

Sustainability

Report

BioSystems

2023

Index

3	BioSystems in 2023
10	A sustainable purpose
20	Biotechnological analytical solutions
28	Innovation and quality throughout the value chain
56	Positive impact on people
70	Responsible environmental performance
79	Sustainable governance and transparency
87	Conclusions and future commitments

BioSystems

BioSystems in 2023

Sustainability Report 2023

Our 10 highlights for 2023

01

776 people around the world.

02

Present in over 100 markets through distributors.

03

19 proprietary sites in 18 countries.

04

2 production plants: Spain and India.

05

Consolidated sales of 79,6M €.

06

Compound annual growth rate (CAGR) for the last 5 years (2019-2023): 6,2 %.

07

BioSystems Biotech Spain. Creation of a new BioSystems subsidiary in Spain to provide a better service to customers in the Spanish market and strengthen our commitment to business development in the areas where we operate. Operational as of January 2024.

08

BioSystems BDPL India celebrates 20 years. This event reunited all people of the company at our headquarters and production site in India, along with BioSystems' management team, members of the board of directors and over 40 distributors via whom we develop our business and support and serve our customers across the continent.

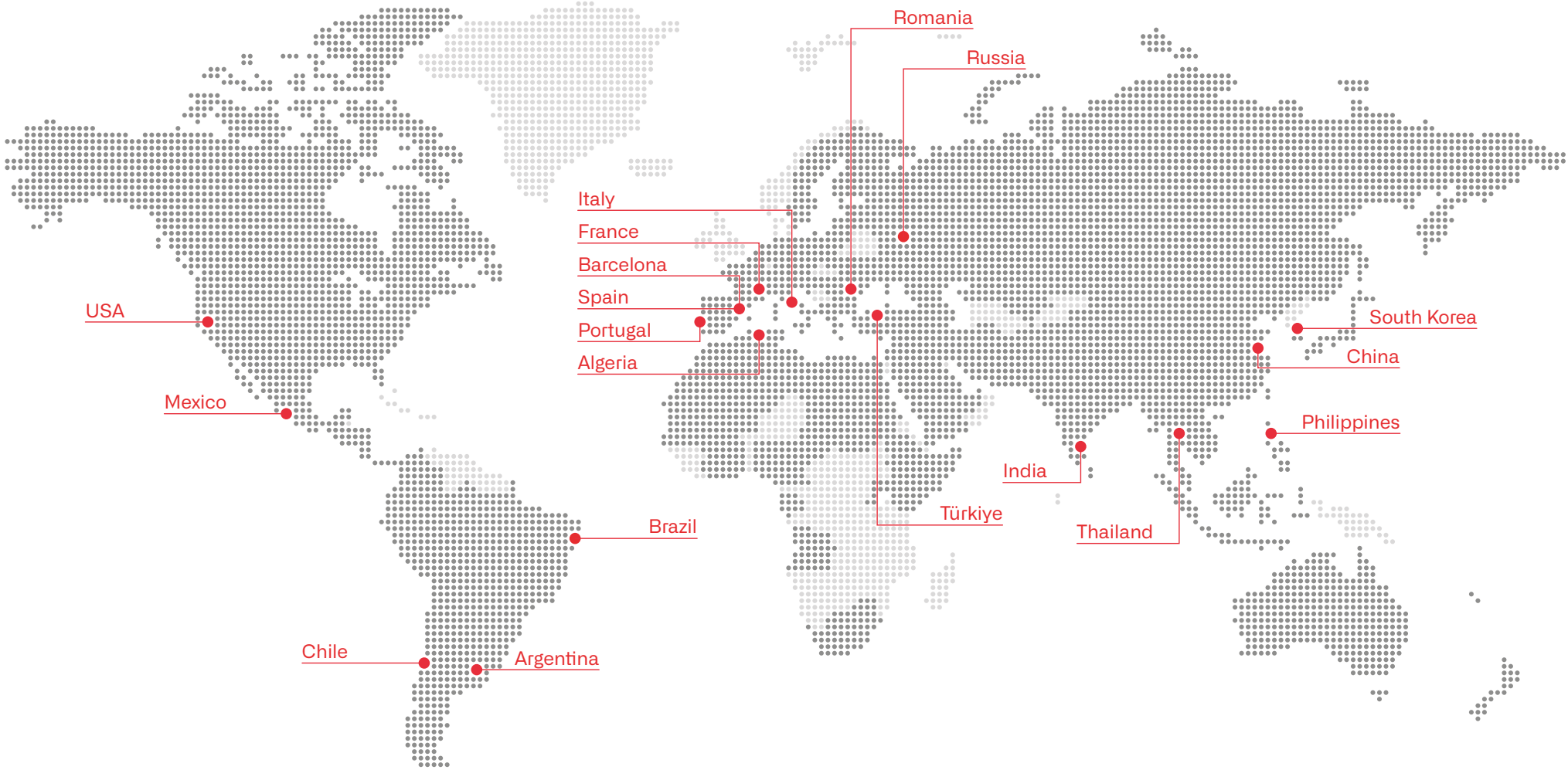
09

Improvements to the BTS. Improvements in performance, robustness and functionality in BioSystems' most historic and well-known product, the semi-automatic BTS analyser, heir to the previous BTR photometers, which follows the success of the BTS350, the first photometer on the market with LED technology.

10

Development of new business management software and implementation of SAP S4 Hana. An intense year of preparing all internal processes to carry out the migration, scheduled for October 2024. A project that will allow us to be more efficient, competitive, plan better and prepare for the future.

Where to find us



Letter from the CEO

Over the past year, the challenging geopolitical context was one of our biggest external obstacles. In the second half of the year, we were able to navigate Algeria's blockade of Spanish-made products by selling them from our Indian company. This allowed our many Algerian customers to keep using our products and solutions. In less positive news, we weren't able to resume the sale of instruments to Russian companies. The sale of these products has been banned since 2022, with the country subject to a blockade as a result of its invasion of Ukraine. As things stand, we are only permitted to sell reagents to Russian companies.

However, thanks to the contribution of many other countries, particularly those in which we operate, our total sales (€79.6M) were 1% higher than our 2022 figures (€78.9M), 6% higher than our 2021 figures (€75.2M). We are satisfied and proud of these figures, despite the fact that the rate of growth is lower than what we would expect under normal circumstances, because they were only possible thanks to the hard work of our teams, particularly those in the business, customer and operations areas.

During this time, many colleagues from all areas of the company (and the entire group of companies) were working tirelessly on product and process improvement projects. I would like to take a moment to highlight some of the projects –all of which were very interesting, complex and necessary– that best encapsulate our activity.

Perhaps because of its importance, magnitude, complexity and the involvement of so many people from so many different areas, I would highlight the preparation work for the implementation of the new **ERP** system (SAP4Hana) due to be implemented in Barcelona as well as in Spain, France and Italy.

This global management tool will help us to be more efficient and effective in all of our processes, ranging from purchasing to production and from sales to shipping. In the coming years, the tool will be implemented in all the countries in which we have headquarters, helping us to improve the service we provide to our customers around the world. It will also give us valuable, real-time information that will help us make quicker decisions to achieve our objectives. This implementation entailed reviewing, re-thinking, redefining and changing all of BioSystems' existing processes, with a clear focus on modernising and streamlining all information.

We hope that the implementation of the new SAP ERP in October 2024 will make it easier for us to bring our products to customers around the world and grow more sustainably as a group.

Another project that I would like to highlight is **BTS**. This photometer was first launched in India in 2020, followed by the rest of the world in 2021. In the last 2 years, however, we have increased the product's robustness and quality and improved its electronics, fluidics, mechanics and user software.

This instrument, while not linked to the large sale of reagents, gives us great excitement. Not only does it remind us of our humble beginnings, but it is also aimed at our humble customers who are trying to run their diagnostic businesses with small numbers of daily samples in order to help people in need. If these customers' companies do well, they are more likely to deal with us in the future when they need an automatic analyser that allows them to process higher quantities of daily samples. For example, they may start with the A15 and later move on to the larger BAs.

We know that more than half of our BA customers began 15, 20 or even 30 years ago with the photometers of the time (the BTS-310, the BTS-320, the BTS-330, and later the BTS-350). We want to continue along these lines, supporting and helping smaller companies to grow and accompanying them in the process.

In 2023, we took the decision to start manufacturing the BTS in Barcelona, as we felt this would allow us to implement the improvements in a standardised way. If we were to continue manufacturing the BTS in both India and Barcelona simultaneously, this would have been more difficult to manage.

Despite the change in the production model of the BTS, and precisely because some of the BTS were manufactured in India for some time, the **Indian production plant** is increasingly able to produce all types of instruments. It currently produces the BAs that we send to Algeria and has also started to manufacture some tabletop instruments that are marketed in India under another BioSystems brand, Concepta, which we had stopped using a few years ago but have now brought back.

I would also like to highlight another product development project: the **autoimmunity** platform. This platform includes a processor for preparing samples on glass slides, the **iPRO**; and a new automated microscope called **MIRA**, which can take photos of up to 16 slides

at a time and store them for future consultation in the platform's information management software, **ARA**. We will soon launch an application for this software that will allow marking patterns to be analysed with AI, to allow laboratory technicians and doctors to take better decisions for those being diagnosed.

This platform uses our glass slides for indirect immunofluorescence. It mainly uses HEp-2 cells to detect anti-nuclear antibodies (ANA) in human sera and *Crithidia* cells to detect anti-DNA antibodies. This helps it to identify autoimmune diseases such as lupus or antineutrophil cytoplasmic antibodies (ANCA), with human neutrophils as a substrate, when diagnosing vasculitis. Slides containing the tissues of animals, ranging from monkeys to rats and mice, allow for the diagnosis of diseases such as coeliac disease, rheumatism, hepatitis, cirrhosis and dermatosis. This product line is continually improving, both in terms of product quality and features in R&D&I and through the modernisation and expansion of the production facilities. After more than 40 years cultivating cells and cutting tissues, we are still able to improve these delicate, sensitive and much-appreciated products. We do all of this to meet the expectations of our customers, ranging from large hospitals and automated laboratories with high expectations of quality and continuous improvement to industrial customers who recognise the outstanding quality of our products in this exclusive market.

This autoimmunity project encapsulates the modern way of developing products that began in 2019 with the proposal of the 3 strategic axes: (1) developing quality products with a focus on the customer and their user experience; (2) working on projects with multidisciplinary teams involving engineers and scientists from the areas of R&D&I, business, customer, operations, quality and finance as a means of ensuring innovation and agility; and (3) global participation. Also, it meets the needs and expectations of users in both the fields of human health (autoimmune disease diagnosis) and the animal health (infectious disease diagnosis in pets), which makes it a global health project. I would like to highlight the contribution of our colleagues from Spain, Turkey, Chile, Argentina and China on this project. I am sure that 2024 will be the year of autoimmunity (AI) and immunofluorescence (IFA).

I could go on and on about our improvement and new product development projects, but the report goes into these in greater detail. I strongly suggest that you read it.

In 2023, we worked tirelessly to set up **BioSystems biotech Spain** with a view to starting operations in January 2024. This new company is, in a way, the original of everyone and everything. In 2016, BioSystems absorbed a distribution company called Àtom, which started BioSystems as we know it in 1981. Since then, however, its commercial activity in Spain did not have its own structure.

We are confident that we'll be able to provide this new company with the resources and tools it needs in order to grow in the fields of human, animal and food health: areas in which we have a proven track record and are regarded as a trusted partner for many laboratories and companies. Our customers range from small family-run laboratories to regional public laboratories, laboratories that form part of multinational corporations and public hospital laboratories nationwide. Other customers include wineries, the majority of which are medium and large in size; large food companies, mainly in the fish sector; and large veterinary laboratories which treat pets and livestock.

Finally, I would like to highlight the contribution of **our teams in different countries**, many of whom are celebrating their 10th or 20th anniversary this year and who, after so much hard work, are now making a significant contribution to BioSystems' overall performance. BioSystems is what it is today thanks to the efforts of each and every person in its 19 different companies and the trust of the more than 100 commercial distributors and their professionals who now view BioSystems as their own.

We aren't only happy about their contribution in terms of sales and performance. Rather, we're also delighted with their contribution to the global project. One such example is the new validation laboratory in South Korea, where we evaluate our tests under laboratory conditions in order to validate the products we develop before they are launched on the market. This allows us to provide analytical systems with greater assurance and safety for patients who are diagnosed with a disease or monitored for treatment whose lives, in some cases, may depend on an accurate analysis.



I would also like to highlight the contribution of other countries, which are bearing fruit in new market niches, in new sectors, and serving new customers or introducing new products that complement our own, and which we can then –if we so decide– internationalise to help other companies to be more attractive or more competitive.

And, above all, we are pleased with the contribution of each and every one of our people to strengthen the pillar of sustainability through environmental, human impact and management actions, and to reinforce our culture –that of all of us– and to make this one of the differential traits and main competitive advantages of our brand.

My sincere acknowledgement and gratitude to all the people from all the companies, including Barcelona as one of the 19, who every day make this project more solid and more recognised for all this and for everything we have done over the course of 42 years of history. We trust in all of you to overcome, once again, all the challenges of 2024 and to continue building this promising future that we are about to embark on.

Pau Vila Cases
CEO

A sustainable purpose

Purpose and legacy

BioSystems is a family company, founded in 1981 in Barcelona by Dr. Josep Bach. Today, Marc Bach, the next generation, leads the business project, which continues in the same spirit of building long-term relationships with customers, partners and suppliers through conversation, debate and active listening. A spirit that encourages the free flow of ideas without fear of making mistakes, because mistakes are understood as valuable learning opportunities.

