Passion for Health

SAMSUNG BIOEPIS

SUSTAINABILITY REPORT 2023

SAMSUNG
BIOEPIS

About This Report

Reporting Scope

This report covers the sustainability management activities and performance of the domestic business. Financial performance information has been prepared in accordance with the consolidated Korean International Financial Reporting Standards (K-IFRS). Both our financial information and non-financial information are reported for the fiscal year based on the financial disclosure standards while data on our energy use and greenhouse gas (GHG) emissions are reported based on the results of emission verification.

Reporting Period

Financial performance contained in this report spans the period between January 01, 2022 and December 31, 2022. This report illustrates our sustainability management performance and related outcomes during the period of January 01, 2021 to December 31, 2022. For some of significant performance outside the reporting period, activities up to the first half of 2023 are included, when necessary, information has been marked for further clarification.

Reporting Principles

This report aligns with the Global Reporting Initiative (GRI) Standards, which are global standards for sustainability reporting. It has been also prepared in consideration of the Sustainability Accounting Standards Board (SASB) standards for the biotechnology & pharmaceuticals sectors. Quantitative performance data for the last three years are provided to measure yearly changes.

Report Verification

To ensure the internal/external credibility of the report-making process and information disclosed, this report has been verified by Korea Management Registrar Inc. as an independent third-party assurance provider. Detailed assurance statements are included in the Appendix.

Forward-looking Statement Disclaimer

This report may include forward-looking statements that relate to the future as well as the present and the past.
Forward-looking statements can be identified by the use of words such as “anticipate”, “pursue”, “expect”, “intend”, “goal”, “strategy”, “estimate” and similar expressions. It is worth noting that this report may contain statements related to Samsung Bioepis’ ESG activity plans as well as the Company’s 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.

Contact Information

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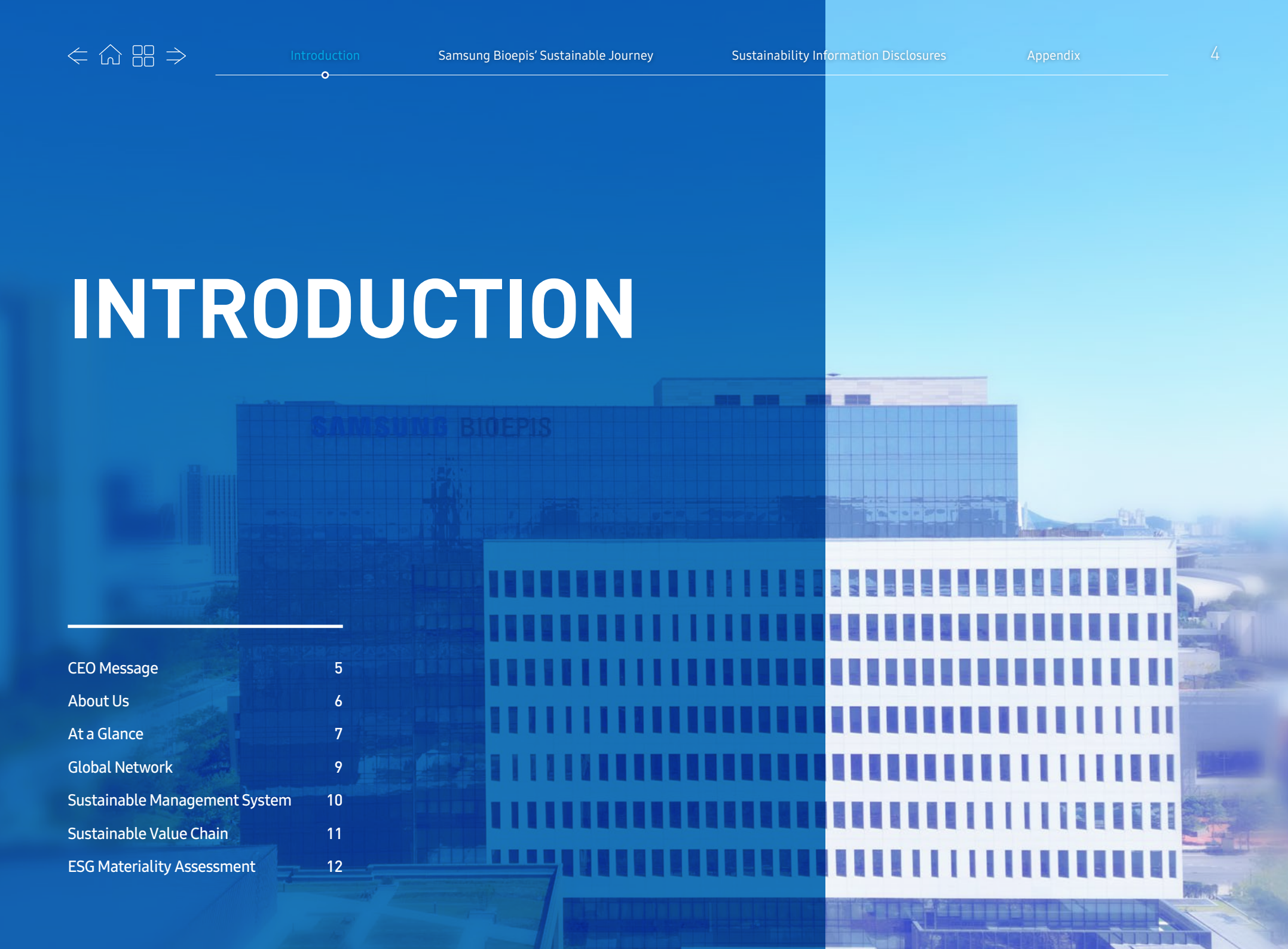
INTRODUCTION



CEO Message

Dear Stakeholders,

In the pursuit of our vision 'Passion for Health', Samsung Bioepis has been dedicated to improving access to high-quality biologic medicines at affordable prices. Over the past decade, we have achieved groundbreaking R&D outcomes driven by our talented biotech colleagues and through our global partnerships, and we have cemented our position as a globally-recognized leader in the biopharmaceutical industry. In recognition of our works and efforts, we received the 'Company of the Year, Asia-Pacific' Award at the Global Generics & Biosimilars Awards in 2022.

As the COVID-19 pandemic, climate change, and global supply chain disruptions further underscore the importance of ESG management, we created the ESG Office to reinforce the foundation of our ESG management and bolster our initiatives across the Environmental, Social, and Governance areas.

We have taken the first step of this journey: we established ISO-compliant environmental and energy management systems and are working to minimize our environmental footprint. In collaboration with Samsung Biologics, we have taken a step forward in driving progress towards the RE100 and the Net Zero by 2050 initiative.

In establishing our sustainable supply chain management system, we closely monitor and manage environmental, health & safety, labor, and human rights risks across our entire value chain. We also team up with our global Contract Manufacturing Organizations in Europe, North America and Asia to ensure our products' stable supply. Furthermore, we take corporate social responsibility to heart by creating a healthy corporate culture that respects human rights and diversity, supporting local communities' growth, and furthering our win-win partnerships.

Our Board of Directors consists of qualified and diverse experts who champion our commitment to responsible business conduct and business ethics to propel our sustainable growth and enhance stakeholder value.

In shaping a sustainable future, Samsung Bioepis is committed to evolving into a 'Multi-product, Multi-modality and Fully Integrated Global Pharmaceutical Company'. We look forward to your unwavering interest and support as we continue to push beyond what is possible and explore ways towards sustainability management.

SAMSUNG BIOEPIS

President & Chief Executive Officer
Christopher Hansung Ko

About Us

Company Profile

Established in 2012, Samsung Bioepis is a biopharmaceutical company dedicated to enhancing access to high-quality biologic medicines for patients. 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 11 biosimilars, and among them, six products were launched in multiple 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.

Company overview

Name of company	Samsung Bioepis Co., Ltd.
Date of establishment	February 28, 2012
No. of employees	970 (as of the end of 2022)
Headquarters	76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea
Overseas subsidiaries	US, Netherlands, UK, Poland, Switzerland, Brazil, Australia, New Zealand, Israel, Taiwan, Hong Kong

Performance Highlights

Medicines

(as of the end of 2022)

Product pipeline	6 products launched / 5 products in development
Patients reached	376,000 persons
Market presence	Approved in 42 countries / launched in 40 countries

Key financial metrics

(in KRW, as of the end of 2022)

Revenue	946.3 billion
Net income	218.4 billion
Total assets	2,834.6 billion

Vision & Mission

Vision

PASSION for HEALTH

Mission

We put our passion to work
We interact with utmost integrity
We strive for constant innovation

Core value

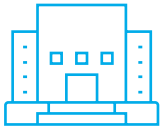
Future of Samsung Bioepis

Building on the achievements we have made in biosimilar business over the past decade, Samsung Bioepis is opening a new chapter. We will acquire future biotechnology across wide-ranging therapeutic areas by harnessing our development, clinical operation and commercialization capabilities. We will also establish a portfolio of products that meet to the unmet needs of patients, driving our innovation into a globally-renowned leader in the biopharmaceutical industry.

At a Glance

Since its foundation in 2012, Samsung Bioepis has rapidly grown into a global leading player in biosimilars. We have developed an industry-leading and broad range of pipelines through advanced development platforms and operational excellence.

Key Milestones



2012
» Samsung Bioepis established
» Opened the first R&D Center in Songdo, Incheon

2013
» Formed marketing partnerships with Merck (MSD)[1] and Biogen

2015
» Infliximab and etanercept biosimilars approved in Korea

2016
» Infliximab and etanercept biosimilars approved in Europe and Australia

2017
» Infliximab biosimilar approved in the US and Canada
» Adalimumab and trastuzumab biosimilars approved in Europe and Korea
» Etanercept biosimilar approved in Brazil

2018
» Infliximab biosimilar approved in Brazil

2019
» Trastuzumab, etanercept, and adalimumab biosimilars approved in the US
» Entered into a new commercialization agreement with Biogen on two ophthalmologic biosimilar candidates
» Trastuzumab biosimilar became the first biosimilar prequalified by WHO

2020
» Bevacizumab biosimilar approved in Europe

2021
» Moved into the new headquarters in Songdo
» Bevacizumab biosimilar approved in Korea and Canada
» Ranibizumab biosimilar approved in Europe and the US

2022
» Ranibizumab biosimilar approved in Korea and Canada
» Trastuzumab biosimilar approved in Canada
» High-concentration adalimumab biosimilar approved in Europe, the US, Canada, and Korea

2023
» Eculizumab biosimilar approved in Europe

2012 | 2013 - 2015 | 2016 - 2018 | 2019 - 2020 | 2021 - 2022 | 2023

1) We maintain partnership with Organon which was spun off from Merck in June 2021.

At a Glance

Product Launch

AMELIVU®
(SB11, ranibizumab biosimilar)
launched in Korea
(Jan 2023)[1]

BYOOVIZ™
(SB11, ranibizumab biosimilar)
launched in the US
(Jun 2022) and EU (Feb 2023)[2]

ADALLOCE®
(SB5, adalimumab biosimilar)
launched in Korea
(May 2021)[3]

Clinical Trials·Approval

EPYSQLI™
(SB12, eculizumab biosimilar)
approved in the EU
(May 2023)

Unveiled the final clinical trial results of SB15
(aflibercept biosimilar)
(Apr 2023)

Global clinical trials completed for SB16 (denosumab biosimilar) and SB17 (ustekinumab biosimilar)
(Dec 2022)

High-concentration HADLIMA™
(SB5, adalimumab biosimilar)
approved in the US
(Aug 2022)[4]

Environmental·Social Performance

Received the Company of the Year, Asia-Pacific Award (Nov 2022)

Received international environmental·energy certifications
(ISO 14001, ISO 50001)
(Sep 2022)

Received iF Design Award
(Apr 2021)

1) AMELIVU®: Samil Pharm as our Korean marketing partner
2) BYOOVIZ™: Biogen is our marketing partner in Europe, the US, and Australia, and the data is presented based on Germany where the product was launched first as the launch timeline in Europe varies by country.
3) ADALLOCE®: Yuhan as our Korean marketing partner
4) HADLIMA™: Organon as our US marketing partner

Global Network

Europe
- Launched 6 biosimilars
(etanercept, infliximab, adalimumab, trastuzumab, bevacizumab, ranibizumab)

North America
- US: Launched 3 biosimilars
(infliximab, trastuzumab, ranibizumab)
- Canada: Launched 6 biosimilars
(etanercept, infliximab, adalimumab, trastuzumab, bevacizumab, ranibizumab)

Asia
- Korea: Launched 6 biosimilars
(etanercept, infliximab, adalimumab, trastuzumab, bevacizumab, ranibizumab)
- Middle East: Launched 3 biosimilars
(etanercept, infliximab, adalimumab)

South America
- Brazil: Launched 3 biosimilars
(etanercept, trastuzumab, adalimumab)

Oceania
- Australia: Launched 4 biosimilars
(etanercept, infliximab, adalimumab, trastuzumab)

Overseas subsidiaries
11

Products available in
40
countries

Key suppliers[1)]
23

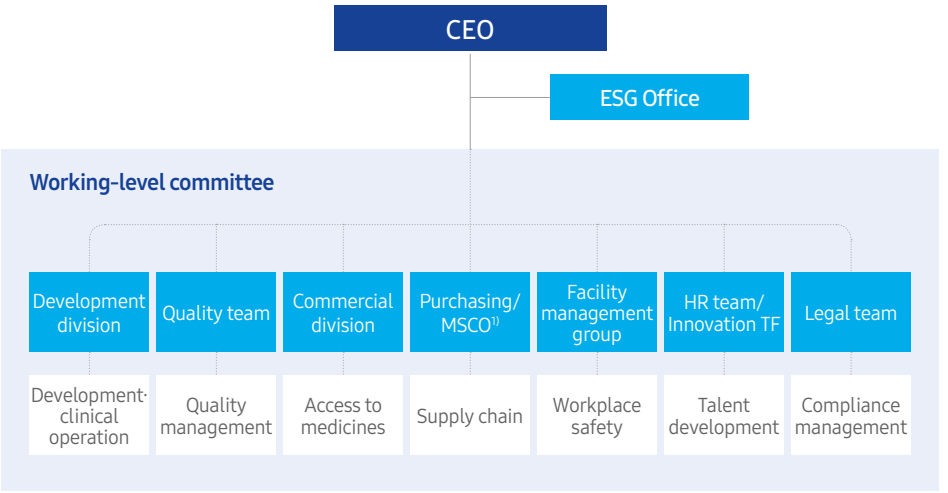
1) Including CMO, CRO, vendor, and CSO

Sustainable Management System

Sustainability Governance

Samsung Bioepis established the ESG Office as a dedicated ESG organization in January 2022 to systematically map out our approach and to implement sustainability management. The ESG Office is responsible for prioritizing improvement tasks for sustainability management and working with company-wide departments. The office regularly reports the implementation of improvement tasks and their progress made to our CEO. We ensure that ESG considerations are fully embedded into our mid/long-term business strategy through senior management consultations. The office is also in charge of managing and disclosing data to communicate with external stakeholders.

Sustainability management implementation system

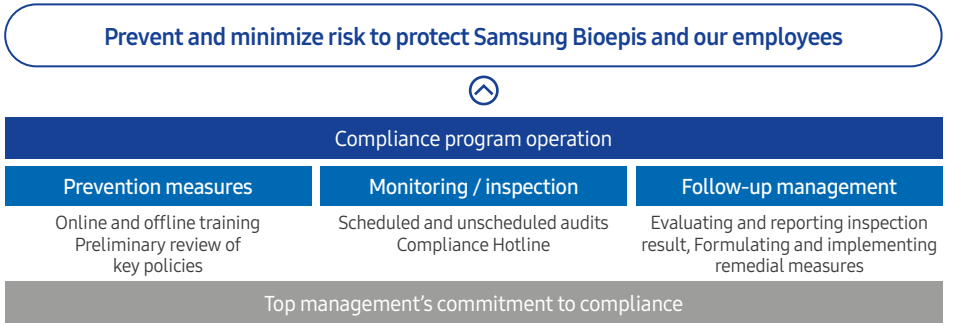


1) Manufacturing & Supply Chain Operation Team

Compliance

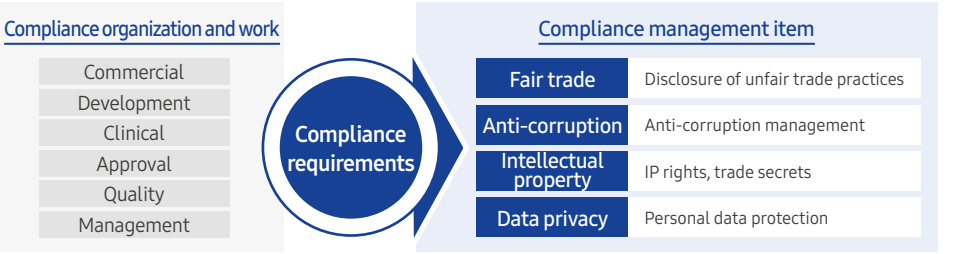
To ensure that we abide by compliance-related laws and regulations required by respective countries, our compliance organization under the direct leadership of the CEO is building and monitoring our compliance process in conjunction with related departments to prevent any business damage and fulfill social responsibility.

