

BioSystems Group

Sustainability Report 2021



CONTENTS

BioSystems	3
Compliance	36
People and Community	45
Environment	81
Product	97



BioSystems

Letter from the CEO

I became CEO of the company in January 2019 and took on responsibility for strategic leadership and management of the BioSystems business. Since then, working alongside the other members of the leadership team, we have completed the generational succession of management from the previous CEO – who was in post from BioSystems formation in 1981 until his retirement in December 2018 – and his management team, and in the process made significant organisational and operational changes in all areas.

We are working on projects that will transform the future of the company and at the same time we have faced and dealt with the consequences of the CoViD-19 pandemic. The company has also done well across the principal indicators of its business, which underline the value of the company and confirm that it has options to continue on a path of sustainable growth in a sustainable manner using the resources generated by the business itself.

I therefore want to express my sincere thanks to the more than 650 people who make up BioSystems for their part in that success. Thanks to their commitment, effort and resilience, we have been able to continue to provide products for clinical analysis and *in vitro* diagnostics, products that are vital to laboratories and hospitals around the world. In doing so, we contribute to improving the health and wellbeing of so many people whose lives have been affected by the impact of the pandemic and in other ways.

We have also continued to help parts of the food and drinks industry – also impacted by the pandemic – to continue to manufacture products of the highest quality. In addition, we continue to make progress in the development of a new line of clinical testing products for veterinary diagnostics to help improve the health and wellbeing of pets and livestock.

After looking back over the most significant events of the last three years, I think it is important to remember all those who are no longer with us or their families today, whether due to CoViD-19 or any other reason. We think of those of us who have lost a friend or someone close. Perhaps lockdown meant we were not able to say goodbye as we would have liked, making a painful experience even more difficult. But it is also important to celebrate the arrival of daughters and sons, grandsons and granddaughters to our families. We have shared moments of joy with our youngsters, watching them grow and overcome the challenges of these years, which have been so difficult from a social point of view, with courage and determination – in greater courage and determination than us.

But these moments of reflection and reminiscence makes us want to look to the future as well. My message to all the people (staff, customers, suppliers, partner organisations and all our stakeholders) who make BioSystems possible and believe in us is a message of optimism and hope.

This enterprise, which started in 1981 in a small place in the Gracia district of Barcelona, has overcome many difficulties over the course of the last 40 years without wavering from its essence and purpose: to move towards the future on the foundations of designing, developing and manufacturing its own high-quality innovative products and expanding its business across the globe.

We always try to provide added value to our customers, dealing with them openly and honestly, adapting to their needs and meeting and, in some cases, exceeding their expectations. We progress by setting up subsidiaries and affiliates around the world to bring our business close to our customers, following a policy of growth based on financial prudence and sustainability.

This 'way of doing things', instilled from the very beginning by the company's founder, Dr Josep Bach, and cultivated with dedication and care by my predecessor as CEO, Dr Antonio Elduque, has allowed the company to face the pandemic and the ensuing challenges over the last two years with confidence and strength.

The new Management with the support of the Board, has also not hesitated at the most difficult moments of the crisis to mobilise and inject resources to continue with all our projects for the development of new products and value creation, in the search for new business and the creation of businesses like those in Thailand, Italy, France and China. Efforts also continue to transform and develop the parent company in Barcelona to adapt to changing times and stakeholder expectations.

Our purpose remains firm: we will continue investing in the creation and development of analytical solutions and products. We aim to improve the services we offer to human and animal healthcare and to promote quality and innovation. We have the same aims in food and drink testing and in the emerging field of testing for industrial bioprocesses and agricultural and environmental testing.

I want to underline the firm commitment and determination of the company's entire management team to sustainability in the sense of respect for the environment, playing our part in society and management based on transparency. That affects all our stakeholders.

The central pillars of BioSystems new reality are good management, transparency, communication, design and development of sustainable products, work-life balance, respect for diversity and a firm commitment to the fight against unjustified inequality, particularly gender inequality. We also want to focus on creating spaces for work and shared experience that contribute to people's personal and professional development in an atmosphere that fosters innovation, creativity, communication and teamwork. We believe that all of those things will help to build the best team and build the trust of our customers and all the other businesses that we work with, seeing our stakeholder group as including both public and private entities and, indeed, the wider community.





