across various fields, including ISO certifications for environmental protection, safety, health, and information security, to ensure the responsible management of ESG risks. We undertake ESG initiatives across a range of areas based on cross-functional collaboration at all levels of the company, focusing on climate change response and Net Zero implementation, responsible supply chain management, and shared growth with local communities. We also do our utmost to establish ethical and sound governance to advance management accountability. Moving forward, Samsung Bioepis will remain committed to fulfilling its social responsibility and delivering on ESG management commitments. In so doing, will build trust with wide-ranging stakeholders including customers, local communities, and supply chains.

Rising to a global top-tier biopharmaceutical company

Since our foundation in 2012, we have been growing into a global leader in the biosimilar business over the past 13 years. In the face of rapidly evolving business landscape, we are wholeheartedly dedicated to achieving sustainable growth. To guide our journey, we have embraced the vision of the “Second Leap” as our management goal for 2025, and we are passionately committed to enhancing our innovative capabilities to bring this vision to life.

Based on the expertise and experience accumulated through our biosimilar business to date, we are actively working to expand our portfolio of therapeutic areas to prepare for the future. Our efforts include promoting open innovation through the utilization of the Samsung Life Science Fund, expanding global collaborations and establishing next-generation technology platforms, and also proactively securing promising future technologies. Building upon these initiatives, we are committed to continuously challenging ourselves to grow into a leading global biopharmaceutical company with exceptional research and development capabilities and innovative strengths.

At Samsung Bioepis, we are driven by a strong sense of purpose to make the world a better place by delivering high-quality biologic medicines at affordable prices. Guided by this mission, we continue to innovate and take on new challenges. We are committed to responsible business conduct to build trust with our stakeholders and fuel our sustainable growth. We look forward to your plentiful support and encouragement as we journey ahead to drive positive change for a healthier future for all.

Kyung-Ah Kim
President & CEO of Samsung Bioepis

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Company Overview

Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, we aim to become the world’s leading biopharmaceutical company.

Company Profile

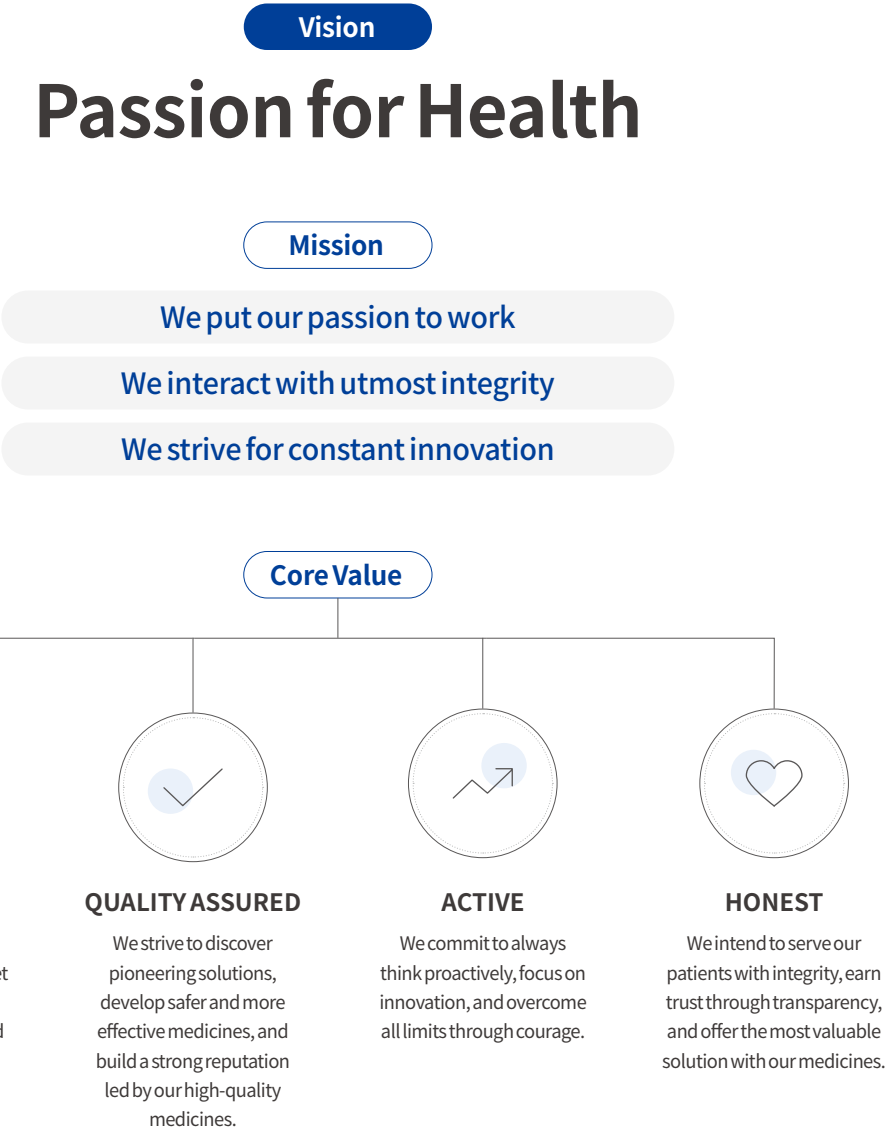
Samsung Bioepis is a biopharmaceutical company dedicated to bringing high-quality, affordable biologic medicines to patients worldwide. Since our foundation in 2012, we have become a global leader in biosimilar industry through innovative research and development platforms, combined with optimized supply chain capability and extensive marketing partnerships. We have developed a broad and industry-leading portfolio of 12 biosimilars, and 9 products of which were launched in over 40 countries around the world. We will continue to drive innovations and find smarter, faster ways of bringing high-quality biologic medicines to patients in need. While continuing with the development of existing products as planned, we also engage in novel therapies development and direct marketing efforts to build momentum for our sustained growth and reach new heights.

“Multi-product, Multi-modality and Fully Integrated Global Pharmaceutical Company”



Name of company	Samsung Bioepis Co., Ltd.
Date of establishment	Feb. 28, 2012
Headquarters	76, Songdogoyouk-ro, Yeonsu-gu, Incheon, Republic of Korea
Overseas subsidiaries	US, Netherlands, UK, Poland, Switzerland, Brazil, Australia, New Zealand, Israel, Taiwan, Hong Kong

Vision & Mission

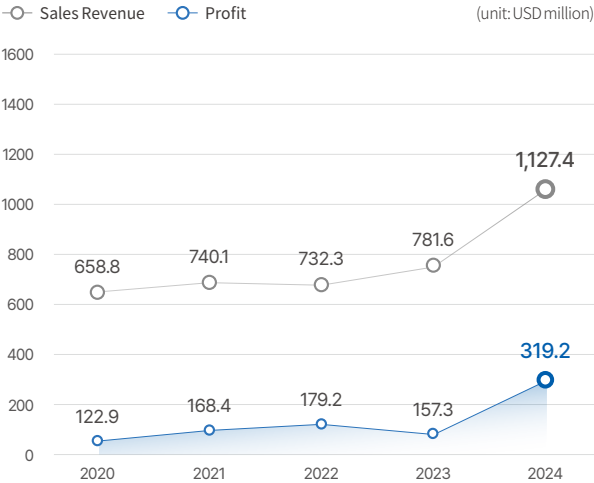


2024 Business Highlights

Samsung Bioepis is dedicated to enhancing access to high-quality biologic medicines for patients.

BIO + EPISTEME = LIFE SCIENCE

Our mission is reflected in our name, bioepis; literally meaning life (“bio”) and science (“episteme”) in Greek. We want to enhance the lives of patients through our pioneering and innovative use of science and technology.



* Rate of currency: Economic Statistics System of B.O.K (Bank of Korea)

Biologics

11 approved, 9 available

Our biosimilars are developed to support patients in their treatment journey. (As of April 2025)

Products Sales

40⁺ countries

We are enhancing access to medicines by providing high-quality biosimilars across global countries.

Employees

1000⁺

We are highly driven and relentless in our efforts to improve the lives of patients.

SAMSUNG BIOEPIS

Since 2012

R&D Workforce

57.8%

Our seasoned professionals are driving our R&D to the global level.

Patients Reached*

about 508,000 patients

Our biosimilars are helping our patients have a better quality of life.

Products Supplied

about 13.4 million units

We strive to ensure supply continuity by work with world-class manufacturing partners in Europe, North America, South America, and Asia.

* Number of patients reached (estimated) = Σ (annual sales volume/annual doses administered)

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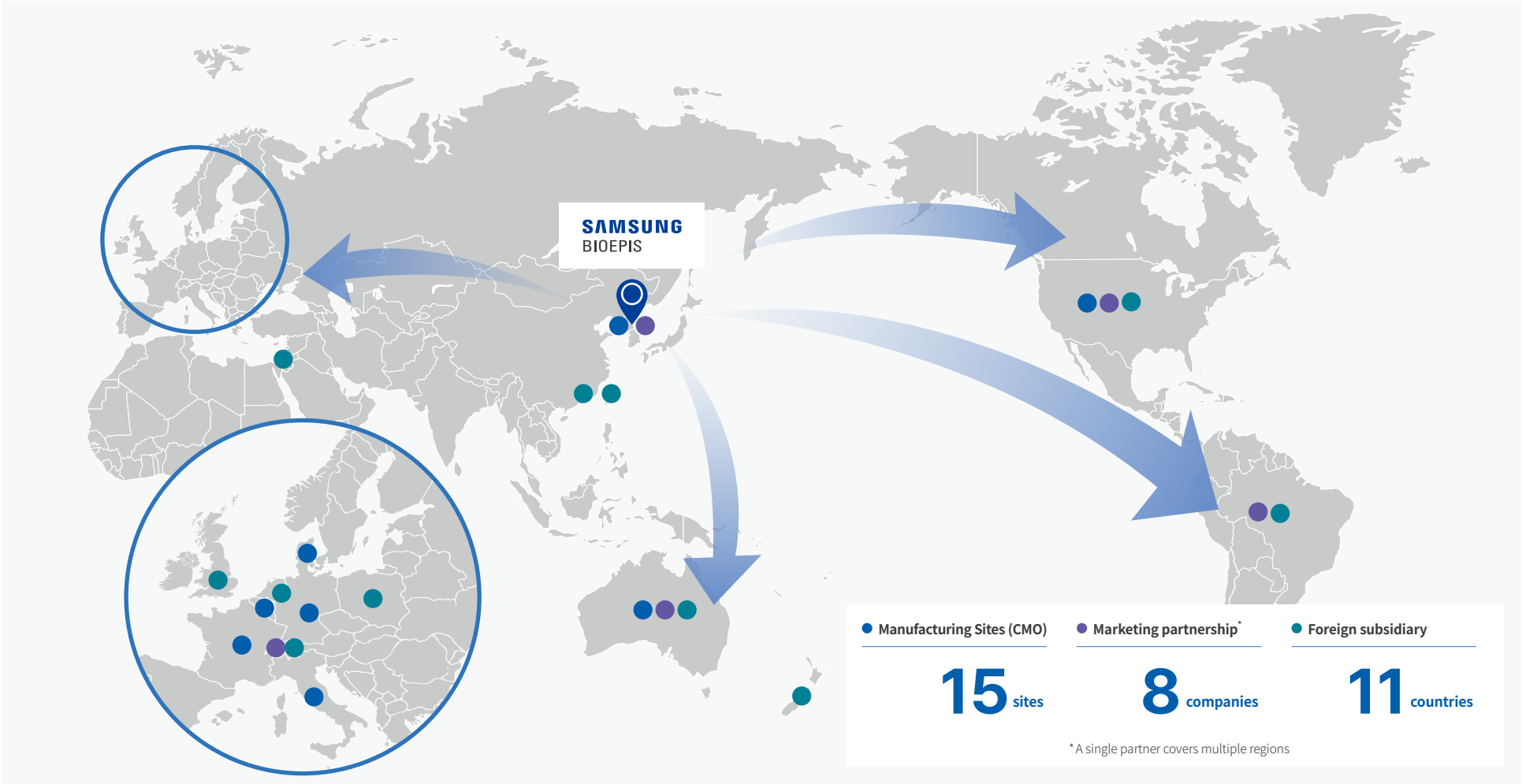
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2024 Business Highlights

* As of April 2025



Headquarter (Korea)	Europe	North America	Oceania	South America	Asia & Middle East
	<div><div>• CMO</div><div>• Marketing Partnership</div><div>• Subsidiary</div></div> <div><div>:</div><div>:</div><div>:</div></div> <div><div>9</div><div>3</div><div>4</div></div>	<div><div>• CMO</div><div>• Marketing Partnership</div><div>• Subsidiary</div></div> <div><div>:</div><div>:</div><div>:</div></div> <div><div>4</div><div>4</div><div>1</div></div>	<div><div>• CMO</div><div>• Marketing Partnership</div><div>• Subsidiary</div></div> <div><div>:</div><div>:</div><div>:</div></div> <div><div>1</div><div>1</div><div>2</div></div>	<div><div>• Marketing Partnership</div><div>• Subsidiary</div></div> <div><div>:</div><div>:</div></div> <div><div>2</div><div>1</div></div>	<div><div>• CMO</div><div>• Marketing Partnership</div><div>• Subsidiary</div></div> <div><div>:</div><div>:</div><div>:</div></div> <div><div>1</div><div>4</div><div>3</div></div>

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2024 Business Highlights

Social Value Creation

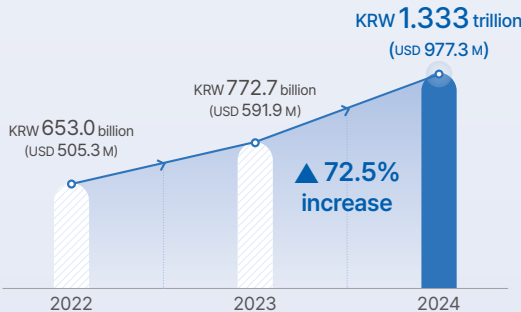
2024 Samsung Bioepis Total Impact Measurement and Management

Samsung Bioepis implements PwC’s Total Impact Measurement and Management (TIMM) methodology to measure its positive and negative business impacts. 2024 is our third year of measurement, and we will annually review measurement outcomes to identify the economic, social, and environmental implications of our financial and non-financial performance, expanding positive impacts while reducing negative impacts on an ongoing basis.

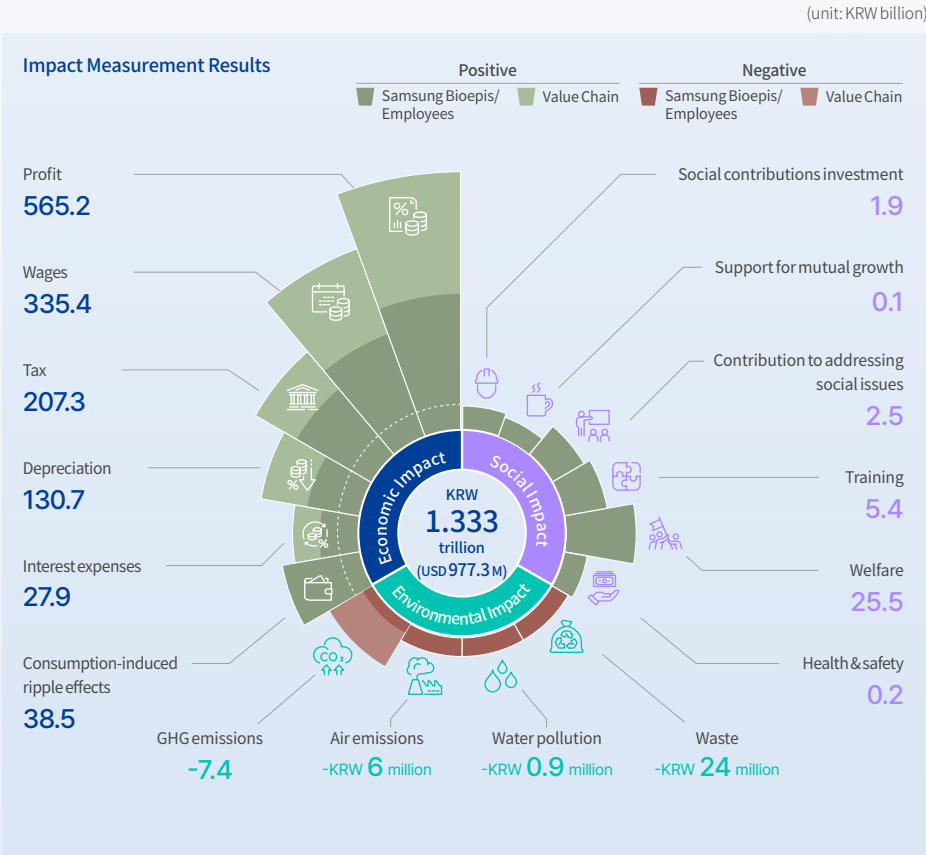
Scope of Impact Assessment	Period of Impact Assessment
We assess the impact of our business performance and the indirect impact generated by our employees. For certain areas including our contribution to addressing social issues, we assess the outcomes of our CSR programs on a program-by-program basis.	Jan. 01 – Dec. 31, 2024

Trends in Impact Measurement Results

In line with our expanding business footprint and efforts to advance ESG initiatives, we have seen a steady rise in measured social value. In 2024, the financial and non-financial impacts generated by Samsung Bioepis amounted to KRW 1.333 trillion (USD 977.3 M) in total, up by 72.5% from the previous year. Notably, economic impacts were assessed at KRW 1.305 trillion (USD 956.7 M) due to increases in net profit and transaction volumes stemming from our corporate growth. To ensure accuracy in measuring environmental impacts, we have included Scope 3 emissions since 2024 to enable a more comprehensively understanding and management of our environmental impacts throughout the value chain. Going forward, Samsung Bioepis will consistently amplify its positive impacts through business operations.



*The results were restated to reflect changes in the calculation methodology from the previous year’s report. For details, please see the quantitative ESG data section of this report.



* Rate of currency: Economic Statistics System of B.O.K (Bank of Korea)

Key Assumptions and Considerations

This measurement exercise is based on the performance data managed by the company and on the reasonable hypotheses defined by using official statistics from national and international organizations or findings derived from relevant research studies. This indicates that the monetary values presented for the year are subject to change in the future.

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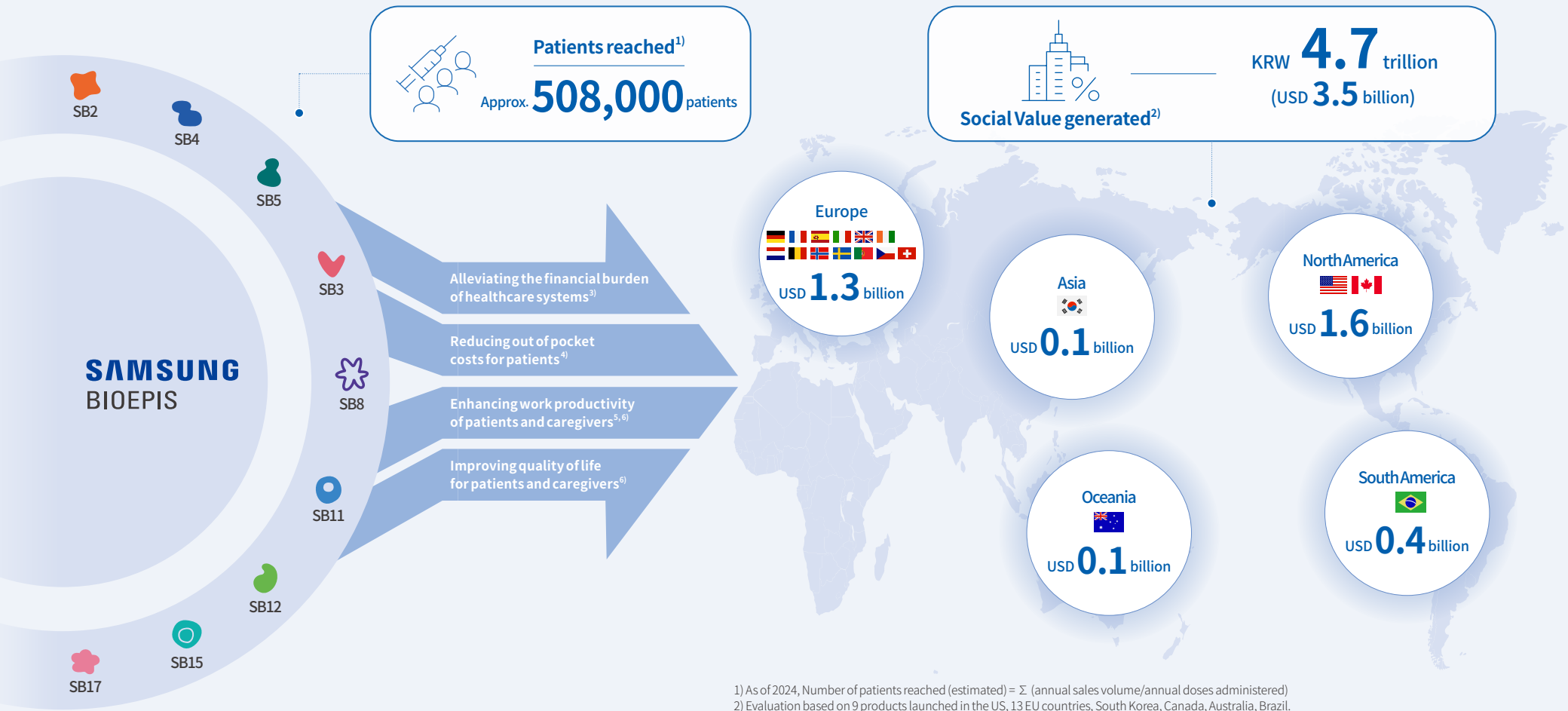
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2024 Business Highlights

Social Value of Our Products

Samsung Bioepis strives to improve patients' quality of life through the development and distribution of high-quality biosimilars. We contributes to reducing the financial burden on the national healthcare systems around the world, easing the out of pocket cost burden for patients, and enhancing both the work productivity and quality of life for patients and their caregivers. In 2024, the provision of these biosimilars generated approximately KRW 4.7 trillion in social value.



1) As of 2024, Number of patients reached (estimated) = \sum (annual sales volume/annual doses administered)
2) Evaluation based on 9 products launched in the US, 13 EU countries, South Korea, Canada, Australia, Brazil.
The number of products launched varies by country. 1 USD = 1,364 KRW.
3) The measurement of the effect of reducing prices of the reference products due to biosimilar introduction is based on the previous quarter's prices.
(Estimated social value of approx. KRW 7.7 trillion based on pre-biosimilar competition prices)
4) Out of pocket cost for patients varies from country to country.
5) Patients are assumed to have returned to work one year after treatment.
6) Based on OECD data and academic literature on productivity and quality of life related to each disease.