Compliance operation



Compliance with major laws and regulations

We implement our internal management process in our day-to-day operations that was developed to abide by applicable country-specific laws and regulations in the areas of fair trade, anti-corruption, intellectual property, and data privacy.



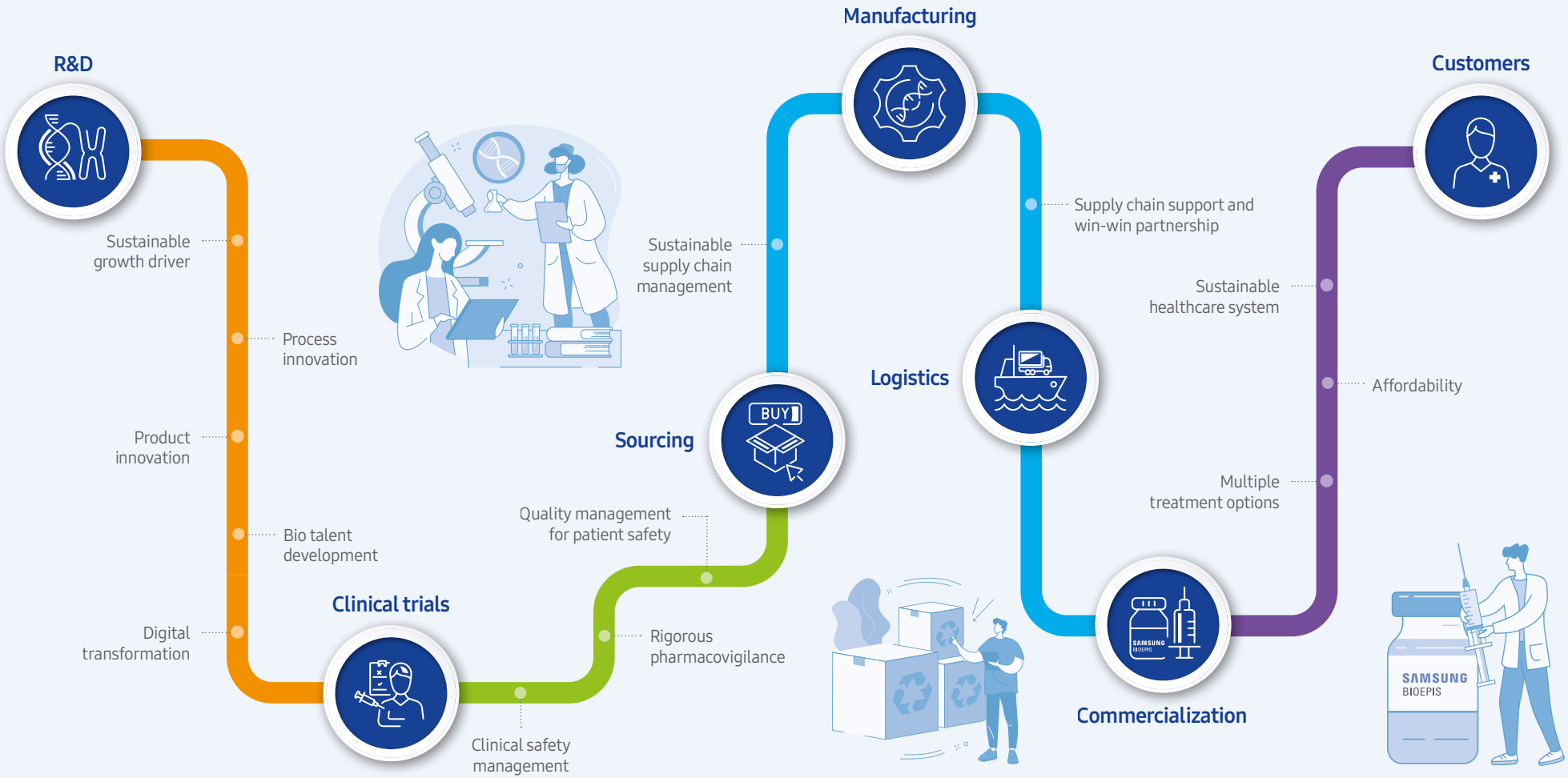
Compliance specific to the pharmaceutical industry

To ensure that we do not engage in any provision of undue economic benefits to healthcare professionals, we perform preliminary compliance reviews and operate a deliberation and reporting process. We also carry out employee training and monitoring activities to strictly prohibit any form of off-label promotion which is advertising the use of medicines for purposes not approved by the authorities.

Sustainable Value Chain

Samsung Bioepis pursues transformation and innovation across our entire business process to drive our sustainable growth and to create value for all stakeholders as a member of our society. From R&D to clinical operation, raw material sourcing, manufacturing, logistics, commercialization and ultimately the social impact of products, our journey continues to embed sustainability into our value chain.

R&D innovation | Product quality and patient safety | Supply chain management | Access to medicines



ESG Materiality Assessment

To determine the key content of our sustainability report and identify material issues requiring intensive management, Samsung Bioepis conducted the following 4-step materiality assessment in accordance with the reporting principles of the GRI Standards 2021.

Materiality Assessment Process

Step 01. Overview our business and create an ESG issue pool

· Create an ESG issue pool by reviewing our business environment and key ESG issues
- Reflect the international standard requirements of global ESG Initiatives (DJSI, MSCI, SASB) and industry-specific requirements (Access to Medicines Index, the Biopharma Investor ESG Communications Initiative)
- Benchmark advanced industry peers
- Review the previous year's sustainability management report and internal data

Step 02. Identify material issues for their impact and characteristics

· Identify the impact and characteristics of each material issue
- Identify external information (industry related laws & regulations, shareholder/ investor surveys) and internal information (grievance mechanisms, corporate risk management system, etc.)
- Characterize the impact in terms of opportunity/risk/potential/actual implications

Step 03. Assess material issues for their impact

· Perform materiality assessment
- Participants: Samsung Bioepis' top management and the working-level ESG committee, external ESG/biopharmaceutical experts (33 persons in total)
- Period: Jan 2023 ~ Feb 2023
- Method: Conduct a paper-based survey on impact for each of the 30 material issues
- Scope: Comprehensively assess how Samsung Bioepis' business operations impact the economy, the environment, and people

Step 04. Reflect materiality assessment results

· Manage and report material reporting topics
- Aggregate materiality assessment results and internal/external stakeholder feedbacks
- Select 15 material topics
- Factor them into the management reporting and management decision-making
- Our management approach & key performance of material reporting topics are addressed in Samsung Bioepis' sustainable journey, and other issues included in material issue pool are described in Sustainability Information Disclosures.

Material Issue Pool

★ Material reporting topic

Environmental	Response to climate change	Water resources management
	Waste and pollutant discharge	Eco-friendliness ★
Social	Multiple treatment options ★	Affordability ★
	Sustainable healthcare system ★	Quality management for patient safety ★
	Clinical safety management ★	User convenience and safety ★
	Rigorous pharmacovigilance ★	Rigorous counterfeit medicine management ★
	Bio talent development ★	DE&I (Diversity, Equity & Inclusion)
	Corporate social responsibility	Personal data privacy and security
	Workforce recruitment and operation	Human resource development
	Workplace health & safety	Human rights protection
	Sustainable supply chain management ★	Supply chain support and win-win partnership ★
Governance	Board of Directors and risk management	Transparent disclosure of non-financial information
	Ethical business conduct	Compliance management
	Ethical marketing	
Business operation	Sustainable growth driver ★	Process innovation ★
	Digital transformation ★	

ESG Materiality Assessment

Materiality Assessment Results

Material Reporting Topic	Samsung Bioepis' Sustainable Journey	Samsung Bioepis' impacts to the economy, the environment, and people	Characteristic of Impact	
Sustainable growth driver Process innovation User convenience and safety Digital transformation Eco-friendliness Bio talent development	R&D Innovation	We engage in innovative R&D activities to develop high-quality biosimilars faster while minimizing risks that may arise in each step of the process to deliver affordable and high-quality medicines, and help resolve global health challenges.	Actual	Opportunity
		We pursue eco-friendly packaging to ensure efficient resources consumption to mitigate our environmental footprint and optimize our devices to ultimately improve patient convenience and safety.	Actual	Opportunity
		Nurturing our employees into bio experts helps them pursue their individual growth. This also enables us to elevate our shareholder value and expand the pharmaceutical market.	Actual	Opportunity
Quality management for patient safety Clinical safety management Rigorous pharmacovigilance Rigorous counterfeit medicine management	Product Quality and Patient Safety	We commit to keep patients healthy and safe by establishing our company-wide quality management system on par with global standards throughout the entire product lifecycle.	Potential	Risk
		We put the safety of clinical trial subjects before all else in conducting clinical trials, and fully abide by the requirements of regulatory authorities concerning clinical and pre-clinical trials.	Potential	Risk
Multiple treatment options Affordability Sustainable healthcare system	Access to Medicines	We expand our portfolios to provide wider treatment options of a host of disease. In so doing, we contribute to improving access to medicines and addressing the unmet medical needs.	Actual	Opportunity
		We deliver biosimilars equivalent to their reference medicines in terms of efficacy at affordable prices to alleviate patients' financial burden and the government's healthcare spending.	Actual	Opportunity
Sustainable supply chain management	Supply Chain Management	Any failure in managing supply chain issues could potentially lead to negative impacts such as the discontinuation of product supply, environmental pollution and human rights violation.	Potential	Risk
Supply chain support and win-win partnership		We conduct regular supply chain ESG assessment and strive to assist our suppliers in bolstering their ESG capabilities by implementing our win-win partnership and shared growth initiatives.	Actual	Opportunity

SAMSUNG BIOEPIS' SUSTAINABLE JOURNEY

R&D Innovation

Management Approach & Key Performances

Sustainable Growth Driver

Broaden our product portfolio to meet unmet needs

Process Innovation

Bring high-quality biologics faster to more customers

Product Innovation

Ensure user convenience & safety and make our products eco-friendly

Bio Talent Development

Develop employees' competency and unlock their full potential

Digital Transformation

Improve work efficiency and advance IT system integration

Sustainable Growth Driver

Over the last decade, Samsung Bioepis has bolstered our capabilities to lay the basis for our growth, ranging from basic research on biologics to their development, manufacturing, and commercialization. We are broadening our product portfolio in diverse drug therapeutic areas with a focus on biosimilars, and are exploring next-generation therapeutic technology to discover growth drivers, making broader treatment options available for more patients.

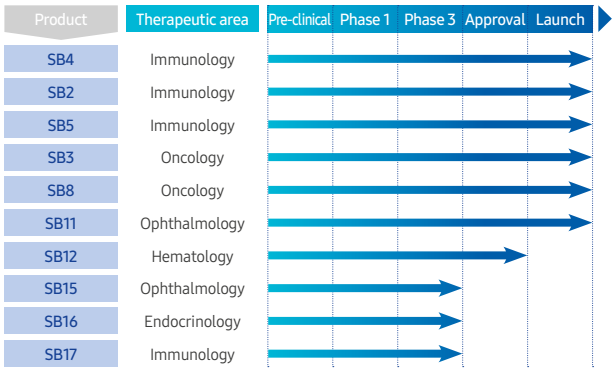
Expanding Our Therapeutic Areas

On the strength of our relentless innovation and advanced development platform, Samsung Bioepis launched six biosimilars in the therapeutic areas of immunology, oncology, and ophthalmology, positioning ourselves as a global leader in biosimilars. We continue our efforts to expand our pipeline into hematology, endocrinology and gastroenterology.

- **Therapeutic area :** 6 areas (immunology, oncology, ophthalmology, hematology, endocrinology, and gastroenterology)
- **Pipeline :** 11 products (6 launched, 5 in development)[1)]

Samsung Bioepis pipeline

Biosimilar pipeline



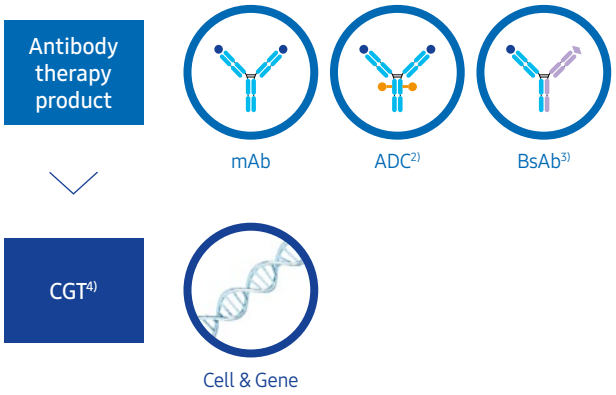
Novel biologic

1) As of June, 2023

Exploring Next-generation Therapeutic Technology

We explore new business opportunities by leveraging our own development capabilities that we have accumulated as well as our commitment to open innovation.
Based on our monoclonal antibody development capabilities, Samsung Bioepis strives to develop next-generation antibody technology such as ADC and bispecific antibody. We also delve into foundational technology for cell and gene therapy to meet unmet needs in the long-term. In so doing, we will provide broader treatment options to more patients and improve their quality of life.

Multi-product & Multi-modality



2) Antibody-drug Conjugate
3) Bispecific Antibody
4) Cell and Gene Therapy

R&D Investment

We have increased our investments in biologic R&D. Our R&D expenses accounted for 17% of total sales in 2022. We will continue to expand our R&D investments.

R&D investments

Unit: 100million KRW, %

Category	2021	2022
R&D expenditure	1,238	1,580
R&D to sales ratio[5)]	15	17

5) R&D expenditure/total sales*100(%)

As of the end of 2022, our dedicated R&D workforce amounted to 559 persons, including 131 Ph.Ds, 207 Master's degree holders, and 221 in the other category. We recruit top-tier talent in the development, clinical trial, regulatory affairs, SCM and marketing functions, and we integrate their expertise into our operational excellency.

R&D workforce

Unit: persons

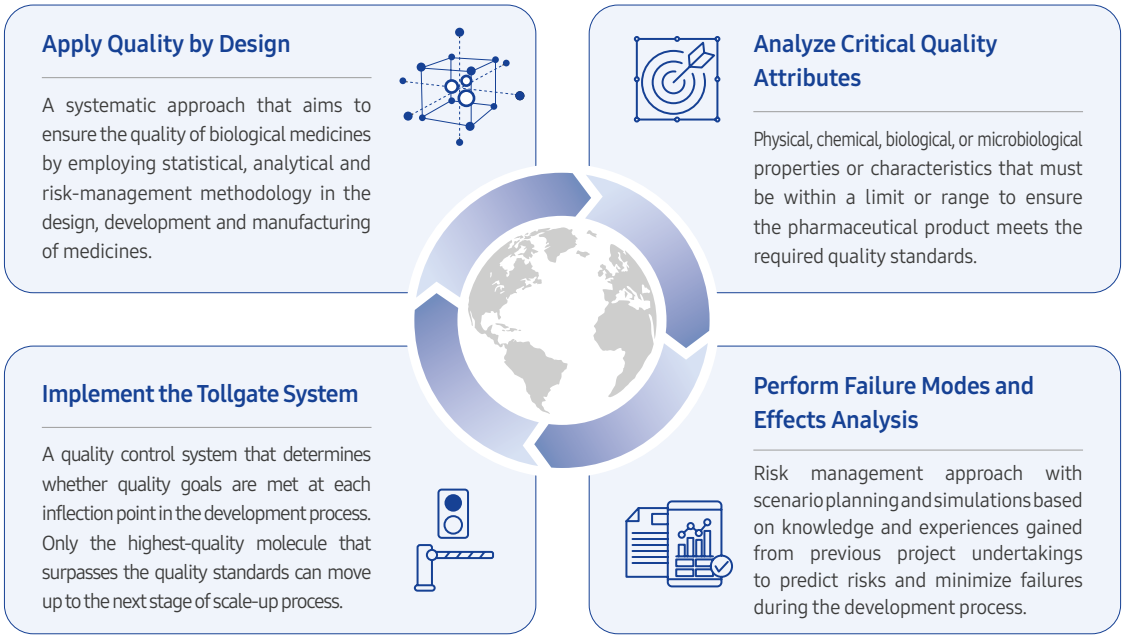
Category	2021	2022
Total	504	559
Ph.D	105	131
Master's	203	207
Other	196	221

Process Innovation

Samsung Bioepis has built an advanced development platform by leveraging our development expertise and manufacturing excellence. We will continue our work to ensure the timely-delivery of affordable biologics for the benefit of patients at all levels.