Commitments are demonstrated by deeds:

- In 2020, we set up a Compliance Committee under the Board of Directors to implement a Compliance Policy and to communicate our new Code of Conduct.
- We promote an open culture to encourage and allow communication. We have different channels – some of them confidential – for reporting any actions that are not consistent with our way of doing things or are in breach of the law.
- In 2021, we created a sustainability work team that oversees and takes forward various projects to make further strides in doing what we see as our duty and our purpose, working transparently and with commitment with all stakeholders.

I particularly want to underline one of my top priorities; the commitment to foster communication at all levels, by and for everyone in the organisation globally. We have set up several communication channels to tell the community about what is happening in the business on a regular basis. We are also having 360° conversations with all BioSystems people around the world. We still have a long way to go and much to do, but I am convinced that together we can forge a path through honest dialogue, with understanding and sensitivity, with respect and generosity.

For all those reasons, we are continuing and will continue to work responsibly and with a clear, firm commitment to sustainability. A commitment that should more clearly bear fruit, even in the long term, when society and people – our future customers and partners – choose to work in and with, invest in, and buy products only from businesses that have a

genuine commitment to sustainability and addressing the needs of all stakeholders. That commitment extends to the wider community, to the planet and to the responsible use of natural resources, with our deepest respect for all living creatures and the habitats in which we live, because no one has the right to make it impossible for others to co-exist.

That conviction and the resources needed to put it into effect will ensure that the BioSystems project will successfully reach its 50th anniversary in 2031 and, why not, can dream of its centenary in 2081.

P. Vila Cases

Pau Vila Cases

Who are we and what do we do?

BioSystems is a group of companies that operates through distributors and directly through subsidiaries and affiliates to supply In Vitro Diagnostic – IVD – products for human clinical testing, veterinary testing and industrial testing – principally for the manufacture of drinks (wine) and the food industry (fruit and vegetables, juices, fish, meat...). BioSystems is also active in other fields in the world of biotech such as testing for bioprocesses (fermentation and cell culture), and agricultural and environmental testing (water and soil). The Group is present in more than 100 countries on five continents.

Clinical testing or **In-Vitro** Diagnostics (IVD) is a form of investigation that consists of taking biological samples from a patient (blood, urine, faeces, tissue, etc.). The samples are then examined in the laboratory to confirm or rule out a diagnosis, detect anomalies or obtain the information needed to use a given treatment or undertake other medical procedures.

Clinical testing is also used in **disease prevention** through early detection of anomalies through screening. That is the role of routine clinical tests that commonly form part of regular health check-ups. Results are used to confirm that a patient's parameters are within normal ranges and to take the appropriate steps to prevent disease progression. For example, periodic monitoring of parameters such as cholesterol, glucose and many other parameters can inform measures to avoid future problems (e.g., the development of diabetes and cardiovascular disease).

It can also **confirm or rule out a diagnosis**. Alongside direct observation and many other types of diagnostic tools, clinical testing is indispensable to the confirmation of diagnoses in human health. Depending on the test, results are expressed qualitatively (positive or negative) or quantitatively (as an absolute number or the level reached on a scale).

Third, clinical testing can also play a decisive role in **research**. Alongside their primary role in normal medical screening and diagnosis, clinical tests are also often used in the context of clinical research to develop new drugs and treatments, as we saw during



the fight against the SARS-Cov-2 coronavirus and the use of Antigen and Antibody and Nucleic Acid (DNA or RNA) tests in vaccine development of vaccines. Clinical testing is also used in a similar way in university research.

Through the testing solutions that we develop for different functions, we aim to make a contribution to improving **health and wellbeing**. Our vision and our expectation is to be universally recognised, not only for developing quality products but also for providing a **good user experience** in the use of our products and associated services and in dealings with BioSystems staff at every level of the value chain.

Today, 40 years on, there are BioSystems businesses and affiliates in Argentina, Brazil, Korea, Chile, China, Spain (in Barcelona, with the Group's headquarters and principal plant), the Philippines, France, Italy, India (where there is a second production plant for the local market), Mexico, Portugal, Romania, Turkey, Thailand, and USA, as well as a Representative Office in Russia.

The parent company and founding business of the Group was created in 1981 in Barcelona. The other business have been set up over the course of those 40 years, either as subsidiaries or as affiliates (India, Brazil and USA).

The **17 businesses** that make up the Group (as at December 2021), are at different levels of maturity depending on the year in which they were formed, how they have been managed and their business and its level of complexity.



There are small or recently formed businesses – 2-10 people – such as China, Italy, France, Turkey and Argentina; medium-sized businesses – 10-50 people – such as the Philippines, Mexico, Chile, Korea and Romania; and large businesses – 80-100 employees – such as India, Brazil and the largest and most complex of all, the parent company in Spain with more than 350 people.