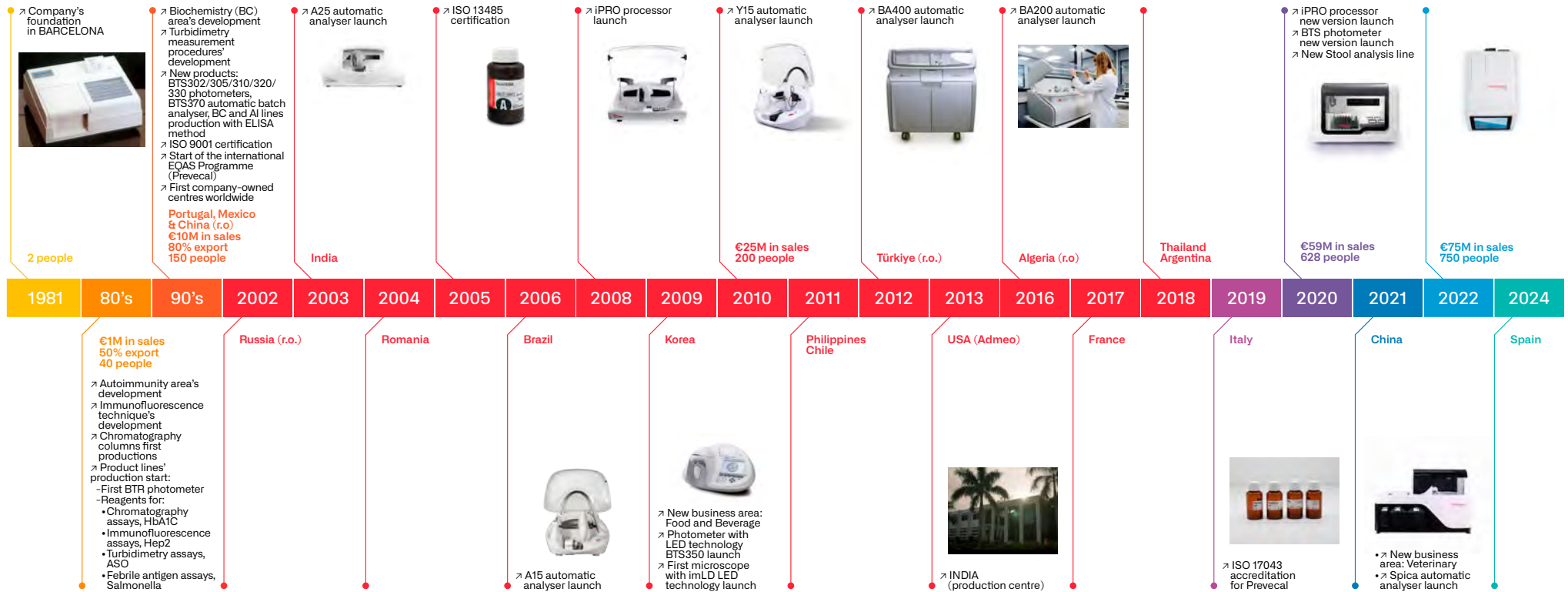
Our purpose is to contribute to improving the health and well-being of people, animals and all living things on our planet. This is made possible by a great team that works to design, develop, manufacture and market biotechnological analytical solutions, devising both the tests (reagents to perform the analyses) and the analysing instruments for *in vitro* diagnostic (IVD) laboratories as well as for industrial purposes. BioSystems also offers continuous service and support to the users of the products.

We work to ensure that our solutions are accurate, reliable and robust so that the users of our products can perform their work satisfactorily and also make the best decisions. All of this focuses on providing a key tool for doctors and veterinarians, to ensure that they can issue proper diagnoses and work on prevention. It focuses also on being a key partner for the food and environmental industry, aiding health and safety checks. In addition, we also have our own solutions for the analysis of bioprocesses such as fermentation and cell culture.

Our motto is "**human-centred biotech**", because people are at the heart of our business model and company philosophy. We focus on the needs of the people who use our products, on caring for the well-being of those who are part of BioSystems, and on always remembering that our activity has global health as its ultimate goal.

Our purpose is to help improve health and well-being through biotechnological analytical solutions.

Historical timeline



Diabetes

BioSystems was founded in the 1980s with the aim of creating diagnostic tests for diabetes, thereby aiding better diagnosis and treatment monitoring.

For this purpose, we developed the chromatography column for measuring glycated haemoglobin (HbA1).

Without any competition in Spain or Europe, we started to export this self-developed system worldwide.

In the following years, we evolved with other technologies and created semi-automatic and automatic diagnostic systems.

LED

In 2007 we pioneered the integration of LED lamps into analysers for *in vitro* diagnostics, enabling users to consistently obtain reliable results and reduce maintenance costs.

India

In 2008 we designed and built a reagent factory in India under European quality standards (ISO13485), inspired by local good manufacturing practices for sanitary products and ancient temple building practices in India Vastu Vasta.

In 2012 we started commercial production in one of the country's most modern plants in the sector. Here, we have implemented a zero-waste and water reuse policy. We have become one of the main benchmarks for laboratories in India.

In 2019 we started production of instruments for the smaller *in vitro* diagnostics laboratory segment, with a semi-automatic photometer designed in collaboration with local customers and professionals.

Our experience in India is a reflection of our way of working, based on an honest observation of the market and the needs of the local sector, as well as an absolute respect for the people, the professionals and the culture of each country.



Primary packaging. Chennai centre, India

Business strategy

Coinciding with the generational change of the owner family, headed by Marc Bach, there was a change of management. Since 2019, Pau Vila Cases has been the Director-General of BioSystems and, with his management team and Marc Bach as a Director of the group, has been outlining the company's business strategy.



Pau Vila Cases and Marc Bach.



Management team: Xus Jara (Chief People Officer), Pau Vila Cases (Chief Executive Officer), Rafel Ferragut (Chief Operations Officer), Alberto Rodríguez (Chief Financial Officer), Petraki Munujos (Chief Research Officer), Teresa Cortès (Chief Quality Officer), Joaquín González (Chief Business Officer) and Silvia Rosell (Chief Customer Officer).

We now have a strategy with a long-term vision for 2019-2030. This is developed through strategic pillars, which we review annually, and which are translated into concrete actions:

Transformation

2019–2022

- Period marked by a review of the company's purpose (Mission & Vision)
- A focus on product development and innovation alongside the customer is at the heart of our decisions
- Changes in the organisational structure
- Organisational renewal and change
- Cultural Transformation
- Transition to the new IVD product regulation
- Evolution of the brand image
- Focus on being a global company.

Consolidation

2023–2026

- A period marked by strategic investments in business development and new group companies
- Product launches
- Renovation and extension of infrastructures in all areas and at the headquarters of several group companies
- Expansion of new market niches, sectors and segments in the 4 Global Health domains
- Implementation of the new ERP
- Personal and professional development of the people in the group with a focus on company values and responsible leadership
- Focus on the Sustainability pillar (ESG) and reinforcement of our aim to improve "Global Health".

Acceleration

2027–2030

- We will respond to all the opportunities generated and created based on the partnerships initiated, and on the new products developed
- Strengthen strategic alliances with IVD and other healthcare companies around the world to penetrate new market niches, new segments, new customers, new sectors and new companies
- New production plants all over the world
- The Globality axis is converging with that of Sustainability
- This stage should prepare the group for the next stage, restarting the cycle of continuous TCA evolution.

Strategic pillars 2023

In 2023, we are guided by 3 strategic pillars, compared to the 4 we had defined in 2022: Pq+UX (Product Quality and User Experience); R+D²+I (Research, Design and Development and Innovation); Globality and Sustainability.

The **3 strategic pillars** that set our course for the year 2023 are detailed in our Quality Policy, a document that describes the essence of the company and an overview of our raison d'être. Those router models are:

- ↗ R+D²+i/a+Q+UX
- ↗ Global presence
- ↗ Sustainability

R+D²+i/a+Q+UX

To focus our activity on our own research, design and development, with a clear goal of innovation and agility with the aim of providing a satisfactory user experience through our quality products and services.

Our contribution:

- Design of a complete system
- To have control of the entire value chain: sourcing of raw materials and development of our own when they are not available on the market, design, production and distribution.
- Conversation with the client as a basis for design
- Have a proper, specialised team to meet the needs of the clients
- Aim to exceed customer expectations
- Have a team with a wide variety of professional profiles

Global presence

Fostering nodal communication of all BioSystems people with all stakeholders, and exploring collaboration and synergy between all of them.

Our contribution:

- Continuing to grow and strengthen relationships with our partners
- Strengthening our international presence
- Working globally as one team, leveraging local talent
- Providing a good technical support service anywhere in the world

Sustainability

To create value for present and future generations through ethical, transparent and responsible management; promoting personal and professional growth, as well as the well-being of people and our stakeholders, and acting with respect, care and as an agent of environmental regeneration.

Our contribution:

- Promoting trust and teamwork
- Promoting personal and professional growth
- Looking after people's welfare:
 - Improving spaces
 - Flexible working hours, blank calendar, work-life balance
 - Accompaniment of individuals and teams
- Communication and transparency
- Willingness to reinvest profits in the sustainability of the business
- Having clear policies to reach out to all stakeholders
- Staying up to date with all current and future regulations in the sectors and countries in which we operate, especially IVD.
- Embracing diversity
- Basing relationships with all stakeholders on conversation
- Developing more sustainable products.
- Minimising our environmental impact.

To ensure that these strategic pillars are taken on board and represent a real path to building the future, we created teams alongside the entire BioSystems community in 2023, looking to nurture these pillars and create joint actions for their growth and evolution.



Quality Control team. BioSystems Spain.

Sustainable value generation

At BioSystems, we take a balanced approach to the way we integrate the development of people and the surrounding community, environmental protection, economic development and good business practices in all our activities, meeting the needs of the present without compromising those of future generations.

In this way, we work on sustainability in order to:

- Become aware of and improve our impact
- Make conscious decisions
- Extend sustainability throughout the value chain

We do this by focusing on 3 axes: Business management, environment and facilities, and people and community.

We also support the principles of the United Nations Global Compact and are committed to the **Sustainable Development Goals** (SDGs). The SDGs are a common framework for action to end poverty, protect the planet and improve the lives of people around the world. That common framework is composed of 17 goals adopted in 2015 by the Member States of the United Nations. As we are aware of the importance of each and every one of them, we wanted to focus our efforts on those where we can have the greatest impact:



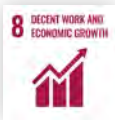
SDG Contribution



We work to improve health and well-being by focusing on prevention. Our solutions enable experts in the human clinical, veterinary and food fields to perform analyses on samples to characterise the condition of people, animals or foodstuffs. Improving health and well-being is therefore at the heart of our activities.



All the energy used in Spain comes from renewable energy sources. Part of this is also self-generated through photovoltaic panels.



We work to ensure that the more than 776 people in 18 countries who are part of the BioSystems project enjoy decent health and safety and working conditions. In addition, we have a strong commitment to diversity and respect for human rights.



We design and develop our own analytical solutions. Each year, we reinvest part of our profits to bring to market, in a dynamic manner, innovative solutions valued by our customers. 90% of our sales come from products designed and produced in Barcelona.

SDG Contribution



We firmly believe that development and growth must be accompanied by measures that favour responsible resource management and consumption. At BioSystems, we work to optimise water use, energy consumption and waste generation. Therefore, we design products for a long service life and have implemented water treatment and circularisation systems.



Our Code of Conduct, available on our website, sets out a clear commitment to legality in all the countries where we operate. We also have communication channels that allow us to become aware of any irregular situations.



Partnership building and awareness raising are key to realising these goals. We actively participate in various industry clusters and strive to communicate our progress and commitments to sustainability to all stakeholders.

Biotechnological analytical solutions

Biotechnology and *in vitro* diagnostics

Biotechnology is the discipline resulting from the fusion of life and biological sciences and engineering, which uses living organisms, or parts thereof, and combines cellular and molecular processes with various technologies to create or improve products and technologies. All of this aims to improve both our health and our quality of life, as well as that of all living beings on the planet.

Biotechnology has various applications:

Red	Bio-health applications, the ultimate aim of which is to improve or cure diseases. Examples: gene therapy, vaccines, cell therapy, nanotechnology, regenerative medicine, etc.	Grey and brown	Applications focused on ecosystems and environmental sciences. Examples: decontamination of soils, industrial gases, removal of heavy metals, etc. as well as in the treatment and use of arid and desert soils using species that are highly resistant to saline and dry soils.
Green and yellow	Applications in the agricultural sector. Examples: transgenic plants, antioxidants, horticulture (cultivation techniques), transgenic yeasts and bacteria used in wine and beer fermentation, etc.	Golden	Applications in bioinformatics developments, peptide sequencing, DNA alteration detection, etc.
Blue	Applied in rivers, seas and oceans. Examples: generation of micro-organisms to decontaminate water, development of food supplements, cosmetics, etc.	Purple	Applications in legal and ethical aspects. Examples: security measures for the protection of patient data, patents, bioethics in issues such as assisted reproduction, cloning, etc.
White	Applications in the industrial sector. Examples: biofuels, the use of enzymes to reduce the formation of toxic substances during paper production, etc.	Orange	Applications in education and outreach.

In vitro diagnostics

In vitro diagnostic (IVD) tests are non-invasive tests used on biological samples and analysed in laboratories by professionals. They provide crucial information about the body's health and physiology, facilitating screening, prevention, early detection, diagnosis, monitoring and prediction of response to treatment. They are essential for doctors and veterinarians, and for ensuring food control. They also play a crucial role in research, contributing to the development of drugs, vaccines and treatments.



CATLAB. Terrassa, Spain.

Our activity

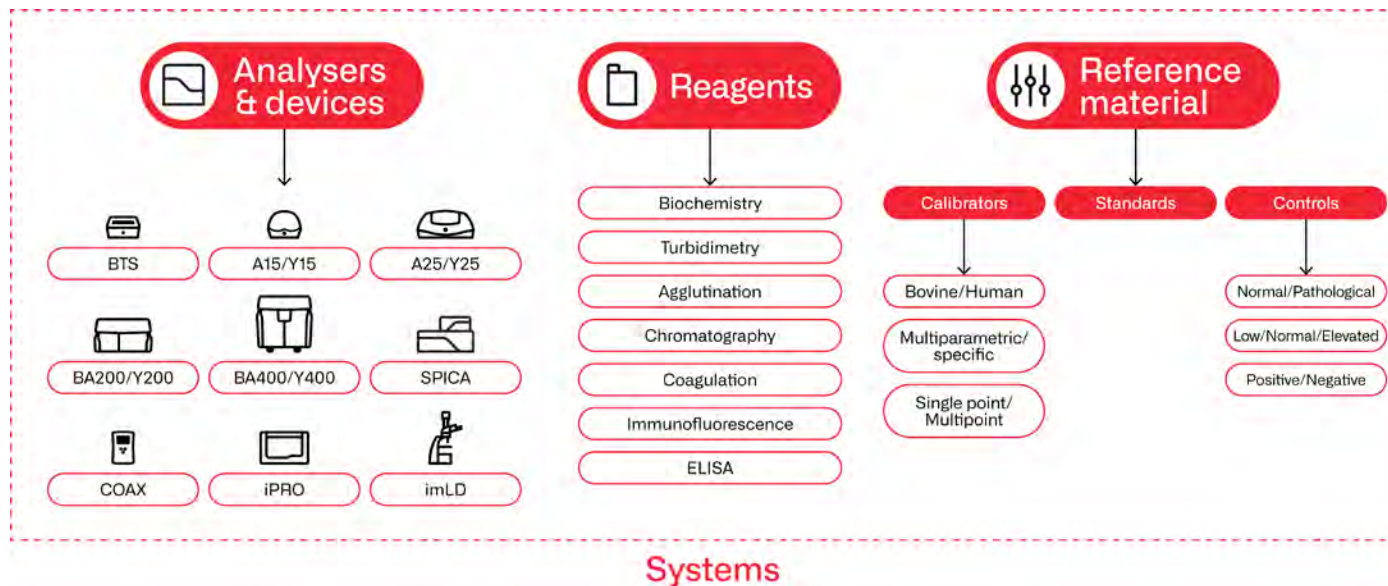
Our **analytical solutions** are –for the most part– designed, developed and produced by BioSystems within our two proprietary production facilities:

➤ We manufacture the following **instruments**: photometers, clinical analysers, industrial analysers and devices for preparing and processing samples for analysis.