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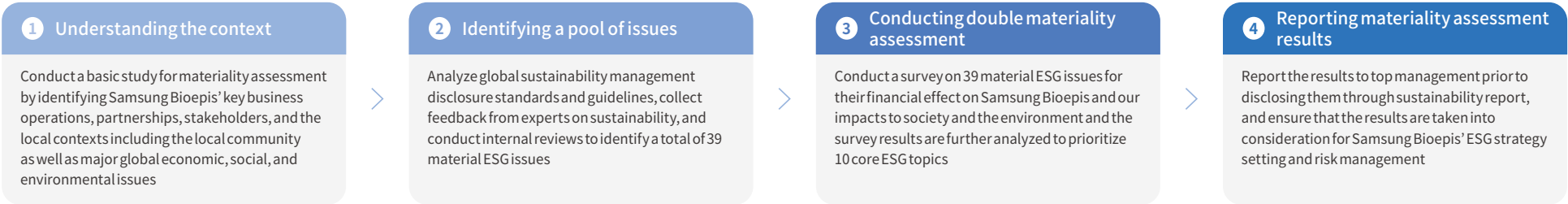
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Materiality Assessment

Double Materiality Assessment Process

Assessment Process



Assessment Methodology

Impact Analysis and Prioritization				ESG Expert Review				
Financial effect	Benchmarking	Analysis of key issues and disclosures among industry peers in 2024	Survey		Financial effect (Magnitude)	• Rate each material issue for its magnitude of effect on business operations on a scale of 1 to 5	Risk and opportunity assessment	• Assess risk & opportunity in full consideration of the scale, scope and likelihood of financial effect
	Analysis of global ESG assessment initiatives and industry-specific metrics	DJSI, MSCI, KCGS, SASB, Biopharma Initiative, and public tender evaluation criteria	Survey period	• Feb. 01, 2025 ~ Feb. 26, 2025				
Social & environmental impact	Media research	Analysis of 1,459 major domestic/ international news articles in 2024	Survey method	• Online survey	Social & environmental impact (Severity)	• Rate each material issue for its severity of impact to stakeholders like employees, customers, environment, and others on a scale of 1 to 5	Impact characteristic assessment	• Assess the characteristics of issues by comprehensively analyzing the scale, scope and likelihood of social & environmental impact (positive/negative, actual/ potential)
	Analysis of ESG disclosure-related international initiatives & guidelines and industry-specific metrics	GRI Standards, ISO 26000, UNGC, SDGs, ESRS, PSCI, 2024 Access to Medicine Index	Survey target	• Samsung Bioepis employees • Suppliers and other external stakeholders • Sustainability management experts				
			Questionnaire	• Gather stakeholder feedback on financial risk & opportunity, and social & environmental impact concerning 39 ESG issues • Select ESG issues that Samsung Bioepis should address for advancing sustainability management				

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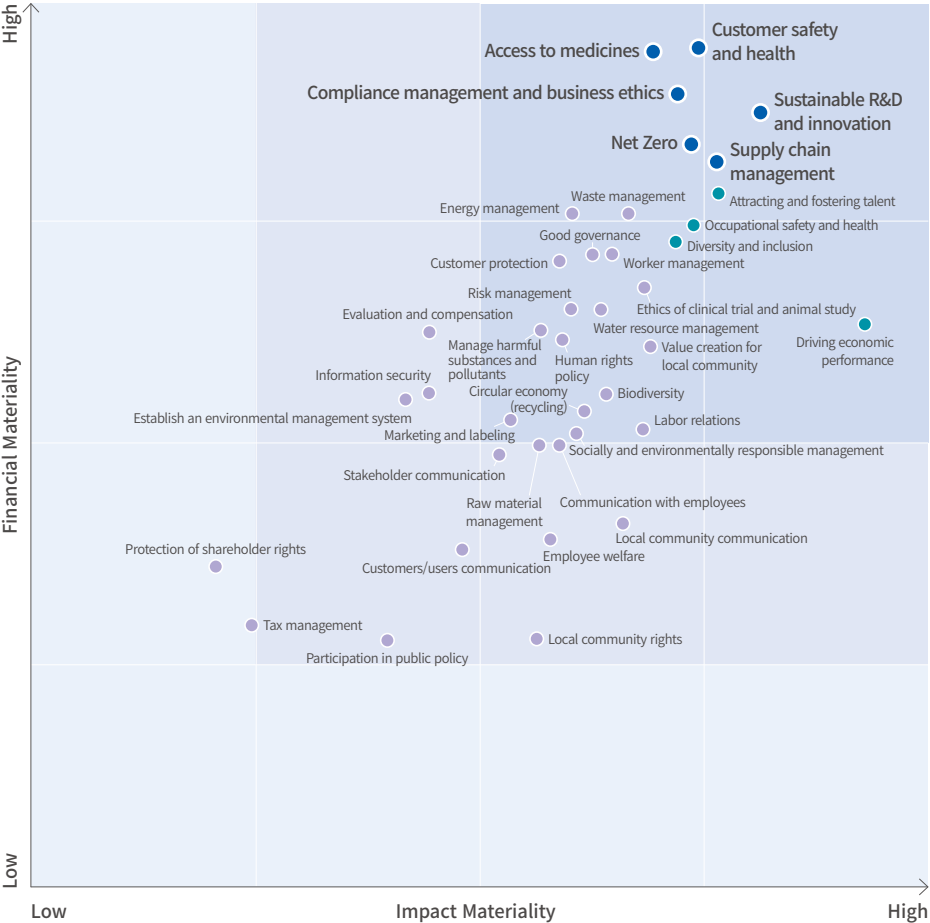
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Materiality Assessment

Double Materiality Assessment Results

Materiality Metrics and Core ESG Topics



Core ESG Topics

No.	Topic	Materiality Assessment		Impact direction	Comparison with 2024	Page
		Financial effect	Social & environment impact			
1	Sustainable R&D and innovation	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Very positive	4th→1st	14~16
2	Customer safety and health	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Very positive	1st→2nd	17~19
3	Access to medicines	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Positive	2nd→3rd	20~23
4	Compliance management and business ethics	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Positive	5th→4th	46
5	Supply chain management	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	A little positive	3rd→5th	41
6	Net Zero	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Negative	6th→6th	26~30
7	Attracting and fostering talent	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Positive	8th→7th	36
8	Driving economic performance	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Positive	New	7, 9, 10, 13
9	Occupational safety and health	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	Very positive	12th→9th	40
10	Diversity and inclusion	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	A little negative	14th→10th	39

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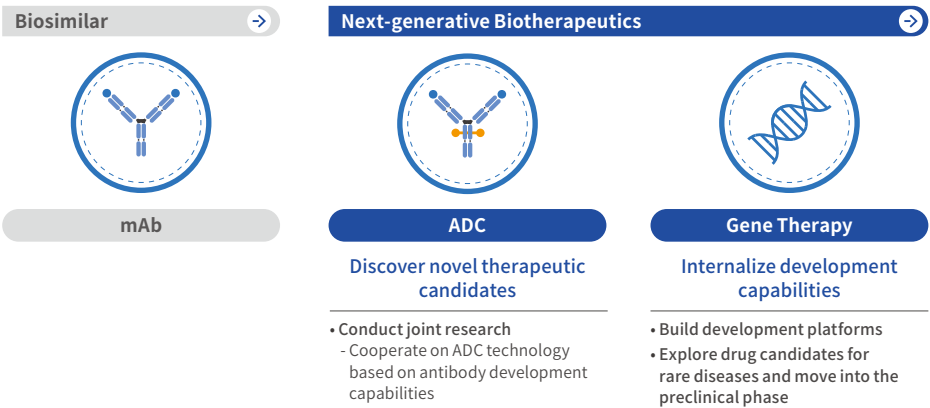
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R&D and Innovation

Exploring Next-generation Growth Drivers

Samsung Bioepis is actively pursuing a diverse range of therapeutic options as part of its strategic vision to become a top-tier global biopharmaceutical company. In the field of antibody-drug conjugates (ADC), we are strengthening our oncology portfolio and discovering novel drug candidates through a combination of in-house research and collaboration with external partners. In the cell and gene therapy (CGT), we continue to promote the development of therapies for rare disease by establishing proprietary gene therapy platforms and engaging in external partnerships.

Multi-product & Multi-modality



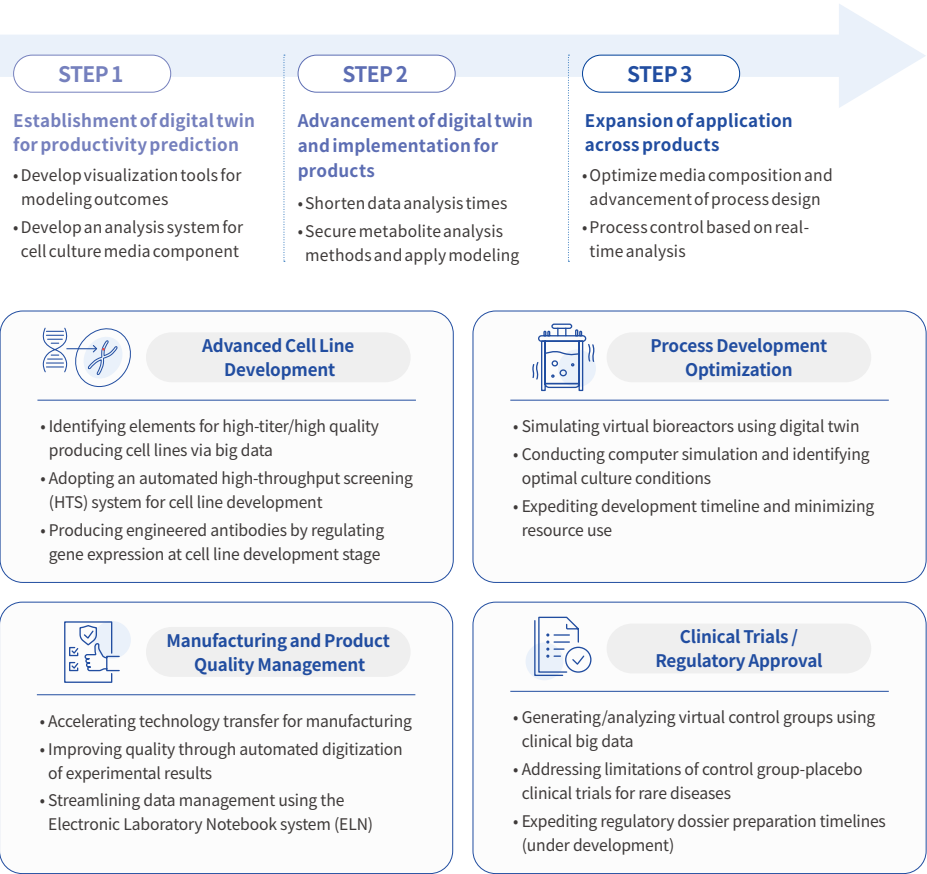
Samsung Life Science Fund (LSF)

The LSF, a venture investment fund jointly established by Samsung C&T Corporation, Samsung Biologics, and Samsung Bioepis, serves as the Open Innovation program to explore next-generation growth drivers in the biopharmaceutical industry. Since the initial capital commitment, a total of eight investments had been executed by 2024, enabling us to establish collaborative partnerships with high-potential biotech ventures possessing next-generation ADC and gene therapy technologies. This Fund will support our continuous efforts to identify next-generation growth drivers and pursue shared growth with innovative venture firms in Korea and overseas.

Timeline	Partner	Foundational Technology
Mar. 2022	Jaguar Gene Therapy	Gene therapy
Aug. 2022	Senda Bioscience	Nanoparticle-based drug delivery system
Apr. 2023	Araris Biotech AG	Antibody-drug conjugate
Sep. 2023	Aimed Bio	Antibody-drug conjugate
Mar. 2024	Brick Bio	RNA therapy
May 2024	Latus Bio	Gene therapy
Jul. 2024	Flagship Pioneering	AI-based drug discovery platform
Dec. 2024	Generated Biomedicines	AI-aided protein engineering

Innovative Process Development Powered by Artificial Intelligence(AI) and Digital Twin

We are promoting the application of AI throughout the entire stages of pharmaceutical development. We are leveraging big data to establish high-titer and high quality producer cell lines and utilizing Digital Twin technology to simulate optimal cell cultivation conditions, thereby identifying strategies to streamline process development and enhance productivity. Additionally, we are applying big data analytics to explore the most suitable clinical trial conditions tailored to our product candidates. We are also in the process of developing methods to shorten regulatory dossier preparation timelines by harnessing generative AI. By systematically advancing process development innovations using AI and digital twin technologies, we are actively committed to pioneering future technological advancements.



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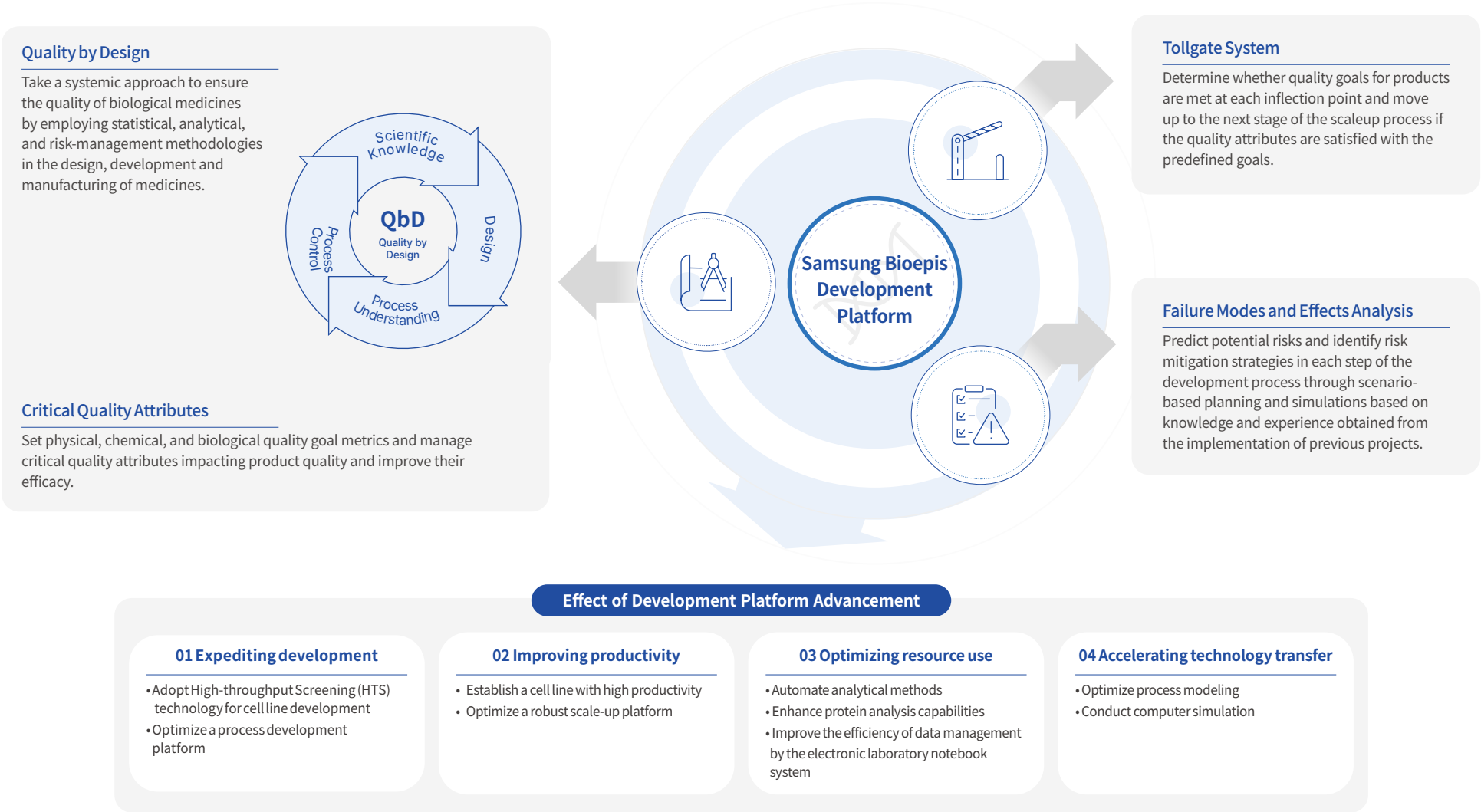
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R&D and Innovation

Advanced Development Platform

Samsung Bioepis commits to continuous process innovation in each step of our development process to enable extensive analyses and rigorous quality management, and is establishing and operating an advanced development platform. This, in turn, allows us to successfully and promptly develop high-quality biosimilars while minimizing risk that may occur in each process step.



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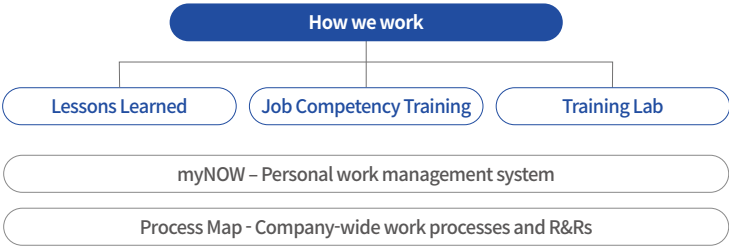
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R&D and Innovation

Bio Talent Development

Samsung Bioepis provides training programs that are anchored on Process Map, spanning from Lessons Learned training program aligned with Process Map and job competency training to Training Lab.

Work Management System and Training Programs



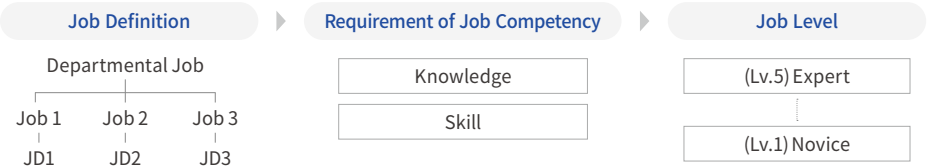
Lessons Learned Training Program

Our Lessons Learned training program identifies key learnings from previous projects in terms of managing risks and opportunities to improve employee trainings and work processes.

Lessons Learned Case Identification		Lessons Learned Training	
<ul style="list-style-type: none">• Reduce time/cost by reviewing past failure and success cases• Register lessons learned in the internal system to make them accessible by personnel from relevant departments		<ul style="list-style-type: none">• Conduct company-wide training for cases with significant organizational impact• Encourage department-level training for function-specific high-impact cases	
Outcomes	Note	Outcomes	Note
Total 3,379 Cases identified	cumulative basis (2017 – 2024)	Total company-wide training conducted: 93 sessions	Conducted since 2020
Average 365 Cases/year	2022 – 2024	2024 sessions: 15	

Job Competency Training

We provide systemic training programs tailored to employees with different job levels and competencies to aid in their growth into job experts.



Job Competency Training Outcomes

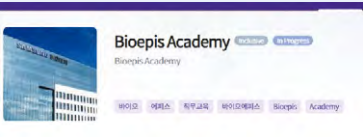
Category	2022	2023	2024
No. of Job positions	116	113	115
Training courses	5,863	5,499	4,444

* Training courses are updated annually to reflect timely relevance and evolving external conditions.

Case

Operation of Bioepis Academy CiC (Creative Intelligence Campus)

The Bioepis Academy CiC is an online education system that allows all executives and employees to autonomously access company-wide education and job training, and regularly provides basic and advanced courses. As of April 2025, a total of 1,971 training programs have been registered.



Training Lab

Training Lab is our tailor-made, intensive training program designed to help our employees develop technical competency. The program is categorized into three tracks to promote proactive skill management at the department level for new hires/newcomers and new experimental methods.

Training Lab Outcomes in 2024

Track	Description	Training Course	Registration
Track 1	Departmental skills management for essential experiment methods	27	71
Track 2	Experiment skills development for new hires	28	45
Track 3	Skills development for new experimental methods and equipment	35	145

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Product Quality and Patient Safety

Safe Clinical Trial Management

Compliance with Clinical Trial Regulations

From clinical trials through regulatory approval and post-marketing, Samsung Bioepis ensures that patient safety and well-being, data integrity, protection of personal information, and patient-centered treatment are incorporated across all clinical processes. All clinical trials related to our products are conducted in accordance with the Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP) of the International Council for Harmonization (ICH) guidelines, and thoroughly comply with the regulations of regulatory authorities by country.

Design and Operation of Patient-centered Clinical Trials

Guided by the principle of ‘patient-centered clinical operations’ which prioritizes patient experience and feedback, we put patient health and safety before all else throughout the entire clinical trial process. In the clinical trial participant screening phase, we provide training to help CROs and investigators comply with our rigorous eligibility criteria and the set clinical trial plan. After kicking off a clinical trial, we keep participants up to date with information on the investigational drug on a regular basis to provide accurate information and strengthen communication with trial subjects. If unexpected side effects are anticipated during the clinical trial, we make sure patients are given the opportunity to reconsent whether to continue their participation in the trial. In the event that any serious adverse event is identified after completion of the clinical trial, we swiftly collect and report information as specified in the regulations and guidelines of national regulatory authorities to take proactive follow-up action.

Minimization of Animal Studies


Leveraging our advanced scientific expertise and capabilities, we strive to demonstrate the equivalence of our products through in vitro studies and engage with regulatory authorities to minimize the need for animal testing and seek exemptions when possible. In the event animal studies are inevitably justified in line with the standards and requirements of national regulatory authorities, we commit to the 3Rs principles to obtain comparable levels of information from the use of fewer animals, minimize unnecessary pain through the review of experimental methods and technology, and consider animal welfare & ethics and management standards.

3Rs Principle

Replacement	Reduction	Refinement
Avoiding or replacing the use of animals as much as possible through non-animal studies	Obtain comparable levels of information from the use of fewer animals	Minimize unnecessary pain and stress when conducting unavoidable animal studies


Strengthening Clinical Trial Capabilities

We have established a data-driven clinical quality monitoring system to bolster our global clinical trial capabilities and seek continuous improvement in quality. This system applies to over 700 clinical trial sites worldwide to help us accumulate global clinical experiences. In particular, we make the safety of clinical trial participants our first priority in designing clinical trials and selecting optimal country sites and CROs to maximize the efficiency of clinical trials. While pooling our global clinical trial experiences, we also build clinical data assets, develop clinical trial Standard Operating Procedures (SOPs), and expand training to nurture our employees to internalize clinical trial capabilities.