Individual turnover is affected by multiple factors. The principal determinant of turnover is the potential of the markets in the country where a business operates, alongside market penetration and time devoted to those markets. Product portfolio, market sector or segments in which a business is active and business development strategy to date are also important.

In most businesses, branded BioSystems Clinical Testing products are the main product line or, when it is not the only line, a very significant part of the portfolio traded in a given country. In other businesses, BioSystems products are complemented by other distributed brands for the same market sector – clinical testing laboratories or food and drink laboratories. Some businesses, such as France, USA and Argentina sell only some BioSystems lines. In those cases, the food and drink testing line is mainly focused on the wine industry.

In those countries, products reach the **end customer** or end user directly through our business or in some cases via local distributors. Where local distributors are in place, they are responsible for marketing and sales and BioSystems offers application support and technical service directly to laboratory users or provides ancillary specialist support to the distributor.

Another sales channel which complements the manufacture, marketing and sales of our own products is **manufacturing for third parties** (private label or OEM products). The plants in Spain and India both manufacture products for other manufacturers who market them under their own brand names.

Clinical testing products are designed and developed, manufactured and marketed under certification for IVD under **ISO 13485 and are CE marked**. In countries where our businesses consists of sales and marketing and in non-IVD market sectors, the business may have quality management certification under ISO 9001.

In other markets, in more than 100 countries, BioSystems operates through **distributors**, local companies that import and supply products to customers in the country through their own sales and service network. As well as promoting and supplying the products, distributors provide technical and commercial support to the customer, training, technical service and on occasion they also invest in the installation of equipment in laboratories for rental on exclusive supply of reagents terms.

Product design and development (R&D²+i/a) and manufacturing are mainly carried out in Spain. They are both carried out in laboratories, facilities with controlled environments or in safety or fume extraction cabinets to ensure the safety of staff and to protect products from contamination (clean rooms or clean rooms with access control).



Required cleaning and tidying procedures and measures and the wearing of personal protective equipment (gowns or scrubs, hats, goggles, gloves, masks, etc.) are implemented for both activities. The activities are very diverse because of the mix of products developed and manufactured, which includes materials of biological origin, such as animal sera, cells, bacteria and tissues, enzymes and other proteins, chemical ingredients or components in powder or liquid form, detergents, preservatives, defoamers and mineral salts.

We use reactors with agitation, analytical and scientific equipment and instrumentation, balances, centrifuges, ovens and incubators, bioreactors, protein purification systems, microscopes, baths, ultrasound, refrigerators and freezers or freezers and reactors of various capacities, weighing equipment, liquid filling and transfer equipment (pumps), dosing machinery for vials and small volume vials and flasks (from 5mL to 1L), labelling machines, bottle cap threaders, label printers, and handling equipment for the consumables in the form of reagents and liquids that form part of testing systems.

BioSystems develops and manufactures automatic testing equipment that requires mechanical, electrical and electronic components, fluid transfer systems, thermostats, photometric components, low (*back-end*), medium (*firmware*) and high level (*user software*) software and programs and numerous components and equipment required for production, such as climatic chambers, dark chambers, and the controls for those highly complex technological instruments. All those activities are carried out in light of the needs and preferences of users of our products. That is why BioSystems seeks to carry out its projects in collaboration with leading entities and laboratories.

Since 2012 some products have also been manufactured in the Chennai (India) factory, mainly products intended for the local clinical biochemistry market and since 2021 a small semi-automatic analyser which is very popular in small laboratories in small towns far from big cities.

The other businesses in the BioSystems group are mainly involved in sales and marketing and services. Because IVD is a highly regulated sector – medical product registrations are required for the products to be put on the market – it is common for there to be an official, often single or exclusive, distributor in each country.



Our mission, vision and strategic pillars

The purpose of BioSystems, reflected in its mission and vision since 2019, is based on the following 3 strategic axes:

PQ & UX

User Experience

BioSystems is fully committed to developing **quality products and services** that are based on an understanding of users' expectations in order to meet their needs and to improve the **quality of their experience** of using those products and services, beyond the quality of products or their specification. The company has shifted its focus and has gone from being product centred to being or wanting to be focused on users and their experience.

R&Di

In-house Research, Design and Development and a clear commitment to Innovation and responsiveness

Although the commitment to in-house design and development has been a fundamental part of BioSystems success, in this new phase we want to emphasise our resolve to offer innovative, competitive solutions and to do so straightforwardly, simply and responsively. That means transforming the organisation to reduce the time products spend in development and validation before they reach customers and meet or exceed all their expectations.