Advanced Development Platform

We operate an advanced development platform designed for extensive analysis, risk management, and rigorous quality management in each step of the development process with an aim to pursue process innovation. This in turn enables us to develop high-quality biosimilars in a short period of time while minimizing risks in the development process.



Our Approach to Process Innovation

Our process innovation aims to make our products more competitive and optimize the development process through expediting development, improving productivity, optimizing resource use, and accelerating technology transfer.

Expediting development	- Adopt HTS[1] technology for cell line construction - Optimize a process development platform
Improving productivity	- Construct a cell line with high productivity - Optimize a robust scale-up platform
Optimizing resource use	- Promote analysis automation - Bolster protein analysis capability - Improve the efficiency of data management through the electronic laboratory notebook system
Accelerating technology transfer	- Optimize process modeling - Computer simulation

1) High Throughput Screen

Product Innovation

User Convenience and Safety

Samsung Bioepis puts patients before all else in our entire development process. We develop differentiated devices to improve user convenience and safety, and explore wide-ranging treatment options to meet the diverse needs of patients.

Differentiated Devices for Patients

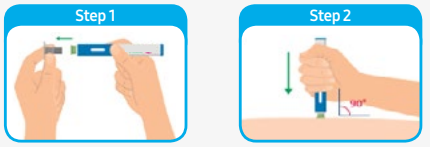
Samsung Bioepis prioritizes patient safety and convenience in developing product devices. We developed button-free autoinjectors with 2-step operation. We also improved our devices to mitigate the risk of pricking when patients use the devices and to reduce their pain at the injection site.

CASE STUDY

SB5 (adalimumab biosimilar) autoinjector device

① Improve patient convenience (PFP)[1]

"Button-free, 2-Step operation"



② Improve patient safety (PFS)[2]

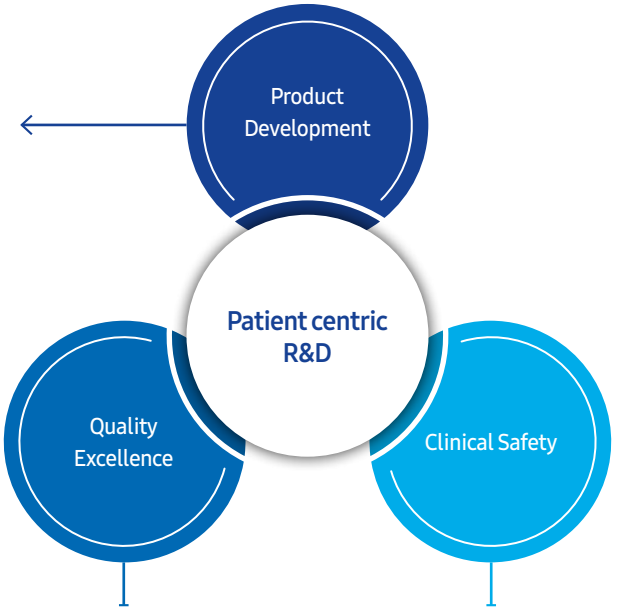
Anti-prick (Needle Safety Shield)

Anti-allergic (Latex-free)

③ Reduce injection site pain (PFS/PFP)

High concentration/ Low dose

Eliminate pain factors (Citrate-free)



1) Prefilled Pen
2) Prefilled Syringe

Offering Wider Treatment Options

We improve our products in terms of formulation, dosing, and device through Life Cycle Management (LCM) to provide patients with wider treatment options.

CASE STUDY

Product LCM

In 2022, we were granted approval by the US FDA for the high-concentration formulation of HADLIMA™ (adalimumab biosimilar), making our product the first adalimumab biosimilar in the US made available in both low/high-concentration formulation. We also designed a prefilled pen (PFP) device to ensure that patients switching from the reference medicine Humira® to our biosimilar do not experience differences during drug administration. By unveiling HADLMA™ in the US market in July 2023 building on its successful launching in Canada and Australia, we are confident that this will provide treatment options to meet the diverse needs of patients.

Product Innovation
Eco-friendliness

Samsung Bioepis takes the environmental impact of our products seriously along the entire product lifecycle. We opt for eco-friendly materials, minimize our product packing size, and increase the proportion of ocean shipping to help drive the circular economy and low-carbon society.

Optimizing Packaging Size

We factor in eco-freiendliness in the whole development process. Specifically, we minimize packaging size and reduce the use of materials along the entire product lifecycle ranging from manufacturing to logistics and disposal.

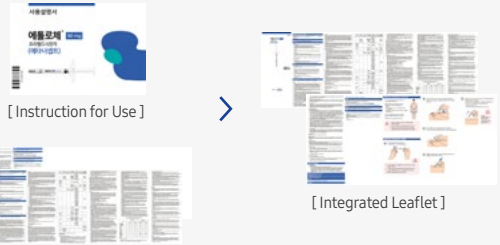
Benefits from eco-friendly packaging development

Development /manufacturing	Logistics	Disposal
· Minimize packaging size · Minimize the use of materials	· Reduce CO_2 emissions	· Reduce waste generation · Increase material recycling

CASE STUDY

Packaging optimization

Our SB4 (eternercept biosimilar) product, which used to contain separate Instruction for Use and Leaflet previously, now comes with an integrated leaflet to reduce our paper consumption by nearly 35-55%.



[Instruction for Use] [Leaflet] [Integrated Leaflet]

Opting for Eco-friendly Materials and Recycling Resources

Given the distinctive characteristics of the biopharmaceutical products that prioritize patient safety, it is difficult to recycle or substitute the materials of medicines. Still, we opt for recyclable materials when possible and reduce waste to minimize our environmental footprint to help achieve the circular economy.

Paper tray

We apply recyclable paper trays to minimize our use of plastics, and ensure that we use non-plastic-laminated paper to make it more easily recyclable.

Recycled shipping box

We use recycled paper for our product shipping boxes to minimize their environmental footprint and to lead the circular economy.

Paper certified for forest protection

We source paper which is free from hazardous materials and certified to forest protection certification standards such as FSC[1] and PEFC[2].

Eco-friendly shipping materials

In wrapping pallets used for product stacking and shipping, we use LDPE instead of PVC that generates dioxins when incinerated.

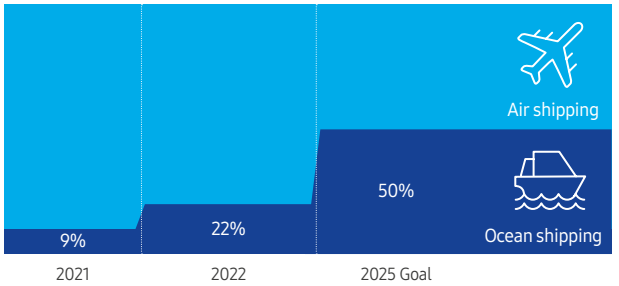
1) Forest Stewardship Council
2) Programme for the Endorsement of Forest Certification
3) The carbon emission factor of ocean transport is 1/1,146 of that of air transport based on the national LCI DB Environmental Product Declaration

Expanding Ocean Shipping to Reduce Carbon Emissions

Samsung Bioepis is working to raise the proportion of ocean transport to minimize the frequency of transport and reduce transport-induced GHG emissions[3]. Except for DS that requires frozen shipping by air, we have increased the proportion of ocean shipping for both DP and FDP, from 9% in 2021 to 22% in 2022, and aim to further increase this number to 50% in 2025.

Product transportation

Product	Shipping condition	Mode of shipping
Drug substance (DS)	Frozen shipping	Air shipping
Drug product/ finished drug product (DP/FDP)	Cold shipping	√ Ocean shipping to reach 50% in 2025



Bio Talent Development

We focus on talent management to assist all our employees in continuously developing their competency and unlocking their full potential. Over the last decade, we have worked to establish a data-driven management system and training programs. Our training programs are designed to support the on-going growth of our employees to build differentiated expertise in their own field.

Our Approach to Nurturing Professionals

Samsung Bioepis provides employees with trainings such as Lessons Learned, Job Competency Training, and Training Lab in line with our Process Map to nurture employees' expertise.

Work management system and training programs

We operate a range of retention programs. For further details, please see GRI 404 (p.46)

Lessons Learned

Samsung Bioepis is creating cultural settings to identify key factors from the successes and failures of the preceding projects. We share them with all employees, and integrate them into our work process to prevent the same failures.

Lessons Learned outcomes in 2022

- Total Lessons Learned accumulated (413 cases)
- Representative Lessons Learned selected (128 cases)
- Representative Lessons Learned trained (company-wide 40 cases, department 88 cases)

"It is important to articulate the meaning of each task which is assigned to each process specifically, learn from our success and failure stories, and then bolster our competitive edges by ourselves.

We dare to try decent approaches in search for optimal solution, not staying with what we have done before. We must be top-notch experts in our own field."

- From our CEO's message in our 10th anniversary

Job Competency Training

We provide systematic training programs tailored for employees with different job levels and competencies so that they can evolve into job experts.

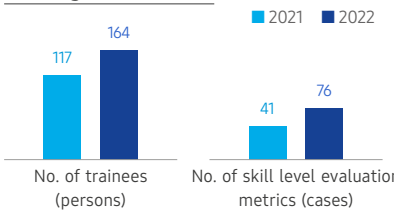
Training outcomes

Category	2021	2022
No. of Job task	94	116
No. of Job training course	5,428	5,863

Training Lab

Training Lab serves as our tailormade, intensive training program that helps develop experiment-related technical competency. We conduct regular monitoring to select employees in need of specific training and provide them with appropriate training opportunity.

Training lab outcomes



Training satisfaction in 2022
94.9%

Digital Transformation

Samsung Bioepis pursues digital transformation across our entire value chain ranging from IT master data to development, clinical operation and production. We further enhance the level of data digitalization and IT system integration to secure operational efficiency, risk management and data integrity.

Implementing Six Digital Innovation Tasks

In the early stages of our business, Samsung Bioepis operated individual IT systems with a focus on implementing essential functions of the value chain in consideration of investment efficiency. Now we are pursuing digital transformation at full scale to strengthen our competitive edges utmost in the biopharmaceutical industry.

- Maximize integration and operational efficiency of IT systems through digital transformation

In 2022, we reviewed the level of digitalization in our value chain and identified six innovation tasks in each of the subcategories including master data, R&D, clinical operation, and SCM as follows.

Six digital innovation tasks

Category	Innovation task
Master data	Establish a master data management system
R&D	Establish the Electronic Laboratory Notebook
	Establish a product management system
Clinical	Establish a clinical risk management system
	Establish a clinical data analysis platform
SCM	Advance an integrated SCM platform

Establishing the Electronic Laboratory Notebook

To keep pace with the Digital Transformation age, we are pursuing the digitalization of our development process, and have taken the first step by introducing the Electronic Laboratory Notebook system (ELN).
The ELN system is expected to not only improve our work efficiency and reduce errors in data documentation but also improve completeness and integrity of data.

- Improve work efficiency and integrity
- Prevent human error

Expected benefits of the ELN

Building a Clinical Data Analysis Platform

We developed an IT platform of clinical data analysis to use our clinical data more efficiently. This enables us to promptly respond to requirements of clinical regulatory authorities, to systematically analyze existing clinical data, and to operate new clinical strategy.

- Predict clinical trial feasibility
- Establish an efficient strategy for a new clinical trial

Clinical data analysis platform overall process

Data collection	· Collect operational data on the country/ hospital/patient
Analysis modelling	· Perform modeling based on AI/machine learning
Trend analysis	· Perform integrated analysis and prediction of clinical data
Decision making	· Make data-driven decisions

Advancing the Integrated SCM Platform

We upgraded our integrated SCM platform to strengthen the organic alignment of our sales, production and inventory management and to optimize our resources operation. Supply issues and inventory management along the whole of our value chain are reviewed to establish our PSI (Purchase, Sales, Inventory) operational plans from the comprehensive viewpoint.

Product Quality and Patient Safety

Management Approach & Key Performances

Quality Management for Patient Safety

Assure product quality to contribute to patient health and safety

Clinical Safety Management

Develop medicines to demonstrate their safety and efficacy

Rigorous Pharmacovigilance

Reinforce pharmacovigilance activities along the entire product lifecycle

Quality Management for Patient Safety

Safeguarding the safety of patients lies at the core of pharmaceutical business. Samsung Bioepis establishes and implements a rigorous quality management system in compliance with global standards to prevent quality risk. If any risk occurs, we promptly pursue quality improvement through clear decision-making. We also strengthen our quality assurance capabilities at all levels in the development and manufacturing process.

Quality Management System

Samsung Bioepis operates a rigorous quality management system ranging from the development of medicines to their administration to manufacture high-quality products. Our quality assurance process was established in conformity with the guidelines of such regulatory authorities as the MFDS, the EMA, and the FDA to ensure quality that is widely recognized both in Korea and abroad.
Our senior management is also committed to overseeing the implementation of quality management through regular Quality Management Review meetings.

Quality Assurance

All our facilities spanning from development to manufacturing are subject to qualification and verification to assure their performance and functionality so that we can systematically manage variation, deviation, complaint and other issues. We also apply a quality assurance procedure to each step of our manufacturing process to deliver high-quality medicines.
In selecting new CMOs, we assess their production capacity and risk management competency to ensure quality management and regulatory compliance, and continue with follow-up monitoring.

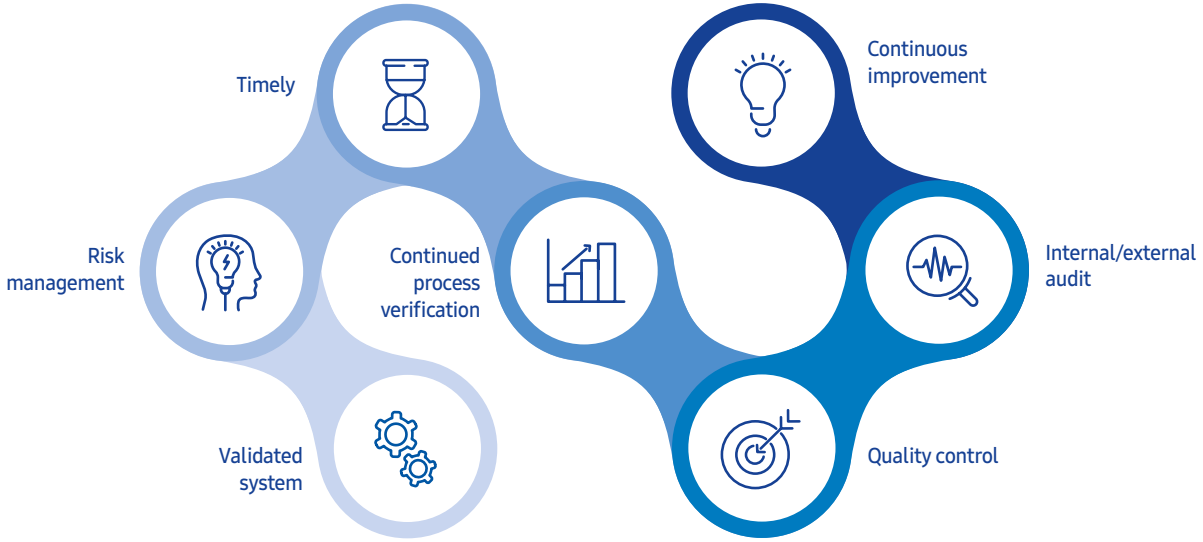
Bolstering QA Competency

We provide systematic internal/external quality training to help our employees bolster their quality improvement competency.
Our new hires receive basic training on our quality management policy, and the departments that have direct impact on product quality receive annual GxP training to strengthen their quality assurance competency on an on-going basis. In so doing, we help our employees improve their awareness and competency on quality management.

Quality Management Outcomes

Our partner suppliers have acquire GxP certification as a result of a total of 18 audits performed in the US, Europe and Korea since 2021, and we regularly analyze inspection findings opened in public, apply established preventative actions to their facilities and also keep monitoring regulatory guidances trends.

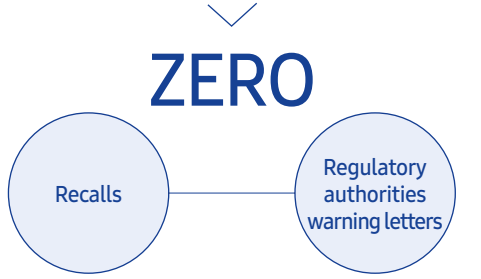
Quality management system



CMO/CLO/CRO inspection status

Unit: cases

Category	2021	2022	2023.1Q
Subtotal	6	9	3
FDA (US)	3	3	0
EMA (Europe)	2	5	2
MFDS (Korea)	1	1	1



Clinical Safety Management

Samsung Bioepis is implementing global clinical development programs. We are conducting real-world studies to continually obtain data for the purpose of demonstrating safety and efficacy. In addition, we ensure the safety of trial participants as our top priority, and strictly adhere to the pre-clinical and clinical trial requirements of regulatory authorities.