➤ We manufacture the **reagents**: components that contain the active ingredients (enzymes, antigens, antibodies, etc.) that react –if at all– with certain specific analytes in the samples.

➤ We develop **reference materials**: they enable the calibration of analytical systems and the quantification of analytes in samples.

➤ We also designed the management systems for the handling of the analysers and the information generated, and communication with the corresponding laboratory management systems.



Analysers and devices

We manufacture both small (semi-automatic) analysers to analyse a few samples per day (1-10 patients), as is the case of the BTS, and automatic analysers with different capacities that can process up to 250 samples/day or even more, and analyse up to 400 biochemistry tests per hour, or 760 tests/hour if ions (sodium, potassium and chlorine) are included.

All of them are designed to work as systems with maximum performance and stability with our reagents, and to be robust solutions for the needs of all customers who rely on BioSystems.

Reagents

The reagents we design and manufacture contain raw materials of the highest purity and quality in their formulation. Some of the most critical components, such as monoclonal antibodies, antigens or enzymes, are produced directly at BioSystems from hybridoma cultures or from proprietary strains of microorganisms.

We produce liquid reagents, which we supply ready-to-use or lyophilised, and solid-phase reagents, with components immobilised in polystyrene microplates, glass microscope slides or latex nanoparticles.

Each batch of reagent produced is subjected to a rigorous functional quality control before being placed on the market. The reagents are produced and packaged in strictly controlled facilities under clean room conditions.

We supply reagents in different formats and volumes to suit our analysers in order to serve laboratories of different sizes and market segments.

Reference materials

We produce calibrators or guides –which make it possible to convert the signal produced by the analytical reaction into the concentration of the measured analyte– for each of the quantitative analytical tests in any of the Global Health fields. In addition, we provide known concentration controls for internal laboratory quality control.

Traceable standards and controls of reference materials are available for all clinical biochemistry and autoimmunity tests.

We have brochures, scientific articles, information and technical support for all our reagents. Sharing information is key to effective collaboration.

Our presence in the biotechnology field

Our solutions are at the service of *in vitro* diagnostics (IVD) for clinical analysis in humans, as well as clinical analysis in animals and also industrial analysis for food and beverages, as well as environmental analysis. We also have analytical solutions for bioprocess monitoring.

We understand health as a broad concept, i.e. we believe that there is a global health, better known under the Anglo-Saxon concept of **One Health**. For human health is closely linked to animal health, as well as to food and environmental health.

More than half of all communicable human diseases are zoonotic –i.e. transmitted to humans from animals– or were so originally, and up to 70% of emerging pathogens are of animal origin. The climate crisis is increasing and accelerating this pathway, with more and more diseases being transmitted from animals to humans and increasing emergence of diseases hitherto considered tropical in non-tropical regions.

Furthermore, the food we eat has a direct impact on the health of people and animals. The water we use, its availability (or rather, scarcity) and its quality, or that of the soil in which we grow our food and feed our animals, and with which we all live, also have a clear impact on health.

In terms of **human health**, we offer analytical solutions for:

- Clinical analysis of the most common biochemical parameters in diagnostic laboratories and special tests of less routine profiles.
- Tests for the diagnosis of autoimmune diseases
- Infectious diseases

In terms of **animal health**, we offer analytical solutions for biochemical profiles and infectious diseases involving:

- Pets
- Livestock
- Competition animals

In terms of **food health**, we offer analytical solutions for:

- Oenology: production and quality of wine and all types of fermented beverages
- Fish: freshness and/or shelf-life indices
- Allergens: presence in food
- Fruit and vegetable juices: concentrates and juices
- Cereals

In terms of **environmental health**, we have analytical solutions for analytes present in:

- Water
- Soils

We also have analytical solutions for **bioprocess monitoring** by controlling and tracking key metabolic parameters in bacterial, yeast and animal cell cultures.

Health is a broad and global concept. We work to add value around what we call One Health: we understand that there is a single global, interconnected health shared by all living beings and the planet on which we live.

Clinical analysis

➤ Human



➤ Animal



Industrial analysis

➤ Food & Beverage



➤ Environmental



➤ Bioprocess



Innovation and quality throughout the value chain

Full value chain

We work along the entire value chain. We like to start the process by listening to the lab technicians. These conversations often lead to an opportunity to meet a need or to improve their experience as users of our products with a new solution.

From there, we research the analytical needs of the industry, develop a solution at the highest level, produce and market it –either directly or through a large global network of distributors–. And, throughout the process and after the sale, we accompany the users of our solutions. We continue to listen and look at how we can help, improve and contribute to offer more robust solutions better adapted to users' expectations. To make your experience with BioSystems as good as possible.



Research and development

Vocation for in-house research and development

We seek to understand the client's expectations in order to co-design the best solution with them. For this purpose, we have a group of more than 100 professionals from different technical and academic disciplines, related to life sciences and engineering, such as biochemists, biotechnologists, biologists, chemical engineers, electronic engineers, mechanical engineers or software engineers, as well as professionals with business and economic backgrounds.

All these people work in interdisciplinary teams that also include professionals from the areas of business development, customer service and support, production engineering, quality, production and finance in order to understand, conceive, design, develop, verify and validate the best solution for the challenge at hand.

We also welcome university students on internships and offer industrial doctorates, as a way of providing society with a space in which to develop the necessary collaboration between teaching and research and biotechnology companies. With the same objective in mind, we organise and participate in courses in collaboration with various universities around the world.

Product development areas

Product design and development at BioSystems is organised around the **One Health** concept with the integrated approach of improving the health of people, animals and the environment and food quality, all of which are part of and interrelated in the same ecosystem. We work in a cross-cutting manner, taking advantage of knowledge from one field to apply it to another.

We organise product development teams in the following health fields and specialties or sectors:

- 1. Human health:** specialising in clinical biochemistry
- 2. Human health:** specialising in autoimmunity and haematology
- 3. Animal health:** specialising in biochemistry and infectious diseases
- 4. Food health:** oenology, allergens, fish, juices and cereal sectors
- 5. Environmental health:** water and soil for the agricultural sector

In each of these areas, we define design and product development projects, which in turn consist of different objectives to ensure the achievement of the complete analytical solution.

The projects are carried out in a collaborative R&D environment alongside universities and technology centres as sources of knowledge, other technology companies as generators of synergies; and government departments as additional sources of funding and optimisation of our taxation. Furthermore, in order to enrich and optimise the different phases of the design and development process, we build collaboration networks with customers who assist us in defining product requirements and the corresponding verifications, with benchmark laboratories to carry out design validations, and finally with expert consultants in the various fields of health in their different One Health domains.



Analytical systems

As a biotechnology-based company, we want to be able to measure any analyte present in any biological sample of any origin. We design complete solutions in the form of integrated **analytical systems** or tests, consisting of the following 4 elements:

1. **Reagents** related to the analyte(s) to be measured or detected
2. **Analysers** that allow us to quantify the presence of an analyte and automate the analytical test
3. **Reference materials:** standards, to calibrate the assay by translating the reaction signal into results; and controls, to monitor the quality of each analytical run
4. **Instructions for use**, either printed or programmed into the analyser.

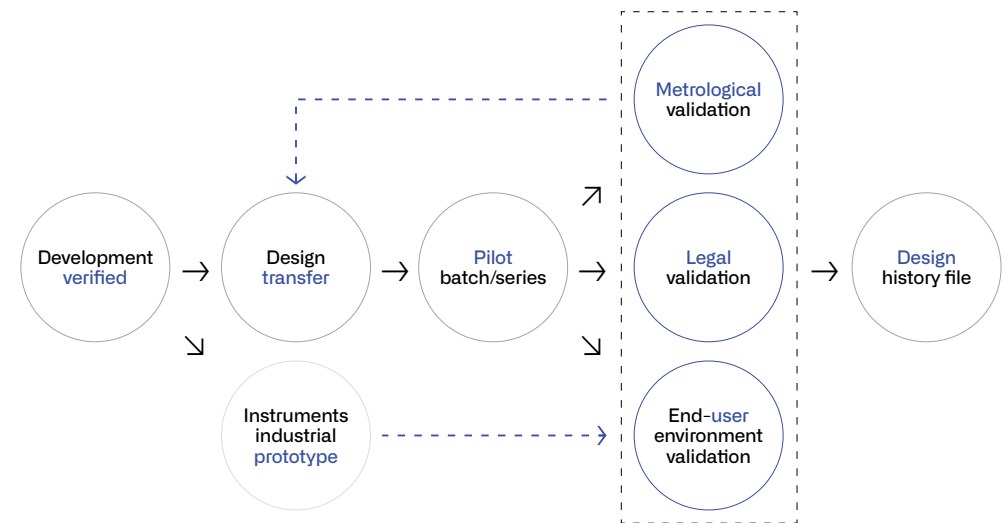
We design these four elements simultaneously to ensure that together, they deliver the best result. In addition, we generate and provide information related to test performance, such as certificates of analysis, metrological studies, information management tools or scientific-technical support documents for the laboratory.

4. When the development reaches a sufficient state of maturity and the requirements have been verified, the design **transfer** starts, i.e. the conversion of the design and development data and results into information needed to be able to produce, control, certify, market and maintain the developed products. There is a significant difference between the design and development of reagents and that of instruments, since in the latter case, the transfer does not take place until the validation of the design.

5. With the information already in the company's management system, the production of pilot batches or industrial prototypes is undertaken, under production-equivalent conditions, which are used for two-stage design **validation**:

- **metrological validation:** the analytical and clinical performance of the test is studied, verifying that the defined measurement requirements are met (precision, linearity, detectability, veracity, stability, diagnostic capacity, etc.).for this purpose, we have a department, the Analytical Validation Unit, independent of the R&D²+I area, which carries out studies according to the criteria recommended by the Clinical and Laboratory Standards Institute (CLSI) for the validation of products for *in vitro* diagnostics, the International Organisation of Vine and Wine (OIV) for products for oenological analysis, or the AOAC (Association of Official Agricultural Chemists) Association of Official Agricultural Chemists) for foodstuffs.
- **validation in a user environment:** the product is subjected to different scenarios representative of real customer-user workflows, verifying that the developed product provides an effective user experience. For this purpose, we have our End-User Environment Basis analytical validation Laboratory (EBL), located in Seoul, Korea.

6. The product design documentation is used to draw up a performance report which, in the case of IVD, is included in the Technical File required for registration and CE marking and for **marketing** the product in Europe.
7. Finally, **post-market surveillance** allows for the collection of user feedback and information that is used to introduce corrections, updates and product improvements.



We distinguish between 4 types of design and development objectives:

- **A new product**, understood as a novel contribution for the customer
- **Product improvement** or performance enhancement
- **Correction** or rectification of any non-compliance with requirements
- **Study**, which provides useful information for application in product development. Both new product design and development projects and modifications to existing product designs are governed by the same process, adapted to the scope and scale of the project.

Monitoring

On a quarterly basis, product development teams review the implementation status of projects and report back to the community through a design review report.

Innovation as a cross-cutting concept

We understand innovation not only as the creation and modification of a product and its introduction to a market, or the application of cutting-edge scientific and technological advances to the field of biotechnology, but also as the result of an organisation's culture, and as the fruit of open conversations between all the collaborators of a project in which flexibility, adaptation to change, active listening and diversity, critical thinking and teamwork are encouraged and appreciated.

Innovation requires interdisciplinary collaboration between scientists, engineers and other experts in the entire value chain of product development to push the boundaries of what is possible in the field of biotechnology. Furthermore, this must happen in workplaces that encourage communication, interaction and generate a sense of well-being.

However, we are not only concerned with innovating in the area of product development with scientific and technological advances, but also with innovating new processes and introducing methods to improve effectiveness, efficiency and competitiveness.

In this way, we can also generate ideas that can provide new services or products and once again bring us closer to our customers by offering them a satisfactory user experience that invites them to continue relying on our solutions.



SPICA, ENOMAQ Innovation Award 2023.

2023 has been a year of development of new products that, for the most part, will be launched in 2024. But it has also been a year of improvements in software, features and user experience of existing products:

Human health

1. New version of BioSystems **iPRO**: immunofluorescence slide processor to improve slide preparation speed and user-friendliness, and improve communication with the laboratory's information management system.
2. Software and hardware improvements in the **BTS photometer** that provide it with greater reliability in results and robustness in operation.
3. New software version of the **BA automatic analysers** that allows automatic uploading to the system of the concentration values of the different analytes of the calibrators and Biochemistry controls. It also provides information on the pre-dilutions made to the sample during the measurement procedure, displaying it on screen, informing the laboratory management system and including it in the results report.
4. A new presentation of the human plasma **Dimer-D** measurement test for the A15 and A25 analysers, for monitoring the balance between intravascular coagulation and fibrinolysis. In addition, ready-to-use multilevel standards have been added to the test.

Food health

5. Adaptation of the **Sorbitol** measurement test in juices as an analytical quality parameter to determine the authenticity of the fruit content in the composition of juice blends.
6. **Reference material** for the calibration of multiple analytical tests to measure the concentration of oenological parameters.
7. Software and hardware enhancements to the **SPICA** analyser for improved reliability of results and product robustness.
8. Application of the "active mixing A15" manoeuvre to the ammonia test to improve **agitation in A15** and achieve better results in tests that, due to their nature and composition, require assistance to achieve homogeneity of the reaction mixture.
9. **New software features in the Y400 automatic analyser** to improve the user experience by self-positioning the samples in the rotor segment. This also shortens the test process time and reduces the likelihood of errors.

Animal health

1. Adaptation of the iPRO immunofluorescence slide preparer for **veterinary** use.
2. Improved **Ehrlichia canis** culture conditions resulting in higher and more stable percentages of infected dog macrophages, which are the substrate in the reagent for the detection of anti-*Ehrlichia* antibodies in dogs.

Sustainable working model and environmental impact review

Our working model assesses the impact of the product at every stage of its conception to ensure minimum environmental impact once the product is finished and throughout its life cycle.

Specifically, we seek to develop products with:

- Use of materials which are sustainably sourced (FSC paper and cardboard) and recyclable
- Reduced use of plastics, use of recycled plastics or recyclable or biodegradable materials
- Less surplus space in reagent kits to minimise storage, preservation or shipping space requirements.
- Eliminate or minimise the use and concentration of materials that are harmful to the environment and to living beings
- Quality components to ensure electronic/radio frequency and communication security.
- Design and use of quality materials to provide analyser instruments with long life and high durability (>15 years)
- A plan to improve its recyclability or reusability.
- Design and ergonomics to offer safety and ease of operation for the user as well as attractive aesthetics and graphics.
- Suppliers that respect our code of conduct and are sensitive to sustainability.