We seek innovation, however, not only in product development, the main driver of value creation, but across the whole business: production, business development, customer relations, professional relationships and people management, design and image, communication strategy, resource management and financial planning.

Global

Global Strategy

Since the very beginning, the BioSystems business has had a clear commitment to international markets and its growth has come from exporting almost 90% of its products worldwide. In the last ten years, we have strengthened our relationships and communication with everyone in the organisation in every country in which we operate directly. Since 2019, that connection has been further strengthened by involving them in drawing up our product and business development strategy and in taking the decisions that concern and affect us, listening to everyone with no preconceptions and giving their vision and opinion the same significance and importance as the views of the parent company. The strategy is devised on a global basis, rather than outwards from the centre, starting with the customer and then to Management, who collect, processes, weighs, prioritises and owns the strategy. They then structure, plan, present, provide, approve, promote, coordinate and supervise the steps and resources required for implementation of the strategy.

Mission

To provide testing solutions to help improve health and wellbeing.

Vision

To be recognised worldwide for providing a good user experience.

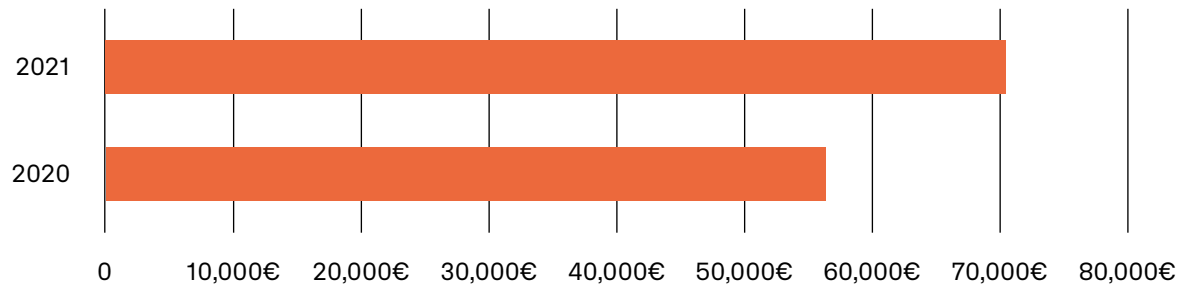
BioSystems Group in numbers



72,184 K€

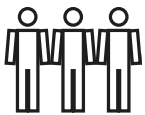
of aggregate consolidated turnover in 2021 (61,471 K€ after consolidation adjustments)

Group consolidated turnover in 2020 and 2021



42

patents and trademarks

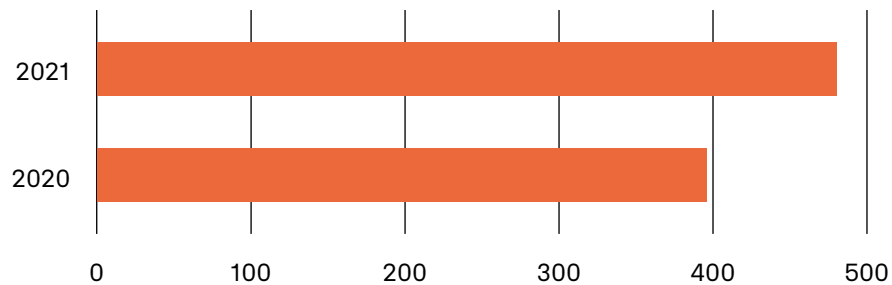


492

people in 2021 in group companies (including Ginper staff)

+650 for affiliates

Headcount in 2020 and 2021



What do we strive for?

To leverage our knowledge to improve

In 2021, which marks three years since the replacement of the previous General Management, saw further consolidation of all the changes made since 2019. Some of those changes are the reorganisation of lines of business and responsibilities at the organisational level to **merge** the former **Reagent Division and Instrument Divisions**. One of BioSystems most valuable assets valued by customers around the world and an advantage over our competitors is mastering the core technologies of two such different businesses to market them as a single system, as a complete solution.