Complying with Clinical Trial Regulations

Compliance with clinical trials guidelines and regulations

In conducting pre-clinical and clinical studies, we comply with global/local regulations and guidelines.
We provide training to CROs and investigators to manage clinical trials according to the clinical trial protocols. In recruiting participants for a clinical trial, investigators should verify and review the eligibility of candidates prior to subject enrollment.

Ensuring the patient-centered operation of clinical trials

We periodically review the available emerging safety information to assess whether there is any new data that may affect the participant's willingness to continue in the trial, or impact the conduct of the trial. Any information in this regard should be communicated to participants, the investigator, and regulatory authorities, as applicable, in a timely manner. If new information emerges that could impact a participant's willingness to continue participation, we include this in the informed consent materials and enable participants to determine whether to continue their participation in the consent process.
We performed overall safety assessments of clinical trials on a regular basis to identify any risks or signals for the safety of clinical participants. This allows us to address immediate hazards to participants and take appropriate remedial actions. In addition, when any Serious Adverse Event (SAE) which is related to the investigational product or study-related procedures after completion of clinical trials is observed at the site, we collect relevant information and report these SAEs to regulatory authorities as specified in regulatory requirements without delay.

Minimizing Animal Study

During the development of biologic medicines, Samsung Bioepis conducts animal studies in accordance with the 3Rs principle and the standards of respective regulatory authorities. Based on our strong scientific expertise and capabilities, extensive studies have been performed to support and demonstrate the comparability of our products as high-quality biosimilars. In addition, we leverage such development capabilities and closely communicate with regulatory authorities to minimize the needs for animal studies and seek exemptions to support similarity assessment.

3Rs principle

Replacement	· Approaches that directly replace or avoid the use of animals
Reduction	· Methods that help obtain comparable levels of information from the use of fewer animals
Refinement	· Experimental procedures that minimize or eliminate animals' pain and distress and improve their welfare

Optimizing Our Clinical Trial Design

In the clinical trial design and planning phases, we tried to optimize the number of clinical participants to be enrolled based on the clinical justification and calculation of power of the trial. This helps to accelerate access to biologic medicines by bringing high-quality and clinically proven biosimilars to patients.

Continuous Improvement of Clinical Trial Implementation Capabilities

Leveraging over a decade of experience in developing biosimilars, Samsung Bioepis established a strategic clinical operational process. We also provide product-specific clinical trial training and keep our training up to date with the revised guidelines of regulatory authorities to strengthen the clinical capabilities of our internal workforce.
We are putting our best efforts to internalize clinical operation capabilities from the planning of clinical trials to their termination. For the internalization of clinical operation capabilities, we are working to leverage clinical data for next clinical trials. We are also enhancing internal/external training for individual capability improvement and are establishing Standard Operating Procedures for clinical trials continuously.

Rigorous Pharmacovigilance

Samsung Bioepis is establishing a data-based pharmacovigilance system, and is collecting and analyzing data on adverse effects based on our pharmacovigilance system. We monitor patient safety throughout the entire development process and deploy an automated signaling analysis system to proactively cope with adverse effects. Data-driven pharmacovigilance enables us to ensure the safety and efficacy of our medicines to produce better treatment results.

Reinforcing Pharmacovigilance Activities Along the Entire Product Lifecycle

Samsung Bioepis has established our pharmacovigilance system along the entire product lifecycle to collect safety data for safety issues that may arise in relation to product use and to perform relevant monitoring. We gather real-world data on drug safety through various channels such as healthcare professionals, Patient Support Programs, call centers, literature research, and regulatory authorities, and also subscribe to intelligence databases to swiftly respond to the requirements of regulatory authorities.

Introducing an automated signaling analysis system

The automated system enables us to identify and analyze adverse reactions in real time and to promptly meet the pharmacovigilance requirements of regulatory authorities. It leads to improved efficiency in analyzing accumulated data so that we can identify any change in product safety information early on and take immediate action, if necessary.

CASE STUDY

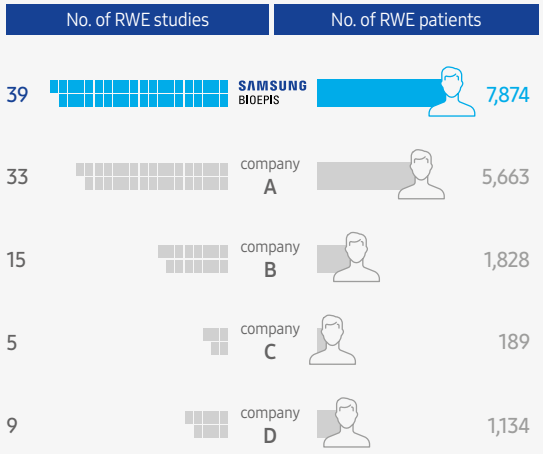
Risk management plan

To ensure the safe and effective administration of our products, we continue to take additional risk minimization action even in the post-market phase. A case in point is Eculizumab; as administering Eculizumab could pose serious risk for meningococcal infection, this prompted countries to implement risk management plans as regulatory requirements. To ensure patients and healthcare professionals detect and promptly prevent this disease, we provide country-specific and customized training materials. We optimize the controlled distribution system to promote the timely administration of the drug and minimize the risk.

CASE STUDY

Real-world Evidence (RWE)

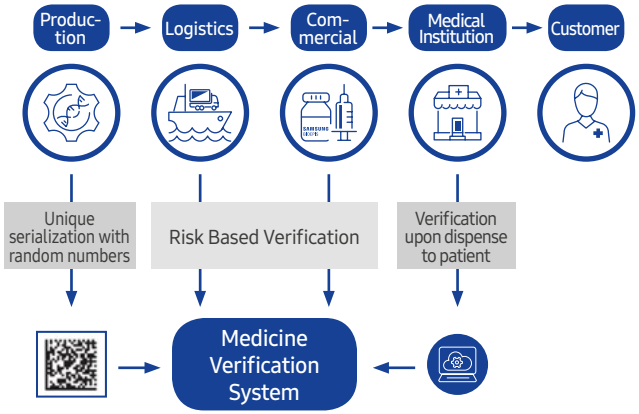
We have gathered extensive medicine-related data on seven indications of SB5 (adalimumab biosimilar) including gastroenterology, rheumatology, and dermatology.
As a result, we rank first among companies developing adalimumab biosimilars in terms of the number of RWE studies and patients, which testifies to the efficacy and safety of our product.



Rigorous Counterfeit Medicine Management

Medicine monitoring system

We assist regulatory authorities in fulfilling their responsibility to protect public health through counterfeit medicine management. We utilize serialization system to tighten security along our supply chains and safeguard patients, and team up with our marketing partners and global regulatory authorities.
Upon receiving relevant information on the distribution of counterfeit medicines, we alert regulatory authorities to take prompt action. In the event that market complaints are raised on product quality, we immediately initiate investigation according to our internal process and recall suspected counterfeit products.



※ Source: European Medicines Verification Organization (EMVO)

Access to Medicines

Management Approach & Key Performances

Multiple Treatment Options

Provide patients with diverse treatment options

Affordability

Ensure affordability compared to reference products

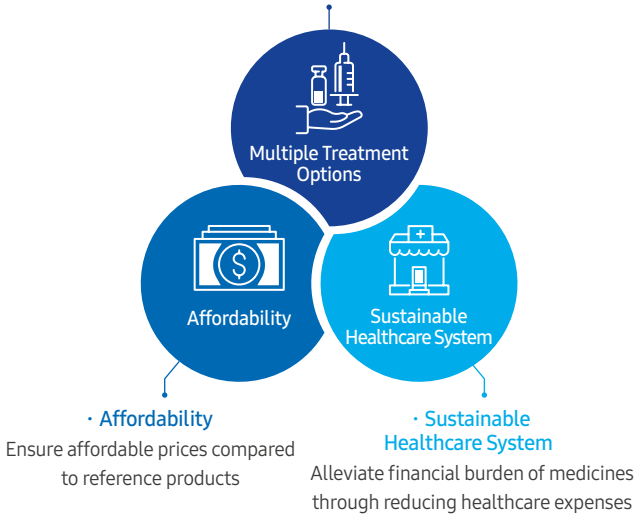
Sustainable Healthcare System

Alleviate governments' financial burden through reduced healthcare costs

Access to Medicines

Driven by our vision 'Passion for Health', Samsung Bioepis provides patients with wide-ranging portfolio of biosimilar products at affordable prices. Ultimately we contribute to a sustainable healthcare system by alleviating the burden of government healthcare costs.

Samsung Bioepis is committed to improving access to medicines in line with the three values delivered by our biosimilars: Multiple treatment options, affordability, and sustainable healthcare system.



6 biosimilar products

40 launched in countries[1]

49 million units delivered[2]

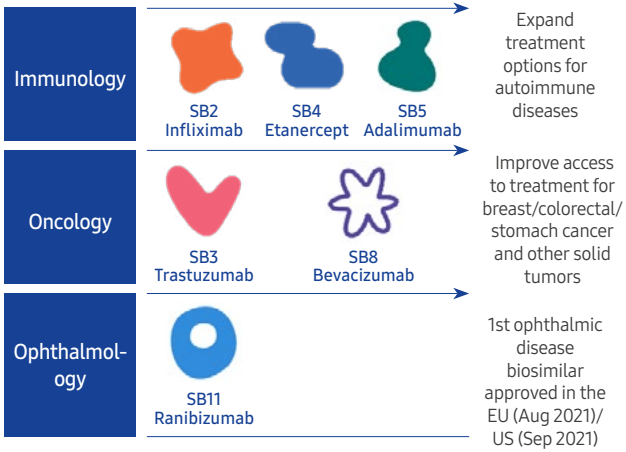
1) The number of products launched varies by country
2) Samsung Bioepis' cumulative supply data (~Mar 2023)
3) Estimated number of patients reached = annual sales volume/annual doses administered (Source: annual sales volume from the IQVIA, annual doses administered calculated based on WHO's Defined Daily Dose)
4) Adalimumab, trastuzumab, and bevacizumab biosimilars
5) Sources: Average Sales Price for 8 biosimilars marketed in the US, calculated based on 'HCPCS Unit Wholesale Acquisition Cost (WAC) Price, Buy and Bill' and 'Medicare part B Average Sales Price, Centers for Medicare and Medicaid Services (CMS)' in Mar 2023

Multiple Treatment Options

Through the launch of six biosimilar products in the immunology, oncology, and ophthalmology therapeutic areas, we help improve access to medicines across the global market.

- The total number of patients reached is estimated to be 376,000 (as of 2022)[3]
- 3 of our biosimilar products were placed on the WHO List of Essential Medicines[4]

Key product category

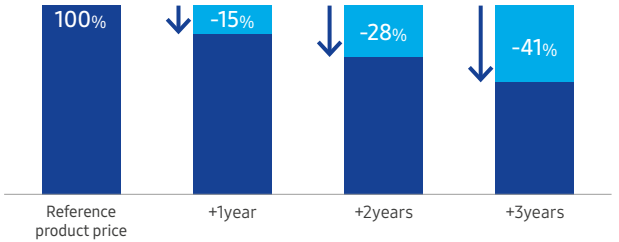


Approved products of Samsung Bioepis

Affordability

We provide patients with affordable biosimilars that deliver efficacy equivalent to their reference products, contributing to mitigating the financial burden of patients.

Average sales price decline after biosimilars launching in the US[5]



Compassionate use

Through a compassionate use program, we intend to improve access to medicines in those diseases or conditions for which patients' unmet needs persist.
Compassionate use is a policy for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product when no comparable or satisfactory alternative options to treat the disease or condition are available.

Access to Medicines

Sustainable Healthcare System

Alleviating the national burden of healthcare expenses

Our biosimilars help reduce government spending on health and welfare while delivering equivalent efficacy so that the savings generated as such can be re-invested in public healthcare. In doing so, we drive progress towards a sustainable healthcare system.

Our products contribution to reducing healthcare spending in EU

PDP program in Brazil

Samsung Bioepis supplies BRENZYS™ (etanercept biosimilar) and ONTRUZANT® (trastuzumab biosimilar) to Brazil, the largest market in Central and Latin America, under the Productive Development Partnership (PDP) program.

This program is run by the Brazilian government to promote the local biopharmaceutical industry. Samsung Bioepis, BioManguinhos, a state-funded research institute, and Bionovis, a local pharmaceutical company, formed a tripartite partnership to engage in technology transfer and joint investment. This gives us the opportunity to provide high-quality biosimilars to patients in Brazil for a specified time period while also contributing to the growth and development of the Brazilian pharmaceutical industry by transferring our production technology.

Raising Awareness on Biosimilars

The Regulatory Strategy and Policy (RSP) unit was newly established within Samsung Bioepis in 2021 to establish our US presence for science-based regulatory strategy and policy in the leading global market for biosimilars. Through collaboration with various trade associations including Biosimilars Forum, Medicines for Europe, and IGBA[3], the RSP unit is committed to supporting and shaping global biosimilar policies that champion a sustainable market for biosimilars which eventually leads to increased patient access. Gillian Woollett, vice president of our RSP unit, has chaired the IGBA Biosimilar Committee since 2023. This will enable Samsung Bioepis to further interact with major international regulatory authorities and influence the agenda of the global biosimilar industry.

Note: The RSP unit presented and discussed biosimilar policy improvements and industry trends concerning latest medicine regulatory amendments in Europe, the US, and Canada among others to improve patient access to medicines while reducing their cost burden at the Biosimilar Medicines Conference held in Brussels, Belgium, in October 2022

1) Source: Biogen Earning Report (Q4 and Full Year 2021), based on 3 TNF-α inhibitor products in Europe between 2016 and 2021
2) Source: Biogen (https://www.biogen.com/science-and-innovation/biosimilars.html)
3) IGBA: International Generic and Biosimilar Medicines Association

Key public relations activities

2020	Published "Education in Biosimilars" whitepaper on biosimilars landscape and understandings in Europe
2021	Published "Improving the Understanding and Acceptance of Biosimilars in the United States" a policy and industry trend whitepaper on the uptake of biosimilars in the US
2022	Hosted two open forums to raise awareness on biosimilars and Samsung Bioepis in the US
2023	Published the first quarterly edition of "Biosimilar Market Report" to provide insights on biosimilars and their latest trends in the US

☞ Click on the booklet to see the whitepaper.

Supply Chain Management

Management Approach & Key Performances

Sustainable Supply Chain Management

Establish supply chain policy and ESG risk assessment

Supply Chain Support and Win-Win Partnership

Assist small and medium enterprises in bolstering their ESG capabilities

Sustainable Supply Chain Management

As sustainable supply chain management has gained prominence in the wake of COVID-19, we are diversifying our supply chains to ensure flexible, cost-effective, and reliable product supply. We also work on multiple fronts in developing a sustainable supply chain policy, updating our Third-Party Code of Conduct, and establishing relevant ESG assessment processes.

Principle and Category of Supply Chain Management

Supply chain management principle

At the core of our supply chain management lies our capability to reliably supply high-quality medicines through cost and lead-time[1] optimization. Meanwhile, the pandemic underscored the importance of supply chain sustainability issues, resulting in the rising demand for supply chain diversification and ESG management. As a global leader in biopharmaceutical industry, Samsung Bioepis strives to reflect social and economic values across our supply chains.

Our supply chain partners by category

We work with a range of partners along the whole of our value chain spanning R&D, clinical trials, raw material sourcing, manufacturing, and commercialization.

Supply chain partners

Type	Description
CRO	Contract Research Organization
Vendor	Supply raw materials to CROs/CMOs
CMO	Contract Manufacturing Organization
CSO	Contract Sales Organization

1) Time from when an item is ordered until the item is delivered and is actually available for use

Supply Chain Management Activities

Rigorous ESG management of supply chain

In line with the tightening requirements for global supply chain due diligence and ESG disclosure, we endeavor to ensure more rigorous management of human rights, environmental and other ESG risks along our supply chains.
As a part of such efforts, we set forth and implement our sustainable supply chain policy, the Third-Party Code of Conduct (CoC), and other relevant ESG assessment processes in 2022.