Rigorous quality management

- Adhere to ICH GCP guidelines and data privacy laws
- Meet clinical quality standards of the FDA¹⁾, EMA²⁾ and other regulatory authorities
- Closely collaborate with CROs³⁾
 - Constantly monitor clinical quality
 - Provide ongoing CRO training and establish a quality management system



Patient-centered clinical trial design

- Put patient safety at the center of clinical trial design
- Continuously monitor and eliminate safety hazards and risks for patients throughout trial execution
- Acquire clinical data valuable from the patient perspective



Maximum efficiency in clinical trial

- Select country sites and CROs by considering target indications and patients
- Directly manage CROs
 - Initiate clinical trials by country
 - Directly manage patient recruitment
- Conduct preemptive risk assessments and develop preventive measures
- Closely consult with CROs and vendors

1) U.S. Food and Drug Administration
2) European Medicines Agency
3) Contract Research Organization

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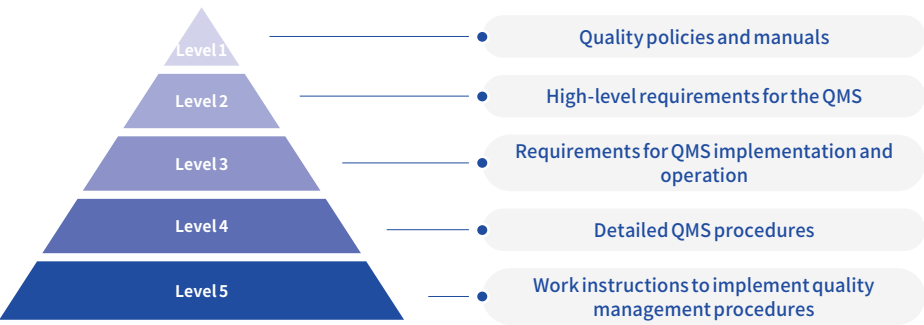
Product Quality and Patient Safety

Quality Management System and Activities

Protecting patient health and safety is fundamental to the pharmaceutical industry. At Samsung Bioepis, we have established and implemented a globally recognized and robust Quality Management System (QMS) designed to proactively mitigate quality risks and enable swift decision-making and corrective actions whenever quality issues arise. We are also continuously strengthening our company-wide quality assurance capabilities across all stages of product development and manufacturing to uphold the highest standards of quality and reliability.

Quality Management System

Our quality management system and related details are operated across five levels. At the highest level, quality policies and manuals serve as the foundation for systematically establishing quality management goals and processes. These goals and processes guide our efforts to conduct qualification assessments throughout the entire process of development, manufacturing, and supply. We also adhere to process-specific quality assurance procedures to ensure the delivery of high-quality medicines.



Quality Risk Management

- Inspection records by regulatory authorities (EMA/FDA)
- Sponsor audits
- CAPA¹⁾ management
- Contingency plan

Supply Chain Management

- Quality monitoring system
- Deviation management
- Change management
- Personnel qualifications
- GxP qualification management

Manufacturing Quality Competencies

- Project execution experience
- Materials management
- Quality control/incoming and release inspections
- Manufacturing facilities/equipment
- Manufacturing capacity

1) Corrective Action and Preventive Action

Bolstering Quality Assurance Capabilities

We provide structured quality training to help employees raise awareness on the importance of pharmaceutical quality and strengthen their quality assurance capabilities. New hires receive basic training on our quality management policies, and employees in departments that directly impact product quality are required to complete annual GxP training. These efforts ensure that individual employees develop quality assurance capabilities and apply them in their day-to-day operations.

Category	Description	Cycle	Cycle
Onboarding training	Promote understanding of our quality management policies	Upon recruitment	New and experienced employees
R&D training	Enhance competencies of employees engaging in Good Development Practice work	Year-round	R&D department staff
GMP ²⁾ training	Enhance capabilities in implementing guidelines and procedures for employees engaging in GMP-related work	Annual	CMO ³⁾ -related department staff
GCP training	Improve understanding and execution of GCP for internal and supplier employees engaging in clinical trial-related work	Biennial	Clinical trial-related staff
PQC ⁴⁾ training	Enhance understanding and execution of procedures to handle quality complaints raised for our products	Annual	All employees

2) Good Manufacturing Practice 3) Contract Manufacturing Organization
4) Product Quality Complaints

Quality Inspection

We strictly abide by and monitor the guidelines of domestic and international regulatory bodies, including the US FDA, EMA, and the Korean MFDS⁵⁾, and receive regular inspections by these regulatory authorities. In total, 36 inspections were conducted over the past three years, including 9 inspections in 2024, and zero warning letters were issued.⁶⁾ As a result, Samsung Bioepis and our third-party manufacturing facilities, laboratories, and research partners successfully achieved GxP certification.

Category	Inspections Conducted (cases)				Warning Letters
	FDA	EMA	MFDS	Others	
Subtotal	15	7	9	5	Zero
2024	5	1	1	2	
2023	7	3	7	3	
2022	3	3	1	0	

5) MFDS: the Ministry of Food and Drug Safety
6) Related solely to Samsung Bioepis products, excluding quality-related matters affecting third-party partners

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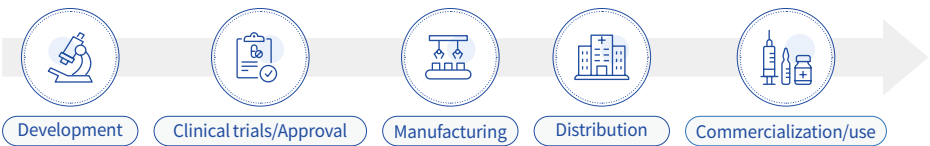
Product Quality and Patient Safety

Quality Management Along the Entire Product Lifecycle

Rigorous Pharmacovigilance

Samsung Bioepis is dedicated to ensuring the safe and responsible supply of medicines throughout the entire product lifecycle from development to patient use. As part of our commitment to product safety, we have implemented a data-driven pharmacovigilance system and monitor safety information through multiple channels, including healthcare professionals (HCPs), patient support programs (PSPs), call centers, and regulatory authorities.

Collection, Analysis, and Reporting of Product Safety Information



Case

Averse Event Signaling Analysis System

We have established a robust pharmacovigilance system to collect and analyze adverse events associated with drug use and to ensure timely compliance with regulatory requirements. By leveraging an advanced case analysis platform, we have enhanced data processing efficiency, enabling prompt identification of safety signals and effective response to evolving regulatory expectations.

Risk Management Action

We perform risk management in pharmacovigilance (PV) aligned with country specific regulatory requirements to ensure the safe use of our medicines. For instance, given the risk of meningococcal infection associated with eculizumab, we provide tailored educational materials for SB12 (eculizumab biosimilar) to support safe and informed use.

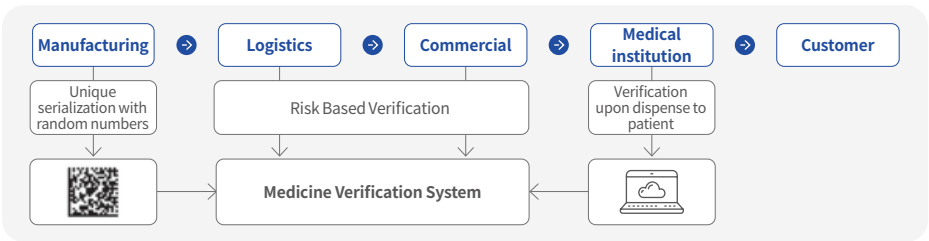
Providing Accurate Medicines Information

Our product labels are designed to provide accurate medicine information to protect consumers while preventing any misuse of medicines. We strictly prohibit off-label marketing which refers to advertising medicines for uses not approved by pertinent authorities, and offer regular training to our employees.

Active ingredient	Main ingredients that provide intended effects	Uses	Symptom(s) that the medicine intends to treat
Dosage and administration	Doses, dosing frequency, maximum daily dose, etc.	Warnings	Precautions, safety information, adverse reactions, etc.
Inactive ingredients	Substances that are added but do not intend to have direct therapeutic effects (preservatives, etc.)	Additional information	Storage and disposal methods, contact information to seek counseling for side effects, etc.

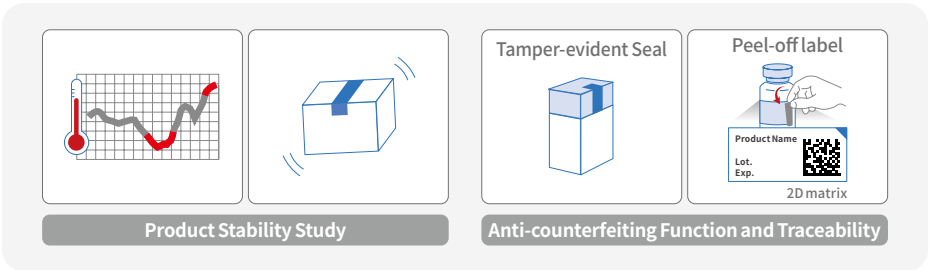
Strengthening Counterfeit Medicine Management

We cooperate with regulatory authorities in fulfilling their responsibility to protect public health through counterfeit medicine management. We employ and support serialization and traceability technology to prevent the distribution of counterfeit medicines and safeguard patients as a result. Upon receiving any reports of counterfeit distribution involving our products, we promptly notify regulatory authorities to facilitate swift action and cooperate to take swift action. In cases where counterfeit medicine is suspected during the post-marketing distribution phase, we take follow-up action in accordance with the medicine verification procedures outlined by regulatory authorities.



Robust Product Supply Management

We conduct rigorous stability studies to ensure product quality is maintained even under extreme environmental conditions. These studies simulate a wide range of scenarios that may occur during manufacturing, storage, and transportation, allowing us to conduct rigorous monitoring to prevent risks such as quality degradation. Meanwhile, our products are packed with tamper-evident seals and peel-off labels detailing product information¹⁾. This aims to ensure consumer (patient) safety and brace for unforeseen incidents involving counterfeit medicines.



1) SB2, SB3, SB8 (400mg), SB12

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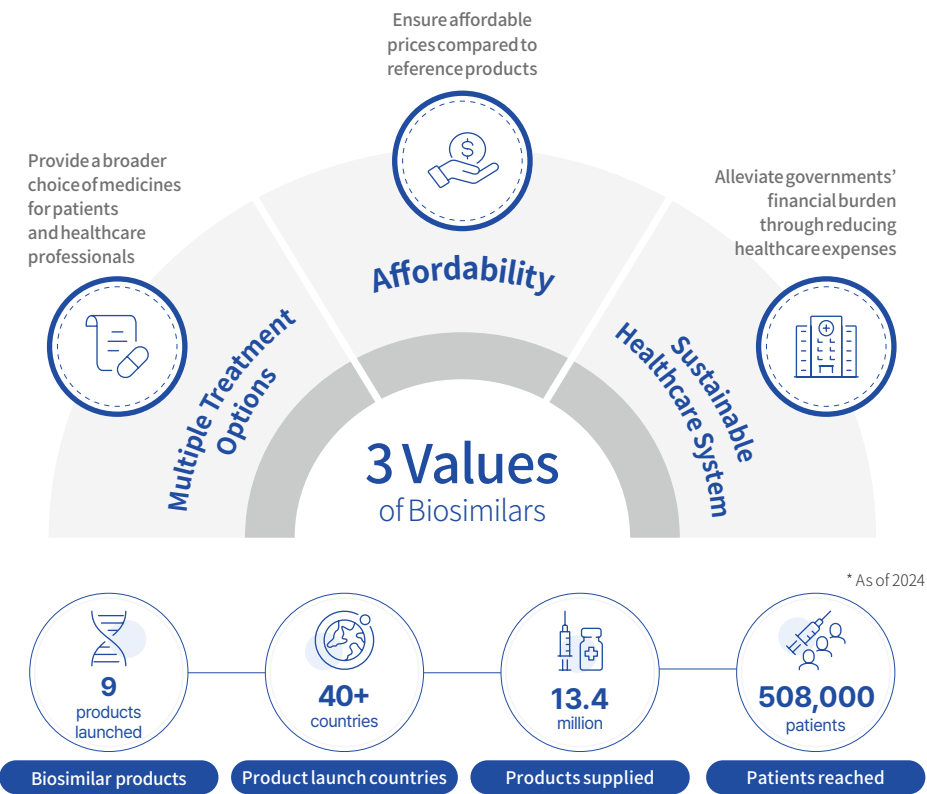
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Access to Medicines

3 Values of Biosimilars

Although biologic medicines are recognized as essential, life-changing medicines for various severe chronic diseases, their accessibility remains limited due to high costs in the absence of dedicated healthcare support. Samsung Bioepis is focused on developing biosimilars across a wide spectrum of therapeutic areas. In addition, we provide high-quality biosimilars at affordable prices compared to reference products to broaden treatment options for patients and healthcare professionals while helping to alleviate governments' financial burden of healthcare costs. We will continue to make efforts to create positive social values by more actively expanding access to medicines for developing countries and the socially vulnerable groups, such as reviewing the use of WHO's Pre-qualification of Medicines Programme (WHO PQP)¹⁾ and contributing to national medical finances.



1) WHO PQP: A program led by the World Health Organization to ensure the quality and efficacy of specific medical products, primarily serving as a procurement prerequisite for medicines supplied to developing and low-income countries

Multiple Treatment Options and Expanding Pipeline

A total of 11 biosimilar products have been approved in the fields of immunology, oncology, ophthalmology, hematology, nephrology, and endocrinology, nine of which have been released in the market, bringing diverse treatment options to over 508,000 patients in over 40 countries around the world. Furthermore, the development of numerous gene therapies and antibody-drug conjugates (ADC) targeting rare diseases is also underway. We will do our best to meet the unmet medical needs of patients that have yet to be resolved by expanding the treatment areas and indications of our products.

Samsung Bioepis Pipeline and Therapeutic Areas by Product * As of Apr. 2025

Therapeutic Area	Product	Molecule	Main Indication	Phase 1	Phase 3	Approval	Launch
Immunology	SB4	Etanercept	Rheumatoid arthritis, psoriasis, axial spondylarthritis				
	SB2	Infliximab	Rheumatoid arthritis, inflammatory bowel disease				
	SB5	Adalimumab	Rheumatoid arthritis, inflammatory bowel disease				
	SB17	Ustekinumab	Psoriasis, inflammatory bowel disease				
Oncology	SB3	Trastuzumab	Breast cancer, gastric cancer				
	SB8	Bevacizumab	Metastatic colorectal cancer, non-small cell lung cancer, solid tumors				
Ophthalmology	SB11	Ranibizumab	Age-related macular degeneration, diabetic macular edema, etc.				
	SB15	Aflibercept	Age-related macular degeneration, diabetic macular edema, etc.				
Hematology / Nephrology	SB12	Eculizumab	Paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome				
Endocrinology	SB16	Denosumab	Osteoporosis				
Bone Oncology	SB16	Denosumab	Giant cell tumor of bone				
Oncology	SB27	Pembrolizumab	Melanoma, lung cancer, renal cancer, bladder cancer, etc.				
Gastroenterology	SB26	Ulinastatin-Fc fusion protein	Acute pancreatitis				

※ SB5, SB3 and SB8 are listed on the WHO Model List of Essential Medicines.

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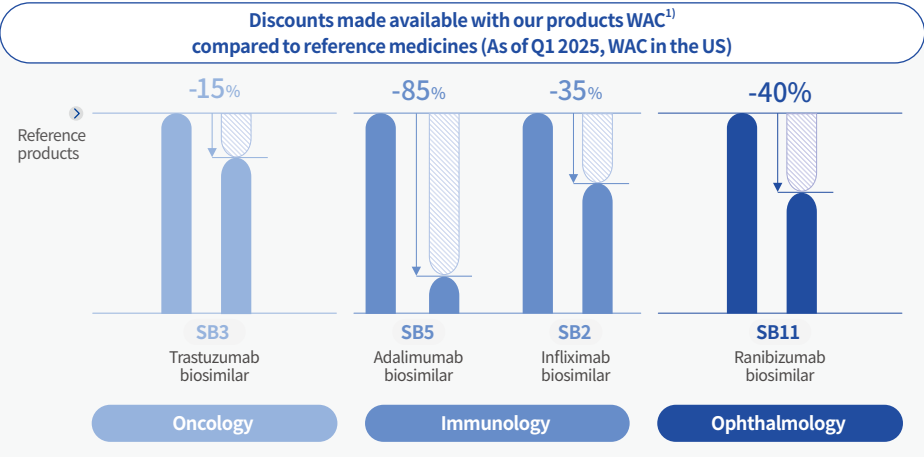
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Access to Medicines

Enhancing Affordability

Pharmaceutical breakthroughs such as medicines and vaccines have been instrumental in reducing the global burden of disease and improving health outcomes worldwide. It should be noted, however, that access to these innovations remains unequal, particularly for patients with severe illnesses that often entail prohibitively high treatment costs. Samsung Bioepis brings high-quality, affordable biosimilars to market, leveraging its proprietary, advanced development platforms, process innovations, and exceptional clinical development capabilities. By reducing the financial burden on patients when choosing treatment options, we strive to enhance access to medicines and contribute to achieving ‘Universal Health Coverage (UHC)’ for all.



1) Wholesale Acquisition Cost

Case

Epysqli and Affordability

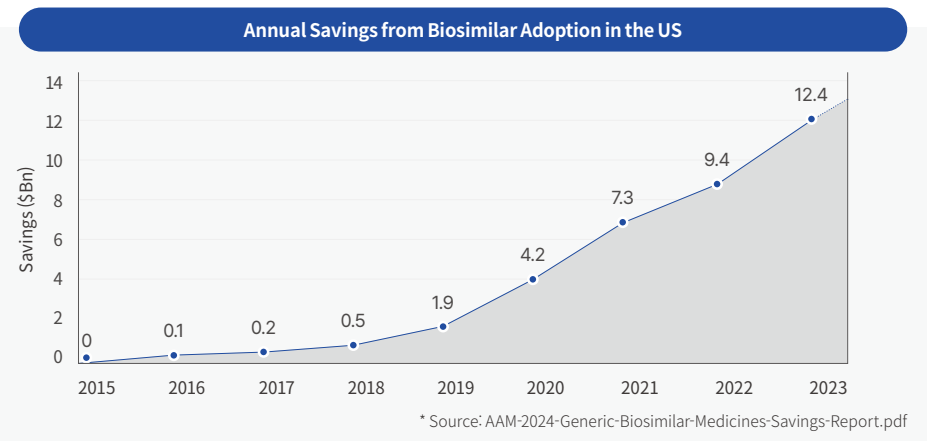
Our hematology treatment Epysqli (eculizumab biosimilar) was launched in July 2023, starting in Germany and subsequently in Italy, Spain, South Korea, France, the Netherlands, and the United States. The reference product, Soliris, is used to treat such rare diseases as paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), and is among the most expensive biologics with significant unmet medical needs in real-world medial settings. In the US, it costs approximately USD 520,000 (KRW 760 million) to treat one PNH patient per year. Samsung Bioepis released Epysqli at a 30% discount compared to the wholesale price of the reference drug in the US market, broadening treatment options and saving costs for patients with rare diseases.



Supporting a Sustainable Healthcare System

Reducing Medicine Costs in the US Healthcare Market

Biosimilars are offered at affordable prices relative to their reference products and thus hold the potential to significantly reduce national healthcare expenditures. This enables countries to direct the savings from biosimilars towards their healthcare sector to establish a sustainable healthcare system. In fact, Samsung Bioepis is supplying four biosimilars to the US Department of Veterans Affairs, helping the US government reduce its healthcare spending. According to the 2024 data from the Association for Accessible Medicines of the US, cumulative savings in medicine spending have amounted to approximately USD 36 billion since 2015 when biosimilars were first launched in the US market.



Expanding the Supply of Biologics to Brazil

By advancing into Brazil, one of the largest pharmaceutical markets among developing countries, we support the development of the local bio industry and deliver biologics to increase access to treatment opportunities. Under the PDP (Productive Development Partnership) program, we have formed a trilateral partnership with BioManguinhos, a research institute under the Brazilian Ministry of Health, and Bionovis, a local pharmaceutical company, to transfer our essential pharmaceutical manufacturing and cell line development technologies. We supply SB3 (trastuzumab biosimilar) for cancer treatment and SB4 (etanercept biosimilar) for autoimmune disease treatment through government tenders, encouraging the local development and production of high-cost medicines. By expanding the supply of SB2 (infliximab biosimilar) for autoimmune disease treatment and SB5 (adalimumab biosimilar), we contribute to broadening treatment options for patients and stabilizing Brazil’s healthcare system.

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Access to Medicines

Improving Patient Convenience

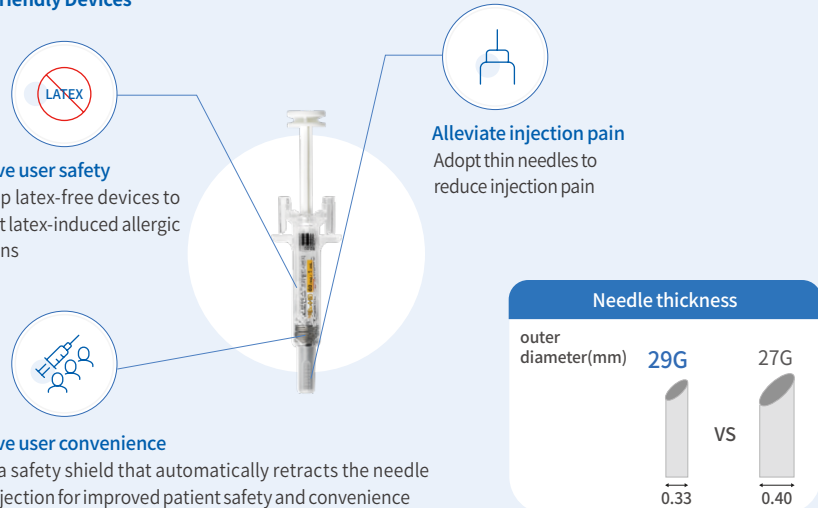
Improving the user safety and convenience of medicines entails increased costs for development and manufacturing in the short-term. Ultimately, however, this plays a critical role in enhancing product value, competitiveness and patient access. Samsung Bioepis puts patient safety and convenience before all else throughout the product development process. We achieve this by constantly exploring ways to deliver improved user convenience for patients and healthcare professionals, including the development of more user-friendly devices and the extension of product shelf life without compromising quality.

User-friendly Devices

Patients with autoimmune diseases often need to self-administer injectable medications. To address needle-related patient anxiety and reduce the risk of pricking injuries that may occur during product use, we are enhancing the structural design and safety features of our delivery devices. We are also seeking various patient-friendly improvements to enhance usability, including the elimination of pain factors and the use of thin needles to help alleviate pain at the injection site.

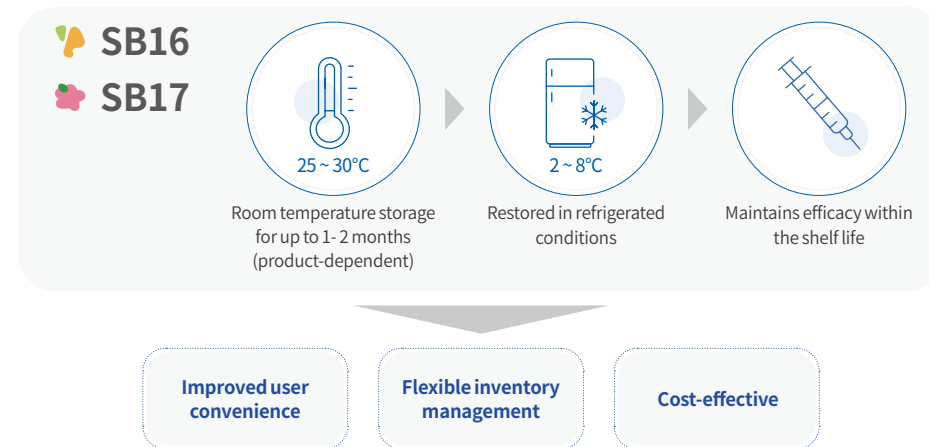
Case

User-friendly Devices



Enhanced Storage Convenience

Biologics are directly administered into the human body and their ingredients are mainly composed of proteins. These characteristics make biologic medicines susceptible to degradation once exposed to room temperature. They also require demanding storage conditions and are limited in maximum duration of room temperature storage. To address these challenges, we focused on significantly improving storage profiles in developing SB17 (ustekinumab biosimilar) for autoimmune disease treatment and SB16 (denosumab biosimilar) for bone disease treatment. In developing SB16 and SB17, we ensured that products remain stable in quality and efficacy when put back into a refrigerator even after up to 30 – 60 days of storage at room temperature. This significantly improved the convenience of storage and lowered the risk of product degradation as compared to competitor products, offering advantages in terms of drug distribution, inventory management, and cost-effectiveness. It also enhances convenience for patients and healthcare professionals.