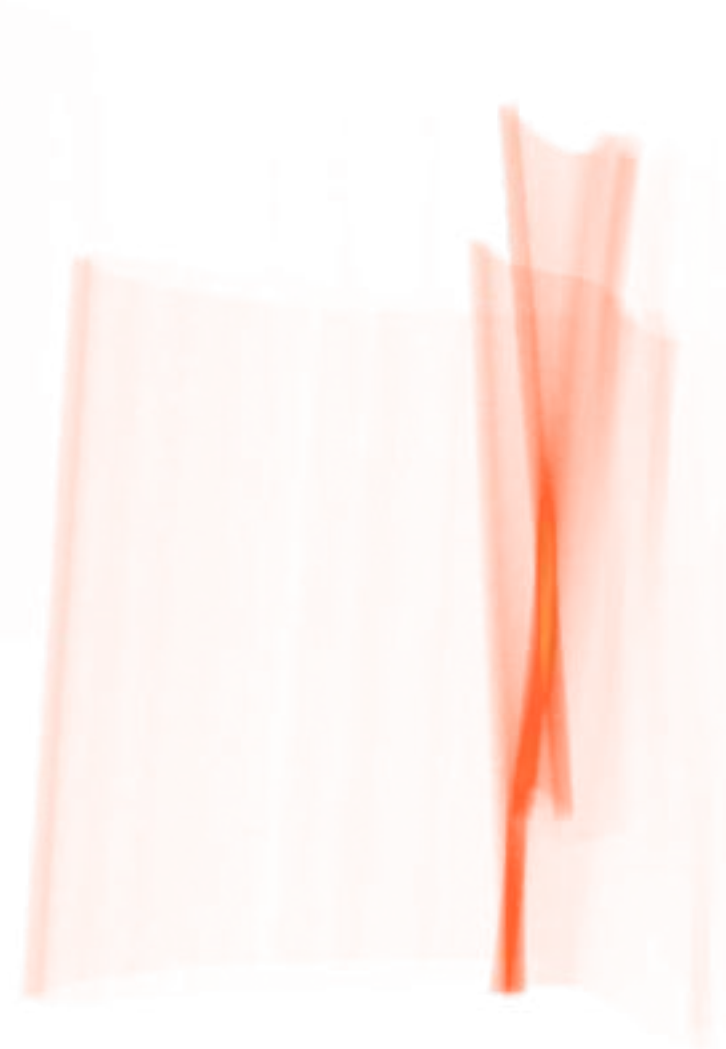
However, especially when we talk about automated systems, both disciplines and technologies, on the one hand, life sciences, and on the other hand, engineering, form a system and these can give more reliable results if they have been developed together and not one as an adaptation of the other.

Conceiving, designing, developing, validating and manufacturing reagents and instruments from the start as a "single" system improves product reliability.

That reorganisation of teams and departments is generating synergies in R&D, Production and Operations. An example of those synergies can be seen across Production Process Engineering and Purchasing, and Production Planning.

In 2021 we have seen the fruit of the changes and ways of working and, thanks to the effort and dedication of many people, it has been possible to improve production capacity and productivity with significant increases in the number of instruments and kits manufactured. That has in turn led to increased sales and gone some way to balancing the outturn for 2020, which was affected by Covid-19.

The consequences of the pandemic included staff absences due to the SarS-CoV-2 virus, lockdown in most countries, difficulty in travel, decreased routine clinical testing, the shutting down of much of the hospitality industry with consequent reductions in sales of food and drink.



Investing in the future

We are very pleased that in the very challenging circumstances of 2021, the people at BioSystems have responded by giving their best. Thanks to the dedication, commitment and effort of many people and to the **adaptation to changes**, as a result both of the pandemic and of the change in the company's management, we have been able to continue to supply our customers with the products they needed to test the samples they were receiving. Every member of staff throughout the organisation made a valuable contribution to meeting our commitment to contribute to improving health and wellbeing.

Thanks to that response and to the support received from the majority of staff, management had sufficient **confidence** to continue to allocate resources to all projects and to look forward to 2021 as a year of recovery for the business and improved sales and competitiveness. The profit for the year shows that we did achieve that objective and that in turn generates greater confidence to continue to invest and strengthen the business.

To have experience and independence to generate the entire value chain

The knowledge and experience gained in 40 years in business, a well-qualified, committed multidisciplinary team, global presence through BioSystems group businesses and our more than 100 business development partners on five continents gives BioSystems 'the keys to the future'. We cover the entire value chain, from conception to design and development, through validation and certification, to manufacture and subsequent delivery of the product and provision of services to the customer.

The way in which the Group's business responds to an industry, market segment or area is determined by our own decisions, actions and resources. As a result, we are less subject to changes in the environment or pressures or conditions in different markets than some other businesses that are more dependent on third parties or on decisions made far from their centres of operation.

Being a family business with direct communication and a worldwide business 'is a treasure' that means that we can be ambitious about our own future.