In 2023, we incorporated consideration of sustainability criteria in the selection of raw materials for design. In addition, ESG (environment, social responsibility and good corporate governance) assessment criteria were incorporated for the initial selection and approval of suppliers. This thereby facilitates alignment with our supply chain as regards environmental, human care and governance issues.



Warehouse. Guadalajara centre, Mexico.

Projects for 2023

In 2023 we continued to work on several product design and development projects, some a continuation of projects started earlier, and others initiated during the course of the year. Projects are classified according to fields and specialities:

Field	Speciality/sector	Project title	Description
Human health	Autoimmunity	New ELISA tests	Development of diagnostic tests for autoimmune diseases via ELISA
		Autoimmunity Platform	Design and development of an automated IFA and ELISA analysis platform, with automatic microscope and information management software
		Reference material for coeliac disease	Design and development of a humanised monoclonal antibody as a calibrator in diagnostic tests for coeliac disease
		Anti-DFS70 antibodies	Determination of anti-DFS70 by knock-down in HEp-2 cells
		Autoimmunity update	Autoimmunity product enhancements
	Biochemistry	Control Serum	Development and production of human and bovine control serum
		Advancement of the BA400	BA analyser improvements: software, optics and contaminations
		Creatinine, enzymatic method	Design and development of a new test for creatinine measurement
		HbA1C	Design and development of a new immunoturbidimetric test for the measurement of haemoglobin A1C
		Dihydropyrimidine dehydrogenase	Design and development of a test for the measurement of dihydropyrimidine dehydrogenase as a companion diagnostic in cancer
		Software update	Redesign of A15/A25 software
		Stool	Development of a stool analysis system for occult blood, calprotectin, elastase, transferrin and Helicobacter pilorii
		Advancement of the BTS	Improvement of the BTS photometer
		Biochemistry update	Biochemistry product enhancements
Food health	Seafood	Fish	In-house development of histamine DH enzyme and AOAC certification of the sulphite test
	Allergens	Gluten	Design and development of an immunoturbidimetric test for the determination of gluten in food
		ALE	Design and development of immunoturbidimetric tests for the determination of ovalbumin, beta-lactoglobulin and casein in foods
	Oenology	Update Food & Beverages	Food & Beverages product improvements
Animal health	Infectious diseases	ZoonDx	EIA and IFA tests for human and animal health: Leishmania, Rickettsia, Babesia
	Infectious and Biochemistry	Update Veterinary	Veterinary product improvements



Creatinine enzymatic reagent, Clinical analysis.

Methodology of work

In 2023, we have increased our focus on strengthening the entire value chain of the marketed product, from the management of suppliers and the purchase of raw materials, to the preparation of technical documentation to enable the registration and marketing of products.

The adoption of the work methodology based on the strategic pillars –product development with R+D²+i/a+Q+UX, globality and sustainability– is consolidating cross-cutting and multidisciplinary teams, without barriers due to technological knowledge or membership of different areas, departments or locations. In 76% of our projects, we interact with customers to get their feedback and keep the user experience at the core of everything we do.

We have improved organisational efficiency through the early involvement in projects of people from other areas or departments who are called upon to intervene at some point in the process.

The number of projects in which work is carried out in **collaboration** with external organisations (universities, technology centres or companies) has increased, moving away from the concept of subcontracting and nurturing a vision of a mixed project team with shared and distributed responsibilities. Such cases include the Institut Català de Nanotecnologia (ICN2), IDNEO Technologies and Leitat Technological Centre, among others.

In 2023, the new user environment validation laboratory (EBL) located at our Korea site was launched. The first projects validated in this environment were the new HbA1C test and modifications to the analyser wash solutions.

In 2023 we launched a search for alternative suppliers, critical raw materials and strategic partnerships for product and business development from our Tech Transfer centre in Shanghai.



EBL. Seoul centre, Korea.



Autoimmunity laboratory. Barcelona centre, Spain.

Incentives to boost development and innovation

We carry out projects co-financed by public entities such as the Centre for Technological and Industrial Development (CDTI), or the Ministry of Science, Innovation and Universities. These incentives provide an impetus for development and innovation.

Some of the projects underway in 2023 have received public funding:

- Development of a reference material for the determination of anti-transglutaminase antibodies in coeliac patients, based on humanised monoclonal antibodies (CELMAb). Call for proposals Challenges-Collaboration 2019 (RTC2019-007324-1). Spanish Ministry of Science and Innovation.
- Development of immunological diagnostic tools for the detection of zoonotic pathogens in humans and pets. (ZoonDx). Call for Public-Private Partnership Projects 2021 (CPP2021-008777). Spanish Ministry of Science and Innovation.
- New automated immunoassay systems for the detection of allergens in food (ALE). Research and Development Projects (IDI-20230493). Centre for Technological and Industrial Development, CDTI.
- Automated fluorescence microscopy for the detection of antibodies in clinical diagnostics (MIRA).

Collaborations

In order to carry out our R&D&I activities, we have built a network of partnerships, aimed at helping in the different phases of the Product Design process:

- Network of technology centres:
 - LEITAT, technology centre (www.leitat.org)
 - Catalan Institute of Nanotechnology (www.icn2.cat)
 - Pilot Fermentation Plant at the UAB (www.uab.cat/ca/enginyeria-quimica/planta-pilot-fermentacio)
 - UAB Platform for Protein Production (www.ibb.uab.cat)
 - Joint Research Centre – Reference Materials (European Commission)
 - CPC Biotech (Italy)
- Network universities:
 - Autonomous University of Barcelona (Spain)
 - University of Barcelona (Spain)
 - Technical University of Catalonia (Spain)
 - University of Cantabria (Spain)
 - University of Murcia (Spain)
 - Marqués de Valcédilla University Hospital (Spain)
 - Institut des Sciences de la Vigne et du Vin (ISVV) de l'université de Bordeaux (France)
 - National Autonomous University of Mexico (UNAM)
 - Jiangnan University (China)
 - East China University of Science and Technology (China)
 - Pontificia Universidad Católica de Chile (Chile)
 - Diego Portales University (Chile)
 - California Polytechnic State University (Cal Poly SLO) - College of Agriculture, Food and Environmental Sciences (USA)
- Validation network:
 - CATLAB (www.catlab.cat/es), Barcelona
 - Reference Laboratories (www.reference-laboratory.es), Barcelona
- Clinical consultants network
 - Experts in clinical biochemistry. Diego Portales University (Chile)
 - Experts in autoimmunity. Rossi Laboratory (Argentina)
- Network companies:
 - Château Latour-Martillac (France)
 - Tentamus CheLab GmbH (Germany)
 - Idneo Technologies, Barcelona (Spain)

Training courses and conferences

We participate in various forums and congresses that allow us to keep up to date and establish relationships with experts in the sector.

- XXV IFCC-EFLM WorldLab-EUROMEDLAB
- 16th Dresden Symposium on Autoantibodies
- Food Allergy Forum - 3rd International Conference

EUROMEDLAB. Rome, Italy.



Operations

All products designed by BioSystems are produced at our factory in Barcelona, Spain, and some of them, also, at our factory in Chennai, India.

Some production processes include outsourced stages, such as the assembly of some subassemblies for instruments at specialised suppliers or the assembly of some auxiliary components for instruments and reagents at socially-focused businesses.

The production process requires significant support from all areas of the company, such as:

- The production teams, with specialists for each activity and production process.
- Infrastructure management, safety and occupational risk prevention.
- Production engineering, which enables the industrial-scale production of what has been developed at laboratory scale, maintains and improves production processes and participates in the resolution of incidents that may affect product performance.
- The various quality control and quality assurance units, to ensure that all processes and products are executed as designed, validated and authorised.

- The support of scientists and development engineers to resolve incidents in the production process that may affect product performance.
- Purchasing and procurement technicians who are in daily contact with our trusted suppliers.
- The planning technicians, who ensure service to customers by maintaining the right levels of product in the warehouses.
- The technicians and warehouse staff who supply and provide everything necessary to feed the production units, store the manufactured products and manage the product deliveries to our customers in a timely manner.
- The support of the people team, accompanying the training of new staff and the reinforcement of consolidated staff.
- The business and planning units, which allow us both to understand our customers' needs and to plan how to meet them.

In total, we have close to 18,000 m² shared between production and product development areas and support activities, with 15,000 m² in Spain and 3,000 m² in India, and all BioSystems sites worldwide with their commercial and administration offices, their application and SAT laboratories and their warehouses and cold rooms.

In 2023, we continue to improve our facilities and processes to continue offering quality products to ever-increasing numbers of customers around the world.

Our production and logistics processes allow us to offer products to the different business areas of BioSystems (human and veterinary clinical analysis and agri-food analysis) based on common production processes, which include:

Procurement, receipt and processing of raw materials and critical components

We have been working for years with leading suppliers in their fields and we intend to continue strengthening these long-term relationships of trust.

We have a systematic process for the inspection of incoming materials, which allows us to ensure the quality of our raw materials and components which guarantee the manufacture of products according to our specifications.

BioSystems also ensures the quality and availability of critical raw materials for the manufacture of reagents by obtaining some of these raw materials –such as enzymes, antigens, monoclonal antibodies, tissues of animal origin, cell suspensions, etc.– directly, and to this end we operate biological safety laboratories (BSL3 Laboratories) where we use bioreactors with capacities of up to 500L to cultivate various strains of microorganisms –which can be wild-type or recombinant– from which we obtain various enzymatic or immunogenic proteins that we use in the manufacture of our Kits.

We also have Laboratories (BSL2) and clean rooms with pressure gradients to preserve the quality of the air and the product (ISO 14,644: class 8 and 7) and work and manufacturing areas in Class II Biological Safety Cabinets (ISO14. 644 Class 5) for cultivating animal cells and for cultivating hybridomas to obtain monoclonal antibodies

These products are purified and conditioned for use in proprietary facilities suitable for protein purification. In this way, we guarantee the quality, continuity, robustness and reliability of our biotechnological solutions.

BioSystems also ensures the quality and availability of critical raw materials for the manufacture of its analysers, such as electronic and mechanical components, through continuous communication with strategic suppliers for these technologies.

Production process

Our main production processes include:

A) Production process of analysers:

It is based on the LEAN methodology, in permanent coordination between the planning, production, quality, supply and product and process engineering teams, to guarantee compliance with product standards and a continuous production flow.

Phases of the process:

1. The preparation of sub-assemblies (optical, fluidic, mechanical, control, etc.)
2. The assembly of the different sub-assemblies, until the analyser as a whole is built.
3. The adjustment of all moving parts of the analyser and its commissioning.
4. The analysers are subjected to stress tests to ensure that all parts of the equipment are correctly assembled and configured.

5. Quality control of analysers.
6. Careful packaging, unit by unit, to ensure the stability of the analyser for subsequent shipment to the customer.



Assembly and start-up. Barcelona centre, Spain.

In 2023, we implemented the LEAN methodology in the analyser packaging process, redesigning the production spaces and the flow of operations. In this way, 100% of the process is carried out under this production system.

B) The production process of liquid reagents is carried out as follows:

1. Water purification through a reverse osmosis process in order to achieve very low conductivity levels with no bacterial contamination.
2. Weighing of raw materials in air filtration and vertical-flow facilities that prevent cross-contamination of ingredients between different product batches or different products.
3. Mixing of ingredients inside automated stainless steel or plastic (PP) production reactors with validated CIP systems and automatic cleaning procedures.
4. Filtration of the manufactured products to ensure the absence of particles (pore diameters from 5 to 0.45 or up to 0.22 microns) and their stability.
5. Packaging and labelling on automatic dosing lines with a capacity of up to 2000 vials per hour.
6. Quality control of reagents, in the laboratories intended for this purpose.

C) The production process for latex suspensions is as follows:

1. Preparation of protein solutions, either antigens or antibodies.
2. Sensitisation of latex nanoparticles with protein solution in stirred and temperature-controlled reactors.
3. Washing of the sensitised nanoparticles.
4. Quality control of reagents.
5. Packaging and labelling on automatic dosing lines.

In 2023 we optimised our equipment by upgrading our filling stations and acquiring a solids dosing machine. In addition, we have designed and implemented a computer vision control system to monitor the number of dosed bottles, allowing us to automate this activity of the production process. Finally, we have improved the process of supplying bottles to the dosing units with a kanban system.

D) The production process of reference materials is carried out as follows:

1. Starting with liquid reagents packaged using high-precision volumetric systems, we freeze-dry these materials to ensure high stability and homogeneity.
2. We assign values to the analytes contained in these materials, based on complex titration processes carried out at BioSystems and in partner analytical laboratories.
3. We generate value sheets for each material.
4. We carry out quality control of materials.



Reagents production. Barcelona centre, Spain.

E) The production process for cell and tissue slides is as follows:

1. We culture cells from tumour strains of animal origin in sterile reactors, and operate in CSB class II and clean room environments.
2. We obtain pieces of different organs from different animals which are immediately frozen to preserve their morphology and antigenic quality.
3. We dispense the cells in clean rooms and adhere the tissues directly to glass slides.
4. We fix the cell structures on the glass slides.
5. We pack the slides in automated facilities under strictly controlled conditions of temperature and humidity.
6. We perform quality control of the slides.

In 2023, work began on improving the production facilities of these production lines, building new clean rooms and renewing the air treatment equipment (HVAC) for climate and environmental control of the rooms.

The construction and commissioning of new automated equipment for printing QR codes on glass slides has also been carried out to improve internal and customer traceability of the product.