Development of Novel Technologies to Better Meet Unmet Medical Needs

While intravenous (IV) formulations enable rapid drug delivery, they require administration by healthcare professionals, necessitating hospital visits and hours of infusion times. In contrast, subcutaneous (SC) formulations not only support faster administration but also reduce pain and infection risks. Such alternative formulations bring advantages in lowering healthcare facility costs in countries where medical expenses are relatively high. Our efforts to develop new formulations embody our commitment to identifying unmet medical needs and making necessary improvements for the benefit of patients.

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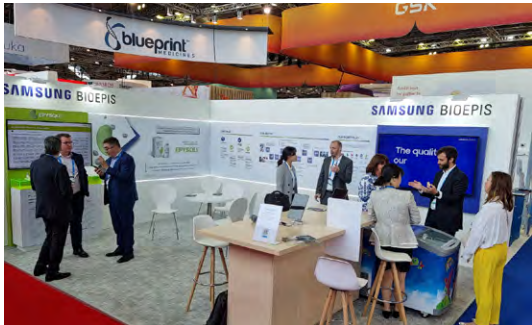
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Expanding Access to Medicines

Raising Awareness on Biosimilars

Samsung Bioepis actively engages with a broad range of stakeholders including patients, healthcare professionals (HCPs), and regulatory authorities to communicate the value of biosimilars and enhance trust through various awareness-raising initiatives. To ensure these efforts translate into improved medicine accessibility, we actively participate in regulatory policy discussions aimed at streamlining biosimilar approval processes and recognizing interchangeability. In particular, we focus on advocating for simplified approval pathways (such as waiving Phase III clinical trials) and interchangeability policies, while continuously monitoring relevant developments to strengthen our product accessibility and competitiveness.



Attending the European Society for Paediatric Nephrology Conference

We attended the Annual Meeting of the European Society for Paediatric Nephrology (ESPN) held in September 2024 to present analytical findings related to the indication expansion of SB12 (eculizumab biosimilar). SB12 is our flagship hematology product with proven clinical equivalence to its reference product in the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Furthermore, SB12 demonstrated its potential applicability to atypical hemolytic uremic syndrome (aHUS). These results showcased the value of SB12 as a cost-effective alternative delivering comparable efficacy relative to the original biologic.

Publishing the Biosimilar Market Report

We publish quarterly Biosimilar Market Reports to help improve understanding of biosimilars and provide in-depth market insights. These reports cover the latest trends and major issues in the US biosimilar market, the overview of our approved and launched products and their commercial performance, and other key topics of the biosimilar market.



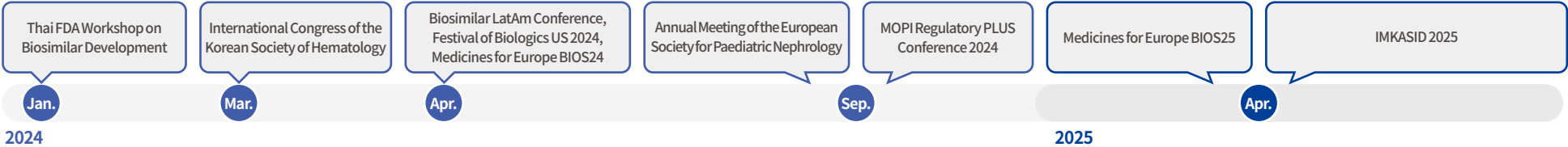
Hosting an Academic Forum Following Product Launch in Korea

Following the launch of SB17 (ustekinumab biosimilar), we hosted the first dedicated academic forum for Korean healthcare professionals to facilitate presentations and discussions on research findings, including clinical experiences with Ustekinumab-based therapies. SB17 was Introduced to the domestic market in July 2024 at approximately 40% below the reference product's price, and has since played an instrumental role in improving access to medicines by offering an affordable alternative and expanding therapeutic options for patients with autoimmune diseases.



Presenting at IMKASID 2025 Conference

At the 8th Intestinal Diseases in conjunction with the Annual Congress of the Korean Association for the Study of Intestinal Diseases (IMKASID 2025) held in April 2025, Samsung Bioepis shared research findings on SB5 (adalimumab biosimilar) including real-world prescription data from Korean patients and potential cost savings expected in major European countries following its market launch. We also operated a corporate booth to introduce our wide-ranging immunology product portfolio to healthcare professionals and industry stakeholders while reaffirming our commitment to broadening treatment options for patients.



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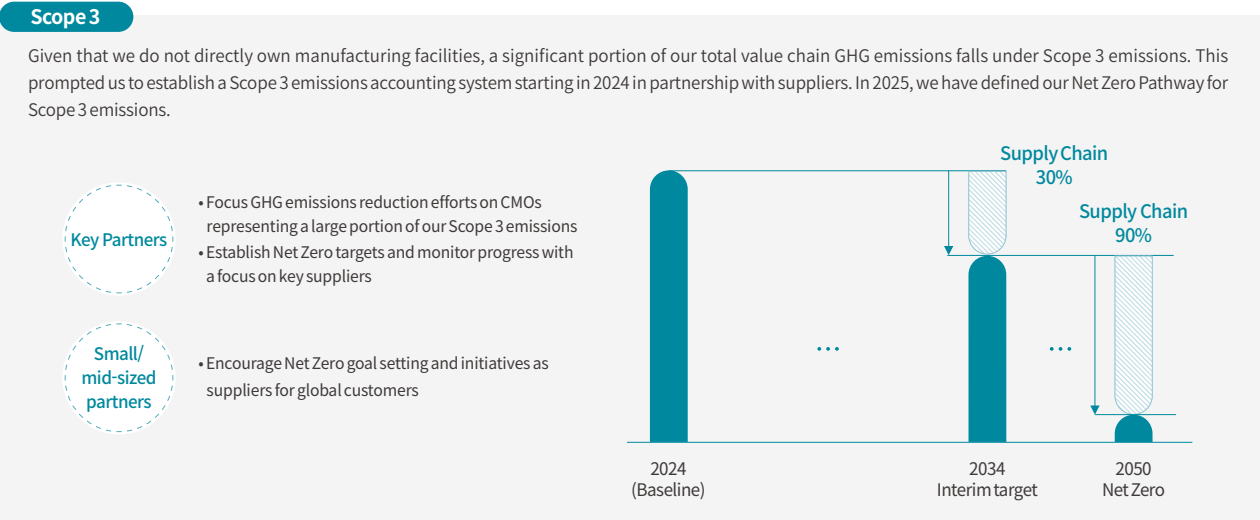
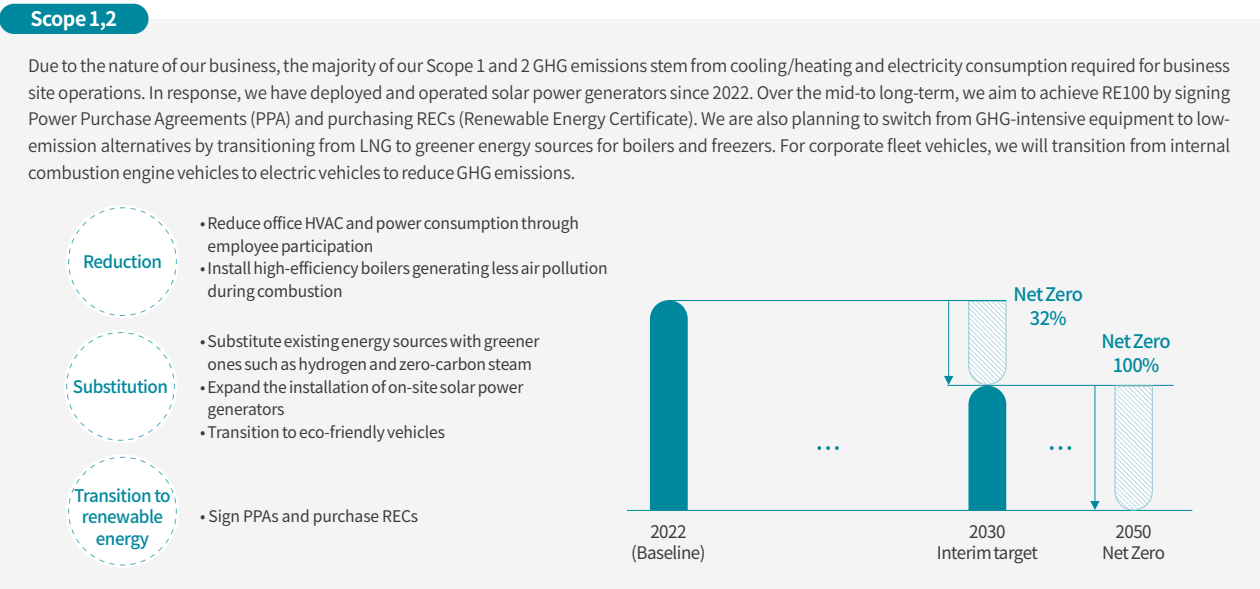
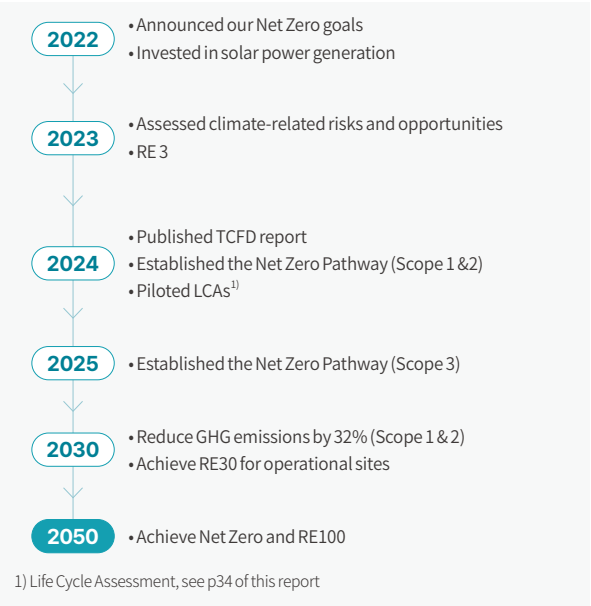
Climate Change Response

Climate Change Response Strategy

Samsung Bioepis is making progress in line with the detailed roadmap established with the goal of achieving Net Zero emissions across all business sites and supply chains by 2050. Our Net Zero pathway is anchored on the three strategic pillars of reduction, substitution, and transition to renewable energy to mitigate Scope 1 and 2 GHG emissions. To reduce Scope 3 emissions, we continue to strengthen collaboration with suppliers.

Net Zero 2050

Our 2050 Net Zero declaration embodies our strong commitment to combatting global climate change. We have defined our Net Zero targets through the analyses of climate-related risks and opportunities, and are implementing specific strategies in line with our Net Zero roadmap. We transparently disclose our interim targets and progress to ensure that our Net Zero declaration goes beyond words and is translated into feasible and actionable commitments.



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Climate Change Response

Analyzing Climate-related Risks and Opportunities

Risk and Opportunity Scenarios and Analysis Methodologies

Samsung Bioepis has analyzed climate-related risks and opportunities based on a range of climate scenarios to assess the impact of climate change on our business operations. We used the climate scenarios published by the IPCC and the IEA.

To identify physical risks and assess their impacts, we referred to SSP (Shared Socioeconomic Pathways) including SSP1-2.6, SSP2-4.5 and SSP-8.5 outlined in the IPCC's 6th Assessment Report. Jupiter Intelligence, a specialized climate modeling tool, was also used to assess the impact of eight key perils – flooding, heavy precipitation, strong winds, extreme heat, wildfires, hail, drought, and cold waves. For transition risks and opportunities, we conducted internal analysis in line with the IEA's NZE (Net Zero Emissions by 2050), APS (Announced Pledge Scenario), and STEPS (Stated Policies Scenarios).

Characteristics of Each Scenario Type

Physical Risk Analysis Scenarios (IPCC SSP)

SSP 5-8.5

- Emphasize rapid advancement of industrial technology
- Assume continued high fossil fuel use and intensive, unregulated development
- Project global temperature rise of 4.4°C by 2100
- Project sea level rise of 0.63~1.01 meters by 2100

SSP 2-4.5

- Assume moderate climate mitigation and adaptation efforts
- Envision intermediate socioeconomic development
- Project global temperature rise of 2.7°C by 2100
- Project sea level rise of 0.44~0.76 meters by 2100

SSP 1-2.6

- Reflect high climate awareness and strong global response
- Envision advances in renewable energy technology, minimal fossil fuel use, and environmentally sustainable growth
- Project global temperature rise of 1.8°C by 2100
- Project sea level rise of 0.32~0.62 meters by 2100

Transition Risk and Opportunity Analysis Scenarios (IEA)

STEPS

- Assume continuation of current policy trends
- Implementation of already announced policies, reduction targets, and plans
- Assume global temperature rise of 2.6°C by 2100
- Project a carbon price of \$89/tCO₂e by 2050

APS

- Assume around 40% GHG reduction by 2030 with full implementation of announced national GHG reduction targets
- Assume global temperature rise of 2.1°C by 2100
- Project a carbon price of \$200/tCO₂e by 2050

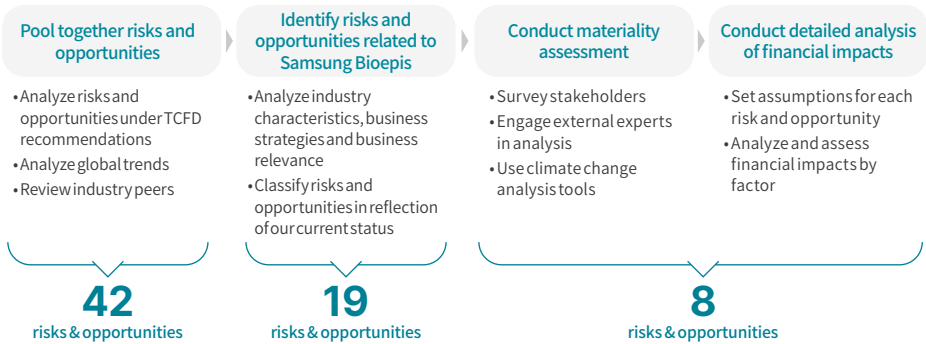
NZE

- Assume a successful phase-out of fossil fuels by 2030 and achievement of global Net Zero emissions by 2050
- Assume global temperature rise of 1.5°C by 2100
- Project a carbon price of \$250/tCO₂e by 2050

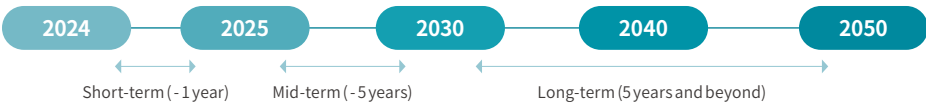
Analysis Overview

We identified climate-related risks and opportunities in consideration of TCFD and CDP recommendations as well as the broader climate response landscape within the biopharmaceutical industry. We then focused on risks and opportunities highly relevant to our business and determined high-priority targets through materiality assessment. This was followed by the assessment of financial impacts from selected key risks and opportunities.

Climate-related Risk and Opportunity Analysis Process



Timeline Setting



Definition of Risks and Opportunities

Risk	Climate hazard ① Natural hazards such as typhoons and floods ② Heat waves	Market ③ Change in customer behavior ④ Increased procurement costs for raw materials	Technology ⑤ Increased costs for low-carbon transition
	Resource efficiency ⑥ Use of efficient production processes	Products and services ⑦ Increased product demand	Reputation ⑧ Strengthened stakeholder communication

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Climate Change Response

Risk and Opportunity Analysis Results

We analyzed climate-related risks and opportunities using the analysis process and methodologies outlined before. Climate-related risks and opportunities were assessed under SSP5-8.5 (for physical risks) and NZE (for transition risks and opportunities) scenarios which were identified as having the most significant financial impacts.

Based on annual average costs ● High: KRW 10 billion or more ● Medium: KRW 2 billion or more and below KRW 10 billion ● Low: Below KRW 2 billion

Category		Risk/Opportunity factor	Background	Potential Financial Impact	Financial Impact Timeline		
					Short-term (~ 2025)	Mid-term (~ 2030)	Long-term (~ 2050)
Physical risk	Acute	Natural hazards such as typhoons and floods	• Increased frequency and intensity of typhoons and floods due to worsening climate change and the resulting extreme weather conditions	• Physical damage to assets including on-site facilities resulting from typhoons and floods with financial losses incurred to restore affected assets	●	●	●
	Chronic	Heat waves	• An increase in the number of extreme heat days resulting from rising temperatures	• Increased cooling costs from heat waves and additional labor costs due to reduced productivity	●	●	●
Transition risk	Technology	Increased costs of low-carbon transition	• Increased investment requirements for low-carbon technology development and transition to meet GHG reduction targets	• Investment expenses and renewable energy procurement costs incurred to achieve the Company's Net Zero goals	●	●	●
	Market	Changes in customer behavior	• Enhanced customer requirements for climate change response including GHG emissions disclosure and Net Zero implementation • Strengthened climate-related demands from stakeholders including shareholders and investors	• Inadequate response to the growing number of customers demanding climate action may result in reduced sales	Qualitative analysis		
		Rising raw material procurement costs	• Potential cost increases associated with enhanced global carbon regulations and climate response requirements	• Increases in carbon costs such as rising carbon credit prices, may prompt suppliers to pass on their climate transition expenses to the Company, resulting in higher raw material procurement costs.	●	●	●
Opportunity	Resource efficiency	Use of efficient production processes	• Increased potential to reduce carbon emission costs through the introduction of efficient product manufacturing	• Productivity gains achieved through process innovation in the development phase lead to improved efficiency in raw material inputs that impact carbon emissions from the Company and supply chains as well as to reduced carbon costs resulting from lower energy consumption.	●	●	●
	Products and services	Increased product demand	• Rising prevalence of climate-related diseases leading to increased demand for related therapies	• Increased sales from growing demand for climate-related disease treatment	Qualitative analysis		
	Reputation	Stakeholder communication	• Growing demand for climate action and disclosure from stakeholders including investors, customers, and investors	• Improved corporate brand reputation resulting from proactive response to climate disclosures and relevant regulations	Qualitative analysis		

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Climate Change Response Risk Management

To ensure stable operations and business continuity, Samsung Bioepis has established a company-wide risk management framework, advancing integrated management of financial and non-financial risks that may bring significant impact on corporate management and business conduct. Since 2024, we have identified and assessed climate-related risks and opportunities that may arise over the short-, medium-, and long-term horizons based on the results of climate scenario analysis. These insights inform our efforts to formulate response strategies with a focus on key risks, and incorporate them in the risk management framework for continuous monitoring.

Risk Identification and Assessment

We identify and assess risks based on global trends concerning climate-related initiatives and assessment categories as well as the overall climate action landscape across the biopharmaceutical industry. From this pool of climate-related risks, key risks are identified through materiality assessment and each of these risks is assessed for their financial impact in terms of cost and revenue implications using methodologies appropriate for the nature of each risk factor.

Samsung Bioepis' Approach to Climate-related Risks

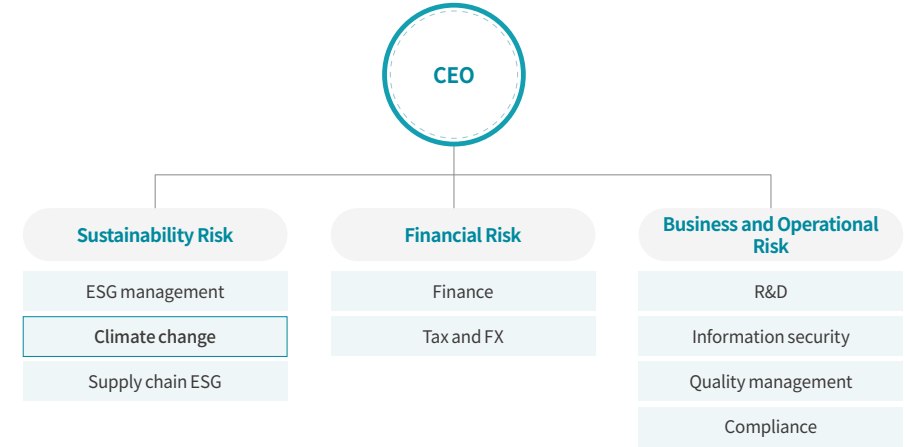
Category		Risk Factor	Potential Financial Impact	Samsung Bioepis' Response Strategy
Physical risk	Acute	Natural hazards such as typhoons and floods	Asset impairments and costs incurred for recovery	<ul style="list-style-type: none">• Operate business continuity plans• Develop scenarios to respond to natural hazards and conduct annual drills
	Chronic	Heat waves	Reduced productivity and loss-related costs	<ul style="list-style-type: none">• Establish and implement heat wave risk response procedures
Transition risk	Technology	Increased costs for low-carbon transition	Increased investment expenses and REC costs	<ul style="list-style-type: none">• Join the RE100 initiative and install solar power panels• Invest in the low-carbon transition over the mid- to long-term by considering the economic feasibility of each green energy source to achieve Net Zero
	Market	Increased raw material procurement costs	Higher raw material procurement costs	<ul style="list-style-type: none">• Strengthen supply chain cooperation to reduce GHG emissions• Refine the Scope 3 emissions accounting system• Improve raw material efficiency and reduce costs through productivity enhancement via process innovation
	Market	Changes in customer behavior	Reduced sales	<ul style="list-style-type: none">• Establish Net Zero goals and implement detailed reduction measures• Expand climate disclosures covering the identification and assessment of climate-related risks and the measurement of financial impacts• Conduct LCA-based PCF¹⁾ measurements

1) Product Carbon Footprint

Risk Response and Monitoring

We have established a company-wide risk management framework to support sustainable operations and business continuity, and address management risks leveraging our accumulated expertise, cross-functional collaboration, and agile decision-making. Our leadership is evaluated based on risk management factors incorporated into their respective MBOs, and climate-related factors are managed as distinct company-level targets.

Company-wide Risk Management Framework and Key Risks



As climate-related risks can directly or indirectly impact a company's business operations and reputation, they are classified as a key factor within sustainability management risks. In the risk identification process, we analyze the potential financial impacts of these risks while developing and implementing countermeasures to enhance our organizational resilience. Our environmental and energy management systems align with internationally-recognized standards (ISO 14001 and ISO 50001) to drive our efforts to proactively address overall environmental and climate-related risks, helping to prevent climate-related factors from evolving into actual risks.