Continuing to expand globally

Some of the **business development** projects in which we have invested over the course of 2020 and 2021 are the formation and commencement of business at three new subsidiaries: one in **China**, which will operate as a technology and knowledge transfer centre with our industrial customers and suppliers, and technology partners. Another in **Thailand**, where forming a subsidiary and strengthening our direct presence is the best way to further develop business in this market. The subsidiary in **Turkey** was also expanded, strengthening our presence there.

That commitment was put into action in 2021 with new relationships with some very large specialist Autoimmunity hospital laboratories which have generated new business and are a first foothold in the diagnosis of autoimmune disease, a complex, unique sector.

In the same way, we continued to develop our still young subsidiaries in France, Italy and Argentina during 2021 whilst continuing to support more mature Group businesses.

For all those reasons, it is important to follow our business development strategy with direct presence and to set up new BioSystems businesses in markets with the greatest potential or that have niches that it would be interesting to explore. In 2022, we will continue to explore markets and opportunities and to invest in asset that is our future.



Improving user experience

In order to improve the user's experience of use of our products and services, it is essential to understand users' expectations and needs before embarking on design and development. Beyond that, we also need to understand which of their recurrent tasks they find unsatisfactory, or cause them disgust, annoyance or aversion or that they feel could be done in a different way, more easily and better integration into their workflow.

It is not enough to ask questions and listen to the answers, we need to shadow them, to be with them in their workplaces without getting in the way. Seeing them move and work without being a hindrance or influencing what they do so that we can see what processes or actions or product capacities could improve the quality of their working life and give a better user experience and better user satisfaction over the course of the working day.

The intention of this approach is for sales to be the result of a 'conversation' with the customer or potential customer and for them to agree to work with us and so help themselves, rather coming from a relationship centred a two-way transactional approach. Thus, products and services are not themselves the subject of the conversation, but a result and consequence of that conversation, generating a mutually beneficial and reciprocal situation.

So as to feed that valuable information back to Product Design and Development, we have had to redefine the relationships between the work previously done by the Marketing and Sales Department and the Reagents R&D and Instruments R&D Divisions, which used to be separate. After these three years of change and development, BioSystems is committed to focusing our product development around the customer, with 'Customer Relations' and R&Di a single shared activity involving multidisciplinary teams and where customers are part of the project and not just the recipients of an outcome.

As a result of all those changes, all our processes and process mapping, and internal documents and procedures have been updated and adapted. The entire basis of BioSystems Quality has been updated, with all the associated documentation, so that we remain legally compliant and compliant with audit requirements in what have been exceptional conditions and able to lawfully continue offer our products for sale.

That has meant an enormous effort on the part of the entire company, but especially the Quality Assurance team who, alongside managing its normal workload, has had to deal with the changes that have taken place in the organisation, all made that much more challenging by mixed remote and on-site working due to the pandemic.

All the documentation required to continue the business under the new regulation on *in vitro* medical diagnostic devices (EU 2017/746) that comes into force in May 2022 has also been prepared.

Those changes have happened at the same time as other organisational and working system changes.

In 2020 we made **Projects** the organizing principle of our work in an attempt to promote multidisciplinary, worldwide teamwork. We believed that this approach would improve our effectiveness and efficiency and our focus on creating value for customers and would also be more transparent and global.

At the same time, our **time management** model shifted to a model where individual responsibility and self-management, with considerable flexibility around working hours and no holidays set by the business other than local and national public holidays.

Those changes would not have been possible without an enormous effort to adapt to change, flexibility and generosity of spirit. They therefore represent a profound **cultural transformation** achieved in times of change, high levels of uncertainty and vulnerability thanks to the pandemic and to changes in management and leadership style.



Extending our testing solutions to the entire Biotech spectrum

The new strategy also envisages continued expansion of the business in all sectors of the world of **biotechnology**. BioSystems has been a leader in clinical diagnostics for biochemical testing in many countries and in market segments for laboratories for many years classed as small and medium-sized. It is an attractive outlet for specialist techniques, such as testing for diagnosis and monitoring of autoimmune diseases, such as celiac disease (gluten intolerance), lupus (affects many organs and tissues), and rheumatoid arthritis (affects the joints), and testing for specific proteins associated with the body's response to attack and lead to inflammation of tissues and organs.

BioSystems also provides attractive solutions for larger laboratories for so-called 'routine' tests (electrolytes such as sodium, potassium and chloride, fats such as cholesterol and triglycerides associated with cardiovascular disease, glucose (sugar), e.g. for monitoring diabetes, and various kidney, liver proteins and enzymes, and others).