Samsung Bioepis Sustainable Supply Chain Policy

Our activities to bolster supply chain ESG management

Establish a sustainable supply chain policy	· Set sustainable sourcing principles · Set supply chain ESG assessment
Update the Third-Party CoC	· Add implementation guidelines for supply chain ESG assessment · Sign the Third-Party CoC
Establish a supply chain ESG assessment process	· Establish a new supplier registration assessment process · Establish a regular supply chain ESG assessment process · Offer assessment result feedback

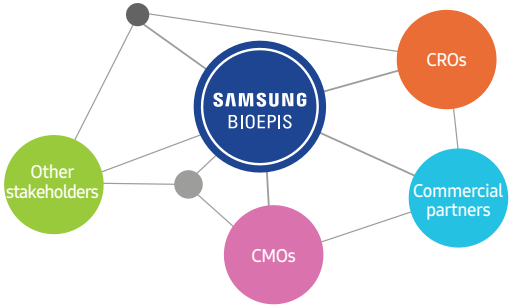
Supply chain diversification

Sustainable supply chain management is pivotal in ensuring the reliable supply of products as well as addressing ESG risks. This is why Samsung Bioepis is making efforts to establish multiple supply chains across the entire value chain. In doing so, we can secure high-quality raw materials to elevate the production quality of our CMOs preemptively bracing for pandemics, natural disasters, and other unpredictable situations.

CASE STUDY

Ensuring reliable supply even in adverse conditions

During the COVID-19 pandemic, Samsung Bioepis closely teamed up with logistics partners to develop flawless execution plans to avoid supply disruptions. Even in the middle of the Russia-Ukraine conflict, we developed and executed alternative delivery routes. Through successful execution, the clinical supplies were delivered to the sites on time without impacting the treatment schedule. In addition, in the face of urgent changes of the volume forecast, we have built successful track records in working closely with our CMOs.



Supply Chain Support and Win-Win Partnership

Samsung Bioepis is establishing a ESG assessment system to manage ESG risks throughout our entire supply chains, and we will encourage our suppliers to bolster their capabilities to manage ESG risks. We undertake initiatives to assist SMEs with ESG capacity-building, leading the way in promoting win-win partnerships across the bio industry ecosystem.

Supply Chain ESG Assessment and Support

Supply chain ESG assessment process

Samsung Bioepis established a supply chain ESG assessment system to bolster our sustainable supply chain management.
In 2023, we plan to conduct regular ESG assessments on our existing supply chains, and review new suppliers for their ethics, human rights, and environmental performance among others. Suppliers identified as a high risk of ESG are recommended to develop and implement ESG risk improvement plans. We support them to make necessary improvements and monitor their progress.

Supply chain ESG assessment system

Categoy	Registration assessment	Regular assessment
Target	New suppliers	Existing suppliers
Period	When new transactions are made	Annual
Assessment item	10 compliance items (ethics, human rights, labor, environment, health & safety)	55 items in overall ESG management

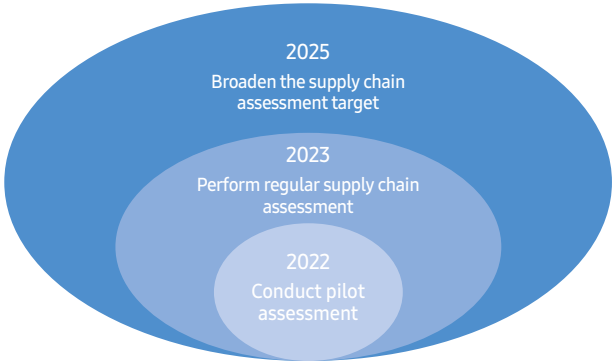
Supply chain ESG assessment process

Plan	· Develop the Third-Party CoC & checklist
Do	· Perform supply chain risk assessment
Check	· Analyze assessment results & identify risk
Act	· Implement improvement activities and monitor the progress

Bolstering supply chain ESG assessment

In the second half of 2022, we did a pilot on supply chain ESG assessment on 10 key suppliers. This revealed that none of these supplies met the high-risk classification criteria that were predetermined in conjunction with a professional third-party consultancy.
We continue to advance our assessment metrics to further fine-tune our supply chain risk management, and plan to perform regular supply chain assessments annually. From 2023 onwards, the scope of our assessment will gradually extend starting with 23 Tier 1 suppliers to bolster their ESG capabilities.

Broadening supply chain assessment



Win-Win Partnership

Assisting SMEs in bolstering their ESG capabilities

Samsung Bioepis is assisting small and medium-sized enterprises (SMEs) in reinforcing their ESG capabilities to step forward to meet the needs and boost interdisciplinary collaboration among bio industry sectors and to strengthen the bio ecosystem.
In partnership with the Korea Bio Association, we surveyed SMEs for their demands for ESG management support. We identified certain areas in need of ESG capacity including environment, ethics, and health & safety.
In doing so, we will take our part in promoting win-win partnership and mutual growth in the bio industry and in supporting SMEs to bolster their ESG capabilities.

Supplier tiering

Tier	Target
Tier 1	Key contracted suppliers (CMO, CRO, etc.), key material suppliers
Tier 2	Over 2 years of continuous suppliers
Tier 3	Less than 2 years / One-time suppliers

SUSTAINABILITY INFORMATION DISCLOSURES

Sustainability Accounting Standards Board (SASB) Index

Samsung Bioepis' SASB Index aligns with the Biotechnology and Pharmaceutical Industry guidelines for its disclosure topics and accounting metrics. Data and information disclosed are sourced from our Sustainability Report 2022 and our website.

SASB code	Metrics	Samsung Bioepis' Disclosure
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	Decisions associated with clinical trials operations are made by prioritizing the safety and rights of participants, and we regularly perform monitoring as part of our clinical trials operations to keep participants safe and maintain the quality of such trials (refer to 'Clinical Safety Management', (p24)).
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) Zero, (2) Zero: we cooperate with regulatory authorities in addressing issues concerning clinical trial management and pharmacovigilance, and make sure we take all necessary actions.
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	Did not incur
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	In line with our vision 'Passion for Health', we provide a large number of patients with high-quality biosimilars at affordable prices compared to their reference medicines. This vision helps improve access to medicines on the back of the core values of biosimilars that Samsung Bioepis aspires to deliver (refer to 'Access to Medicine' (p.27)).
HC-BP-240a.2	List of products on the WHO life 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.
Affordability & Pricing		
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a define time period	Not applicable as this metric concerns new drugs
HC-BP-240b.2	Percentage change in : (1) average list price and (2) average net price across US product portfolio compared to previous year	We sell our products in global markets except for some countries such as Korea, through marketing partnership agreement with Biogen and Organon.
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 available. Samsung Bioepis is not recognized for any potential safety issues by the MedWatch Safety Alerts for Human Medical Products database or the US FDA.
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	All fatality information associated with our products is reported in the FDA Adverse Event Reporting System.
HC-BP-250a.3	Number of recalls issued, total units recalled	No recalls

Sustainability Accounting Standards Board (SASB) Index

SASB code	Metrics	Samsung Bioepis' Disclosure
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	Did not incur
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violation of current Good Manufacturing Practices (cGMP), by type	Did not incur
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 apply serialization and anti-counterfeiting/forgery technologies to respective packaging units in conformity with country-specific regulations (refer to 'Rigorous Pharmacovigilance' (p.25)).
HC-BP-260a.2	Discussion of process for alerting customer and business partners of potential or known risks associated with counterfeit products	To bolster security along the supply chain and safeguard our products and patients, we support the use of serialization and tracing technologies, and work with marketing partners and global regulatory authorities (refer to 'Rigorous Pharmacovigilance' (p.25)).
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 incur
Ethical Marketing		
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Did not incur
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	We make our code of conduct regularly 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.
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, and increase investment in recruiting and retaining our research and development personnel while supporting their continuous development (refer to 'Sustainable Growth Driver' (p.16) and 'Bio Talent Development' (p.20)).
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 GRI 401 Employment(p.44)
Supply Chain Management		
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier 1 suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	Result of pilot assessment for 10 suppliers: 80% for EcoVadis and 30% for 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 incur
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 provide relevant status reports in line with the HCP interaction guidelines of the CPMS (refer to 'Compliance' (p.10) and GRI 205-2 Market Presence (p.38)).
Activity Metrics		
HC-BP-000.A	Number of patients treated	Estimated at approximately 376,000 patients (refer to 'Access to Medicine' (p.27)).
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	(1) 6, (2) 5

GRI 2: General Disclosures 2021

GRI 2: The organization and its reporting practices
2-1 Organizational details
2-2 Entities included in the organization's sustainability reporting
2-3 Reporting period, frequency, and contact point
2-4 Restatements of information
2-5 External assurance

About Us About This Report

GRI 2: Activities and workers
2-6 Activities, value chain, and other business relationships

Sustainable Value Chain

2-7 Employees
2-8 Workers who are not employees

Refer to GRI 405-1 Diversity of governance bodies and employees

GRI 2: Governance
2-9 Governance structure and composition
2-10 Nomination and selection of the highest governance body
2-11 Chair of the highest governance body
2-12 Role of the highest governance body in overseeing the management of impacts

Roles and composition of the Board of Directors

- We have established a professional and diverse board to enable reasonable decision-making and support the sustainable growth of Samsung Bioepis.
  - Appointed the head of R&D as an inside director in 2021 and the head of Samsung Biologic's EPCV[1] as a non-executive director in 2022
  - Provide objective and expertise-based oversight and advice to top management
  - Advance diverse governance by appointing female executives

1) Engineering, Procurement, Construction, Validation

Principles and process for appointing the Board of Directors

- Make it a rule to prohibit discrimination on the grounds of gender, race, nationality, ethnicity, or place of origin in appointing directors
- Appoint directors with three-year tenure by gaining approval at the Annual General Meeting of Shareholders pursuant to the Korean Commercial Law and the Articles of Incorporation

Board profile[2]

	Christopher Hansung Ko	Kyung-Ah Kim	Kun Lo
Position	Chair of the Board, President & CEO	Inside director, Executive Vice President of R&D	Non-excutive director
Gender	Male	Female	Male
Term	10 year 10 months	1 year and 3 months	10 months
Key experience	(Current) CEO (Former) Head of Bio Health Lab, Samsung Advanced Institute of Technology	(Current) Vice President (Former) Senior Vice President, Samsung Advanced Institute of Technology	(Current) Head of EPCV Center (Former) Executive Vice President, New Business Division, Samsung Engineering
Expertise	· Biopharmaceutical business development and research · Leadership	· Biopharmaceutical research · Leadership	· Biopharmaceutical process design and construction · R&D on chemicals business

Board composition[3]		Unit	2020	2021	2022
Composition	No. of directors	Persons	6	6	3
	Inside directors		2	2	2
	Non-executive directors		4	4	1
Diversity	Male		6	4	2
	Female		0	2	1
Expertise	No. of biopharmaceutical experts		5	5	2

2) The term of board members was calculated as of the end of December 2022.
3) The composition of the board of directors was prepared as of the end of each year.

GRI 2: General Disclosures 2021

Operation of the Board of Directors

- Convened 3 times in 2022 to decide on key agendas concerning business operations, including transactions with affiliates, borrowing limits, and approval of the 2023 business plans

Date	Agenda & Decision	Attendance
February 9, 2022	· Approval of financial statements for the 10th fiscal year · Approval of the 2022 health and safety plan · Approval of convening of an Extraordinary General Meeting of Shareholders · Approval of convening of the Annual General Meeting of Shareholders	100%
September 30, 2022	· Approval of 2022 transactions with Samsung Biologics · Approval of a new borrowing limit · Approval of withdrawal of the existing borrowing limit · Approval of convening of an Extraordinary General Meeting of Shareholders	100%
December 8, 2022	· Approval of the 2023 business plan · Approval of 2022 transactions with Samsung Life Insurance · Approval of the amendment of the Board of Directors' regulations · Approval of the abolishment of the Management Committee regulations · Approval of 2022 donation payments	100%

2-14 Role of the highest governance body in sustainability reporting

ESG Materiality Assessment

2-18 Evaluation of the performance of the highest governance body

2-19 Remuneration policies

Board assessment and compensation

- Inside directors receive base annual salary and bonuses within the compensation limit approved by the AGM.
- The 2022 AGM approved 6.7 billion KRW as the board compensation limit.
- The alignment between inside directors' compensation and business performance has been strengthened through the Samsung Group-wide long-term performance incentive program.

GRI 2: Strategy, Policies and Practicies

2-22 Statement on sustainable development strategy

CEO Message

2-23 Policy commitments

Samsung Bioepis Human Rights Charter

- As a global biopharmaceutical company, we respect the human rights of stakeholders across our business operations, and advance human rights management.
- We honor international human rights principles and norms, such as the Universal Declaration of Human Rights, the UN Guiding Principles on Business & Human Rights, ILO Fundamental Conventions, the OECD Guidelines for Multinational Enterprises, the UN Convention on the Rights of the Child and the Corporate Human Rights Benchmark, and comply with labor/human rights laws and regulations in the countries and regions where we operate.

2-25 Process to remediate negative impacts

2-26 Mechanisms for seeking advice and raising concerns

Grievance handling process

Grievance received → **Verify & review** → **Notify review outcomes** → **Grievance handled**

- Receive grievances via hotline, the anonymous bulletin board, and other whistle-blowing channels
- Establish the factual ground
- Protect whistleblowers
- Review action to be taken according to verified facts
- Notify review outcomes and collect feedback
- Take action and other HR measures
- Provide training to prevent recurrence

Employee feedback collection channels

Channel	Tools	Cycle	Purpose and expected benefits
Anonymous bulletin board	Online	Year-round	Handle employee grievances through the anonymous bulletin board 'Our Voice', address inquiries and requests
'Bamboo Forest' meeting	Meeting	Quarterly	Facilitate employee communication through quarterly 'Bamboo Forest' meetings
Labor-Management Council	In-person meeting	Weekly/ Monthly/ Quarterly	Receive employees' feedback through regular Labor-Management Council meetings, and improve employees' work life through quarterly Council meetings
Counseling center	1:1 coaching	Year-round	Promote employees' mental healthcare through the regular operation of the counseling center

GRI 2: General Disclosures 2021

Grievance handling policy

- Number of grievances received in 2022: 446 in total (cf. 135 through the anonymous bulletin boards, 45 through 'Bamboo Forest', others through the counseling center and the Labor-Management Council)
- Ensure that whistleblowers remain anonymous and information confidential
- While grievances received are handled through immediate action and result notification in principle, issues whose prompt resolution is not viable are addressed by notifying action plans and the timeline within 24 hours to facilitate their smooth resolution.

Grievance handling status

Type	Unit	2020	2021	2022
No. of human rights-related grievances submitted, identified, and resolved through official grievance channels	Cases	0	0	0
No. of labor practice-related grievances submitted, identified, and resolved through official grievance channels		0	0	0

Grievance management

Quarter	Grievance raised	Improvement made
1Q 2022	Lack of information on the location of meeting rooms on each floor	Displayed information on the location of meeting rooms and their directions at the entrance of each floor
2Q 2022	Lack of guidance on telecommuting working standards	Notified the proportion of telecommuting in line with the enforcement severity of the Korean government's social distancing policy
3Q 2022	Lack of information on person in charge	Posted campaign materials to encourage employees to update information on their job responsibility
4Q 2022	Static electricity at the drinking fountain of the cafeteria	Installed grounding devices at the drinking fountain

2-27 Compliance with laws and regulations

Type of violation		Unit	2020	2021	2022
Non-compliance within the reporting period	Total number of cases	Cases	0	0	0
	Penalties imposed on non-compliance		0	0	0
	Non-monetary sanctions		0	0	0
Penalties paid due to non-compliance	Total number of cases		0	0	0
	Total amount	million KRW	0	0	0
	Amount of penalties paid for non-compliance in the current year		0	0	0
	Amount of penalties paid for non-compliance prior to the current year		0	0	0

2-28 Membership associations

Annual membership fees by association[1]		Unit	2020	2021	2022
Korea Biotechnology Industry Organization	Regular member, chair company	million KRW	-	20.4	34.8
Korea Biomedicine Industry Association	Regular member		-	18.0	18.0
Korea Pharmaceutical and Bio-Pharma Manufacturers Association	Associate member		-	1.4	2.9
Incheon Chamber of Commerce & Industry	Regular member		-	80.0	80.0

1) First reported in 2021

GRI: Stakeholder Engagement

2-29 Approach to stakeholder engagement

Stakeholder group	Communication channel	Communication issues
Customers	Website, media, social networks	Company news, status of product development, product information, general inquiry
Employees	In-house bulletin board, internal communications channel 'EPIS IN', Labor-Management Council, counseling center, whistleblowing channels	Company news and events, organizational culture, benefits, HR system, employee and department profiles, industry news
Suppliers	CMO working-level meetings	Discuss weekly/monthly production status for each process of products
	CMO working-level & mid-level manager meetings	Review annual production status and KPIs, Identify improvements and verify performances
	CMO management meetings	Ensure supply chain continuity by reviewing on-going projects and verifying their outcomes, developing long-term strategic plans, and discussing investment opportunities
Universities	Research Note competition at universities	Nurture industry talents
Communities	CSR activities	Contribute to local economies and undertake CSR activities
Governments, Industry associations	Meetings, seminars, newsletters, websites, social media	Monitor industry trends and policies, create jobs, provide feedback and proposals concerning laws and policies, network with industry peers, and support small/mid-sized bio companies (materials/parts/equipment test program, ESG consulting, etc.)