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Targets and Metrics

Key Metrics for Managing Climate-related Risks and Opportunities

Key metrics for the assessment and management of climate-related risks and opportunities

- Scope 1 & 2 emissions and emissions intensity (GHG emissions against consolidated sales)
- Scope 3 emissions
- Product carbon footprint
- Total energy consumption and energy intensity (energy consumption against consolidated sales)
- Renewable energy consumption and non-renewable energy consumption

To assess and manage climate-related risks and opportunities, Samsung Bioepis tracks such key metrics as GHG emissions, energy consumption and reduction, energy intensity, and renewable energy generation. While we are not covered by the nation’s GHG emissions regulations, we have voluntarily undergone third-party verification of our Scope 1, 2 and 3 emissions and energy consumption to ensure the structured management of relevant targets and metrics. We also transparently disclose our annual performance through sustainability reporting.

Given the nature of our business which does not involve any direct operation of manufacturing facilities, Scope 3 emissions represent over 90% of total emissions. Samsung Bioepis is clearly aware of the importance of GHG emissions management encompassing the overall value chain including supply chains as well as its own operations. We plan to strengthen collaboration with supply chains in calculating Scope 3 emissions and setting reduction targets.

Upstream 45,174 tCO ₂ eq		67.8%	Own Operational Site 6,324 tCO ₂ eq		9.5%	Downstream 15,166 tCO ₂ eq		22.7%
• Purchased goods and services	56.7%		• Direct emissions (Scope 1) 1,220 tCO ₂ eq	1.8%		• Downstream transportation and distribution	2.1%	
• Capital goods	1.1%		• Indirect emissions (Scope 2) 5,104 tCO ₂ eq	7.7%		• Processing of sold products	20.7%	
• Fuel and energy-related activities	1.0%					• Investments	0.0%	
• Upstream transportation and distribution	4.9%							
• Waste generated in operations	0.4%							
• Business travel	2.1%							
• Employee commuting	1.6%							

* Discrepancies of less than ±1 may occur between totals and individual figures due to rounding down.

Targets for Managing Climate-related Risks and Opportunities

Targets for the management of climate-related risks and opportunities

- Reduce Scope 1 and 2 emissions to 32% by 2030 from the 2022 base year
- Achieve Net Zero by 2050 based on emissions from the 2022 base year
- Expand renewable energy consumption to 30% by 2030 (RE30)
- Reach 100% renewable energy consumption by 2050 (RE100)

Samsung Bioepis has established roadmaps to deliver on 2050 Net Zero and RE100 commitments, implementing a range of pathways to achieve these goals. In 2022, we joined the RE100 initiative alongside Samsung Biologics. In 2024, we generated 276Mwh in total by operating solar power generators, meeting nearly 3% of our annual power needs. We also opt for high-efficiency equipment, improve heating/cooling systems, and launch energy-saving campaigns to enhance energy efficiency while reducing consumption, covering building heating/cooling equipment which represents a large portion of our energy use. Over the mid-to long-term, we will progressively transition to optimal greener energy sources by assessing the economic feasibility of each energy source.

In line with our Net Zero Pathway, we aim to reduce our Scope 1 and 2 emissions by 32% by 2030 from the 2022 baseline. Most of our Scope 1 and 2 emissions arise from electricity consumption, and we continue with efforts to implement effective measures to reduce GHG emissions in parallel with increasing renewable energy use. Such efforts allowed us to deliver year-on-year reductions in both GHG intensity-based emissions and energy intensity-based consumption in 2024.

To ensure effective and tangible management of climate-related risks and opportunities, we will regularly monitor targets and outcomes by key metric to further advance our management performance. While refining our Scope 3 emissions accounting through collaboration with suppliers, we are also conducting supply chain ESG assessments to review suppliers’ progress in achieving Net Zero goals and reducing GHG emissions.

Furthermore, we are piloting product carbon footprint assessments to make our products even greener. This will enable us to enhance productivity through process innovation early in the development phase, reducing annual batch production volumes to lower energy consumption required for manufacturing. This will also help us streamline raw material use to ultimately contribute to reducing carbon emissions.

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Environmental Management

Environmental Management Framework

Samsung Bioepis is committed to minimizing the environmental footprint of its business conduct while ensuring sustainability throughout the whole of the value chain including its own operations. To this end, we have certified our environmental and energy management systems to international standards (ISO 14001 and ISO 50001) in 2022, and will continue to upgrade these systems to advance environmental management in alignment with global standards.

Environmental Management Policy

We have established our safety, environmental and energy management policy and pursue eco-friendly business practices accordingly, fulfilling our responsibility for environmental stewardship and building trust with varying stakeholders. Our dedicated environmental management organization operates under the Chief Safety Officer (CSO) to develop and implement environmental management plans covering a broad array of areas including energy reduction, wastewater and waste management, and hazardous substance reduction. We have also established systemic standard operating procedures in line with the environmental management system to minimize the environmental impact of our business operations.



Operating the Environmental Management Council

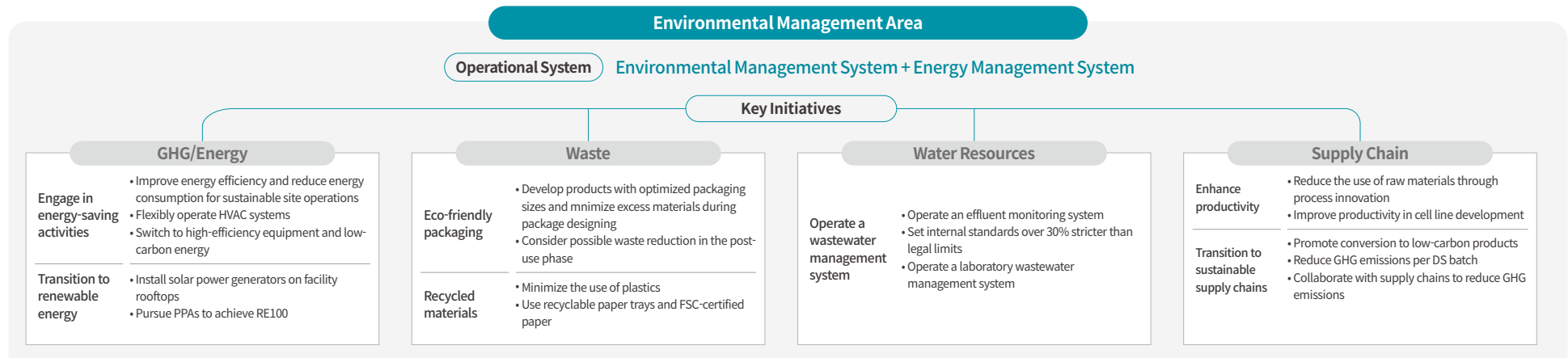
In 2025, we launched the Environmental Management Council under the leadership of the CSO. The Council will convene each quarter to discuss our annual company-wide environmental goals and their implementation plans and specific measures to achieve these goals.

Environmental Management Council Operation (Q1 2025)

Key Agenda	
• Establishment of the Council	• 2025 carbon emission targets
• Progress review on the 2050 Net Zero roadmap	• GHG emissions reduction activities

Environmental Impact Assessment

We conduct annual environmental impact assessments to regularly identify the environmental implications of our business operations and reduce potential adverse impacts. These assessments cover the consumption of primary resources and the discharge of substances to ensure compliance with predefined management standards. In case these criteria are not met, corrective actions are taken. The 2024 assessment showed that we satisfied the required standards across all categories of environmental impact assessments.



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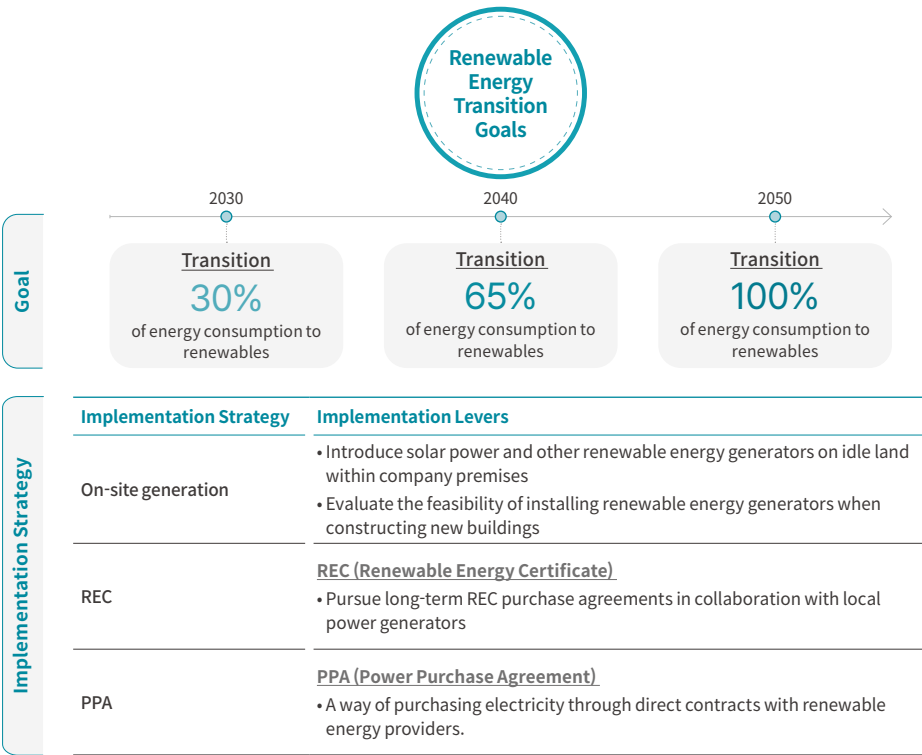
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Energy Management Framework

Energy Management and RE100 Implementation

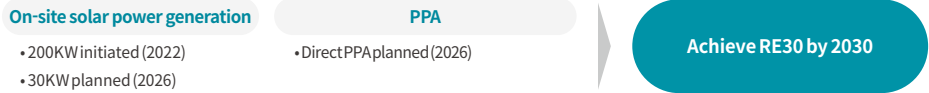
Samsung Bioepis is committed to managing and reducing energy consumption in accordance with its safety, environmental, and energy management policy. Our approach to addressing climate change is mitigating environmental impact through the efficient management of key energy sources, such as building heating/cooling equipment and electricity. We announced our 2050 Net Zero commitment and joined RE100 alongside Samsung Biologics. To deliver on our RE100 commitments, we pursue renewable energy sourcing with a focus on electricity which accounts for over 70% of our total operational emissions.

RE100 Goals and Key Implementation Strategies



Transitioning to Renewable Energy

In December 2022, we installed 200KW-capacity solar panels on the rooftop of our office building. These facilities produced 272MWh in 2023 and 276MWh in 2024, meeting approximately 3% of our annual power needs. We are planning to expand our on-site daycare center with a goal of completion by the end of 2026, and are considering the additional installation of 30KW-capacity solar panels to achieve green building certification. Furthermore, we are reviewing the implementation of direct PPAs starting in 2026. These efforts will help us expand the use of renewable energy continuously.



Energy-saving Efforts

Our office building on Songdo is solely fitted with LED lighting, along with high-efficiency equipment such as high-efficiency heat pumps, power factor correction capacitors, and standby power saving outlets, to reduce energy consumption. We are also deploying an HVAC system using district heating and absorption chiller-heaters. Additionally, we have allocated 2% of the entire parking lot exclusively for EVs and installed on-site EV chargers, playing a role in saving energy and transitioning to greener energy.

Energy Assessment

To establish cost-effective and efficient energy use plans, we have conducted energy assessments covering from our current energy consumption practices to factors causing energy losses. This involved analyzing the operational conditions and diagnostic data of facilities currently under operation including heat source, power, and substation equipment. The findings helped us identify and implement practical improvement measures.



Installing a high-efficiency power transmission system for exhaust fans



Operating solar panels

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Natural Resources Management

Water Resources Management

Climate change gives rise to a variety of risks associated with water resources. Samsung Bioepis is establishing and implementing structured water sources management strategies to address these risks and help restore the natural ecosystem. In so doing, we strive to drive sustainable water stewardship through optimal use and increased use of water resources.

Water Quality Management

As part of our efforts for sustainable environmental management, we focus on improving the quality of wastewater. Leveraging cutting-edge technologies and precise water quality analysis techniques, we efficiently treat wastewater generated from our operations and proactively implement measures for water quality enhancement. These efforts include the rigorous oversight and monitoring of effluents and the development and implementation of internal management (discharge) criteria exceeding legal requirements, ensuring improved transparency for the discharge of water resources that we use. Currently, the effluents from our operations satisfy the ‘clean area’ standards, the most stringent discharge criteria stipulated under Korea’s Water Environment Conservation Act.

Water Pollutant	Unit	Legal Limit	Clean Area Criteria	Effluent Quality (2024)
Total Organic Carbon (TOC)	mg/L	50	25	2.65
Suspended Solids (SS)	mg/L	80	30	0.5
Total Nitrogen (T-N)	mg/L	60	30	13.76
Total Phosphorus (T-P)	mg/L	8	4	0.38

Effluent Monitoring and Wastewater Treatment System

We conduct daily effluent monitoring to ensure the end-of-pipe water quality remains within 30% of the set legal discharge limits. To achieve this, we have installed facilities capable of treating all pollutants in wastewater discharged from bio labs while operating a wastewater treatment system documenting and managing the properties and volumes of discharged wastewater.

Biodiversity Protection

As a subsidiary of Samsung Biologics, Samsung Bioepis honors the biodiversity pledge of the parent company. Our operational sites are surrounded by numerous Key Biodiversity Areas, including the Songdo Tidal Flat registered as a Ramsar site in 2014. As such, we set rigorous standards for effluents and manage them accordingly for biodiversity conservation and minimal environmental impact in these critical areas.

Waste and Pollutant Management

Waste Management

If waste generated from product research and development is not lawfully discharged and treated, this may result in soil contamination, water pollution and other types of environmental degradation. Biologically active substances, the primary type of waste from biopharmaceuticals, are similar to proteins in their natural state and tend to break down rapidly and broadly without causing harm to the environment. Still yet, we are strengthening our waste management system and strictly abide by disposal procedures to minimize the environmental impact of waste.

Waste Management Method

We ensure the rigorous treatment of all waste generated from our operational sites through the ‘Allbaro’ waste disposal system. All waste generated on-site is separately stored at designated storage facilities, and its disposal is outsourced to specialized treatment companies. In particular, designated waste (hazardous waste) is managed using medical waste RFID readers to support full traceability from generation to disposal. In selecting waste disposal vendors, we assess their qualifications based on treatment capacity, preventive measures against environmental and safety accidents, and licensing status, to address risks associated with waste treatment.

Air Pollutant Management

We have established internal standards that exceed the discharge limits stipulated under the Clean Air Conservation Act to ensure rigorous air pollution management and reduce air pollutants generated from our operations. Emissions of nitrogen oxides (NOx), sulfur oxides (SOx), and particulate matter (PM) generated from utility facilities are regularly measured by certified third-party labs (semi-annually) and the results are submitted to the Korea Environment Corporation. Since 2022, we have switched to low-NOx boilers for our entire operations to reduce air pollutant emissions and pursue energy efficiency.

Hazardous Chemicals Management

We operate a chemical substances and materials management system to abide by the Chemical Substances Control Act, the Act on the Registration and Evaluation of Chemical Substances and other applicable regulations governing hazardous chemicals. For all chemicals that enter our operational sites, the MSDS (Material Safety Data Sheet) is generated while preliminary safety assessments are conducted. The entire process from receiving to use and disposing of these chemicals is rigorously managed to prevent any incidents involving hazardous substances. In parallel, we conduct full chemical inventory assessments (quarterly), work environment monitoring (semi-annually), and ad-hoc risk assessments to ensure stringent oversight of our on-site facilities handling hazardous substances.



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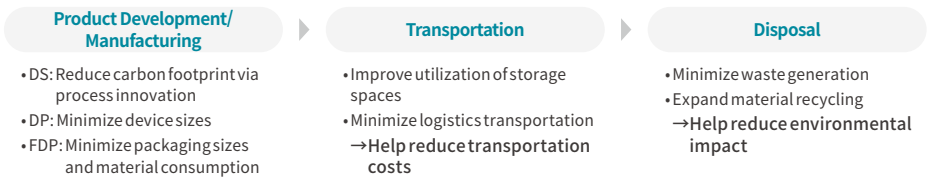
Circular Economy

Resource Circularity Management

Samsung Bioepis recognizes its social and environmental responsibility towards products, and strives to improve efficiency in raw material use and minimize waste generation throughout the product lifecycle, expediting the transition to a circular economy. Specifically, eco-friendly packaging adopted for our products not only helps reduce waste but also contributes to enhancing stacking efficiency during product transportation and storage. Going forward, we will improve the environmental impact of our products with greater accuracy.

Eco-friendly Packaging

The biopharmaceutical industry puts patient safety first and thus applies rigorous standards to the use, storage, and packaging of raw materials, which makes it less feasible to opt for recycled materials. Still, Samsung Bioepis is committed to reducing waste early from the product development phase to minimize any adverse environmental impact of its products.



Participating in the e-Labeling Pilot Project

To improve access to medicine information via mobile devices, Samsung Bioepis is participating in the pilot e-labeling project led by the Korean Ministry of Food and Drug Safety. E-labeling allows consumers and healthcare professionals to use their mobile devices to scan the QR code or bar code affixed to the container or outer packaging of medicines and check on their compliance information in real time. Through our participation in this project, we enable users to access the latest information associated with medicine safety more swiftly and efficiently while avoiding paper consumption to help mitigate carbon emissions. Going forward, we will actively support national policies aimed at encouraging the adoption of e-labeling.

Using Shipping Boxes Made of Recycled Materials

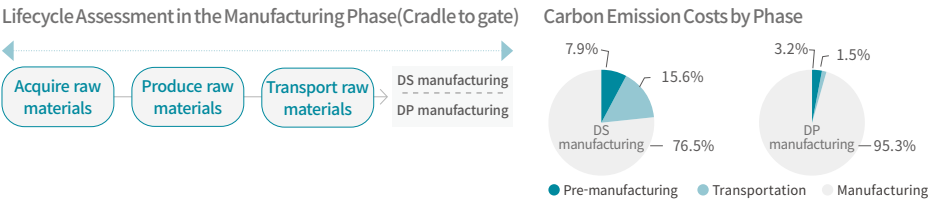
We use recycled paper for product shipping boxes to minimize our environmental footprint while upholding the value of eco-friendliness. To minimize the environmental impact of these materials, our shipping boxes are packed with LDPE wraps in lieu of PVC which generates dioxins when incinerated.

Life Cycle Assessment

The mounting global interest in environmental issues and growing consumer demand for environmental protection further underscore the importance of sustainable and environmentally friendly product development and manufacturing. As a pharmaceutical company, Samsung Bioepis values sustainability and environmental considerations across the entire product lifecycle, from raw material sourcing to development, manufacturing, distribution, and disposal. It is with this awareness that we develop measures to address environmental impact in each phase of the product lifecycle, minimizing risks resulting from our products in the process.

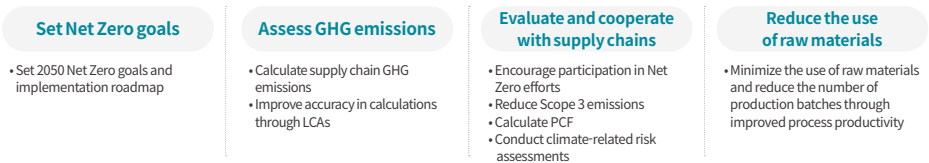
Lifecycle Assessment Implementation in 2024

We aim to enhance accuracy and transparency in capturing any adverse environmental impact throughout the product lifecycle, ranging from the production of drug substances to the distribution, use, and disposal of finished products. In 2024, we established our carbon footprint assessment methodology that aligns with ISO 14040, an international standard for product and service lifecycle assessment, and conducted pilot assessments. In 2025, we plan to extend the scope of products receiving LCAs, and the results will inform our decision-making across the entire production process including product design and supplier selection.



Circular Economy Initiatives across the Supply Chain

Due to the nature of our business which relies on contract manufacturing, we take responsibility for addressing environmental impact from our supply chains, including GHG emissions. In the development phase, we pursue productivity innovation to minimize the consumption of raw materials fed into the drug substance manufacturing by CMOs. We also seek yield enhancements to reduce the number of production batches. These efforts contribute to reducing carbon emissions within our operations and across the supply chain. Furthermore, we encourage suppliers to join Net Zero efforts through supply chain ESG assessments while continuously monitoring the climate action undertaken by our supply chain. This is achieved by reviewing suppliers' climate change responses, identifying areas for improvement, and providing support to strengthen their climate resilience.



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Corporate Culture and HR Management

E.P.I.S. Way

Since established in 2012, Samsung Bioepis has been dedicated to defining our distinct identity by establishing our own set of values and corporate culture. These efforts have propelled the stable growth of our biosimilar business and solidified our industry-wide leadership over the years. In 2025, we recognized the need to redefine our corporate culture to drive our next breakthrough towards becoming a global top-tier biopharmaceutical company. In response, we have established E.P.I.S. Way as our renewed corporate culture initiative to move us forward in the next chapter of our collective journey.



Our E.P.I.S. Way aligns all our employees towards a corporate culture where employees work efficiently with a practical mindset, communicate with respect and integrity, and pursue global top-tier expertise to achieve a shared passion to advance health for all and enhance patients' quality of life.

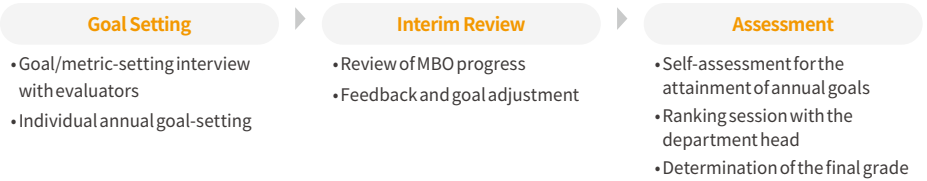
Recruitment and HR Management

Recruitment

Attracting talent with expertise in biotechnology is essential in driving performance and supporting business expansion. We have established a fair, competency-centered recruitment process and implement blind hiring practices that exclude factors such as gender, age, and academic background. In line with our expanding business portfolio, we hired 79 employees in total (34 new and 45 experienced employees) in 2024.

Performance Evaluation and Compensation

Our performance management system is anchored on the Management by Objectives (MBO) process that ties individual goals with corporate strategies and goals. In parallel, we conduct multi-source assessments to improve the completeness of our performance evaluations, along with various efforts to strengthen the fairness and credibility of the overall process. As of 2024, all our employees received regular performance evaluations. Our performance-based salary grading system ensures that employees are compensated appropriately according to their achievements.