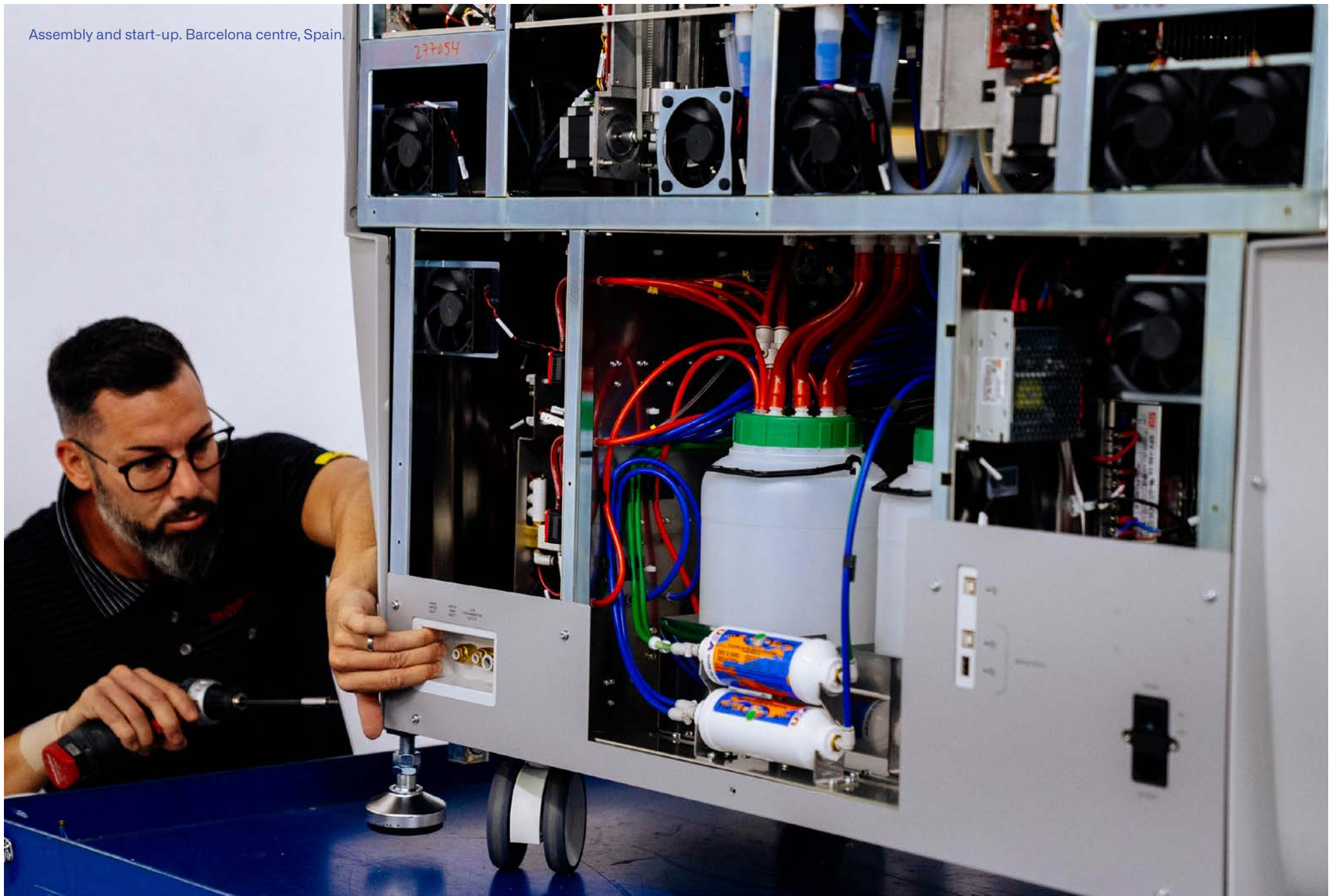
F) The packaging and assembly process for the preparation of reagent kits is carried out as follows:

It is based on the LEAN methodology, in permanent coordination between the planning, production, quality, supply and process engineering teams, to guarantee compliance with product standards and a continuous production flow.

1. We assemble our kits with all the components.
2. We incorporate instructions for use and value sheets when reference material is included
3. All products undergo rigorous quality control, batch by batch, before being released for sale.

In 2023, the eINFO tool has been implemented for the telematic consultation of IVD product documentation, which has helped to reduce handling of finished products by minimising the need to include instructions for use and value sheets in the kits.

Assembly and start-up. Barcelona centre, Spain.



Business development and customer service

We work together with distributors, our business partners, in the promotion of BioSystems products and customer service.

Our way of doing business is through talking and listening. We network with people from laboratories with specific needs and exchange information and opinions. This assertive communication, based on cooperation and a determination to serve, results in sales. In this way, our clients are those who advocate for this type of relationship, which is built over time and which is the key to the growth of both.

We have user customers, industrial customers and commercial business partners (distributors or subsidiaries) who distribute our products in the various markets.

In some countries, especially the larger ones, we have several distributors with exclusivity according to geographical area, and in others we have several distributors operating in different sectors or segments of the market.

In most countries, our distributors are the official importer and keep the necessary registrations with the health authorities. We collaborate to make our products known in each of the markets, we support each other in promoting sales and in establishing links with benchmark customers in each country, in order to determine the particularities of each user.

They are our business partners as we work together to jointly develop the business and make it sustainable in the long term.



Enomaq. Zaragoza, Spain.



Medlab. Dubai, United Arab Emirates.

Our global presence in 18 countries, with our own centres, allows us to have direct relationships with various markets and a deep understanding of our clients' needs.

We also participate in scientific congresses and events in the field of clinical and medical diagnostics, veterinary and food diagnostics and other applications in biotechnology sectors. The aim is to listen, learn or present our scientific and technological achievements to the community, share knowledge and stay abreast of any developments that may be of interest to us.

In addition, our presence allows us to further strengthen our links with universities and research centres, as well as with professionals, healthcare providers and other companies with whom we establish partnerships.

We are also present at the most important trade fairs in each sector in which we operate, in order to be close to our customers.

In 2023 we actively participated in 19 such conventions:

Line	Name	Place	Date
Bioquímica	Euromedlab	Rome, Italy	25/5/2024
	Medlab	Dubai, Emirates	6-9/02/2023
	Healthcare Expo	Algiers, Algeria	21-23/09/2023
	Syndicat Algerien des Laboratoires d'Analyses Medicales 'Salam'	Algiers, Algeria	2-3/10/2023
Autoinmunidad	FMC Conference on immunology and autoimmunity	Annaba, Algeria	21/10/2023
	16th Dresden Symposium on autoantibodies	Dresden, Germany	11-15/09/23
	MEDICA	Germany	13-16/11/23
	IV Congress of the Clinical Laboratory Medical Society of Chile	Chile	23-24/11/23
Food & beverage	Anfaco Tuna Congress	Vigo, Spain	1/9/2023
	Seafood Expo Global	Barcelone, Spain	1/4/2023
	Technical Workshop IFU	Viena, Austria	1/3/2023
	Food Allergy Forum	Amsterdam, The Netherlands	1/9/2023
	Foodtech	Barcelone, Spain	1/9/2023
	Labforum	Madrid, Spain	1/9/2023
	Fruit Attraction	Madrid, Spain	1/10/2023
	Beverage Crop Symposium	Murcia, Spain	1/4/2023
	Enomaq	Zaragoza, Spain	1/2/2023
	Congreso OIV (Jerez)	Jerez, Spain	1/6/2023
Veterinaria	AMVAC	Romania	11/8/2023

Having a direct presence in 18 countries gives us the opportunity to better understand our customers, their expectations and needs, and to establish long-lasting relationships with all of them.

Results 2023

During 2023, despite the major geopolitical impact –mainly experiencing a decline in sales in Russia and Algeria– we achieved consolidated sales of 79.3M. These sales were made in 108 countries. In 17 of them, this was via BioSystems companies, and in the rest via 165 distributors. 50% of our products are distributed through official distributors.

In terms of turnover by area, human health (biochemistry and autoimmunity), our main activity, accounts for 85% of sales, food health for 14% and animal health for 1%.

Highlights of 2023:

- The Food & Beverage line has grown compared to 2022. This growth is due to the sale of some new reagents, such as Histamine, as well as the installation of Y400 equipment in large and prestigious warehouses. The Y15 and Spica instruments remain central to this business line.
- The Autoimmunity line has grown by 4% compared to 2022.
- We wish to highlight the positive results from the centres in India, Mexico, Korea, Turkey and Chile, where customer relations and good management are the key to success.



Histamine kit, Food & Beverage analysis.

Determination to serve

From the relationship initiated with our customers and business partners, we strive to provide all the necessary information and support so that the customer has:

- A satisfying experience that will lead to a strong relationship.
- BioSystems as their preferred choice.
- A personalised service adapted to the nature of each user.

Their experience serves as a source of information for R+D²+I and by adding new developments and functionalities, improve existing products and services, collaborating with the definition of requirements. This closes the circle of the user's experience.

We have a professional team of product specialists and technical service engineers to help customers get the most out of our solutions. These professionals are located in the different countries where we are present and work in a coordinated manner, sharing experiences and establishing direct channels of communication to facilitate the dissemination of knowledge among their various colleagues around the world.

Similarly, we work with our distribution partners to ensure quality customer service and technical support.

We keep track of all customer and distributor enquiries via Salesforce management software. On this platform, we also work in communities to facilitate the exchange of information with distributors. In these communities, dealers can determine or directly view the statuses of their enquiries.

In 2023, we received a total of 6,455 queries. For all of them, we monitor the resolution time in order to resolve them as quickly as possible.

We pay special attention to the management and follow-up of orders, trying to keep the customer informed at all times.

We also develop information, support and knowledge materials to enable the optimal use of our products, and make them available to our customers and partners on a community platform. These materials are classified as follows:

- Informative articles on the basics of metrology and photometry.
- Scientific material on quality control concepts.
- Video tutorials for technical service interventions.
- Service and technical information manuals for our analysers.
- Video tutorials on the software configuration of our analysers.
- Guidelines for the interpretation of qualitative results.
- Guidelines for the resolution of common incidents.
- Frequently asked questions and answers about our products (FAQs).
- Videos on sample preparation.
- Reference charts for our systems.

In total, we have more than 1,000 documents explaining our products and their features, helping our support teams around the world. In 2023 we published 103 new articles.

We also develop promotional material to raise awareness of our analytical solutions. During 2023 we produced or updated 87 documents with promotional material.

We have a team of professionals, consisting of product specialists and service engineers, located in various countries to help customers get the most out of our solutions.

Continuous training for our customers is one of the pillars of our support for an optimal user experience. During 2023 we conducted 19 training workshops and seminars for users, industrial customers and distributors.

Some relevant actions carried out during 2023 with the aim of providing a better service to users of our products include:

The various challenges of the wine sector, with climate change and the high competitiveness when it comes to offering quality wines, are making the winemaking process considerably more technical.

In this scenario, we have taken a step forward in the interpretation of results with the Phenolic Profile. Winemakers need it to obtain relevant information on the potential of different grapes and the most appropriate winemaking practices, or to develop predictive models of wine development. This allows wineries to get the maximum potential out of each batch of grapes and supports better decision making throughout the winemaking process.

The sub-processes involved will be optimised in terms of time and resources in the winery by obtaining a phenolic profile, which will help wineries to produce quality wines consistently and more sustainably.

In order to take our autoimmunity solutions a step further, we collected feedback from customers in Turkey, Argentina, Italy and Spain.

As conclusions, they highlighted the need to have full traceability of immunofluorescence results, with images and in an agile way.

These conversations and conclusions are the basis for the design of the ARA platform.

ARA allows to work in an interconnected way, to store and trace all the results obtained in the autoimmune diagnostic laboratory.

For now, this platform is immunofluorescence and is scheduled to be finalised in 2024. It will, however, have the capacity to be extended to other techniques and other fields.

Quality management

The BioSystems Quality Management System provides the necessary framework to establish and maintain high quality standards in all our processes, in particular those directly involved in the design, development, manufacture, marketing and review of the marketed product. All of this with a clear objective: to promote continuous improvement in order to satisfy the needs of our customers.

To this end, we have various policies and procedures in place, as well as the identification of risks, opportunities, mitigation actions and areas for improvement. This system is regularly reviewed, both internally and externally, through auditing processes.

Product recall and health surveillance system

Our products have an impact on health and well-being. For this reason, we have traceability records and procedures for product recalls and notifications to health authorities and health professionals. These involve both BioSystems and distributors, to ensure an efficient recall and replacement of products in the event that we detect that they are not working properly. No notifications to health authorities or product recalls were necessary in 2023.

In addition, we have a customer service centre to report any incidents present in the market that may compromise safety during use.

We have a Medical Device Technical Manager under licence to operate and a Person Responsible for Regulatory Compliance (PRRC), as required by Regulation (EU) 2017/746 regulating *in vitro* diagnostic Medical Devices, meaning that the safety of patients and users of IVD medical devices is guaranteed.

Communication to the user of product features and its handling

BioSystems provides for all its products labels, instructions for use (IFU) and safety datasheets (SDS), which comply with the European regulations for labelling and user protection in the handling of products under the REACH and CLP Regulations, and the standards for product information (ISO 15223 and ISO 18113).

Any limitations or contraindications are also indicated in the instructions for use, together with any risk mitigation actions, as indicated in the ISO 14971 standard on risk management of medical devices.

Our clients have at their disposal a tool for the digital dissemination of all product-related documentation. This tool, called eINFO, can be accessed via the BioSystems website or via the QR codes indicated on the kits.

Promotional, informational or communication material is reviewed by the parties involved, with a final Quality Assurance check, to ensure that the information included is accurate and matches the actual characteristics of the product as stated in its instructions for use.

External Certifications and Licences

We have the following certifications and licences for the design, manufacture, marketing and after-sales follow-up of our products. These certifications or licenses are granted by Notified Bodies, Certification Bodies and Competent Authorities.

- ISO 9001: Quality Management Systems.
- ISO 13485: Medical Devices – Quality Management Systems.
- ISO/IEC 17043:2010: Intercomparison Provider (Prevecal).
- Preliminary Medical Device Operating Licence.
- Licence for the manufacture and importation of animal health products.

In 2022, we conducted and successfully passed external audits for the certification of our products against Regulation (EU) 2017/746 regulating *In Vitro* Diagnostic Medical Devices, and in 2023 we conducted a follow-up audit which we also successfully passed.

As of 2023, we are also actively working with the Notified Body on the review of the technical documentation and certification of our *in vitro* diagnostic products according to Regulation (EU) 2017/746 regulating *In Vitro* Diagnostic Medical Devices.

This new regulation raises the levels of rigour and demand in quality and safety for users, approaching the standards required of the pharmaceutical industry.



Quality control. Barcelona centre, Spain.

Positive impact on people

Focus on active listening and conversation



Conversation is at the heart of our corporate culture.

We talk to the users of our products, understand their concerns and then work on how we can improve their day-to-day activities through our solutions.

We talk to our partners and collaborators to understand how, together, we can create better analytical solutions to meet current and future needs in our areas of operation.

We talk with our colleagues to broaden our horizons, to bring new projects to fruition, to be more efficient and achieve better results, to learn and to grow.

And yes, talking involves active listening, understanding concerns and needs, reaching consensus and seeking solutions and continuous improvement. It is not always easy. But, for us, it is fundamental.

Corporate culture

The corporate culture at BioSystems is one of the company's main competitive advantages and the backbone of its long-term sustainability.

This culture is based on respect, trust and individual responsibility. We believe that if people can organise their time, find a healthy balance with their personal lives and develop as professionals and as individuals throughout their journey at the company, they will be able to make a better contribution to the project at hand. By feeling committed to the purpose and sharing the culture, values and strategy, they will work more efficiently and effectively. This will result in better products, services and solutions, all of which will lead to greater satisfaction for our customers and all our business partners.

We therefore promote policies in line with this cultural vision, applying them whenever possible, depending on the nature of each workplace and the legislation in force in the country where we operate.

Time management

Since 2020, we have used flexible start and finish times between 06.30 am and 10 pm (except for shifts that may start at 6 am and end at 10 pm) adapted to each team, person and process.

Flexible start and finish times allow people to achieve a better work-life balance and embodies the values of trust and individual responsibility.