GRI 3: Material Topics 2021

3-1 Process to determine material topics

- We performed materiality assessment in accordance with the updated GRI 3 Material Topics 2021 to enhance the reliability of the materiality assessment and reflect the latest disclosure standards for the 「2023 Samsung Bioepis' Sustainability Report」.

3-2 List of material topics

Material reporting topic	Impact on	Level of impact	Topic group	Page
Sustainable growth driver	People, Economy	●●●●●	R&D Innovation	16
Process innovation	People, Economy	●●●●●		17
User convenience and safety	People	●●●●●		18
Digital transformation	Economy	●●●●●		21
Eco-friendliness	Environment, Economy	●●●○○		19
Bio talent development	People, Economy	●●●●○		20
Quality management for patient safety	People	●●●●○	Product Quality and Patient Safety	23
Clinical safety management	People	●●●●○		24
Rigorous pharmacovigilance	People	●●●●○		25
Rigorous counterfeit medicine management	People	●●●○○		25
Multiple treatment options	People	●●●●●	Access to Medicines	27
Affordability	People, Economy	●●●●●		27
Sustainable healthcare system	People, Economy	●●●●●		28
Sustainable supply chain management	Economy, People	●●●●○	Supply Chain Management	30
Supply chain support and win-win partnership	Economy, People	●●●●○		31

3-3 Management of material topics

- The materiality assessment process and the list of material topics are made available in the Materiality Assessment section of the report (p.12), and the table of contents was organized by categorizing 15 material issues along with relevant items.
- We elaborated our achievements and future plans regarding material topics in the Samsung Bioepis' Sustainable Journey section, and other relevant ESG topics are described in the Sustainability Information Disclosure section.

GRI 200: Economy

GRI 201: Economic Performance 2016

201-1	Direct economic value generated and distributed	About Us	Financial Performance
201-2	Financial implications and other risks and opportunities due to climate change	TCFD	

GRI 202: Market Presence 2016

			Unit	2020	2021	2022
202-1	Ratios of standard entry level wage by gender compared to local minimum wage	Average	%	143	144	141
		Male		143	144	141
		Female		143	144	141
202-2	Proportion of senior management hired from the local community (above mid-level manager)	・Number of local hires: 20 persons ・Proportion of managers out of local hires:100%				

GRI 205: Market Presence 2016

		Category	Details
205-2	Communication and training about anti-corruption policies and procedures	Common training	・Compliance program ・Off-label promotion and violation ・Provision of economic benefits for HCPs ・Improper Solicitation and Graft Act, whistleblowing, etc.
		Compliance pledge	・Mandate all employees to sign the pledge to practice compliance management within the Compliance Management System (CPMS) and review their implementation
		Executive training	・Provide in-person training to strengthen responsible executives' awareness on compliance ・Encourage responsible executives to strengthen their compliance accountability by reflecting training results in their executive KPIs
205-3	Confirmed incidents of corruption and actions taken	No cases of corruption or related legal action taken during the reporting period.	

GRI 206: Market Presence 2016

206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	No cases of unfair trade practices and related legal action taken during the reporting period

GRI 302: Energy 2016

GRI 302 Management Approach

- Improving the efficiency of energy use and opting for renewable energy is essential in responding to climate change and reducing our overall organizational environmental impact.
- Samsung Bioepis does not have our own manufacturing facilities, and most of our energy use goes to power cooling/heating and for electricity consumption at buildings where we conduct business.
- We implement environmental management across the board with our Facility Management Group leading the way, and manage our energy consumption for major sources of consumption (heating/cooling equipment at buildings) to mitigate impact on climate change.
- Together with Samsung Biologics, we committed to join the Net Zero by 2050 initiative and the RE100, and will roll out a range of activities to strategically respond to climate-related risks and opportunities.

302-1 Energy consumption within the organization

302-3 Energy intensity

Energy consumption		Unit	2020	2021	2022
Non-renewable energy consumption[1]		TJ	137	148	132
Direct energy consumption (Scope 1)	Subtotal		27.136	31.272	21.444
	LNG		23.683	28.247	18.277
	Gasoline		3.090	2.843	2.985
	Diesel		0.362	0.182	0.182
Indirect energy consumption (Scope 2)	Subtotal		110.610	117.152	111.046
	Electricity		109.566	98.175	94.087
	Steam		1.044	18.978	16.959
Renewable energy consumption[2]	PV		-	-	0.039
Energy intensity		TJ/100million KRW	0.018	0.017	0.014

1) Energy consumption of 2020 before moving into our new building in 2021 was calculated by combining consumption at our Suwon site and our old Songdo site
2) The photovoltaic power generators started operation in Dec, 2022

Activities to reduce energy consumption

- Achieved ISO 50001 (energy management system certification) in Sep 2022
  - Improved energy management efficiency and established a management system on par with global standards
- Opted for high-efficiency equipment
  - Switched to LED lights for 90% of total at our Songdo office building
  - Switched to high-efficiency heating pumps, power factor correction capacitor, and reduced standby power consumption
- Reduced energy consumption
  - Turned off lighting and air conditioning during hours when employees are not in the office
  - Deployed an HVAC system featuring inverter control, district heating, and absorption chiller-heaters
  - Installed EV chargers
- Other activities
  - Issued in-house SHE (Safety, Health, Environment) newsletters, communicated environmental management activities at all levels, and raised employee awareness on environmental management
  - Launched campaigns to reduce energy use

Installing and operating photovoltaic power generators (Dec 2022)

- Installed 200kW photovoltaic power generators on the roof of the building
- Expected to generate 300MWh per year to substitute 3% of forecasted power consumption of 2023
- Aim to achieve the RE100 in 2050 by expanding the transition to renewable energy through Power Purchase Agreements and Renewable Energy Certificates.

GRI 303: Water and Effluents 2016

GRI 303 Management Approach

- If wastewater generated from the product development process is not discharged and treated legally, it may cause environmental pollution such as soil and water pollution.
- We perform annual water quality inspections on all our water supply facilities in accordance with Standard Operating Procedure (SOP), and in the event that the legally permissible discharge threshold is exceeded as a result of inspection results, we clean or replace the water pipes.
- We implement the overall development process in line with the meticulously-developed plan to reduce water consumption and prevent unnecessary generation of wastewater.

303-2 Management of water discharge-related impacts

- **Effluent monitoring system:** Ensure end-of-pipe water quality does not exceed 30% of the legal threshold (daily)
- **Wastewater treatment system:** Manage all wastewater that could be generated by our bio laboratory for their property and discharge volume (capacity: 190 tons/day)
- **Establish an emergency response system:** Secure 2-day's reserve capacity for the wastewater storage tank, and outsource wastewater treatment when urgent

303-3 Water withdrawal
303-4 Water discharge
303-5 Water consumption

Water usage[1]		Unit	2020	2021	2022
Water withdrawal[2]		ton	37,672	65,914	66,713
Water consumption			-	-	-
Water recycling and reuse			-	-	-
Wastewater discharge[3]	Domestic wastewater		28,903	53,896	48,245
	Wastewater treatment		8,769	12,018	18,468

1) Before moving into new building in Songdo in 2021, status of water usage is only for old building in Songdo not including Suwon site.
2) All of our water is sourced from city water.
3) All wastewater generated in the R&D process is discharged after going through the legal treatment process.

Discharge of water pollutants[4]	Unit	2020	2021	2022
Total organic carbons (TOC)	mg/L	21.60	3.90	5.74
Suspended solids (SS)		8.40	0.00	1.08
Total nitrogen (T-N)		12.20	9.46	4.90
Total phosphorus (T-P)		0.20	0.05	0.08

4) Water pollutants were combined with those from Samsung Biologics and were discharged and treated accordingly until 2020. Discharge threshold: TOC 75 mg/L and below, SS 120 mg/L and below, T-N 60 mg/L and below, T-P 8 mg/L and below

GRI 305: Emissions 2016

GRI 305 Management Approach

- Greenhouse gases are the main cause behind climate change. GHG reduction is a promise made by the international community at the United Nations Framework Convention on Climate Change and is a prerequisite for the sustainability of the earth.
- Neither Samsung Bioepis nor the industry itself was designated by the government for the potential to generate significant GHG emissions due to relatively lower energy consumption. We calculate our GHG emissions and work to reduce such emissions to recognize our social responsibility and join in on the efforts to combat climate change as a global company.
- We achieved environmental management (ISO 14001) and energy management (ISO 50001) certifications to establish an environmental management system in line with global standards (Sep 2022).
- Most of our GHG emissions are generated from power consumption, and this is why we consider expanding renewable energy as a key tool for us to mitigate GHG emissions. We teamed up with Samsung Biologics to join the Net Zero Initiative and the RE100 to continuously commit to reducing GHG emissions.

305-1 Direct (Scope 1) GHG emissions
305-2 Energy indirect (Scope 2) GHG emissions
305-4 GHG emissions intensity

GHG emissions		Unit	2020	2021	2022
Total GHG emissions		tCO_2eq	6,729	6,851	6,087
Direct (Scope 1) GHG emissions	Subtotal		1,433.412	1,635.431	1,139.697
	LNG		1,200.262	1,431.541	926.274
	Gasoline		207.714	191.116	200.670
	Diesel		25.436	12.775	12.753
Energy indirect (Scope 2) GHG emissions	Subtotal		5,296.110	5,215.878	4,947.807
	Electricity		5,243.302	4,698.176	4,502.554
	Steam		52.807	517.702	445.253
GHG emissions intensity		tCO_2eq/100 million KRW	0.866	0.809	0.643

305-7 NOx, SOx, and other significant air emissions

Air pollutant emission[1]	Unit	2020	2021	2022
Nitrogen oxides (NOx)	kg	-	862.6	713.7
Sulfur oxides (SOx)		-	23.2	-
Particulate matter (PM)		-	23.4	-

1) Air pollutant emissions were integrated into Samsung Biologic's disclosure on emissions in 2020, and SOx and PM were not measured as exempt from the measurement in 2022.

Activities to reduce air pollutant emissions

- We have measured the emissions of NOx, SOx, and PM twice a year since April 2021.
- For NOx, we have installed low-NOx burners for all NOx-emitting equipment to minimize their generation: 3 boilers with ultra low-NOx burner and 2 gas absorption chiller-heaters with low-NOx burner.

GRI 306: Waste 2020

GRI 306 Management Approach

- If waste generated from the product development process is not discharged and treated legally, it may cause environmental pollution such as soil and water pollution.
- In accordance with our waste treatment regulations, we sort and discharge waste generated from offices and laboratories to avoid mixing such waste. All our waste is outsourced to professional treatment service providers for their disposal and incineration.
- Active Pharmaceutical Ingredients (APIs) generated in the biopharmaceutical development process, are similar to natural proteins and tend to degrade rapidly and widely, which means they do not pose risk to the environment. Still, we continue to monitor our API discharge to reduce even such seemingly insignificant environmental impact.

Pharmaceuticlas in the Environmental policy

306-3 Waste generated
306-5 Waste directed to disposal

Waste generation	Unit	2020	2021	2022
Total[2]	kg	113,822	72,376	75,599
Designated waste		90,192	58,666	63,469
General waste		23,630	13,710	12,130
Waste recycling/reuse		-	-	-

2) All wastes were consigned to the waste disposal company.

Waste reduction activities

- Provide individual mugs to reduce paper cups as well as discounts at the in-house cafe
- Use paper bags for take-out food and provide disposable utensils only when asked
- Establish the ELN to go paperless company

Samsung Bioepis material topic: Sustainable supply chain management

GRI 308: Supplier Environmental Assessment 2016

GRI 308 Management Approach

- If we do not pay attention to the environmental impact that arises as a result of our business activities along the supply chains, this may give rise to actual or potential negative environmental impact.
- To ensure sustainable supply chains and manage supply chain ESG risks, we conduct supply chain ESG assessment on key suppliers, and the scope of such assessment covers a range of areas including human rights and ethical management as well as environment (for more details, refer to the material topic 'Supply Chain Management' (p.29)).

Samsung Bioepis Sustainable Supply Chain Policy

308-1 New suppliers that were screened using environmental criteria

308-2 Negative environmental impacts in the supply chain and actions taken

Supplier environmental assessment[1]		Unit	2020	2021	2022
Proportion of new suppliers that received environmental risk screening	Number of new suppliers	Companies	-	-	0
	Number of new suppliers that received environmental risk screening		-	-	0
	Proportion of suppliers that received environmental risk screening	%	-	-	0
Environmental impact assessment	Number of suppliers that received environmental impact assessment	Companies	-	-	10
	Number of suppliers verified for their actual/potential negative environmental impact		-	-	0
	Suppliers that agreed to make improvements		-	-	No improvement needed
	Proportion of suppliers that agreed to make improvements	%	-	-	-
	Suppliers whose contract terminated due to actual/potential negative environmental impact	Companies	-	-	0
	Proportion of suppliers whose contract was terminated due to actual/potential negative environmental impact	%	-	-	0

Environmental regulatory non-compliance	Unit	2020	2021	2022
Total amount of penalties imposed	100 million KRW	0	0	0
Lawsuits filed	Cases	0	0	0
Non-monetary sanctions imposed		0	0	0

1) First implemented in 2022

GRI 401: Employment 2016

GRI 401 Management Approach

- Securing and retaining bio professionals will contribute to generating our business performance and expanding our business territory.
- As to employee benefits that support work-life balance, we provide flexible work arrangements, expand fringe benefit programs, and ensure maternity protection.
- We achieved the family-friendly business certification (Jan 2023), and will continue to create a pleasant work environment and support work-life balance to provide our employees with satisfying working conditions.

401-1 New employee hires and employee turnover

New hires		Unit	2020	2021	2022
Total		Persons	130	82	94
By gender	Male		58	34	48
	Female		72	48	46
By age	Under 30		73	46	49
	30's and 40's		55	32	42
	50's and older		2	4	3

Turnover		Unit	2020	2021	2022
Total turnover		Persons	71	86	42
Total turnover rate[1]		%	7.5	9.3	4.3
By gender	Male	Persons	26	52	26
	Female		45	34	16
By age	Under 30		3	6	3
	30's and 40's		63	78	36
	50's and older		5	2	3
By position	Executives		3	2	4
	Junior management		0	2	2
	Middle management		49	47	20
	Non-management		19	35	16
By type	Dismissal		0	0	0
	Voluntary termination		70	86	42
	Retirement		0	0	0
	Others		1	0	0

1) Turnover rate=(Total turnover for the reference year)/(total employees at the end of the reference year) (based on full-time employees, excluding those transferred to related companies.

401-2 Employee benefits

Benefit programs

Category	Program	Category	Program
General employee benefits	Support for personal annuity savings	Convenient working conditions	Flextime
	Tuition assistance		In-house café, convenience store
	Group life insurance		Library
	Welfare point payment		Commuter buses
Health promotion	Health check-ups	Support for family health	Subsidies for medical expenses (for dependents under health insurance plan)
	Subsidies for medical expenses		Childcare leave of absence
	Musculoskeletal disease prevention center		Leave of absence and subsidies for medial expenses for fertility treatment
	Fitness/gym	Support for expectant mothers	Maternity protection spaces
	In-house clinic, pharmacy		Telecommuting and reduced work schedule for childcare, etc.
	Psychological counseling center	Family-friendly programs	Maternity/paternity leave
	Vaccination (flu and others.)		Parental leave: until the 6th grade in elementary school
Self-development	In-house hobby clubs		Reduced work schedule for childcare : until 12 years old
	Support for buying books		In-house daycare center

401-3 Parental leave taken

Parental leave		Unit	2020	2021	2022
Eligible employees	Male	Persons	296	297	302
	Female		145	150	166
Employees who took parental leave[2]	Male		6	10	9
	Female		29	21	32
Employees who returned to work	Male		1	2	3
	Female		17	17	10
Reinstatement rate[3]	Male	%	100	67	43
	Female		89	85	91
Proportion of employees who continued to work after parental leave[4] (12 months)	Male		67	100	80
	Female		81	81	61

2) While data were aggregated based on employees taking parental leave as of the reference year in our previous report, this changes to 'employees who newly applied for parental leave by the end of the reference year' from the current reporting period and afterwards.
3) Reinstatement rate: Employees who returned to work after parental leave / employees who will return to work in the current year after taking parental leave in the previous reporting period * 100
4) Rate of employees who continued to work after parental leave: Employees who continued to work 12 months after parental leave / employees who returned after parental leave during the previous reporting period * 100

GRI 403: Occupational Health and Safety 2018

403 Management Approach

403-1 Occupational health and safety management system

- An organization's commitment to creating a safe workplace and preventing occupational injuries ensures that employees feel psychologically confident and fully engage in their production activities. Any failure, however, to properly cope with accidents and injuries may undermine the quality of life for employee families as well as the health of employees themselves.
- Samsung Bioepis puts the safety and health of stakeholders, including customers, employees, and suppliers, above all else. To this end, we stipulated our safety, health, and environmental principles in 2022 and have since worked to improve our working environment and disseminate a culture of safety.