Talent Development

Guided by our talent training philosophy that ‘a company’s growth is driven by the growth of its employees’, we support our employees in strengthening their job competency and honing their competitive edge. We provide a wide spectrum of training programs – onboarding training for new hires, GxP job training, and a job training development program – to help employees plan their own career path and build expertise. We also operate internal job posting and mentoring programs to support employees’ faster adaptation and assimilation within the organization.

Talent Development Program	Cycle	Target and Program Description
Leadership assessment & Individual consulting	Annual	Executives and department heads, Support leadership development and reinforcement
Group leadership training	Annual	Department head candidates, Develop organizational management capabilities and leadership skills
Job posting	As needed	All employees, Provide the opportunity to take on their desired roles through internal job transfers
Mentoring	As needed	All employees, Support new hires with early onboarding and role adjustment

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Corporate Culture and HR Management

Sound Corporate Culture

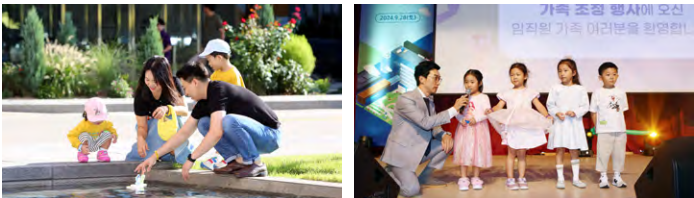
Employee Benefits

Samsung Bioepis fosters a corporate culture where employees thrive through work-life balance. We offer a variety of support programs, including flexible work hours and an in-house daycare facility to become a leading family-friendly company. We also implement a range of health initiatives, including the 10-week Health Challenge, the promotion of in-house fitness facility use, and smoking cessation campaigns, to support employee health and wellness. As a result of these efforts, we obtained health-friendly business certification and were named a leading company in health-friendly management in December 2024.

Category	Benefits Program	Category	Benefits Program
General benefits	Support for personal pension contributions	Workplace convenience	Flexible work hours
	Tuition support		In-house library
	Group insurance coverage		Commuter bus
Employee health support	Welfare points	Family health support	Medical expense support for dependents under (health insurance)
	Health checkups		Family care leave
	Medical expense support		Leave and medical expense support for fertility treatments
	Musculoskeletal disorder prevention center	Maternity support	Maternity protection room
	Fitness/gym facilities		Work-at-home, reduced work hours during pregnancy
Self-development	On-site clinic/pharmacy	Family-friendly programs	Maternity leave/spouse leave
	Psychological counseling center		Parental leave: Up to 6th grade in elementary school
	In-house employee clubs		Reduced work hours during parenting: Up to age 12
	Book purchase support		In-house daycare center

Family Invitation Event

We hosted the third family invitation event since moving into our office building in Songdo in 2021. The event was noted for enthusiastic participation, with 1,979 attendees including 473 employees and 1,506 family members registering during the pre-event sign-up period. Based on feedback from satisfaction surveys conducted after previous events, we expanded the program offerings and provided tours of laboratories and office spaces, giving families a firsthand look at our actual work environment.



Fostering Labor-management Communication

We are committed to facilitating communication across the organization by arranging a wide range of labor-management communication channels. This enables our employees to voice their opinions through diverse avenues, and the company remains responsive to such inputs, establishing a culture of communication driven by mutual respect and consideration.

	Leadership communication with millennials and Gen Z	Our leadership, including the CEO, joined the events marking employees' 1st, 3rd, and 5th year anniversaries at Samsung Bioepis as well as CA roundtable meetings to communicate on a range of topics, covering employee concerns and the company's present and future.
	Corporate culture improvement	Change Agents (CA), our departmental corporate culture leaders, are responsible for planning and implementing departmental-level initiatives to enhance communication and corporate culture, contributing to fostering a healthy corporate culture. CAs also plan GWP (Great Work Place) programs to facilitate unity and communication at the department level.
	Corporate culture assessment	Drawing on findings from the SCI (Samsung Culture Index), Samsung Group's proprietary employee satisfaction survey, we identify issues and develop specific improvement measures at the department, division, and company-wide levels, driving positive change and enhancement of corporate culture. (see p.38 for Samsung Bioepis' corporate culture improvement initiatives)
	Labor-Management Council	Our Labor-Management Council convenes quarterly and does so more often when needed. Employee feedback is gathered via the anonymous bulletin board 'Our Voice' and other various channels. For critical issues, the Council officially proposes agenda items to the Company as the employee representative body to engage in consultations.

Case

Launching the 6th Labor-Management Council

For two days starting May 23 of 2024, an electronic vote was conducted to elect employee representatives for the 6th Labor-Management Council. Five representatives were elected, commencing their three-year term. These Council members not only serve to gather employee feedback but also act as formally recognized representatives of the Company's workforce, upholding labor rights as stipulated in the nation's constitution.

Key Activity Plans of the 6th Labor-Management Council

Communication	• Publish quarterly activity newsletters, host regional roundtable discussions, and conduct on-site activities
Feedback management	• Operate in-person Council communication channels and systematically implement the employee feedback consultation process (weekly) regular meetings, (bimonthly) meetings with the HR team lead, (quarterly) executive consultations, (annual) wage negotiations
Events	• Organize regular events including holiday, family month, and family invitation events

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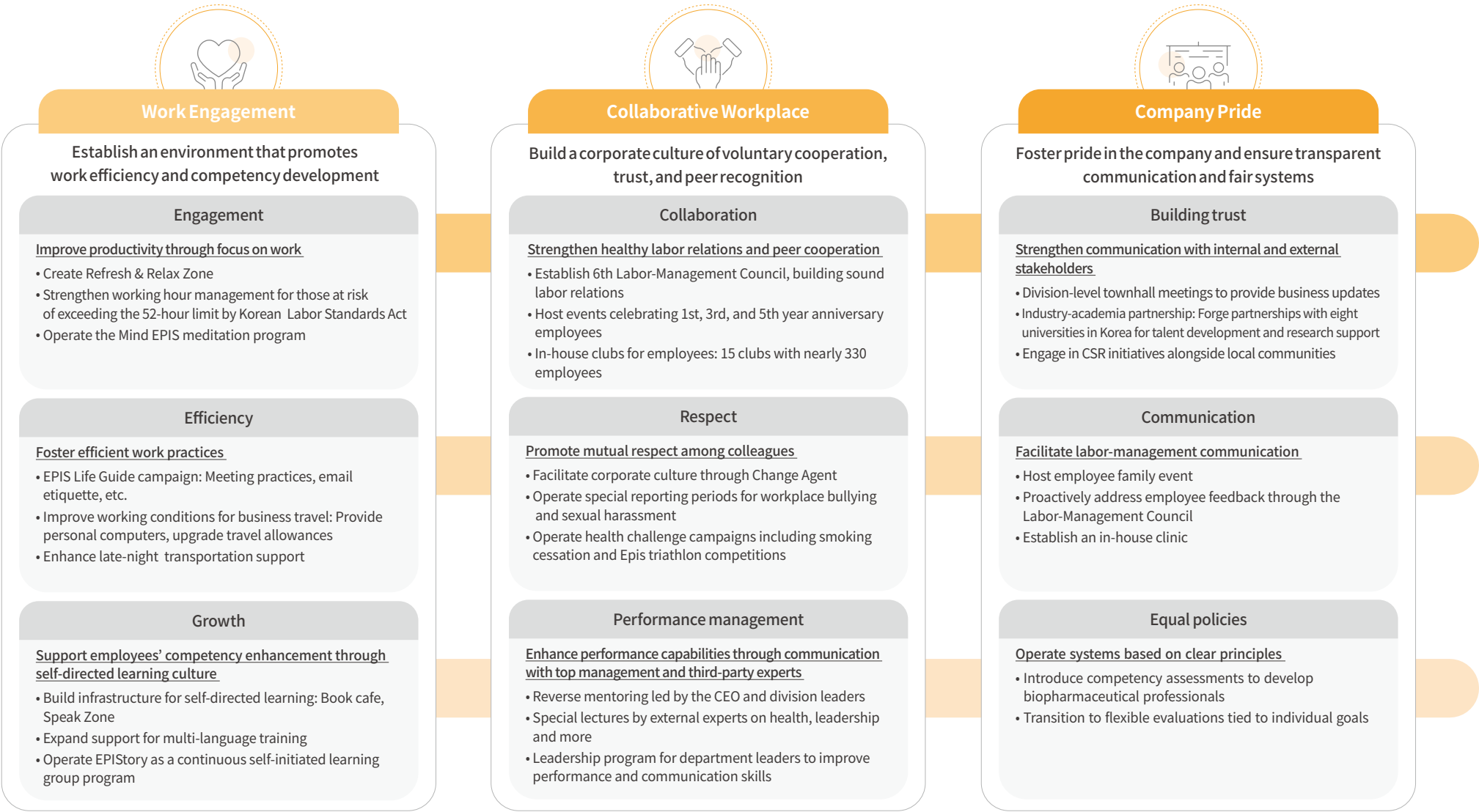
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Corporate Culture and HR Management

Samsung Bioepis' Corporate Culture Enhancement Initiatives in 2024

To enhance our corporate culture, Samsung Bioepis engages in a broad array of initiatives across three key areas: work engagement, collaborative workplace, and company pride.



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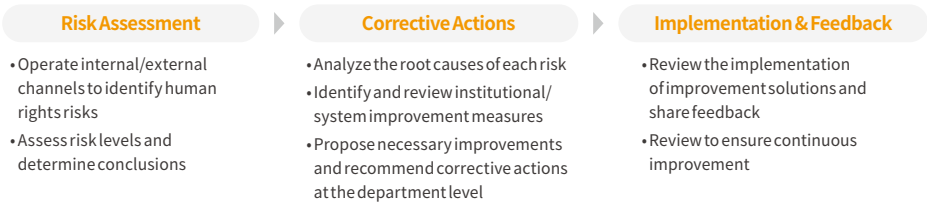
Human Rights Management and Diversity

Human Rights Management and Diversity Promotion

Samsung Bioepis' Human Rights Policy

Samsung Bioepis makes sure that employees are not discriminated against on the grounds of gender, race, ethnicity, nationality, religion, disability, age, or political association. We stipulated our Human Rights Charter in 2022 specifying the principles of equal pay for work of equal value and zero tolerance for sexual discrimination or racial discrimination. The Human Rights Charter serves to improve the non-discrimination principle stated in the employment regulations, and set the course ahead in advancing human rights management.

Human Rights Risk Management Process



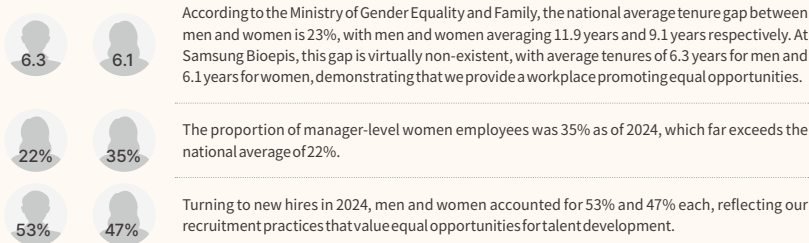
Diversity and Non-discrimination

We are committed to fostering an environment where employees from diverse perspectives and backgrounds freely engage in interactions to achieve best-possible outcomes. To this end, we ensure equal pay for work of equal value for all employees, irrespective of gender, religion, race or other factors. In particular, we fairly recognize the contributions of women and support greater female participation in society.

Case

Equal Opportunity at Samsung Bioepis

At our domestic operations, men and women account for 50.2% and 49.8% of our total workforce respectively. This demonstrates that Samsung Bioepis is evolving beyond simply preventing discrimination or protecting rights towards fostering an environment of equal opportunity for all.

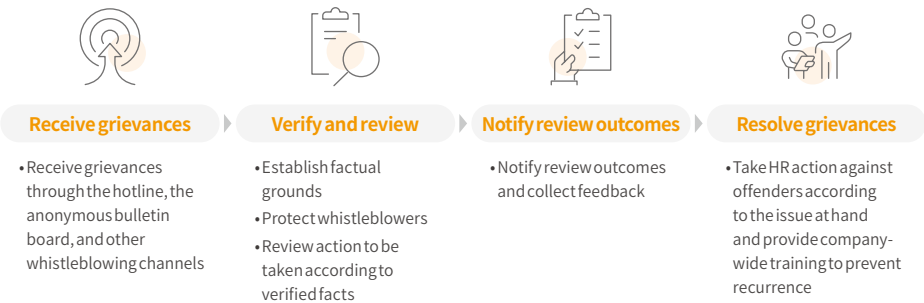


Employee Grievance Handling

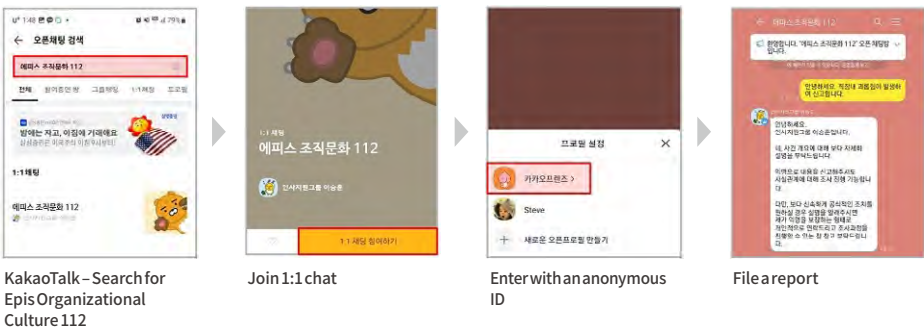
Grievance Handling Procedures

In receiving grievances, we ensure the identity of whistleblowers and their concerns remain confidential to protect them from any disadvantages. While we immediately take action and notify the results for concerns raised in principle, we address issues that elude immediate resolution by communicating our action plan and timeline within 24 hours to ensure their smooth handling.

Grievance Receiving and Handling Procedures



Samsung Bioepis' Anonymous Hotline for Whistleblowing



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Health and Safety

Health and Safety Management

Enhancing Our Health and Safety Management Framework

Samsung Bioepis puts the health and safety of all our stakeholders, including customers, employees, and suppliers, above all else. In 2022, we established our safety, environment, and energy management principles to improve the work environment and disseminate a safety-first culture. In 2023, we achieved ISO 45001 for health and safety management system to ensure the credibility of our health and safety management framework. By establishing and implementing this framework, we aim to prevent high-consequence injuries and foster workplace safety.

Health and Safety Committee

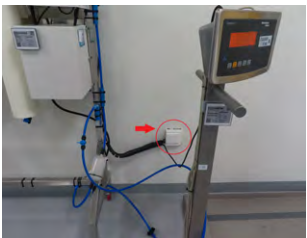
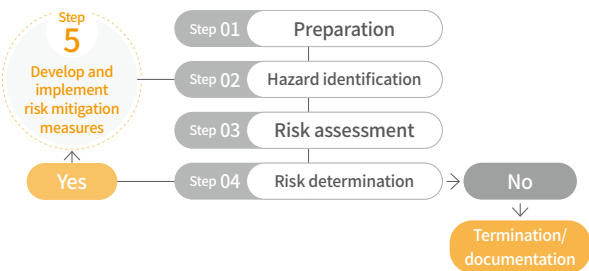
Our health and safety activities span the overall value chain. The occupational safety and health committee brings together labor and management to deliberate and decide on company-wide health and safety agendas, and the supplier health and safety committee serves to communicate with suppliers on health and safety issues. The biosafety management committee which consists of internal and external experts convenes to perform risk assessments on Living Modified Organisms (LMO) to review the safety of the entire laboratory process on an on-going basis.

Health and Safety Activities

Workplace Risk Assessment

We implement a rigorous risk assessment system to prevent the risk of occupational injuries from ever occurring. Annual risk assessments are conducted to analyze, evaluate, and address team/process-specific risks under the guidance of the dedicated health and safety department. In addition, the potential risk identification competition is hosted each quarter with participation from all employees to identify safety-related risks across the overall internal operations and make necessary improvements. The 2024 risk assessments helped us identify a total of 90 risks, all of which were addressed through corrective measures.

Risk Assessment Process



Waterproof outlet

Health and Safety Impact Management

Our health and safety assessment system, supervised by our Chief Safety Officer (CSO) and safety and environment management supervisors, serves to raise company-wide awareness of the importance of health and safety and foster a self-directed safety culture. Health and safety qualification assessments also ensure that suppliers are selected based on their outstanding safety management performance. Suppliers whose scores declined are supported with safety training to enhance overall safety management performance at Samsung Bioepis and suppliers.

Employee Health Management

We support our employees with differentiated facilities and programs for their physical and mental health management. Our musculoskeletal center and in-house clinic provide consultations and exercise guidance for work-related musculoskeletal disorders. As part of our employee benefits, we also offer health checkups and flu vaccinations. Meanwhile, our psychological counseling center established for employees' mental health support, is staffed by professional counselors who offer one-on-one sessions in a strictly confidential setting. Furthermore, we operate a range of policies and support programs to promote healthy lifestyle habits, including modern fitness equipment and personalized training, walking trails around the office building and running walking campaigns, and healthy, nutritious meals.

Category	Benefits Program	Description
Well-being	Health checkups	Annual health checkups for employees and their families
	Vaccinations (flu and others)	Ensure employee health through infectious disease prevention
Support facilities	Musculoskeletal disorder prevention center	Provide consultations and exercise guidance for work-related musculoskeletal disorders
	In-house clinic	Provide medical consultations and treatment for acute conditions
	Fitness center/gym facilities	Provide personalized training with fully-equipped modern fitness facilities
	Psychological counseling center	Staffed with professional counselors, guarantee confidentiality for all sessions
Other	Health promotion programs	Encourage walking habits, improve dietary habits, and offer other various support programs

Case

Opening an In-house Clinic and Pharmacy

The Labor-Management Council meeting held in Q3 2024 served to reach a final agreement to establish an in-house clinic. Following six months of preparation, the clinic officially opened in April 2025. The in-house clinic and pharmacy will drive our steady commitment to promoting employee health and healthcare management.



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Supply Chain Management

Supply Chain Risk Management

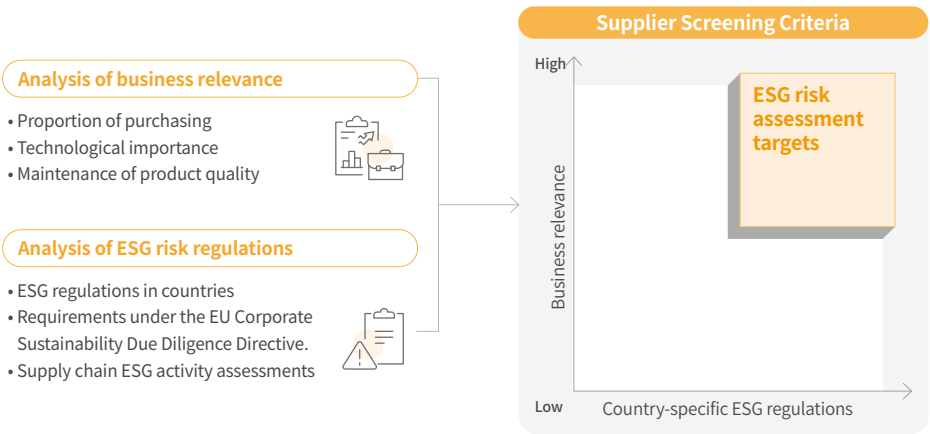
Global geopolitical tensions and climate-related risks, coupled with proposed US tariffs on biopharmaceutical products, are giving rise to uncertainties across the global bio industry landscape. This prompted global leading bio companies to take a strategic approach to securing and managing suppliers, minimizing supply chain risks in so doing. Samsung Bioepis’ goal is to deliver high-quality medicines at reasonable costs and optimal lead times. We achieve this by building reliable and sustainable supply chains while factoring strategic and geographical considerations in supply chain management to mitigate relevant risks.

Supply Chain ESG Management Framework

In step with enhanced global requirements for supply chain due diligence and ESG disclosures, we established our sustainable supply chain policy, Third Party Code of Conduct, and supply chain risk assessment process. These efforts are aimed at encouraging our business partners to abide by these norms and reviewing their compliance to proactively prevent supply chain ESG risks.

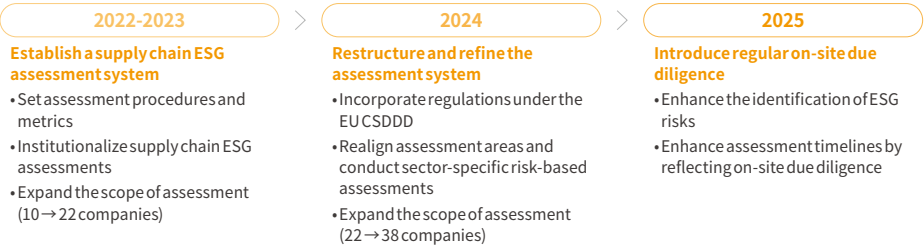
Supplier Screening

Our supplier screening process is up and running to systematically manage supply chain ESG risk. This enables us to comprehensively analyze and prioritize key suppliers in terms of their relevance with our business and levels of ESG risk. Business relevance is determined by suppliers’ proportion in our total purchasing, technological importance, and quality performance. In conducting ESG risk analyses, we identify suppliers requiring ESG risk management by referring to ESG regulations of countries where these suppliers are based as well as the EU Corporate Sustainability Due Diligence Directive.



Supply Chain ESG Assessment

We have been aligning our supply chain ESG management system in preparation for the implementation of the EU Corporate Sustainability Due Diligence Directive (CSDDD). This Directive applies to companies operating in the EU, mandating them to reduce their negative impact on human rights and the environment across the supply chain. In response, we have conducted supply chain ESG assessments since 2022, working to reduce supply chain ESG risks by expanding the scope of assessment and conducting sector-specific risk-based assessments and on-site due diligence.



Assessment Area	Assessment Score		Assessment Area	Assessment Score	
	2023	2024		2023	2024
ESG management system	83.3	88.6	Environmental management, Net Zero	56.4	75.4
Ethical management and supply chain	79.0	76.2	Health and safety	86.3	89.1
Labor and human rights	86.3	86.6	Total	78.3	83.2

*Discrepancies in assessment outcomes are due to changes in assessment items and areas from the previous year.

In February 2025, the European Commission proposed the EU Omnibus Package with a view to reducing regulatory compliance burden. Still yet, this does not exempt companies from their responsibility to address negative issues occurring within their supply chains. Regardless of this regulatory relief, we remain committed to aligning its supply chain ESG assessment system with global requirements.

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Local Communities and Win-Win Partnerships

Corporate Social Responsibility

CSR Framework

As corporate citizens, companies can generate profits drawing on the support and encouragement of the communities in which they operate. This brings with it the obligation and responsibility to contribute to tackling social issues by giving back. Samsung Bioepis and Samsung Group affiliates are committed to addressing a range of social challenges in areas such as youth education and win-win partnerships, guided by Samsung’s overarching CSR vision ‘Together for Tomorrow! Enabling People’. Samsung Bioepis specially focuses on Dream Class, Steppingstone of Hope, and other programs supporting socially underprivileged groups including teens from multicultural families and seniors.