Blank calendar

BioSystems people are provided with a blank holiday calendar where they can manage their days off in consultation with the team they work in and according to the allowance set under the collective bargaining agreement.

This blank calendar is based on freedom, trust, personal responsibility and leadership, seeking the formula that maximises the efficiency of processes to impact the bottom line and allows for a framework of a healthy work-life balance.

Remote working

We have the necessary infrastructure and resources available to people to make teleworking a feasible option, as long as the needs of the process allow it and with the agreement of the team.

All workspaces are retained so that it is up to the teams and individuals to choose which is the most efficient option: working face-to-face or remotely.

We promote continuous **feedback** within teams and encourage constructive critical thinking, initiative and teamwork.

In 2023 we scheduled a 3-month feedback programme to ensure that everyone has the necessary tools to put it into practice. We have also included it naturally, through conversations or online forms, in more activities to reinforce the habit and thus achieve continuous improvement.

Mentoring programme: a mentor is assigned to each new recruit to help them get to know, live with and grow within the BioSystems culture. All of this goes beyond their area, process, or job position, promoting communication and diversity as sources of enrichment, without vertical or horizontal barriers, because we believe in the value contribution of each and every person.

In 2023 we carried out training for mentors, to accompany the people who accompany our new recruits.

We believe in **accompanying people and teams** to promote their development and growth, both professionally and personally. In this way, we ensure that each person can focus on his or her greatest potential and improve every day.

We work both on self-leading –accompanying the development of the person to improve their self-knowledge– and team-leading, accompanying the development of teams and people who coordinate other people, to improve the team's results.

In this respect, we launched a number of activities in 2023:

Self-leading:

- Self-knowledge accompaniment for 28 people, and individual accompaniment for a total of 93 people from various countries (Spain, Mexico, Italy, Thailand, India, Romania, Philippines, Chile and Turkey).
- Workshop on difficult conversations, with art as a tool for introspection and expression.

Team-leading:

- 2 multi-session leadership workshops for team coordinators.
- 'From the Back of the Room' training workshop to promote more dynamic and impactful training.
- Implementation of work dynamics to foster cooperation, trust and complicity with 12 teams from various countries (Barcelona, Romania, Chile, Turkey, Spain and Portugal).

We consider the provision of meeting spaces –both formal and informal– and the systematic renewal of work spaces essential to create this culture of communication.

In 2023 we created new collaboration and meeting spaces in Barcelona (SAP rooms and a Workshop room); we refurbished work spaces (new rooms, floor improvements and new air-conditioning equipment) and reinforced fire and safety facilities; we also implemented improvements in the Montcada centre (new flooring and aesthetic improvements to walls and ceilings).



BioSystems Romania team.

Climate survey

For BioSystems, corporate culture is one of the main drivers of good performance, well-being and satisfaction of the people who are part of the project. For this reason, in 2023 we implemented a climate survey for the first time, allowing us to measure the work climate and work on aspects related to corporate culture.

On this first occasion, we started by asking questions of the entire community in Spain.

We start from the basis that a good work environment is one in which we can operate freely, in which there is good harmony with the people in our team and with the people in other processes, in which interpersonal relationships are based on respect and collaboration. Some of the results obtained are as follows:

- Work climate is rated 7.1/10
- When asked whether BioSystems is a good place to work and whether they would like to continue working here, they gave a score of 7.8/10.

These results represent an interesting starting point for continuous improvement. To this end, we will work on providing tools to team coordinators to continue fostering people's personal and professional development.



R&D Automation team. BioSystems Spain.

Efficient management

In 2023 we implemented **mySpace**, a personal digital space for the entire BioSystems community. Here, each person has his or her employment documents stored, various forms with an advanced application approval system, a portal for new career opportunities and the digitised onboarding process. All of this is done via simple, confidential management.

In 2023, we have also strengthened external partnerships for recruitment processes.



Training

Our training philosophy proposes a model focused on self-learning that promotes individual responsibility in the development and training of each person and the sharing of knowledge among the people who form part of the project. We want everyone in the community to be able to develop and get the best out of their professional career. We are our own best trailblazer for our careers and professional development.

On the one hand, teams can identify training opportunities each year and submit them to team coordinators for possible inclusion in the training plan.

In 2023 we were engaged in partnerships with educational and scientific training institutions such as the Lean Institute, the IFCC and Netmind, for example.

On the other hand, we provide a wide range of programmes and resources to enable people to develop themselves, adopt new learning and enhance their skills. Some of the key tools for 2023 include:

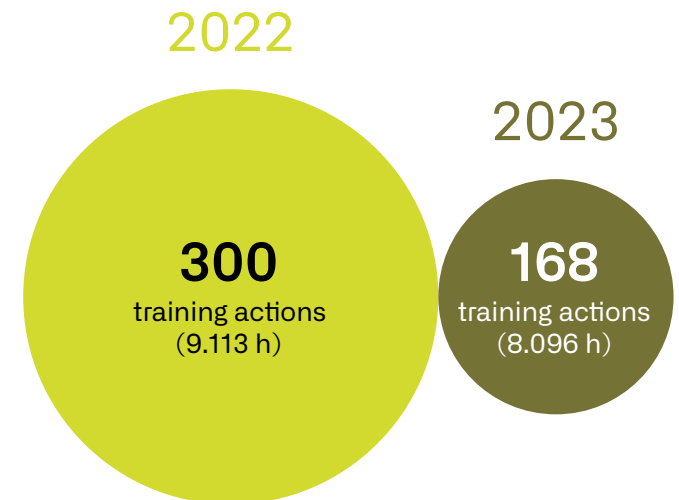
- Plural Sight: e-learning tool for software developers, IT managers and creative professionals.
- In-house e-learning: we conduct annual compliance training using a new digital training system.

In addition, we carry out specific organisational training courses to gain an in-depth understanding of developments in the way BioSystems works. In 2023, for example, we all came together to learn about the new OneERP Sap project – a new management software that will allow us to be more efficient and better serve our customers, and which will be a reality in 2024– and to learn about the improvements to the iconic BTS analyser.

In 2023 we continued to carry out cross-disciplinary training sessions once a quarter with the team in Barcelona, Montcada and the rest of Spain, as we obtained very good feedback from this initiative which started in 2022. The objective is to share with new recruits and people who have been with the company for a long time many of the aspects that are necessary for their alignment with the culture and the way of working in the different areas and processes that apply to them: Communication, Compliance, Code of Conduct, Health and Safety, Quality Management and IT.

Training meetings with specific stakeholders, mainly taught by the Quality, R&D&I and Customer Service areas concerning technologies used in the products, such as technical service applications, analyser functionalities, interpretation of Prevecal reports, etc.

In 2023, a total of 168 training actions were carried out, with an estimated 8,096 hours of training.



Cross-disciplinary training session. Barcelona centre, Spain.



Commitment to diversity and equality

At BioSystems we embrace diversity and see it as an opportunity for growth and enrichment. Diverse teams in which people can take the initiative and find their own voice allow different ways of seeing things and different opinions to coexist.

Transparent, respectful communication in diversity is key to fostering new ways of thinking and working that drive learning and overall personal and professional growth.

We promote the inclusion of people with disabilities and encourage it in our day-to-day work.

Through our internal communication channels, we promote diversity, the use of inclusive vocabulary and the sharing of collaboration with foundations.

At BioSystems Spain we have an Equality Plan, which has been in place since 2021, with measures to be implemented until 2025. It sets out the principles that determine the way we act in relation to gender equality and equal treatment and opportunities in access to employment, professional training and promotion, and working conditions.

During 2023, actions were taken to promote equality in the organisation:

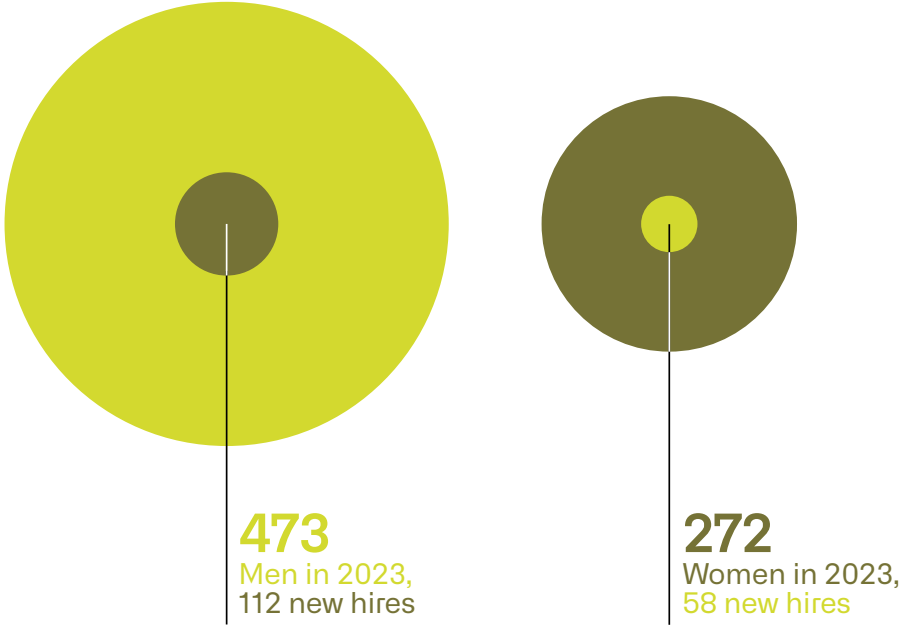
- Creation of a new BioSystems Harassment Prevention Policy.
- Training and guidance on how to carry out inclusive onboarding, by the Eurofirms Foundation.
- 'Perception of Equality Policies' questionnaire carried out in BioSap, to understand what and how the actions carried out in this area have an impact.
- To ensure that internal promotion and professional development processes respect equal opportunities.
- Flexibility and work-life balance measures that support the right to work-life balance.
- Celebration of International Women's Day with a global video interviewing female colleagues from Turkey, Spain, Mexico and India. In parallel, local activities took place in some countries. In Spain, for example, a session was held with Laia Arcones, an expert in equality, where people had the opportunity to broaden their perspective on gender equality and reflect on women's leadership; in Chile, experiences were shared to raise awareness and reflect.
- Training in Barcelona and Montcada to raise awareness, prevent and act against sexist attitudes in the workplace, given by Laia Arcones.
- Collaboration with AMPANS, an entity that accompanies people who have disabilities or are in vulnerable situations to make their life projects a reality.
- Empowerment and leadership dynamics with the Indian women's team.

In 2023 we received recognition from the AMPANS Foundation for our commitment to the social and occupational inclusion of people with diverse abilities. The award was presented at the XI AMPANS and Business Meeting in Manresa, Spain.



Recognition from the AMPANS Foundation.

A total of 170 people were hired in 2023, 58 women and 112 men.



Women's team. Chennai centre, India.

Physical, mental and emotional well-being

For a person to perform at his or her best professionally, he or she has to be well on a personal level. That is why at BioSystems:

- **We establish policies that help to achieve a good work-life balance.** We consider self-care and family care –in the broadest sense of the word– to be a fundamental part of our well-being and one of the pillars for professional development. We want to foster a culture that helps to find and maintain this balance between oneself, one's hobbies, one's personal environment, one's family and one's work. The family business values that have characterised us throughout our history are still valid today.
- **We provide tools for professional and personal growth, providing accompaniment to support people during the more emotional stages. We provide individual and team accompaniment.** In 2023, we are continuing to work on individual accompaniment, carrying out personality studies as the basis for personal growth and team accompaniment. These have been carried out at a global level to promote self-knowledge and ensure the well-being and performance of people.

- **We organise activities to improve people relations and interpersonal communication** and create an atmosphere that provides people with moments of relaxation, fun, mental disconnection and leisure. These activities also aim to promote healthy habits. In Spain, such activities include the following:

- Yoga and mindfulness one day a week: maintaining healthy lifestyle habits helps us to improve our health and well-being.
- We ensure that the work spaces are adequate and comfortable for the development of professional activity. We improved facilities or equipment in our centres in Chile, Barcelona, Mexico, and India.
- Salsa classes one day a week.
- Following our aim to improve health and wellbeing, in Spain, after intense heat waves, we distribute IDESCO moisturisers to everyone.
- In Barcelona, fruit is available to everyone on Wednesdays.
- In Barcelona and Montcada we are already a cardio-protected community. In 2023 we installed 5 Automatic External Defibrillators (AEDs) to be used preferably by first responders, or even by anyone in the event of a cardiac arrest.



Stakeholder engagement and collaboration

Strategic collaborations

Collaboration is part of our culture.

We collaborate with a range of different types of organisations. We are members of various professional and corporate associations, or ones that promote and help business development in the countries in which we have a presence. Some of the organisations we collaborate with include:

- ACCIÓ, the Catalan Agency for Business Competitiveness
- CataloniaBio & HealthTech, a body that represents companies in the biomedicine and health sector in Catalonia
- BIOCAT, Bioregió de Catalunya
- ICEX, the Spanish Institute for Foreign Trade
- Pimec: Employers' organisation representing small and medium-sized companies in Catalonia

We are a member of associations related to the specific industries in which BioSystems is active. They include:

- AACC, the American Association for Clinical Chemistry
- ACB, the Association for Clinical Biochemistry and Laboratory Medicine
- SEQC, the Spanish Society of Clinical Chemistry
- ANIAE, the National Association of Agronomic and Wine-making Engineers of Chile
- IFU, the International Fruit and Vegetable Juice Association.
- PMA, the Philippine Medical Association
- ICAP, the International Consensus on ANA Patterns
- SEEC, the Coeliac Disease Society of Spain
- European Commission, Joint Research Centre

We are also members of other organisations that allow us to keep up to date with regulatory issues and other matters of significance for the conduct of our business:

- MedTech Europe
- ASCOM, the Spanish Compliance Association
- Team PRRC, a European non-profit association dedicated to "persons responsible for regulatory compliance"

We have formed and maintain professional collaborations with medical bodies and laboratories for measurement studies and product validation and application verification. Apart from the centres mentioned in the 'Research and development' section (page 22), some key collaborating centres are:

- CATLAB
- Bellvitge Institute for Biomedical Research Foundation (IDIBELL)
- Germans Trias i Pujol Hospital, Can Ruti
- Vall d'Hebron Hospital
- Hospital of Santa Creu i Sant Pau Private Foundation
- Reference Laboratory
- AMBAR, Anàlisis Clínicas Barcelona

We also carry out scientific and technological development projects with various companies, as well as academic or outreach activities with universities and scientific entities, such as:

- The Australian Wine Research Institute (Australia)
- The University of Guadalajara (Mexico)
- The Autonomous University of Baja California (Mexico)
- The Austral University of Chile
- Maltepe University (Turkey)
- St. Luke's Medical Centre College of Medicine (Philippines)
- Busan National University (Korea)
- Jiangnan University (China)
- UC Davis University (USA)
- Cornell University (USA)

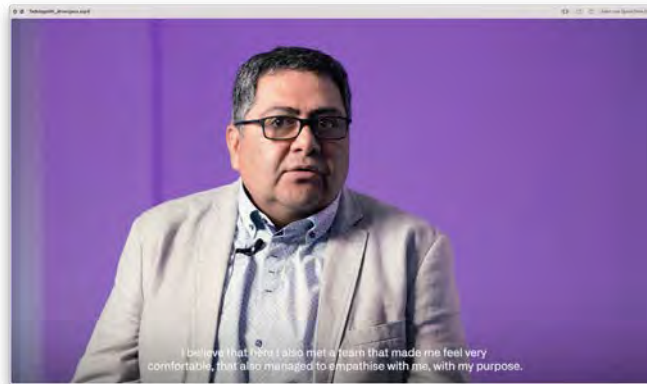
Finally, our key partners for the support and financing of Research and Development projects are the CDTI –Centre for Industrial Technical Development– and the Ministry of Science and Innovation. The rest of the funding comes mainly from reinvestment of profits.