Continuing with the diversification of our testing product line and driven by the success begun ten years ago with testing of grape, must and wine production for the wine industry and expansion to other drinks and foods, in 2020 we started to develop new product lines for customers in the fields of veterinary medicine and industrial bioprocesses.

In 2021, we began to see the results of this strategy to diversify the business's value propositions. In 2022, we expect to make further progress with further diversification and the creation of roadmaps for biotech area: human and animal health, food and drink testing, bioprocessing and environmental testing.

To be a business with a purpose

Another pillar of the new strategy is to put **sustainability** at the heart of the organisation. As early as 2020, a project was initiated to calculate our environmental impact and the commitment of our owners to sustainability. We set up a work team that over the course of 2021 has combined an analysis of BioSystems situation under the **B-Corp** standard with the initiation of projects for the digitisation of product documentation and the installation of solar panels at the Barcelona plant for the self-generation of part of the energy used. We are also members of CataloniaBio's Shared Value group to identify common sustainability objectives.

Renew our image and communication strategy

In the course of the last three years, a diagnosis of the brand image has been carried out. The brand has been reviewed and renewed together with the communication strategy to strengthen our image in the industries and markets in which we are active.

Thanks to this work, the BioSystems brand is solid, coherent, contemporary, technological and up-to-date. That involved transformation of the brand image, the typography and the logo. We also added the *claim (human-centred biotech)* which showcases the true focus of BioSystems: people. That claim is about users and staff, the people with whom we work and all stakeholders, however they are associated with us. Because in every stakeholder group there are people who care about the quality of life and the health and wellbeing of all living beings.

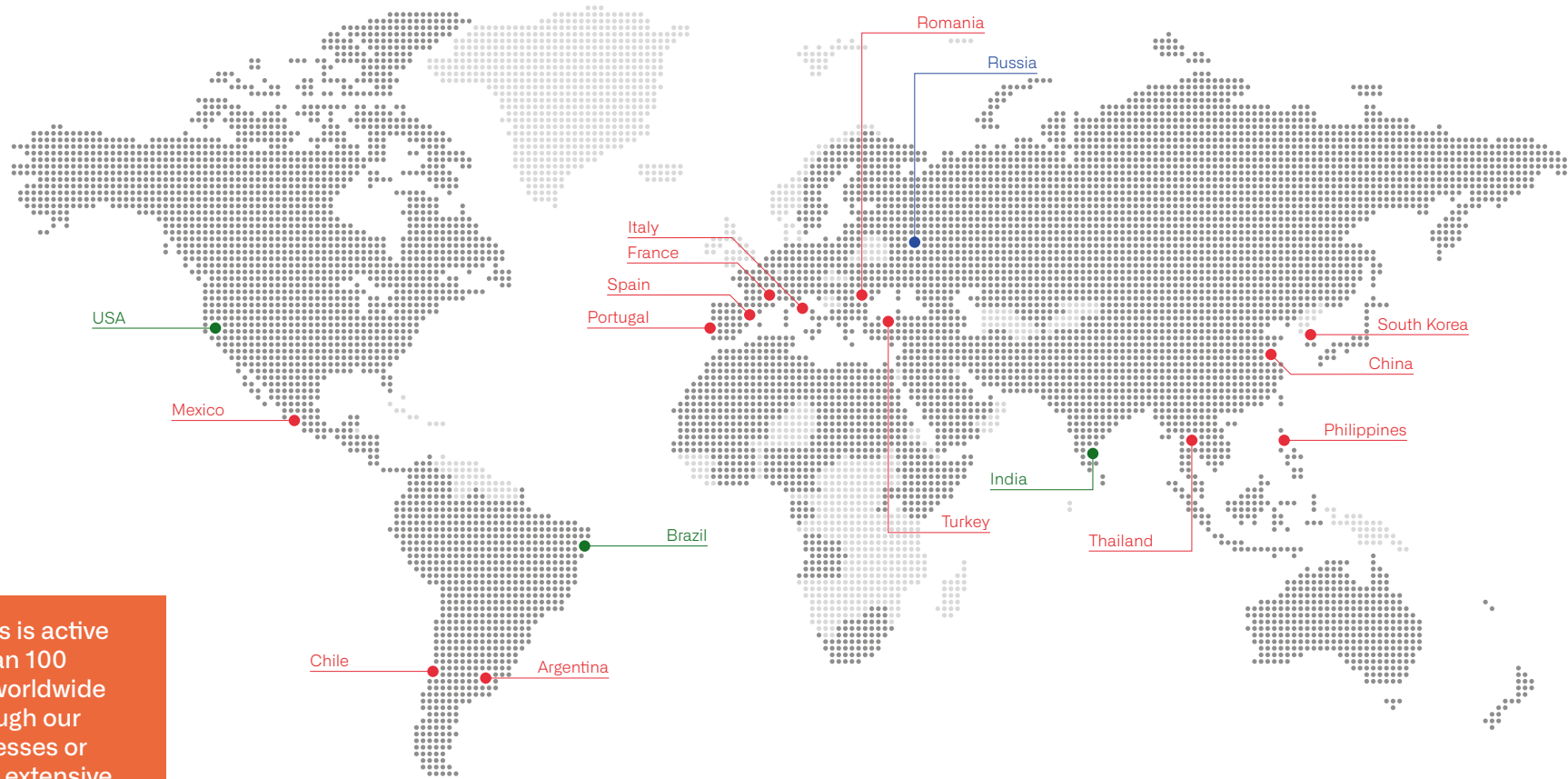
Establish partnerships, seeking synergies and alliances for the future