Safety, Health, and Environmental Management Principles

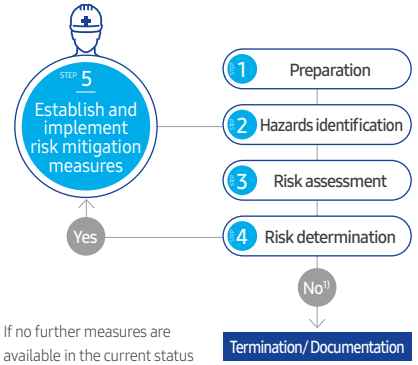
403-2 Hazard identification, risk assessment, and incident investigation

Implementing a risk assessment system

- Conduct regular safety inspections on worksite facilities and equipment
- Promote self-directed safety practices by conducting risk assessment and hosting competitions to identify potential risks

Category	Frequency	Description
Risk assessment	Annual	Identify and improve potential risks at the team level
Potential risk identification competition	Semi-annual	Identify internal risks at the lab/office and develop improvement measures, continue with risk inspection

Risk assessment process

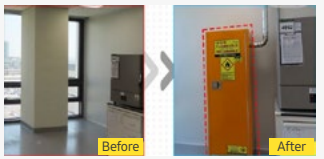


1) If no further measures are available in the current status

Improvements based on risk assessment results

- A total of 40 improvements completed in 2022

Tape marking to make stairs more visible for safety



Preventing musculoskeletal disorders

403-3 Occupational health services

403-4 Worker participation, consultation, and communication on occupational health and safety

Strengthening the health and safety management system

- Establish and implement the health and safety management system to prevent high-consequence injuries in the workplace
  - Appoint the Chief Safety Officer: Mandate the Head of the Corporate Management Division to oversee and manage company-wide health and safety operations
  - Operate a dedicated health and safety organization: Mandate the Facility Management Group under the Corporate Management Division to implement company-wide health and safety activities

Operation of a dedicated health and safety department

Role

1) Develop company-wide health and safety plans and implement activities
2) Prevent occupational injuries and fires, and establish an emergency response system
3) Promote the health of employees and create a safe working environment
4) Ensure the timely supply of equipment and provide optimal office and lab conditions
5) Conduct compliance assessment to verify the implementation of the health and safety plan (quarterly)
6) Issue SHE newsletters : Share information concerning energy consumption and company-wide health and safety activities, and raise awareness (monthly)

Operation of health and safety committees

Committee	Composition and operation	Role
Occupational safety and health committee	Consist of 4 representatives each from both labor and management, hold quarterly meeting	· Establish company-wide health and safety goals and plans · Deliberate and decide on major health and safety activities such as working environment measurement, potential risk improvement, employee safety training, and health check-ups · Disclose activity details to employees and encourage their participation in health and safety activities
Supplier health and safety committee	Consist of 4 contractor representatives and 9 subcontractor representatives, hold monthly meeting	· Gather and improve supplier feedback · Conduct joint safety inspections · Provide health and safety information to suppliers, and support safety training, etc.
Biosafety management committee	Consist of internal and external experts, hold regular and ad-hoc meetings	· Perform LMO[2] risk assessment of the whole life cycle from introduction to handling and disposal · Review safe experimentation methods

2) Living Modified Organism

Potential risk identification competition

SHE newsletter

403-5 Worker training on occupational health and safety

Training course	Target	Duration	Frequency	No. of Trainees 2020	2021	2022
Orientation training	Recruited personnel	8 hours	Upon employment	130	79	96
Regular training[1]	Employees	3 hours (office personnel) / 6 hours (research personnel)	Quarterly	858	856	907
Fire drill[2]	Employees	3 hours	Annual	-	-	345
Special health & safety training	Researchers	16 hours	Before initial work	43	45	40
Manager & supervisor training	Lab team leaders	16 hours	Annual	13	12	14
LMO training	Researchers	2 hours	Annual	161	125	141
Safety training support[3]	Suppliers	2 hours	Semi-annual	-	-	66

1) Statutory regular training is conducted four times a year, with the total number of trainees recorded for each session.
2) Fire drills are conducted annually but were postponed in 2020/2021 due to COVID-19.
3) Per session

403-6 Promotion of worker health

Category	Program	Description
Benefits	Health check-ups	Provide annual health check-ups for employees and their families
	Vaccination (Flu and others)	Manage employee health through infectious disease prevention
Support facilities	Musculoskeletal disorder prevention center	Provide counseling and exercise therapy for work-related musculoskeletal issues
	Fitness/gym	Provide cutting-edge fitness facilities and personal training programs
	In-house clinic/pharmacy	Provide medical consultations and acute illness treatments
	Psychological counseling center	Make full-time professional counselors available and ensure counseling conversations remain confidential
Others	Health promotion program	Encourage walking and dietary habit improvement, offer a range of support programs

403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships

Category	Frequency	Description
Chemicals safety management	Frequently	Perform safety assessment in importing chemicals, control hazardous substances
	Continuously	Provide customized protective gear and fume hoods for each task
	Continuously	Prepare emergency response supplies and utilize install laboratory safety showers
	Annually	Conduct drills in preparation for harmful substance leaks
	Semi-annually	Measure the work environment and evaluate the exposure to hazardous substances
	Annually	Provide special health check-ups to workers
Work safety management	Continuously	Operate the Permit to Work (PTW)
	Semi-annually	Operate a health and safety evaluation system for suppliers
Lab safety management	Continuously	Apply non-slip flooring materials and install anti-collision guards
	Continuously	Ensure basic protective is always worn and provide guides/protective equipment for each high-risk task
	Annually, Monthly	Conduct third party safety inspections (annual) and self-initiated safety inspections (monthly)
	Semi-annually	Identify and improve potential risks in the lab
	Continuously	Install oxygen monitoring devices (in areas of handling high volume of nitrogen gas)
	Annually	Make AEDs available and provide CPR training
Facility safety management	Semi-annually	Conduct regular safety inspections on facilities (compressed gas, electricity, and fire)
	Semi-annually	Conduct safety inspections on building structures

403-8 Workers covered by an occupational health and safety management system

403-9 Work-related injuries

Workers covered by an occupational health and safety management system		Unit	2020	2021	2022
Total worksites		Business sites	2	1	1
Worksites where work-related injuries occurred[4]	No. of worksites		1	0	1
	Percentage of worksites	%	50	0	100
Total employees	Employees	Persons	920	925	970
	Suppliers		65	121	121
Total annual hours worked[5]	Employees	Hours	1,943,040	1,935,600	2,048,640
	Suppliers		137,280	255,552	255,552
No. of accidents (injuries)	Employees	Cases	1	0	1
	Suppliers		0	0	0
Injury rate	Employees	%	0.11	0	0.10
	Suppliers		0	0	0
Lost time injury frequency Rate (LTIR)[6]	Employees	cases/200,000 person-hour	0.103	0	0.098
	Suppliers		0	0	0
No. of fatalities	Employees	Cases	0	0	0
	Suppliers		0	0	0
Work-related injuries		**Unit**	**2020**	**2021**	**2022**
No. of fatalities from work-related illnesses	Employees	Persons	0	0	0
	Suppliers		0	0	0
No. of incidences of work-related illness	Employees	Cases	0	0	0
	Suppliers		0	0	0

4) Operated two sites in Suwon and Songdo until 2020
5) Total annual hours worked = No. of employees * 8 hours * 22 days * 12 months
6) LTIR = No. of injuries / total annual hours worked * 200,000 (based on 200,000 manhours)

GRI 404: Training and Education 2016

404 Management Approach

- Providing employees with various capacity-building opportunities through job training, mentoring, and leadership training enables us to build a professional workforce and to improve our corporate competitive edge and business territories.
- In line with our philosophy 'our growth as a company is driven by the growth of our employees', we provide systematic training programs with a goal of nurturing employees into top-tier experts in their own field.
- For further details on our training programs for employee expertise enhancement, refer to the material topic 'Bio Talent Development' (p.20).

Employee training overview

- The following table outlines our entire training programs provided to employees, including statutory training (for training related to upgrading employee skills, refer to the material topic 'Bio Talent Development', p20).

404-1 Average hours of training per year per employee

404-2 Programs for upgrading employee skills and transition assistance programs

Employee training hours			Unit	2020	2021	2022
Total employee training hours			Hours	112,676	129,320	148,718
Average training hours	Average hours per employee		Hours/ Person	112.5	139.5	153.1
	By gender	Male		111.8	138.4	152.5
		Female		112.7	140.1	154.3
	By employment type	Regular & Fixed-term		112.6	139.6	153.2
		Contract		111.0	138.1	152.1

Training course	Unit	2020	2021	2022
General training[1]	Hours	111,544	128,535	129,445
Ethical management training		885	933	971
Anti-sexual harassment training		963	945	948
Workplace harassment prevention training[2]		-	926	934
Disability awareness improvement training		920	929	967
Personal data privacy training		459	462	487

1) Including job/leadership training for employees
2) Initial implementation in 2021

Leadership training and various transition assistance programs

Program	Frequency	Participants and contents
Leadership evaluation and consulting	Annual	Develop and bolster leadership skills for executives and departmental heads
Offline leadership training		Develop management and leadership skills for departmental head candidates
Job posting	Frequently	Provide all employees with opportunities to work in their desired function through internal relocation
Mentoring program		Help new hires with their early onboarding and assimilation to their role for all employees

404-3 Percentage of employees receiving regular performance and career development reviews

Performance appraisal system

Goal setting
- Goal/metric-setting interview with appraisers
- Individual annual goal-setting

Interim review
- Review of MBO progress
- Feedbacks and goal adjustment

Evaluation
- Self-evaluation for the attainment of annual goals
- Ranking session with the departmental head
- Confirm final grades

- Operate a Management by Objectives (MBO) system that enables employees to set clear goals and perform their duties based on these goals
- Train appraisers for their capacity building and provide SOPs for appraisal interviews
- Conduct follow-up surveys to enhance fairness and pursue continuous improvements

Compensation system

- Operate a salary grading system based on performance evaluations, and raise salary and pay bonuses according to one's salary grade
- Ensure fair compensation by aligning bonus pay with individual performance

Overview of performance appraisal and compensation	Unit	2020	2021	2022
Performance appraisal rate	%	100	100	100
Management by Objectives		99.5	97.0	99.0
Multi-source performance assessment		58.5	41.4	36.3
Ranking employees through comparative analyses conducted on those in the same job position category		95.2	95.7	95.0

GRI 405: Diversity and Equal Opportunity 2016

GRI 405 Management Approach

- An inclusive corporate culture that provides a diverse workforce with fair opportunities directly improves employee satisfaction, and this in turn boosts innovation and performance at the company level.
- We seek to respect the diversity of employees and pursue fairness in human resources operation, with a particular focus on ensuring gender diversity and nurturing female talent.

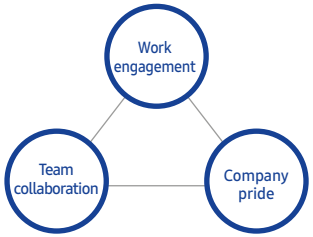
Respect for diversity and equity

- We build a workplace where people from diverse backgrounds and perspectives unlock their full potential and generate synergy.
- We guarantee equal pay for work of equal value for all women and men, including young people and employees with disabilities. In particular, we properly recognize the value of women's labor to increase their social participation and provide them with fair economic opportunity.
- We promote diverse communication and organizational culture activities to embed diversity and equity into our unique corporate culture.

Strengthening internal communication and efforts to improve organizational culture

- Change Agent (CA) activity: Given that those in their 20s and 30s account for 80% of our employees, we designate one CA for each department to promote department-level communication and corporate culture activities with an aim to encourage inter-generational communication and build a wholesome organizational culture.
- Samsung Culture Index (SCI): We conduct the SCI survey each year to identify our strengths and points of improvement, and gauge employee satisfaction with our work environment.

CA activities



Three pillars of SCI

405-1 Diversity of governance bodies and employees

- Refer to GRI 2-9 Governance structure and composition for the diversity of governance bodies

Employee Composition		Unit	2020	2021	2022
Total Employees		Persons	920	925	970
By gender	Male		475	453	475
	Female		445	472	495
By age	Under 30		298	265	239
	30s and 40s		603	644	706
	50s and older		19	16	25
By employment type	Regular & Fixed-term		914	922	965
	Male		469	450	470
	Female		445	472	495
	Non-regular & Non-fixed-term		6	3	5
	Male		6	3	5
	Female		0	0	0
Female employees in management positions	Executives		5	6	8
	Senior management[1]		15	13	12
	Middle management		158	180	217

405-2 Ratio of basic salary and remuneration of women to men

Ratio of compensation of women to men by employment type[2]	Unit	2020	2021	2022
Executives	%	107	97	90
Senior management		102	100	96
Middle management		96	96	96
Non-management		100	100	100

1) Restatements made in the number of female employees in management positions for 2020 and 2021: As all female executives are managers, they were double-counted until the previous reporting term.
2) Calculation formula = (Women's average base pay in a given position)/(men's average base pay in a given position) * 100
- Excluding employees who are contract workers, lawyers, and monthly-paid employees
- Executives recruited from outside the Company could be subject to differences in pay by gender as their compensation reflects the treatment they received in their previous role.

GRI 406: Non-discrimination 2016

GRI 406 Management Approach

- Unreasonable practices inside an organization, ranging from unfair treatment and discrimination to bullying by force, may demotivate employees and even bring adverse impact by violating the human rights of those affected.
- We strictly prohibit all forms of unfair treatment and discrimination against employees for any reason, and are laying the cultural foundation for employees to respect each other.

Establishing the Human Rights Charter

- We stipulated the Human Rights Charter in 2022 to ensure that we do not discriminate against employees in terms of recruitment, promotion, training on the grounds of gender, race, ethnicity, nationality, religion, disability, age, and political orientation. We also guarantee equal pay for work of equal value, and apply the principle of zero tolerance to gender-based and racial discrimination.
- While the principle of non-discrimination was set forth in our existing rules of employment, we further bolstered this principle in the Human Rights Charter and will advance human rights management across our entire business operations.

Samsung Bioepis Human Rights Charter

406-1 Incidents of discrimination and corrective actions taken

Incidences of discrimination[1] and corrective actions taken	Unit	2020	2021	2022
Cases submitted	Cases	0	0	0
Corrective actions taken		0	0	0

1) Cases of discrimination on the grounds of gender, race, age, position, etc.

GRI 407: Freedom of Association and collective Bargaining

GRI 407 Management Approach

- The freedom of association and the right to collective bargaining are basic rights guaranteed by the Korean Constitution and comprise the International Labour Organization (ILO) fundamental conventions, playing a pivotal role in ensuring that employees communicate with their employers on an equal footing.
- We consult on a range of agenda items to improve our employees' working conditions concerning wage, fringe benefits, and health & safety through our Labor-Management Council 'Compassionate Companionship', and are working to build stronger trust between labor and management through mutually-respectful communication.

Labor-management council activities

Composition	Role	Activity
· 4 employee representatives elected through the votes cast by 75% of our employees	· Consult on key labor-related issues as a body representing employees, receive and address employee feedback	· Weekly working-level meetings · Monthly regular meetings · Quarterly Labor-Management Council meetings · Continuous collection of employee feedback & grievances

2021	2022
· Consulted on 25 agenda items, including: - wage adjustment for 2021, - improvement of working hour calculation standards, - more flexible working hours, - expansion of fertility leave - broader choices for comprehensive health check-ups	· Consulted on 14 agenda items, including: - wage negotiations for 2022 - relaxed core time operation standards - expansion of the childcare center capacity - expanded paternity leave

407-1 Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk

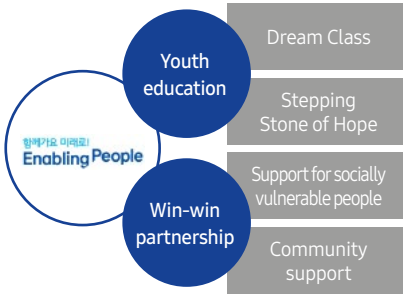
- None of our operations are available for this disclosure.

GRI 413: Local Communities 2016

GRI 413 Management Approach

- As we create profit on the back of the encouragement and support our society places in us, we bear the obligation and responsibility to help resolve social issues by giving back to society as a corporate citizen.
- Under Samsung's CSR vision of 'Together for Tomorrow! Enabling People,' we undertake initiatives for teen education and win-win partnerships. In particular, our flagship programs include bio education for teenagers that reflects our distinctive business characteristics and support for socially underprivileged groups provided by taking community needs into account.