Stakeholder engagement initiatives and programmes

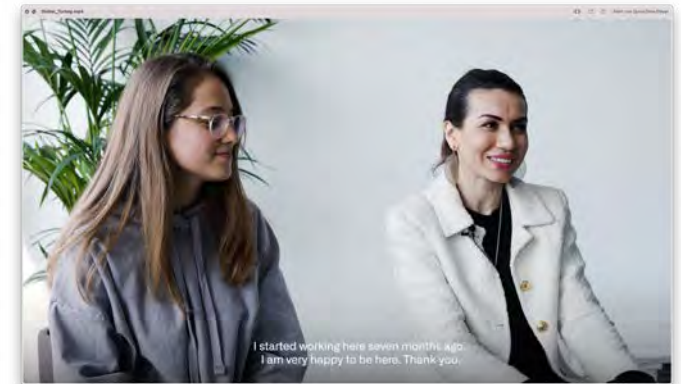
The ongoing conversations and collaborations we have with our stakeholders help us to evolve the business and learn every day. As part of our desire to expand this knowledge and learning, we have launched initiatives of interest for various groups:

- **Talking with.** We hold meetings with key opinion leaders, experts from universities or from some of our working sectors, to delve deeper into different topics while sharing these meetings with the rest of the BioSystems community. This can be in video, podcast or documentary summary format.

- **Global experiences.** Audiovisual capsules whereby we gather the testimony of colleagues from various countries to discover and share the most cultural, interactive and collaborative aspects of BioSystems.



Dr. Christian Vergara, Biochemical Engineer academic at the Universidad de La Frontera, Chile.



Eda Karagoz, Product Specialist and Işıl Saraç, Accounting Administrative Executive, BioSystems Türkiye.

Contribution to the community and society in general

We remain committed to contributing to the creation of a fairer, more equitable society in which everyone has access to equal opportunities. To this end, we have 3 main lines of action that allow us to focus our cooperation resources on:

- Improving health
- Having a positive impact on the communities around our workplaces
- Knowledge sharing

In 2023, the main collaborations were the following:

Vicente Ferrer Foundation

An entity centred around childhood and the most vulnerable families. We help the Foundation by supporting them in the laboratories of their hospitals in India. In addition, each year we donate a portion of the profits from BioSystems India.

Laia Foundation

Since 2018, we have been collaborating annually with the Laia Foundation, an organisation that contributes to the social and economic development of communities at risk of exclusion in southern India.

CEL Foundation

An organisation in the Bon Pastor neighbourhood of Barcelona that accompanies children, young people and families in vulnerable situations in the neighbourhood. BioSystems makes a contribution so that children can take part in summer camps, as well as other more interactive collaborations such as visits by young people from the neighbourhood to BioSystems' facilities.

Banc de Sang i Teixits

This is a public company of the Department of Health of the Generalitat de Catalunya, Spain, whose mission is to guarantee the supply and proper use of blood and tissues in Catalonia, being the reference centre for diagnostic immunology and the development of advanced therapies. BioSystems Barcelona and Montcada carry out an internal blood donation campaign.

Eurofirms Foundation

Grants for the training of women with disabilities and their entry into the workforce.

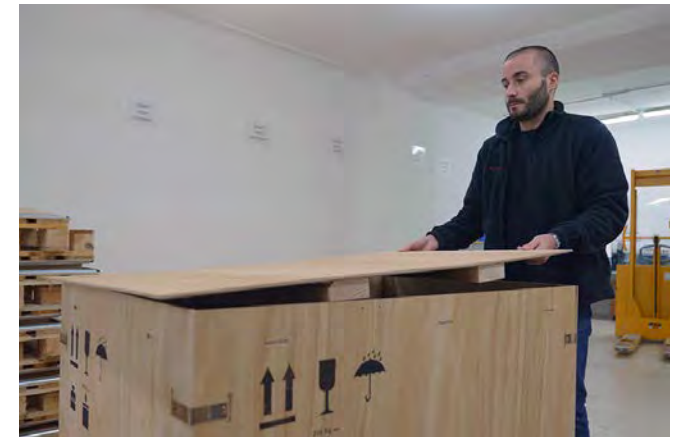
Furthermore, in 2023 donations of food and furniture were made to local entities along with a special donation of basic necessities to the area of Hatay, Turkey, due to the earthquakes that occurred in February. A donation was also made to the Lliga Protectora d'Animals de Sabadell, Barcelona to support animal care and welfare.

Responsible environmental performance

BioSystems is directly present in 18 countries on four continents. The size and structure of each work centre is very diverse, ranging from centres such as the Barcelona headquarters, where activities of the entire value chain are carried out –occupying more than 21,000 m²– to smaller centres with commercial activity and customer support in centres of less than 100 m².

In all our centres we seek to make efficient and sustainable use of resources, as well as to carry out appropriate waste management in order to preserve the environment. We therefore monitor the main aspects that make up our environmental impact: energy consumption, water management and waste generation.

As of 2023, in addition to approving the **Sustainability Policy**, we will include sustainability criteria in the evaluation of our suppliers with the aim of improving the environmental impact in our value chain as well. We also incorporate an analysis of environmental impact in the design process of new products; in our offices we eliminate single-use plastics such as plastic cups and improve waste segregation in our common areas. As of this year, we have a document for our customers indicating how to treat the waste from our equipment.



Wooden packaging. Barcelona centre, Spain.

The regenerative role of business in mitigating the effects of climate change

Greenhouse gas emissions

We measure our impact on the climate by calculating our carbon footprint. In this respect, we are implementing measures that enable us to reduce the amount of Greenhouse Gas (GHG) tonnes.

The calculation of GHG emissions is organised into three categories:

Scope 1

We have identified the fuel consumption of the own fleet, the use of refrigerant gases, the use of a diesel generator and the diesel consumption of the steam boiler for some of the production processes as sources of Scope 1 emissions.

Scope 2

Indirect emissions from energy production. We carry out the calculation based on the contracted energy (market based) and based on the market mix (location based) to be able to assess the impact of our decisions on the reduction of tons of CO₂ emitted.

Scope 3

Other indirect emissions generated by other companies involved in the whole value chain. BioSystems has not yet started to calculate this set of emissions, which includes business travel, transport of goods and raw materials, among others.

It can thus be observed that the installation of solar panels for self-consumption and the choice of renewable energy sources in Barcelona has led to a saving of 493 tonnes of CO₂ equivalent in 2023.

Scope	Emissions	2023 (t CO ₂ equivalent)	Total 2023	2022 (t CO ₂ equivalent)	Total 2022
Scope 1 – direct emissions from proprietary sources	Cars	358	370	463	479**
	Gases (air coolants)	0		0*	
	Caldera de vapor	12		16	
Scope 2 – emissions associated with electricity generation	Purchased electricity (market based)	565	565	518	518
	purchased electricity generation based on the country's energy mix (location based)	1058	1058	834	834

* The refrigerant gas conversion factors for the year 2022 have been updated

** When the conversion factors for the year are updated, the total of Scope 1 is updated for 2022.

Our commitment to renewable energy has saved us 493 tonnes of CO₂ equivalent in 2023.

Energy consumption

The highest electricity consumption is concentrated in Europe. Specifically, the Barcelona headquarters –where the main production plant is located– accounts for 70% of energy consumption.

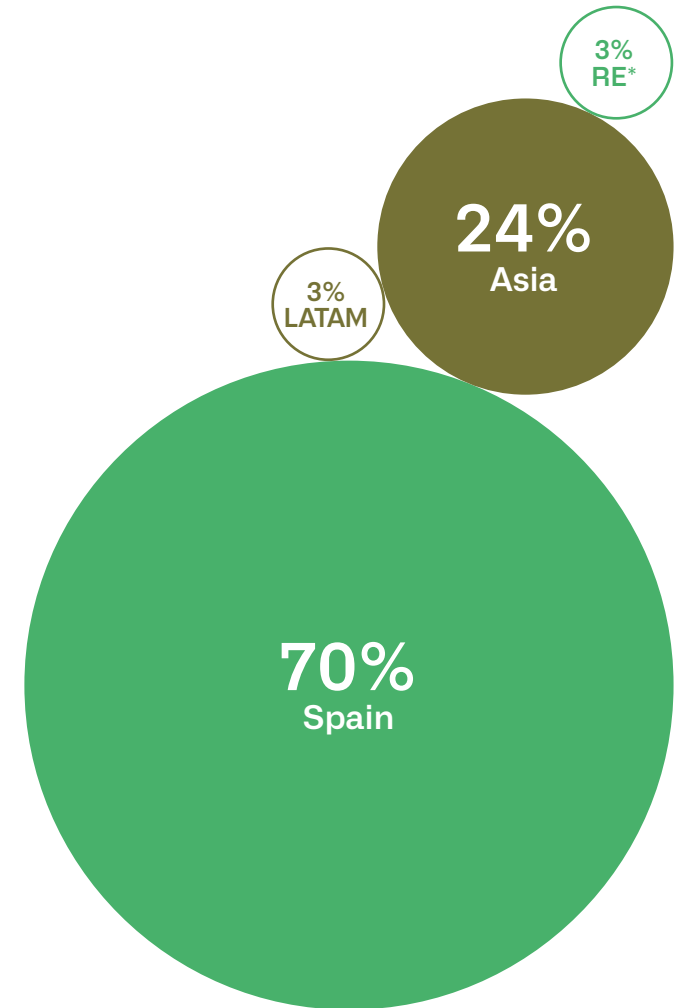
100% of the energy used in Barcelona is of renewable origin, and we have also had solar panels since 2022 that allow us to ensure the self-supply of part of the energy consumed on days with sunlight.

In Chennai, India, we have another production plant, which means that the second highest percentage of electricity consumption is concentrated in Asia. The Chennai plant consumes 20% of the group's total electricity.

Efforts to minimise energy consumption are focused on improving the energy efficiency of the building, both through cladding and thermal insulation and through the installation of LED lighting and management systems for air conditioning, cold rooms where the product is preserved and production facilities, trying to minimise inappropriate or unnecessary use.

In addition, through collaboration with an energy efficiency engineering company, we continuously monitor our photovoltaic plant in order to track and resolve any incidents quickly.

We also have 14 analysers distributed in our Montcada and Barcelona buildings to determine the consumption and demand, and simulate the monthly bill. This information also allows us to know how our centres are performing throughout the year and to set reduction targets for the coming year.



* RE: Rest of Europe

Actions to prevent pollution

Waste water treatment

BioSystems complies with state and local wastewater disposal regulations.

Non-production wastewater is discharged into the municipal sewer. The BioSystems production plant in Barcelona has a wastewater treatment station that treats the water resulting from production before it is discharged into the public sewer, thus avoiding the risk of contamination.

The resulting sludge is managed by our waste manager. This sludge totalled 62 tonnes in 2023.

Nearby providers

Around 53% of BioSystems' suppliers are located within 300km of Barcelona, which significantly reduces the emissions generated by the transport of raw materials to our plant. In addition, 70% of suppliers are based in Spain, and 20% in other European countries.

The use of raw materials

The raw materials that we use most in the reagents department are enzymes and other reagents and inorganic substances, and sheet metal and mechanical components as packaging material for the instrument department.

To incorporate environmental criteria into product design, a product sustainability scoring guide was developed with a Life Cycle Analysis approach that allows products to be scored and a decision made as to whether it is viable to move forward with development. This made it possible to incorporate essential issues to ensure the least environmental impact in the research and development process.

We monitor the raw materials we source, as well as our suppliers, to ensure compliance with REACH and ROHS regulations.

Water management



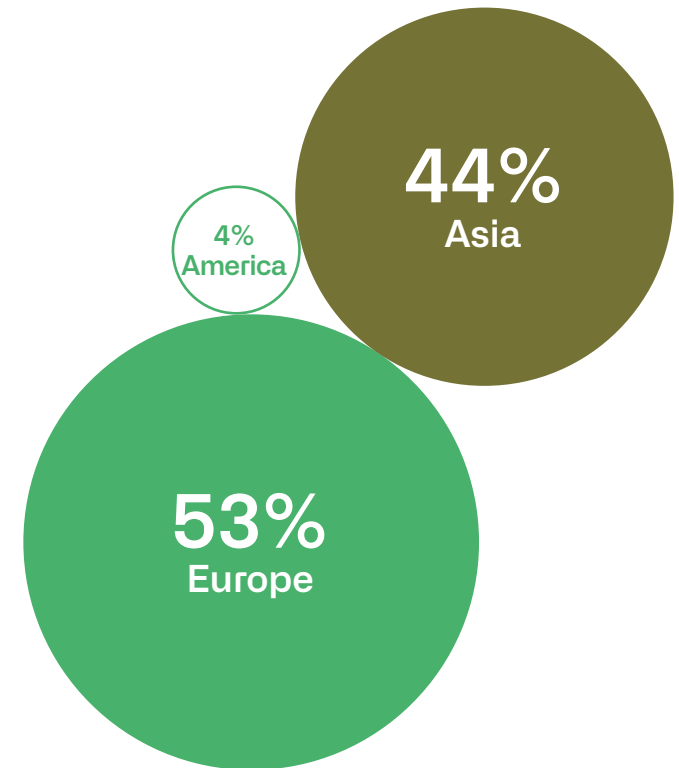
Chennai centre, India.

Water consumption is equally divided between Asia and Europe.

BioSystems consumed a total of 11,367,635 litres of water in 2023 (146,365 litres less than in 2022). Of this, 10,126,000 litres were consumed between the production sites in Barcelona and India.