Samsung Group’s CSR Approach

Together for Tomorrow!
Enabling People

Youth Education

- SSAFY
(Samsung Software Academy For Youth)
- Dream Class*
- Smart School
- Junior SW Academy
- Steppingstone of Hope*
- Blue Elephant*
- Technical training for the WorldSkills Competition

Win-Win Partnership

- Smart Factory C-Lab (Inside/Outside)
- Future technology development project
- Win-win partnership funds/payment support funds
- Supplier incentives
- Fine Particle Labs
- Local young activist support project
- Environmental problem resolution/safety incident prevention
- Support for the socially underprivileged* (people with disabilities/broken families/teens from multicultural families/elders)
- Respect for life (suicide prevention)
- Traffic Safety Academy / guide dog project
- Facial deformity surgery project
- Local restaurant support in Jeju
- Free-of-charge sight restoration project
- Sharing Kiosk
- NGO calendar production

*Samsung Bioepis’ CSR support programs



Dream Class	• Math and English tutoring and career path mentoring by undergraduate mentors
Steppingstone of Hope	• Support program for young adults transitioning out of care facilities
Blue Elephant	• Cyberbullying prevention education
Support for vulnerable groups	• Support for multicultural youth and seniors, voluntary fundraising through Kiosk for sharing
EPIS’ in-house CSR initiatives	• Happy EPIS kit production: Produce kits containing daily supplies for underprivileged children in Incheon
	• Fundraising for sharing events: Host in-house One Day Pub events, raise funds for donation
	• Blood donation campaign: Visit on-site blood donation buses and participate in the in-house blood donation drive
	• Support for industry-academia cooperation: Nurture physician-scientists and bio talent, host the Research Note competition for undergraduates



Happy EPIS kits



Kiosk for sharing



Industry-academia cooperation



Research Note competition for undergraduates

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Win-Win Partnerships

Industry-Academia Partnerships Tailored to the Biopharmaceutical Industry

Samsung Bioepis actively engages in industry-academia partnerships tailored to the biopharmaceutical industry, nurturing next-generation bio talent. Not only do we provide scholarships to support the development of physician-scientists, but also host the Research Note competition with major universities in Korea. These wide-ranging partnerships contribute to fostering future leaders in the bio industry at an early stage and providing students with opportunities to gain global-level R&D knowledge during their undergraduate years.

Support for Bio Materials, Parts, and Equipment Companies

We have implemented the Bio Materials, Parts, and Equipment Test Program since May 2022 to advance the nation's bio industry and help domestic biomaterials, parts, and equipment companies strengthen their global competitive edge. This program supports participating companies to enhance the maturity of their products, improve processes, and achieve cost savings, which eventually elevates their competitive strengths over the long-term. Samsung Bioepis also benefits from deeper understanding of the products currently in use while securing capable suppliers to meet potential replacement needs in preparation for supply chain diversification. We will continue operating this program to support competitiveness enhancement and localization for domestic materials, parts, and equipment companies.



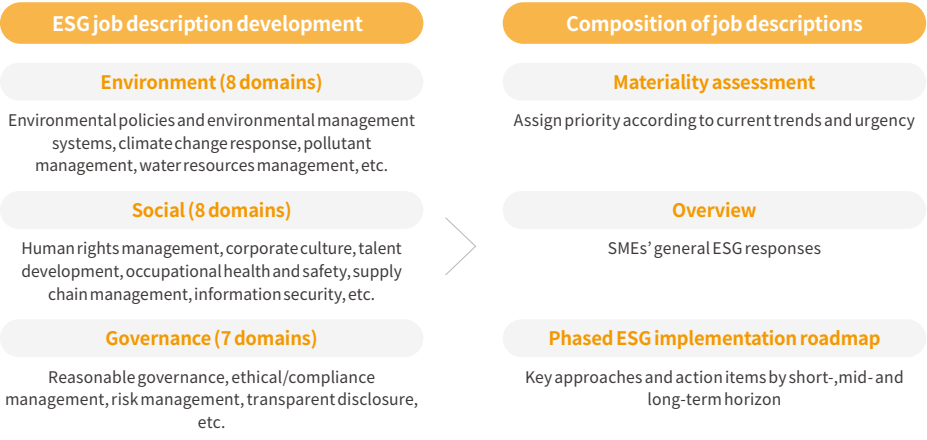
Category	Description	Progress
2022	Culture media, single-use bioreactors, single-use 2D bags, etc.	16 cases completed*
2023	Residual DNA analysis kits, single-use cell culture bags, etc.	3 cases completed
2024	Enzyme engineering platforms, media additive materials, etc.	2 cases completed, 3 in progress
Total		21 cases completed/ 3 in progress

* In the previous year's report, two separate tests from one company were reported as a single case, which has been restated in this year's report.

ESG Management Support for Small/mid-sized Biotech Companies

In response to tightening ESG regulations, we support ESG capacity enhancement for small/mid-sized biotech companies facing difficulties in improving ESG performance and complying with disclosure requirements in partnership with the Korea Biotechnology Industry Organization (KBIO). The Organization serves as an official channel for its members, identifying their consulting needs for ESG capacity building and surveying companies interested in receiving consulting support. Samsung Bioepis, in turn, selects companies likely to benefit most from ESG consulting among those expressing interest, and provides ESG consulting accordingly. Once a consulting recipient is selected, tailored ESG job descriptions are developed by matching the company's areas of interest with Samsung Bioepis' ESG management know-how. Based on these descriptions, a four-week consulting engagement is conducted. We have established a standardized database of job descriptions outlining short/mid/long-term roadmaps for a total of 23 work domains in each of the environmental, social, and governance areas. This paves the way to implement ESG improvement tasks in a phased manner in sync with the growth stage and the level of ESG maturity of these small/mid-sized companies.

ESG Consulting Content



Since the initiation of this project, we have provided ESG consulting to six companies in total, engaging in in-depth discussions on pending ESG issues and sharing ESG experiences in each area of interest. These efforts drive our commitment to promoting win-win partnerships within the bio ecosystem comprising the KBIO and small/mid-sized biotech companies.

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Board of Directors and Enterprise-wide Risk Management

Management Accountability Led by the Board of Directors

Composition of the Board of Directors

To establish Board-centered management and reasonable decision-making and promote mid-to long-term growth, we prohibit discrimination on the grounds of gender, age, nationality or religion and prioritize expertise in the biopharmaceutical industry in the composition of the Board of Directors. We also ensure transparency in the director appointment process and independence of the Board in accordance with the Korean Commercial Act and our Articles of Incorporation.

* As of April 2025

Name			
	Kyung-Ah Kim	Peter Seongwon Hong	Kun Lo
Position	Chair of the Board, President & CEO	Inside director, Executive Vice President	Non-executive director
Gender	Female	Male	Male
Date of Initial Appointment	Sep. 29, 2024	Mar. 28, 2025	Feb. 29, 2022
Tenure	Sep. 28, 2027	Mar. 27, 2028	Mar. 27, 2028
Career	Current) CEO, Samsung Bioepis Former) Vice President, Samsung Advanced Institute of Technology	Current) Executive Vice President Former) Director, New Drug Research Center, LG Life Sciences	Current) Head of the EPVC Center, Samsung Biologics Former) Senior Vice President, New Business Division, Samsung Engineering
Expertise	• Biopharmaceutical business development and research • Leadership	• Biopharmaceutical research • Leadership	• Biopharmaceutical process design and construction • Chemical business R&D

Board Evaluation and Compensation

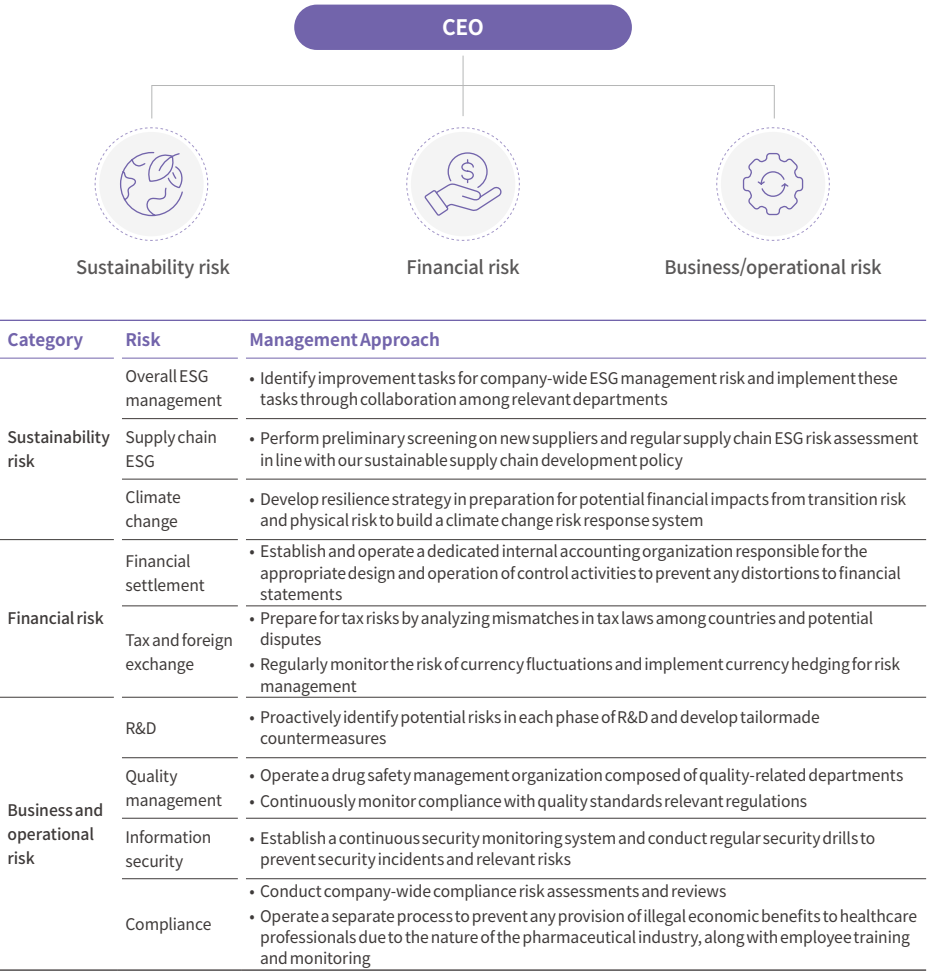
We provide inside directors with compensation that consists of base pay and performance pay within the limit approved by the Annual General Meeting of shareholders. Performance evaluations of members of the Board align with the long-term performance incentive program governed by the relevant guidelines of Samsung Group as well as risk management items. Compensation for inside directors reflects Samsung Bioepis' business performance to promote more accountable Board-driven management.

Operational Performance of the Board

In 2024, our Board of Directors convened seven times in total to deliberate and decide on key issues across the entire business operations, including discussion of major business issues, inter-affiliate transactions (Samsung Biologics), approval of research contracts, and donations. Director attendance was 95.2%, indicating all our directors faithfully fulfill their role at the Board of Directors.

Enterprise-wide Risk Management System

Companies today face increasingly complex and diversifying risks amid the rapidly-evolving business landscape and the advancement of long-term value creation. To ensure reliable operations and business continuity, Samsung Bioepis has established an enterprise-wide risk management framework, driving proactive risk management based on expertise, cross-functional collaboration, and agile decision-making.



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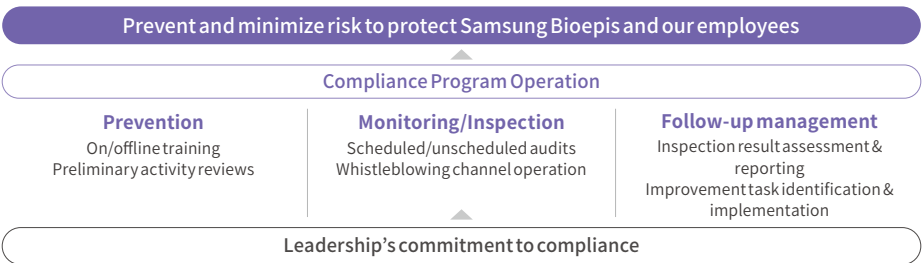
Business Ethics and Compliance Management

Ethical Management and Compliance

Principles of Ethical Management

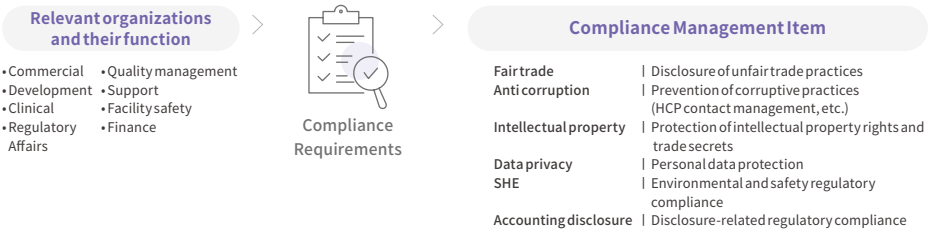
Samsung Bioepis prioritizes ethical management and regulatory compliance as its utmost value and is fully committed to fulfilling its social responsibility by translating this value into action. To ensure the importance of business ethics and compliance management permeates throughout the organization, we announced the Samsung Bioepis Compliance Management Regulations, a revised version of our existing compliance regulations, in April 2025. Our compliance organization operates directly under the CEO to establish an anti-corruption and compliance management system in alignment with global standards while continuously monitoring and addressing relevant risks.

Company-wide Compliance Program



Organization-level Compliance Management

We have established an internal management process to abide by country-specific laws and regulations governing fair trade, anti-corruption, intellectual property, and data privacy, and integrate this process into our day-to-day operations.



Compliance Specific to the Pharmaceutical Industry

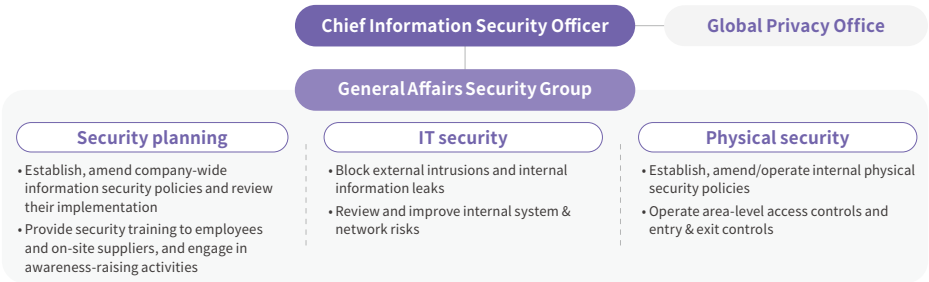
Our compliance policy ensures that we do not engage in any provision of undue economic benefits to healthcare professionals in reflection of the distinctive characteristics of the pharmaceutical industry. We also strictly prohibit any form of off-label promotion which refers to advertising the use of medicines for purposes not approved by the regulatory authorities.

Information Security

Information Security Management Framework

As a company designated as holding national core technologies (NCT), Samsung Bioepis is fully committed to ensuring information security. Any unauthorized overseas transfer of our technologies could negatively impact national security and the economy due to their substantial technological and economic value. Given the inherent nature of the biopharmaceutical development industry, we also handle personal data for wide-ranging stakeholders including clinical trial subjects, patients, and healthcare professionals. This indicates that any breach of such data could result in significant harm to our business operations. We engage in a broad array of information security initiatives based on our robust information security framework to safeguard our critical information assets including stakeholders' personal data collected throughout the entire value chain.

Information Security Organization



Information Security Management

We have operated the Security Agent (SA) system since 2022 as an employee-led initiative to raise vigilance around information security and protection through enhanced communication. In August 2023, we achieved ISO 27001, an international standard for information security management systems, establishing a globally-recognized information security framework that support the confidentiality, integrity, and availability of our information assets.

Case

ISO 27001 Surveillance Audits and Company-wide Security Training

In April 2024, we underwent a surveillance audit for the ISO 27001 certification that we obtained in the previous year. We successfully passed the surveillance audit following the review of security checklists across all departments in collaboration with departmental SAs as well as additional interviews and work reviews with personnel from key security departments. In parallel, we provide company-wide security training to communicate the importance of security and to share new enhanced security policies, raising security awareness across the organization.



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Stakeholder Response

Samsung Bioepis reaches out closer to stakeholders through a wide array of channels. We fully gather feedback from key stakeholders and integrate it in our overall business operations and ESG materiality assessment process.

	 Customer	 Employee	 Supplier	 Investor / Shareholder	 University and Research Institute	 Local Community	 Government / Media / Association
Definition	Stakeholders provided with Samsung Bioepis' products	Core of business activities at Samsung Bioepis	Stakeholders who supply products and services required for our business operations	Stakeholders who provide us with financial capital	Institutions which nurture professionals expected to become employees of Samsung Bioepis	Local communities and stakeholders impacted by the Company's business operations	Stakeholders who influence domestic/ international business by who enacting laws related to the bio-pharmaceutical industry and determine the level of regulations
Key issues of interest	Quality management from the customers' perspective, strengthen customer privacy, ethical management, increased communication	Corporate culture, benefits, win-win labor relations, Fair performance assessment and compensation, competency development	Fair trade, shared growth, occupational health&safety, transparent communication	Good governance, risk management, ethics, Increased communication	Business and R&D, job creation	Environmental protection, development to the local economy, job creation, social contribution activities	Response to domestic/ international regulations and policies, industry trends, job creation, business expansion
Communication channel	Homepage, Media, Social media	In-house bulletin board, EPIS-IN(internal communication channel), counseling center, labor-management council, whistleblowing channels	Regular committee meetings with CMOs	Annual audit reports, media	Recruiting website, mentoring programs for bio talent, industry-academia partnership, research note competition for university students	Social contribution activities	Meetings, seminars, newsletters, homepage, Social Media
Responsible organization	Communication	People, Communication	Production operation, Purchasing	Finance, Communication	People	People, ESG	Communication, ESG, PM, RSP [*]

^{*} PM: Program Management RSP: Regulatory Strategy and Policy

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Financial Performance

Consolidated Statements of Financial Position

Category	Unit	2022	2023	2024
Assets				
I . Current assets	KRW million	1,632,058	1,604,188	1,920,348
Cash and cash equivalents	KRW million	123,727	126,842	85,034
Trade and other receivables	KRW million	289,093	317,595	469,034
Prepaid income tax	KRW million	8,863	2,624	134
Inventories	KRW million	1,163,558	1,098,184	1,258,898
Other current assets	KRW million	40,442	58,943	106,006
Other current financial assets	KRW million	6,375	-	-
Contract assets	KRW million	-	-	1,242
II . Non-current assets	KRW million	1,202,565	1,293,738	1,372,022
Non-current financial assets	KRW million	1,954	3,230	7,198
Other non-current receivables	KRW million	6,137	8,204	22,887
Property, plant and equipment	KRW million	224,174	229,018	220,377
Intangible assets	KRW million	718,597	779,144	778,222
Right-of-use assets	KRW million	974	969	911
Deferred tax assets	KRW million	247,909	272,227	309,836
Other non-current assets	KRW million	1,799	946	3,191
Employee benefits	KRW million	1,021	-	-
Contract assets	KRW million	-	-	29,400
Total assets	KRW million	2,834,623	2,897,926	3,292,370
Liabilities				
I . Current liabilities	KRW million	1,295,986	1,273,856	1,292,701
Trade and other payables	KRW million	184,147	206,523	466,100
Short-term borrowings	KRW million	532,783	434,500	207,000
Current portion of long-term borrowings	KRW million	88,019	145,000	120,000
Unearned revenues	KRW million	442,940	399,818	399,829
Current lease liabilities	KRW million	476	496	424
Current tax liabilities	KRW million	44,845	25,012	96,500
Advance received	KRW million	-	79	16
Withholdings	KRW million	2,776	2,366	2,653
Contract liabilities	KRW million	-	60,062	179
II . Non-current liabilities	KRW million	362,541	271,429	278,187
Long-term borrowings	KRW million	220,000	120,000	95,000
Non-current lease liabilities	KRW million	129	32	115
Other non-current payables	KRW million	8,713	14,372	16,430
Non-current unearned revenues	KRW million	133,699	1	-
Contract liabilities	KRW million	-	131,907	155,966
Employee benefits	KRW million	-	5,117	5,547
Other non-current finance liabilities	KRW million	-	-	-
Tax liabilities	KRW million	-	-	5,129
Total liabilities	KRW million	1,658,527	1,545,285	1,570,888

Category	Unit	2022	2023	2024
Equity				
I . Equity attributable to owners of the company	KRW million	1,176,096	1,352,641	1,721,482
Share capital	KRW million	103,419	103,419	103,418
Share premium	KRW million	930,267	930,267	930,267
Accumulated other comprehensive loss	KRW million	-4,533	-8,613	-11,721
Retained Earnings (Accumulated deficit)	KRW million	146,943	327,568	699,518
II . Non-controlling interests	KRW million	-	-	-
Total equity	KRW million	1,176,096	1,352,641	1,721,482
Total liabilities and equity	KRW million	2,834,623	2,897,926	3,292,370

Consolidated Statements of Comprehensive Income

Category	Unit	2022	2023	2024
I . Revenue	KRW million	946,340	1,020,297	1,537,700
II . Cost of revenue	KRW million	-365,634	-408,271	-519,199
III . Gross profit	KRW million	580,706	612,026	1,018,501
IV . Selling, general and administrative expenses	KRW million	-349,170	-406,665	-583,135
V . Operating profit (loss)	KRW million	231,536	205,361	435,366
VI . Non-operating profit (loss)	KRW million	-18,794	-16,957	6,492
Other non-operating income	KRW million	733	6,819	308
Other non-operating expenses	KRW million	-213	-928	-23,221
Finance income	KRW million	110,939	77,400	144,248
Finance costs	KRW million	-130,253	-100,248	-114,843
VII . Profit before income tax	KRW million	212,742	188,404	441,858
VIII . Income tax expense (profit)	KRW million	5,681	-7,778	-69,909
IX . Profit for the year	KRW million	218,423	180,626	371,949
X . Other comprehensive income (loss)	KRW million	1,765	-4,080	-3,108
Items that will never be reclassified to profit or loss:	KRW million			
Defined benefit plan remeasurement	KRW million	1,552	-4,384	-3,835
Items that are or may be reclassified to profit or loss:	KRW million			
Foreign currency translation differences for foreign perations	KRW million	213	304	727
XI . Total comprehensive income for the year	KRW million	220,188	176,546	368,841