Key CSR programs



Dream Class	Math/English education support offered by undergraduate mentors, mentoring support for career discovery
Stepping Stone of Hope	Self-reliance program for youth in shelters
Support for socially vulnerable people	Support for multicultural childeren, children raised by grandparents and voluntary fundraising through Sharing Kiosk
Community support	Santa expedition (Christmas gift delivery in Incheon) and blood donation campaign

413-2 Operations with significant actual and potential negative impacts on local communities

- None of our operations are available for this disclosure.

Samsung Bioepis material topic: Sustainable supply chain management

GRI 414: Supplier Social Assessment 2016

GRI 414 Management Approach

- As supply chain ESG management regulations become increasingly stringent at the global level, issues associated with labor rights and employment practices in the supply chain can potentially have negative impact on society.
- To establish sustainable supply chains and manage supply chain ESG risks, we are working to conduct ESG assessment on our key suppliers, and the scope of such assessment covers a range of areas including environment and ethical management as well as human rights and labor (for more details, see the material topic 'Supply Chain Management', p.29).

414-1 New suppliers that were screened using social criteria

414-2 Negative social impacts in the supply chain and actions taken

Supply chain social assessment[1]		Unit	2020	2021	2022
Proportion of new suppliers that received social risk screening	Number of new contracted suppliers	Companies	-	-	0
	Number of new contracted supplier that received social risk screening		-	-	0
	Proportion of new suppliers that received social risk screening	%	-	-	0
Social impact assessment	Number of suppliers evaluated for social impact	Companies	-	-	10
	Number of suppliers confirmed to have actual/potential negative social impact		-	-	0
	Suppliers that agreed to make improvement		-	-	No improvement needed
	Proportion of of suppliers that agreed to make improvement	%	-	-	-
	Number of suppliers whose contract terminated due to actual/potential negative social impact	Companies	-	-	0
	Proportion of suppliers whose contract terminated due to actual/potential negative social impact	%	-	-	0

1) First implemented in 2022

Dream class

Sharing kiosk


Santa expedition


Blood donation campaign

Samsung Bioepis Material Topic: Quality management for patient safety

Rigorous Pharmacovigilance | Rigorous counterfeit medicine management

GRI 416: Customer Health and Safety 2016

GRI 416 Management Approach

- As medicines, in essence, have direct impact on consumer health and safety, this warrants rigorous quality management and assurance throughout the entire value chain from development to production, distribution, and sales.
- In addition, continuous monitoring is required for the health and safety impact of products on consumers by closely identifying adverse events and take appropriate action when necessary even after the product use phase.
- We abide by global quality and manufacturing standards, the regulation of regulatory authorities establish and operate a company-wide quality management system, and bolster our internal capabilities for quality assurance.
- As to our policies and activities regarding customer health and safety, refer to the material topic 'Product Quality and Patient Safety' (p.22).

416-1 Assessment of the health and safety impacts of product and service categories

416-2 Incidents of non-compliance concerning the health and safety impacts of products and services

Health and safety impact assessment of products/services		Unit	2020	2021	2022
Safety and health impact assessment on main products/services	Main product/service categories	Products/services	5	5	6
	Main product/service categories that received health and safety impact assessment		5	5	6
	Proportion of main product/service categories that received health and safety impact assessment	%	100	100	100
Non-compliance with health and safety laws/regulations related to products/services	Number of cases where penalties were imposed for non-compliance	Cases	0	0	0
	Number of cases that warnings were issued for non-compliance		0	0	0
	Number of cases where internal regulations were violated		0	0	0

Samsung Bioepis Material Topic: Rigorous counterfeit medicine management

GRI 417 : Marketing and Labeling 2016

GRI 417 Management Approach

- Drug manufacturers and related organizations have the responsibility to provide accurate information on their medicines to safeguard consumers and prevent the misuse of medicines. Otherwise, the health and safety of users could be negatively impacted. This may give rise to economic losses pursuant to applicable regulations.
- Our products are prescription drugs, and product advertising towards the general public is prohibited in principle in conformity with applicable laws and regulations. Since our foundation, no sanctions have been imposed for non-compliance with marketing-related laws.

417-1 Requirements for product and service information and labeling

Information disclosed through drug labeling

Active ingredients	The main component that brings about the effect of the drug	Efficacy and effects	Symptoms the drug treats
Usage and dose	Dose, dose frequency, maximum daily dose, etc.	Precautions	Prior warnings, safety information, side effects
Auxiliary ingredients	Substances added for non-medicinal reasons (preservatives, etc.)	Additional information	Storage and disposal methods, where to consult in case of side effects, etc.

- In relation to off-label use (using drugs for purposes other than the approved indications), we prohibit such practices and provide all our employees with regular training in this regard.

417-2 Incidents of non-compliance concerning product and service information and labeling

417-3 Incidents of non-compliance concerning marketing communications

Non-compliance with laws/regulations related to marketing and labeling		Unit	2020	2021	2022
Product/service information and labeling	Number of cases where penalties were imposed for non-compliance	Cases	0	0	0
	Number of cases that warnings were issued for non-compliance		0	0	0
	Number of cases where internal regulations were violated		0	0	0
Marketing communication	Number of cases where penalties were imposed for non-compliance		0	0	0
	Number of cases that warnings were issued for non-compliance		0	0	0
	Number of cases where internal regulations were violated		0	0	0

GRI 418: Customer Privacy 2016

GRI 418 Management Approach

- Given the distinctive nature of the biopharmaceutical development industry, we handle a range of personal data for clinical trial subjects, patients, and healthcare professionals. This means that any leak of personal data due to substandard information security management may result in negative impact including regulatory non-compliance and damage to those affected.
- We engage in wide-ranging information security activities to safeguard our key information assets including intellectual properties, product information and personal data collected from stakeholders along the entire value chain.

Information security organization

Roles

Security planning	IT security	Physical security
· Establish/amend information security policies · Offer security training to employees and on-site suppliers	· Block external intrusions and internal information leakage · Review and improve internal system and network risk	· Establish/amend/operate internal physical security policies · Operate access control system


Training about inspection procedure and methods

Promotion of security activities through PC screen

Training program for on-site suppliers

Information security activities		Description
Prevent security breaches and establish a response system	Establish a 24/7 security control system	· Establish the security control system to respond to physical intrusion and attempt to steal information
	Prevent security incidents	· Establish systems to detect and respond to malicious codes and attacks early on · Review and improve our website for vulnerabilities each month · Regular security training: Malicious email simulation training (monthly), physical security simulation training (quarterly), DDoS response simulation training (half-yearly) and others
Improve the reliability of our information security system	Operate and reinforce our global information security management system	· Continue with improvement and investment in security planning/IT/physical security · Plan to obtain ISO 27001 and align security management systems among overseas subsidiaries in 2023
Embed information security into our day-to-day operations	Strengthen internal regulations and handling policies	· Establish and amend information security regulations and personal data handling guidelines (annually)
	Disseminate a culture of information security	· Security Inspection Day (monthly): Conducting internal security inspections along with security officers and employees who violated security regulations · Security newsletter (monthly): Publish newsletters sharing external security threats, security incidents and others to raise security awareness among employees · Information security campaign: Publicity activities using PC screen protectors/elevators, and reinforce security operations for specified periods (year-end holidays, vacations)
	Provide information security training	· Regular security training (annually): Employees and on-site suppliers · Training on information security tailored for new hires and administrative staff

418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data

Non-compliance with data privacy laws and action taken	Unit	2020	2021	2022
No. of incidences of non-compliance	Cases	0	0	0
Penalties imposed for non-compliance	million KRW	0	0	0

TCFD Framework

Area	Recommended disclosures	Progress made by Samsung Bioepis
Governance	a) Describe the board's oversight of climate-related risks and opportunities	· Key issues of climate change, such as transition risk and climate-related physical risk, are reported to the management, and our CEO oversees Samsung Bioepis' overall response to climate change. · Our CEO is mandated to take responsibility and authority for addressing such key issues as developing a climate change response strategy, identifying implementation tasks, and making investments. The ESG Office reports to the management on our ESG implementation plans and progress made. The Environment Safety Health (ESH) department monitors environmental management issues, including climate change, in the workplace at environmental safety meetings and consults on major issues.
	b) Describe management's role in assessing and managing climate-related risks and opportunities	
Strategy	a) Describe the climate-related risks and opportunities the organization has identified over the short, medium, and long term	· Samsung Bioepis classifies risk factors into transition risk and physical risk to identify the financial impact of climate change risks and opportunities on our business. - Transition risks: Increasing costs to meet tightening environmental regulations such as the Net Zero and circular economy initiatives and EU's tender regulations. - Physical risks: Increasing risk of suspending facility operation due to natural hazards such as floods and sea level rises, climate change and the resulting heat waves and/or new infectious diseases that could undermine our productivity and raise operational costs. - Opportunities: Expansion into new markets through preemptively responding to tender requirements for environmental sustainability. · As global climate change disclosure regulations continue to tighten, this could impose net zero obligations on our business and incur increasing investment and offset costs over the long haul, although we are not currently subject to any GHG emissions trading scheme. The increasingly tighter requirements under the tender program to manage and reduce GHG emissions may also bring direct impact on our financial performance if we fail to properly address climate change issues.
	b) Describe the impact of climate-related risks and opportunities on the organization's businesses, strategy, and financial planning	
	c) Describe the resilience of the organization's strategy, taking into consideration different climate-related scenarios, including a 2°C or lower scenario	
Risk Management	a) Describe the organization's processes for identifying and assessing climate-related risks	· We conduct environmental impact assessments with relevant departments with the ESH department leading to assess climate-related risks concerning business operations, product planning, and external trends. We also manage our operational GHG emissions and receive third-party assurance to review the credibility and consistency of our emissions data.
	b) Describe the organization's processes for managing climate-related risks	· We introduced environmental management (ISO 14001) and energy management (ISO 50001) systems. · The ESH department monitors our energy consumption, GHG emissions and climate change impact while the ESG Office regularly consults with the parent company, Samsung Biologics, to manage climate change-related risks.
	c) Describe how processes for identifying, assessing, and managing climate-related risks are integrated into the organization's overall risk management	· Climate change-related regulations have effect on our business performance and reputation. We manage non-financial risks including climate change risks.
Metrics and Targets	a) Disclose the metrics used by the organization to assess climate-related risks and opportunities in line with its strategy and risk management process	· To assess and manage climate-related risks and opportunities, we monitor such metrics as energy consumption, reduction in energy consumption, GHG emissions generation, and energy intensity in terms of business operations.
	b) Disclose Scope 1, Scope 2 and, if appropriate, Scope 3 greenhouse gas (GHG) emissions and the related risks	· Total energy consumption: 132TJ · Scope 1 GHG emissions: 1,139tCO_2eq, Scope 2 GHG emissions: 4,947tCO_2eq
	c) Describe the targets used by the organization to manage climate-related risks and opportunities and performance against targets	· We work with Samsung Biologics in achieving the RE100 and the Net Zero initiative by 2050. · We installed 200kW photovoltaic power generators on the rooftop spaces. · We attained our goal of reducing energy consumption and waste generation by 3% from the 2021 base year, and mitigated GHG emissions by 11% over the same period.

APPENDIX

Financial Performance

Consolidated Statements of Financial Position

(in millions KRW)

Category	2020	2021	2022
Assets			
I. Current assets	1,582,668	1,718,448	1,632,058
Cash and cash equivalents	97,727	107,681	123,727
Trade and other current receivables	186,941	247,397	289,093
Prepaid income tax	12,480	8,214	8,863
Inventories	1,216,521	1,289,939	1,163,558
Other current assets	68,999	64,878	40,442
Other current financial assets	0	339	6,375
II. Non-current assets	1,035,335	1,065,523	1,202,565
Non-current financial assets	3,385	4,588	1,954
Other non-current receivables	5,506	8,817	6,137
Property, plant and equipment	219,963	224,136	224,174
Intangible assets	592,034	630,620	718,597
Right-of-use assets	1,262	933	974
Deferred tax assets	199,304	191,210	247,909
Other non-current assets	13,881	1,974	1,799
Other non-current financial assets	0	3,245	0
Employee benefits	0	0	1,021
Total assets	**2,618,003**	**2,783,971**	**2,834,623**
Liabilities			
I. Current liabilities	1,277,931	1,498,458	1,295,986
Trade and other payables	290,971	231,015	184,147
Short-term borrowings	566,850	464,450	532,783
Current portion of long-term borrowings	0	344,000	88,019
Unearned revenues	409,891	440,532	442,940
Current lease liabilities	784	410	476
Current tax liabilities	6,839	14,511	44,845
Withholdings	2,596	3,540	2,776
II. Non-current liabilities	537,461	329,605	362,541
Long-term borrowings	390,140	185,565	220,000
Non-current lease liabilities	381	329	129
Other non-current payables	5,798	3,798	8,713
Non-current unearned revenues	129,444	133,699	133,699
Employee benefits	10,475	6,214	0
Other non-current financial liabilities	1,223	0	0
Total liabilities	**1,815,392**	**1,828,063**	**1,658,527**

Category	2020	2021	2022
Equity			
I. Equity attributable to owners of the company	802,611	955,908	1,176,096
Share capital	103,419	103,419	103,419
Share premium	930,267	930,267	930,267
Accumulated other comprehensive loss	-7,603	-6,298	-4,533
Retained Earnings (Accumulated deficit)	-223,472	-71,480	146,943
II. Non-controlling interests	0	0	0
Total equity	**802,611**	**955,908**	**1,176,096**
Total liabilities and equity	**2,618,003**	**2,783,971**	**2,834,623**

Consolidated Statement of Comprehensive Income

Category	2020	2021	2022
I. Revenue	777,374	846,977	946,340
II. Cost of revenue	281,870	332,250	365,634
III. Gross profit	495,504	514,727	580,706
IV. Selling, general and administrative expenses	350,457	321,989	349,170
V. Operating profit (loss)	145,047	192,738	231,536
VI. Non-operating profit (loss)	-2,880	-18,168	-18,794
Other non-operating income	1,104	2,039	733
Other non-operating expenses	-142	-162	-213
Finance income	87,380	49,057	110,939
Finance costs	-91,222	-69,102	-130,253
VII. Profit before income tax	142,167	174,570	212,742
VIII. Income tax expense (profit)	4,204	22,578	-5,681
IX. Profit for the year	137,963	151,992	218,423
X. Other comprehensive income (loss)	-1,235	1,305	1,765
Items that will never be reclassified to profit or loss:			
Defined benefit plan remeasurement	-1,162	1,248	1,552
Items that are or may be reclassified to profit or loss:			
Foreign currency translation differences for foreign perations	-73	57	213
XI. Total comprehensive income for the year	136,728	153,297	220,188

Independent Assurance Statement

To readers of SAMSUNG BIOEPIS Sustainability Report 2023

Introduction

Korea Management Registrar (KMR) was commissioned by SAMSUNG BIOEPIS to conduct an independent assurance of its Sustainability Report 2023(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
- · Universal standards
- · Topic specific standards
  - GRI 308: Supplier Environmental Assessment
  - GRI 404: Training and Education
  - 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 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.

Independent 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 2021. 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.

June 2023 Seoul, Korea

CEO E. J Hwang

KMR SRV1000 Sustainability Committee Assurance AA1000 Licensed Report 000-129/V3-9G2E6

Greenhouse Gas Validation Report

The Korea Management Registrar Inc. (hereinafter "KMR") has conducted the verification on the greenhouse gas (hereinafter "GHG") emission (Scope 1,2) of Samsung Bioepis Co., Ltd. (hereinafter "the Company") from 2020 to 2022.

SCOPE

Verification of the place of business and emission facilities under the control of the Company.

STANDARD

- ISO 14064-1:2006, ISO 14064-3:2006
- IPCC Guidelines for National Greenhouse Gas Inventories (2006)
- Guidelines for Reporting and Certification of Emissions in the Greenhouse Gas Emissions Trading Scheme

LIMITATION

The verification has inherent limitations that may arise in the process of applying standards and methods.

RESULT

- GHG verification has been performed to meet the limited assurance level according to the verification standards.
- We express that no significant errors were found in the calculation of emissions during the verification process, and that relevant activity data and evidence were appropriately managed and calculated. As a result, we express an "qualified" opinion.

GHGs Emission	Direct emission (Scope1)	Indirect emission (Scope2)	Total (tCO_2-eq)
2022	1,139.697	4,947.807	6,087
2021	1,635.431	5,215.878	6,851
2020	1,433.412	5,296.110	6,729

Energy Consumption	Fuel	Electricity	Steam	Total (TJ)
2022	21.444	94.087	16.959	132
2021	31.272	98.175	18.978	148
2020	27.136	109.566	1.044	137

※ Total emissions are summed by company after cutting the decimal point at the workplace.

June 12th, 2023 Seoul, Korea

CEO E. J Hwang

KMR KMR ISO 14064-1

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BIOEPIS