Aware of the impact of water use, we have carried out various actions in recent years that have allowed us to improve water use efficiency. By way of example:

- At the Chennai plant, physico-chemical and biological treatments are carried out on part of the water from the production plant, allowing it to be reused for irrigation of the landscaped area around the factory. The gardens also grow indigenous trees, fruits and medicinal plants, which are distributed among the factory's people.
- In Barcelona, we implemented a system of circularisation of water for cooling the freeze-dryer compressors, which has enabled us to save approximately 5,640 m³ of water in 2022 and 5,220 m³ in 2023



Circular economy and waste prevention and management

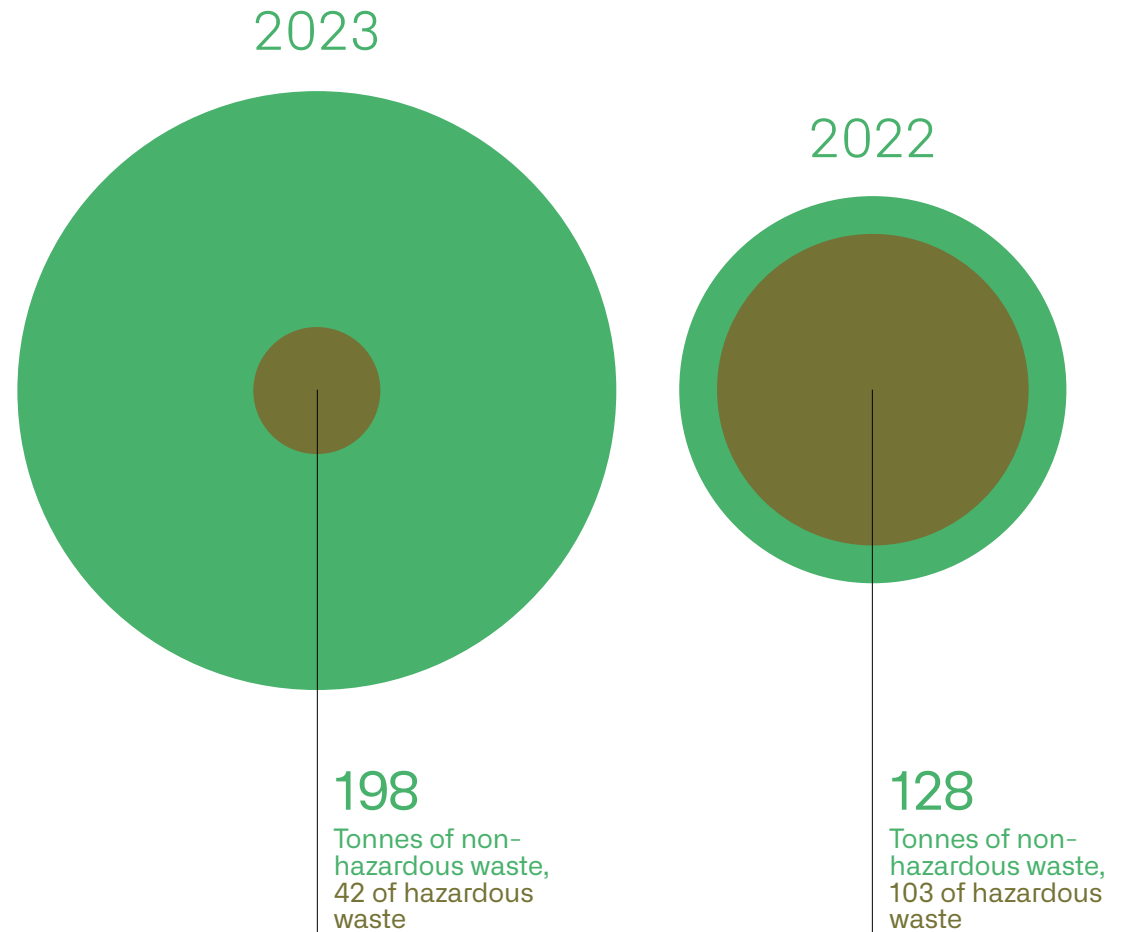
Our business generates different types of waste, depending on the quantity and type of products manufactured.

The information related to waste generation focuses on Barcelona and India, the production sites where the most significant amount of waste is generated. However, it is in Barcelona where there is most activity and, therefore, where most waste is generated.

In our efforts to reduce waste in the production phase, we work to optimise the use of raw materials and cleaning chemicals in the production process, we analyse and improve waste segregation, we work to minimise the impact of packaging and we recondition disused equipment.

Most of the waste generated is non-hazardous and can therefore be recovered. In 2023 we carried out circular economy actions through the direct recovery of materials from defective products such as bottles, caps, and jugs made of materials such as HDPE, PP, PE. A total of 0.8 tonnes were recovered.

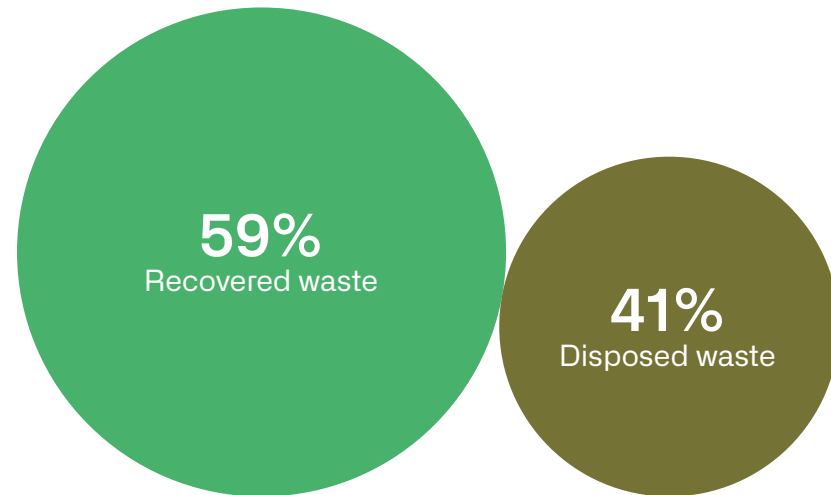
Hazardous waste, on the other hand, is disposed of in accordance with current regulations in order to avoid damaging the environment.



Destination of waste

At Biosystems Barcelona, where we generate the largest amount of waste, we recognise the importance of good internal waste segregation, such as final disposal by the waste manager. That is why, through close collaboration with our waste managers, we ensure that each discarded material receives the appropriate treatment, whether recycling, reuse or safe disposal, thus helping to reducing our environmental impact.

Tonnes of waste by final treatment



Sustainable governance and transparency

How are we organised?

The medium-term and long-term strategic vision is set by the CEO together with the ownership. This is always with the support of the management team, made up of 8 people, mostly corresponding to the heads of the different functional departments or chiefs who, with a critical and collaborative spirit, help both to define the designed strategy and make it a reality.

The functional areas of BioSystems




Functional areas strive for their best performance and collaboration to work through process and project work:

- **Process-based** working helps us to identify everything we do at BioSystems to bring value to the customer, linking all people and activities throughout the process. This way of working makes it possible to know the value contribution of each part of the process to a common goal, and promotes communication between people in the organisation and facilitates teamwork.
- **Projects** help us to focus, to have clear completion dates and, therefore, to achieve better results.

BioSystems' processes





Each of our business processes has an identified process owner who has knowledge of the process from start to finish. Process Owners or Managers, in collaboration with other people, are responsible for identifying risks and opportunities that may hinder or enhance the achievement of process objectives.

Risks and opportunities are influenced both by the activity itself and by the situation and changes in the environment. Therefore, the Management and Strategy team (management team) conducts a periodic analysis of the context and stakeholder expectations.

From the analysis carried out by the Process Owners and the Management and Strategy Team, an assessed picture of risks and opportunities is obtained and risk mitigation measures are identified, implemented on a routine or ad hoc basis. Improvements in operation are then defined. Closing the circle, and respecting our robust quality system at all times, we follow up on objectives, projects and the implementation of defined improvements.

The Business Process Management unit is responsible for coordinating all these actions, as well as proposing actions to help improve process efficiency.

One of the improvement actions with the greatest impact in 2023 has been the OneERP SAP project, the ultimate goal of which is to implement SAP S4Hana in all the group's centres. This change will allow us to have a single point of reference for detailed analysis and insight into most of our processes. It will also make us more efficient and able to better serve our customers.

It is expected that during the second half of 2024 we will be able to work in the SAP environment in Spain as well as in France and Italy.

This is a cross-cutting project that has forced us to improve communication and organisation between the different areas and processes in order to rethink how we will work in the coming years.

SAP project team. Barcelona centre, Spain.



Ethical and legal standards

We are aware of our responsibility as a company towards our stakeholders, society and our environment. In a changing and demanding environment in which we interact with a wide range of people, conflicts and doubts about the best way to deal with a situation can arise.

For this reason, and always with the aim of offering confidence and security to all our stakeholders, at BioSystems we have a **compliance model** in which we show a clear commitment to respecting human rights and current legislation, highlighting the fight against corruption and bribery, in line with what is described in the Sustainable Development Goals. In this regard, we have not identified any incidents related to corruption or bribery in any of our activities throughout 2023.

In addition, our teams regularly review our legal obligations and put in place the necessary measures to enable us to comply with them, relying on external advisors where necessary.

The measures imposed are mainly aimed at preventing and detecting possible breaches of regulations in order to react appropriately in the event that they are found. Therefore, our policies and procedures provide for the imposition of labour sanctions in the event that compliance deviations are detected.

The measures implemented include training and awareness-raising for all persons on compliance obligations and the existence of an Alert Channel that allows all stakeholders to report any situation anonymously and confidentially. In addition, all BioSystems people have communication and consultation channels available to those responsible for compliance through which they can communicate their doubts or concerns about potential situations of conflict with the commitments they have made.

All these aspects are detailed in the **Code of Conduct** available on our website.

In 2023, BioSystems adapted the Alert Channel to align with Law 2/2023, dated 20 February and regulating the protection of persons who report regulatory violations and the fight against corruption. Among the changes is the inclusion of a direct link on the website as well as sufficient documentation for all stakeholders to report non-compliance through this channel.



Communication and transparency

Communication is part of the BioSystems culture. We work to ensure it is honest, two-way, transparent and effective. To this end, teamwork and transversality are considered fundamental axes.

We have tools that promote teamwork and transversality. The fundamental pillars around which this revolves are:

The process and project work model

This allows us to quickly visualise our process within the whole BioSystems network, and we can participate on different initiatives with different departments. In this way, we gain a broader view of the company, enrich our development and broaden our contribution. Effective teamwork is essential to the achievement of our objectives.

The distribution and approach of the workplace

We consider the provision of meeting spaces, both formal and informal, to be fundamental to creating this culture of communication. Everyone also has a workplace, but they are not limited to it. In other words, they can work in any area of BioSystems according to possibility, practicality or need.

Connection and encounters

We have technological tools that allow us to stay connected, such as Teams in Outlook 365, and we promote mobility and face-to-face meetings with colleagues and customers to enhance teamwork and trust.

We have an internal communication channel that allows us to stay well connected among colleagues, as well as to keep up to date with company developments. **BioSap** connects all the people involved in the project. Among other functionalities, the channel includes the sharing of news on sales, results, new policies, participation actions, surveys, etc. Not to mention providing the main links to common tools such as the Brand Center (brand resources) or the link to the website.

In 2023, we implemented **mySpace**, a personal digital space for the entire BioSystems Spain community. Here, each person has his or her employment documents stored, various forms with an advanced application approval system, a portal for new career opportunities and the digitised onboarding process. All of this is done via simple, confidential management.

To ensure that everyone is aware of how this new channel works, we are conducting an official presentation and training in small groups, as well as making reference guides available to everyone.

In addition, more management support functionalities, such as training traceability, will be included throughout 2024 with the development of the Learning & Performance module.



BioSystems Chile team.

We also have external tools and actions that allow us to show and share our contribution to the different sectors in which we operate and to society, as well as to establish conversations that may lead to new collaborations:

- The **website** is not only the public face of BioSystems, but also the resource centre for various partners. We have a global website and are gradually developing local websites. In 2023 we developed the websites for Italy and France.
- LinkedIn is the external social network through which we explain our product and scientific developments, talk about the topics that are important to us and share knowledge. As with the website, we have a global LinkedIn BioSystems and are developing local pages. In 2023 we developed the Turkey, Chile and Mexico pages.
- **Trade fairs, conferences.** We participate in trade fairs in the sectors in which we operate, both on an international and local level, to raise awareness of our analytical solutions, maintain our links with professionals from all sectors in the countries where we operate and dialogue with potential new partners.



Conclusions and future commitments

Chennai centre, India.



In 2023, we made a great collective effort to achieve the objectives we had set ourselves. Despite not quite achieving the results forecast for the year, we still grew in terms of group-wide sales and delivered **positive results**.

However, we remain determined to make progress on all ongoing projects, aiming to **improve in all areas and companies of the group** without being discouraged by the current situation. We are confident that “continuing to do all those things we want to do” is the best approach to achieving our objectives.

Many of these projects were geared towards **updating and improving our existing products** by making them more robust or introducing new features; carrying out studies to certify them as IVD products and CE mark them or launch them with better guarantees and greater safety for patients and users; manufacturing them more efficiently or in greater quantities while preserving their quality and features; and marketing them to better serve our customers.

Other projects were aimed at **launching new products** in order to increase our competitiveness; to better serve our existing customers by meeting their expectations and high demands; and to serve new customers in new areas, sectors and segments. They were aimed at ensuring continued growth which would allow us to launch new products and continue to create, develop, manufacture and sell.

Our **new company information management system** is another international project. We are planning to implement it in our Barcelona, Spain, France and Italy centres in October 2024.

As 2023 drew to a close, we were aware that many of these projects would be completed in 2024 and that many products would launch the following year. This motivated us to keep working, efficiently and rigorously, to make all this a reality at the earliest possible opportunity.

We ended the year aware that we were preparing for a new stage of sales growth, a new cycle that should bring us 2025 and beyond, to recover the sales numbers, growth, results, and economic and financial balance that we need to move forward for many years to come and that we deserve, thanks to the effort and dedication of many, for the commitment of the majority, and to meet the expectations of new people who see BioSystems as a place where they can realise some of their professional dreams or, in some cases, their personal wishes.



I see a clear future for BioSystems, full of opportunities all around, not free of challenges and difficulties, but with a project that excites, that attracts collaborators from all over the world and from many disciplines, who are proud to work in an organisation that puts people first and makes products that improve health and wellbeing. In the same way, it is an attractive project for clients and users of our products and solutions, for collaborators, scientists, researchers and professors from all over the world, and for some companies –small, medium or large– that want to collaborate with us and like the way we do things.

Sometimes the day-to-day work, the meetings or the changes in the context do not allow us to see and appreciate all that we are doing and, especially, how we are doing it, but when we pay attention to it or when someone from the outside comes and sees us and tells us what we are doing, we realise that what we are doing is extraordinary, exceptional, unique, authentic and original.

That is why I am optimistic, because I know that with hard work, enthusiasm, rigour, patience and perseverance we have a long road of success ahead of us.

BioSystems, a human-center biotech Co. Better every day, bigger every day, more international every day, more sustainable every day. Every day more.

www.biosystems.global