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GRI Standards Index

Universal Standards

GRI 2: General Disclosures 2021

	Disclosure	Page
The organization and its reporting practices	2-1. Organizational details	6
	2-2. Entities included in the organization's sustainability reporting	6
	2-3. Reporting period, frequency and contact point	2
	2-4. Restatements of information	Data book
Activities and workers	2-5. External assurance	54-56
	2-6. Activities, value chain and other business relationships	7,8
	2-7. Employees	Data book
	2-8. Workers who are not employees	Data book
Governance	2-9. Governance structure and composition	45
	2-10. Nomination and selection of the highest governance body	45
	2-11. Chair of the highest governance body	45
	2-12. Role of the highest governance body in overseeing the management of impacts	29, 45
	2-13. Delegation of responsibility for managing impacts	N/A
	2-14. Role of the highest governance body in sustainability reporting	29, 45
	2-15. Conflicts of interest	45, 46
	2-16. Communication of critical concerns	29, 45
	2-17. Collective knowledge of the highest governance body	45
	2-18. Evaluation of the performance of the highest governance body	45
	2-19. Remuneration policies	45
	2-20. Process to determine remuneration	45
	2-21. Annual total compensation ratio	Data book
	2-22. Statement on sustainable development strategy	5
Strategy, policies and practices	2-23. Policy commitments	39
	2-24. Embedding policy commitments	39
	2-25. Processes to remediate negative impacts	39
	2-26. Mechanisms for seeking advice and raising concerns	37, 39
Stakeholder engagement	2-27. Compliance with laws and regulations	Data book
	2-28. Membership associations	57
	2-29. Approach to stakeholder engagement	47
	2-30. Collective bargaining agreements	37

GRI 3: Material Topics 2021

	Disclosure	Page
3-1. Process to determine material topics		11
3-2. List of material topics		12, 50
3-3. Management of material topics		50

Material Topic Management

Core ESG Topics	Impact and Management	Nature of Impact	
Sustainable R&D and innovation	Broader treatment options and productivity gains made possible through R&D and innovation create a range of business opportunities. We strengthen collaboration with third-parties and build advanced development platforms to reinforce our R&D capabilities.	Actual	Opportunity
Customer safety and health	Given the nature of the biopharmaceutical industry, product quality issues bring immense impact on business operations as well as to customer safety. We operate a rigorous quality management system and engage in relevant management activities to prevent quality issues from ever occurring.	Potential	Crisis
Access to medicines	While advances in medicine contributed to improving health outcomes for many people globally, the benefits remain unequal. Our approach to improving access to medicines is anchored on the delivery of broader treatment options, affordability, and support for a sustainable healthcare system.	Actual	Opportunity
Compliance and ethical management	Non-compliance with business ethics constitutes a breach of societal standards and carries risks comparable to those of business failures. We have established a compliance management system aligned with global standards and are strengthening ethical management practices at all levels of the company.	Actual	Crisis
Supply chain management	Failure to manage issues related to supply chain human rights and environmental impacts could bring adverse impact throughout the value chain. We are expanding the scope of our management responsibilities by establishing a supply chain ESG assessment system and conducting regular assessments.	Potential	Crisis
Net zero	As climate action emerges as a key agenda of the global community, companies are required to put in efforts on multiple fronts to reduce GHG emissions. We have set a goal of achieving Net Zero emissions and RE100 by 2050, and are implementing initiatives to reduce our energy consumption and GHG emissions in light of our business circumstances.	Actual	Crisis
Talent recruitment and development	Securing professional bio talent is instrumental in driving performance and expanding business. We ensure fairness in our hiring process, performance evaluation, and development system operation, helping employees sharpen their competitive strengths and promoting stable growth.	Actual	Opportunity
Generation of sound economic performance	In the face of the uncertain business landscape characterized by global geopolitical tensions, climate challenges, and proposed US tariffs, we delivered exceptional products and engaged in reasonable business management, which allowed us to achieve a notable year-on-year growth in business performance.	Actual	Opportunity
Occupational health and safety	Employee health and safety management is a critical driver of employee satisfaction and organizational pride. We have established a health and safety management system and conduct regular facility safety inspections while ensuring employee health management, fostering a safe and healthy workplace.	Actual	Crisis
Equal opportunities	Ensuring equal opportunities for employees from diverse backgrounds is directly associated with increased employee satisfaction and reduced turnover. We respect the diversity of employees and prohibit discrimination. We also offer a range of programs to nurture talented women and uphold maternity protection.	Potential	Opportunity

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GRI Standards Index

Topic-specific Standards

Core ESG Topics

Disclosure	Page
Core ESG Topic 1: Sustainable R&D and innovation	
Non-GRI	14~16
Core ESG Topic 2: Customer safety and health	
GRI 416: Customer Health and Safety 2016	
416-1. Assessment of the health and safety impacts of product and service categories	18, Data book
416-2. Incidents of non-compliance concerning the health and safety impacts of products and services	18, Data book
Core ESG Topic 3: Access to medicines	
Non-GRI	20~23
Core ESG Topic 4: Compliance management and business ethics	
GRI 205: Anti-corruption 2016	
205-1. Operations assessed for risks related to corruption	Not happened
205-2. Communication and training about anti-corruption policies and procedures	Data book
205-3. Confirmed incidents of corruption and actions taken	Data book
GRI 206: Anti-competitive Behavior 2016	
206-1. Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Not happened
Core ESG Topic 5: Supply chain management	
GRI 308: Supplier Environmental Assessment 2016	
308-1. New suppliers that were screened using environmental criteria	41, Data book
308-2. Negative environmental impacts in the supply chain and actions taken	41, Data book
GRI 414: Supplier Social Assessment 2016	
414-1. New suppliers that were screened using social criteria	41, Data book
414-2. Negative social impacts in the supply chain and actions taken	41, Data book
Core ESG Topic 6: Net Zero	
GRI 305: Emissions 2016	
305-1. Direct (Scope 1) GHG emissions	30, Data book
305-2. Energy indirect (Scope 2) GHG emissions	30, Data book
305-3. Other indirect (Scope 3) GHG emissions	30, Data book
305-4. GHG emissions intensity	Data book
305-5. Reduction of GHG emissions	Data book
305-6. Emissions of ozone-depleting substances (ODS)	We do not discharge ODS.
305-7. Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions	Data book

Disclosure	Page
Core ESG Topic 7: Attracting and fostering talent	
GRI 401: Employment 2016	
401-1. New employee hires and employee turnover	36, Data book
401-2. Benefits provided to full-time employees that are not provided to temporary or part-time employees	37
401-3. Parental leave	Data book
GRI 404: Training and Education 2016	
404-1. Average hours of training per year per employee	Data book
404-2. Programs for upgrading employee skills and transition assistance programs	16
404-3. Percentage of employees receiving regular performance and career development reviews	36
Core ESG Topic 8: Driving economic performance	
GRI 201: Economic Performance 2016	
201-1. Direct economic value generated and distributed	Data book
201-2. Financial implications and other risks and opportunities due to climate change	27, 28
201-3. Defined benefit plan obligations and other retirement plans	Data book
201-4. Financial assistance received from government	Data book
Core ESG Topic 9: Occupational safety and health	
GRI 403: Occupational Health and Safety 2018	
403-1. Occupational health and safety management system	40
403-2. Hazard identification, risk assessment, and incident investigation	40
403-3. Occupational health services	40
403-4. Worker participation, consultation, and communication on occupational health and safety	40
403-5. Worker training on occupational health and safety	Data book
403-6. Promotion of worker health	Data book
403-7. Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	40
403-8. Workers covered by an occupational health and safety management system	40, Data book
403-9. Work-related injuries	40, Data book
403-10. Work-related ill health	40, Data book
Core ESG Topic 10: Diversity and inclusion	
GRI 405: Diversity and Equal Opportunity 2016	
405-1. Diversity of governance bodies and employees	39, Data book
405-2. Ratio of basic salary and remuneration of women to men	Data book

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GRI 200: Economic Topics 2021

Disclosure	Page
GRI 203: Indirect Economic Impacts 2016	
203-1. Infrastructure investments and services supported	9~10, Data book
203-2. Significant indirect economic impacts	9~10, Data book

GRI 300: Environment Topics 2021

Disclosure	Page
GRI 302: Energy 2016	
302-1. Energy consumption within the organization	Data book
302-2. Energy consumption outside of the organization	Data book
302-3. Energy intensity	Data book
302-4. Reduction of energy consumption	32, Data book
302-5. Reductions in energy requirements of products and services	32, 34
GRI 303: Water and Effluents 2018	
303-1. Interactions with water as a shared resource	33
303-2. Management of water discharge-related impacts	33
303-3. Water withdrawal	Data book
303-4. Water discharge	Data book
303-5. Water consumption	Data book
GRI 304: Biodiversity 2016	
304-1. Operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas	33
GRI 306: Waste 2020	
306-1. Waste generation and significant waste-related impacts	33
306-2. Management of significant waste-related impacts	33
306-3. Waste generated	33
306-4. Waste diverted from disposal	Data book
306-5. Waste directed to disposal	Data book

GRI 400: Social Topics 2021

Disclosure	Page
GRI 406: Non-discrimination 2016	
406-1. Incidents of discrimination and corrective actions taken	Data book
GRI 407: Freedom of Association and Collective Bargaining 2016	
407-1. Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	Not happened
GRI 408: Child Labor 2016	
408-1. Operations and suppliers at significant risk for incidents of child labor	Not happened
408-1. Operations and suppliers at significant risk for incidents of child labor	
409-1. Operations and suppliers at significant risk for incidents of forced or compulsory labor	Not happened
GRI 413: Local Communities 2016	
413-1. Operations with local community engagement, impact assessments, and development programs	42, 43
413-2. Operations with significant actual and potential negative impacts on local communities	Not happened
GRI 415: Public Policy 2016	
415-1. Political contributions	59
GRI 417: Marketing and Labeling 2016	
417-1. Requirements for product and service information and labeling	16, 46
417-2. Incidents of non-compliance concerning product and service information and labeling	Data book
417-3. Incidents of non-compliance concerning marketing communications	Data book
GRI 418: Customer Privacy 2016	
418-1. Substantiated complaints concerning breaches of customer privacy and losses of customer data	Data book

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SASB Index

Health Care(Biotechnology & Pharmaceuticals)

SASB code	Accounting Metric	Reference	Page
Safety of Clinical Trial Participants			
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	We put the safety and rights of participants as our top priority throughout the entire clinical trial process, and operate clinical trials according to clinical trial monitoring plans.	17
HC-BP-210a.2	“Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in:(1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)”	“(1) 3, (2) 0 We commit to cooperating with regulatory authorities and taking all necessary action to address issues including clinical trial management and pharmacovigilance.”	Data book
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	Did not occur.	-
Access to Medicines			
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	Under our vision Passion for Health, Samsung Bioepis provides many patients with high-quality biosimilars at affordable prices compared to their reference drugs. This vision guides our efforts to improve access to medicines.	20
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	SB3 (trastuzumab biosimilar) is listed on the WHO List of Prequalified Medicinal Products.	20
Affordability & Pricing			
HC-BP-240b.2	“Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year”	We sell our products in global markets through marketing partnership agreement with Biogen, Organon and others. Therefore, we cannot disclose the list/net price of products as it is related to the pricing policies of our partner and our company.	-
HC-BP-240b.3	“Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year”		
Drug Safety			
HC-BP-250a.1	List of products listed in the Food and Drug Administration’s (FDA) MedWatch Safety Alerts for Human Medical Products database	Not applicable. None of our products are listed in the FDA MedWatch Safety Alerts for Human Medical Products database.	-
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Not applicable, and all fatality information associated with our products is reported in the FDA Adverse Event Reporting System.	Data book
HC-BP-250a.3	Number of recalls issued, total units recalled	No recalls	18, Data book
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	No products have been accepted for takeback, reuse, or disposal due to recalls.	Data book
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	Did not occur.	18, Data book

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SASB Index

Health Care(Biotechnology & Pharmaceuticals)

SASB code	Accounting Metric	Reference	Page
Counterfeit Drugs			
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	We employ serialization and tamper-evident labeling for each package in accordance with country-specific regulations, and work with marketing partners and global regulatory authorities.	19
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products		
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	Did not occur.	-
Ethical Marketing			
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Did not occur.	Data book
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	We make our code of conduct constantly available on our website to declare our commitment to ethical and compliance management. Our code of conduct stipulates that we do not advertise the safety or efficacy of unauthorized products.	19, 46
Employee Recruitment, Development & Retention			
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	We categorize our research personnel pursuant to Article 14-2 of the Basic Research Promotion and Technology Development Support Act by Korean government, and increase investment in recruiting and retaining our research and development personnel while supporting the continuous development of our employees.	16, 36
HC-BP-330a.2	“(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others”	Refer to Data book.	Data book
Supply Chain Management			
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent thirdparty audit programs for integrity of supply chain and ingredients	Out of 38 suppliers that responded to our 2024 supply chain ESG assessment, 82% of them participated in EcoVadis and 39% of them in the PSCI.	-
Business Ethics			
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Did not occur.	Data book
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	We manage the provision of economic benefits to HCPs in advance and in line with the HCP interaction guidelines within the CPMS (Compliance Program Management System), and provide relevant status reports.	46
ACTIVITY METRIC			
HC-BP-000.A	Number of patients treated	Estimated total reached patients at approximately 50.8 million patients as of 2024.	7, 20
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	(1) 11 products approved, 9 products launched, (2) 2	20

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Third-party Assurance Statement

To readers of Samsung Bioepis Sustainability Report 2025

Introduction

Korea Management Registrar (KMR) was commissioned by Samsung Bioepis to conduct an independent assurance of its Sustainability Report 2025 (the “Report”). The data and its presentation in the Report is the sole responsibility of the management of Samsung Bioepis. KMR’s responsibility is to perform an assurance engagement as agreed upon in our agreement with Samsung Bioepis and issue an assurance statement.

Scope and Standards

Samsung Bioepis described its sustainability performance and activities in the Report. Our Assurance Team carried out an assurance engagement in accordance with the AA1000AS v3 and KMR’s assurance standard SRV1000. We are providing a Type 2, moderate level assurance. We evaluated the adherence to the AA1000AP (2018) principles of inclusivity, materiality, responsiveness and impact, and the reliability of the information and data provided using the Global Reporting Initiative (GRI) Index provided below. The opinion expressed in the Assurance Statement has been formed at the materiality of the professional judgment of our Assurance Team.

Confirmation that the Report was prepared in accordance with GRI standards 2021 was included in the scope of the assurance. We have reviewed the topic-specific disclosures of standards which were identified in the materiality assessment process.

- GRI Sustainability Reporting Standards 2021
- Universal standards
- Topic specific standards
 - GRI 201: Economic Performance
 - GRI 205: Anti-corruption
 - GRI 206: Anti-competitive Behavior
 - GRI 305: Emissions
 - GRI 308: Supplier Environmental Assessment
 - GRI 401: Employment
 - GRI 403: Occupational Health and Safety
 - GRI 404: Training and Education
 - GRI 405: Diversity and Equal Opportunity
 - GRI 414: Supplier Social Assessment
 - GRI 416: Customer Health and Safety

As for the reporting boundary, the engagement excludes the data and information of Samsung Bioepis’ partners, suppliers and any third parties.

KMR's Approach

To perform an assurance engagement within an agreed scope of assessment using the standards outlined above, our Assurance Team undertook the following activities as part of the engagement:

- reviewed the overall Report;
- reviewed materiality assessment methodology and the assessment report;
- evaluated sustainability strategies, performance data management system, and processes;
- interviewed people in charge of preparing the Report;
- reviewed the reliability of the Report's performance data and conducted data sampling;
- assessed the reliability of information using independent external sources such as Korean Financial Supervisory Service’s DART and public databases.

Limitations and Recommendations

KMR’s assurance engagement is based on the assumption that the data and information provided by Samsung Bioepis to us as part of our review are provided in good faith. Limited depth of evidence gathering including inquiry and analytical procedures and limited sampling at lower levels in the organization were applied. To address this, we referred to independent external sources such as DART and National Greenhouse Gas Management System (NGMS) and public databases to challenge the quality and reliability of the information provided.

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Third-party Assurance Statement

Conclusion and Opinion

Based on the document reviews and interviews, we had several discussions with Samsung Bioepis on the revision of the Report. We reviewed the Report’s final version in order to make sure that our recommendations for improvement and revision have been reflected. Based on the work performed, it is our opinion that the Report applied the GRI Standards. Nothing comes to our attention to suggest that the Report was not prepared in accordance with the AA1000AP (2018) principles.

· Inclusivity

Samsung Bioepis has developed and maintained different stakeholder communication channels at all levels to announce and fulfill its responsibilities to the stakeholders. Nothing comes to our attention to suggest that there is a key stakeholder group left out in the process. The organization makes efforts to properly reflect opinions and expectations into its strategies.

· Materiality

Samsung Bioepis has a unique materiality assessment process to decide the impact of issues identified on its sustainability performance. We have not found any material topics left out in the process.

· Responsiveness

Samsung Bioepis prioritized material issues to provide a comprehensive, balanced report of performance, responses, and future plans regarding them. We did not find anything to suggest that data and information disclosed in the Report do not give a fair representation of Samsung Bioepis’ actions.

· Impact

Samsung Bioepis identifies and monitors the direct and indirect impacts of material topics found through the materiality assessment, and quantifies such impacts as much as possible.

Reliability of Specific Sustainability Performance Information

In addition to the adherence to AA1000AP (2018) principles, we have assessed the reliability of economic, environmental, and social performance data related to sustainability performance. We interviewed the in-charge persons and reviewed information on a sampling basis and supporting documents as well as external sources and public databases to confirm that the disclosed data is reliable. Any intentional error or misstatement is not noted from the data and information disclosed in the Report.

Competence and Independence

KMR maintains a comprehensive system of quality control including documented policies and procedures in accordance with ISO/IEC 17021 : 2015 - Requirements for bodies providing audit and certification of management systems. This engagement was carried out by an independent team of sustainability assurance professionals. KMR has no other contract with Samsung Bioepis and did not provide any services to Samsung Bioepis that could compromise the independence of our work.

May 2025 Seoul, Korea

CEO *E. J. Hwang*



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GHG Verification Report

The Korea Management Registrar Inc. (hereinafter “KMR”) has conducted the verification on the greenhouse gas (hereinafter “GHG”) emission of SAMSUNG BIOEPIS Co.,Ltd.

SCOPE

Verification of places of business and emission facilities under the control of SAMSUNG BIOEPIS Co.,Ltd.

STANDARDS

- ISO 14064-1:2018, ISO 14064-3:2019
- IPCC Guidelines for National Greenhouse Gas Inventories (2006)
- Operational guidelines for emission reporting and certification of the Greenhouse Gas emissions trading scheme(Ministry of Environment, 2024-155)
- WRI/WBCSD GHG Protocol (2013)

PROCEDURE

The assurance was conducted by the KMR based on a risk analysis approach and data evaluation. The data and factors applied to the calculation of GHG emissions were determined to be appropriate based on objective evidence.

INDEPENDENT

KMR does not have any stake in the verified entity and does not conduct verification with biased opinions/ views. We have drawn an independent and objective verification conclusion based on the verification standards, and reviewed the every aspect of the verification we performed throughout the entire verification process through internal review.

LIMITATION

The verification team verified the related reports, information and data presented by the audited institution by sampling or enumeration methods. As a result, there are many inherent limitations, and there may be disagreements in the interpretation of appropriateness. Although we have tried to faithfully perform verification that meets the verification standards, we suggest that errors, omissions, and false statements that could not be found may be latent as the limitations to the verification.

OPINION

- The assurance engagement was performed to satisfy a limited assurance level, and no significant distortions were found in the verification results
- According to KMR's approach, nothing was found that would lead to a finding that SAMSUNG BIOEPIS Co.,Ltd. failed to disclose data and information that was accurate and reliable in all material respects.

GHG emissions & Energy Consumption

GHG emissions		Direct emissions (Scope 1)		Indirect emissions (Scope 2)		Total (tCO ₂ eq)
2024		1,220.325		5,103.525		6,323.850
Energy Consumption		Fuel	Electricity	Steam	Total	
2024	TJ	23.121	98.876	16.651	138.649	
	MWh	6,422.537	10,472.014	4,625.367	21,519.919	

RESULTS

Based on the above assurance criteria, we did not identify any inappropriate calculations or errors for the emissions of major emitting facilities.

May 27th, 2025
Authorized By

CEO E. J. Hwang



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GHG Verification Report

Verification Scope

Other indirect emissions (Scope 3) of Samsung Bioepis Co., Ltd.'s domestic headquarters and overseas corporations in 2024

Verification level

Limited Level of Assurance

Data Verified:

Annual greenhouse gas other indirect emissions (Scope 3) for 2024 are as follows:

[Unit: ton CO₂-e/yr]

Scope 3 category		2024 Emissions
category 1	Purchased goods and service	37,809
category 2	Capital goods	740
category 3	Fuel and energy related activities not included in scope 1&2	634
category 4	Upstream transportation and distribution	3,236
category 5	Waste generated in operations	266
category 6	Business travel	1,416
category 7	Employee Commuting	1,073
category 9	Downstream transportation and distribution	1,379
category 10	Processing of sold products	13,787
category 15	Investments	0
Total Emissions		60,340

※ Details including limitations and assumptions for calculating emissions by Scope3 category are described in the verification report.

Verification Criteria and Protocol

The verification was performed at the request of Samsung Bioepis using the following verification standards.

- WRI/WBCSD GHG Protocol Corporate Value Chain (Scope 3) Standard
- ISO 14064-1:2018
- ISO14064-3:2019
- BSI GHGEV Manual

Verification Opinion:

As a result of the verification in accordance with the standards listed above, it is the opinion of BSI that:

- In conducting this verification, no visits to the verification target business site or verification of the authenticity of the data provided by Samsung Bioepis were carried out.
- This verification may be affected by limited factors such as the limitation of provided data, non-execution of on-site verification, and sampling. Due to the limitation of this verification, there is an unavoidable risk that important errors may not be found and exist.
- The data quality was considered corresponding to the international key principles for GHG emissions verification.
- No material misstatements in the GHG emission calculations were detected, related records were maintained appropriately.

27/05/2025

For and on behalf of BSI:
Managing Director Korea, SeongHwan Lim



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Awards

Date	Awards	Host
2024.10	Global Generics & Biosimilars Awards 2024 Company of the Year, Asia Pacific	Citeline
2024.11	2024 Outstanding Companies for Workplace Innovation	Korean Ministry of Employment and Labor
2024.12	2024 Health-Friendly Management Excellent Company	Korean Ministry of Health and Welfare

Associations and Sponsorships

Article 31 of Korea’s Political Funds Act stipulates that foreigners, corporations and organizations in Korea and abroad are prohibited from contributing any political funds, and that no one should contribute any political funds from any corporation or organization both in Korea and abroad. In accordance with this Act, Samsung Bioepis does not provide any political funds, voting-related election funds, and lobbying funds for political organizations. Yet, we have remained our sponsorship for non-political associations as follows.

(Unit: KRW million)

Association	Status	Fees
Korea Biotechnology Industry Organization	Regular member, Chair	35
Korea Biomedicine Industry Association	Regular member	18
Korea Pharmaceutical and Bio-Pharma Manufacturers Association	Associate member	3
Incheon Chamber of Commerce & Industry	Regular member	107

Certifications

Environmental management certification



Certification	2022	2023	2024
ISO 14001 (Environmental management system)	Certified	Remain certified	Remain certified



Certification	2022	2023	2024
ISO 50001 (Energy management system)	Certified	Remain certified	Remain certified

Health and safety management certification



Certification	2022	2023	2024
ISO 45001 (Health and Safety management system)	-	Certified	Remain certified

Information security management certification



Certification	2022	2023	2024
ISO 27001 (Information Security management system)	-	Certified	Remain certified

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