It is crucial for us to develop the skills to construct alliances and build working relationships on a global scale because BioSystems has to bring value to customers responsively and effectively through solutions that use the latest technology and because the life sciences – chemistry, physics, biotechnology, biomedicine, engineering, technology – are developing at an astonishing speed so that we cannot meet that challenge alone.

This work, which was previously mainly focused on supplier-customer relationships, whether for services or product, is becoming increasingly important to BioSystems strategy in the world of today.



Who uses our products and where are they used?



BioSystems is active in more than 100 countries worldwide either through our own businesses or through an extensive network of experienced distributors.

Companies • Joint ventures • Representation office

Our presence in the biotechnology field

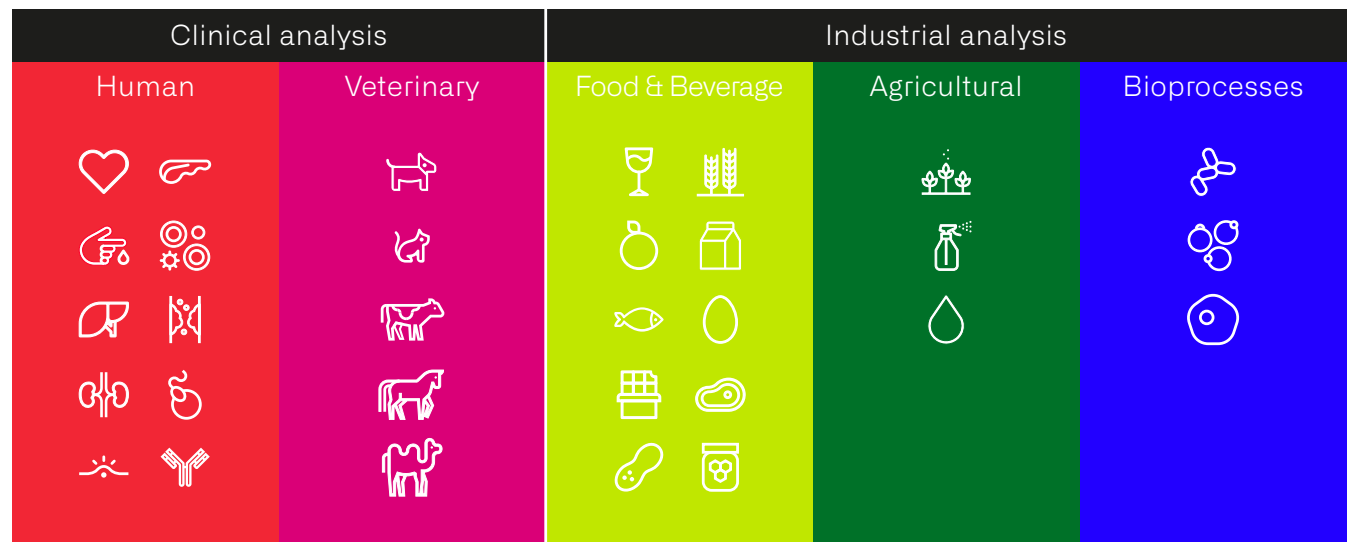
Our products cover a wide range of areas within biotechnology.

We group the fields according to their requirement, such as clinical testing and industrial testing. All products developed by BioSystems are for **use in professional laboratories** (not for home or personal use or for testing in pharmacies or *point of care*) and so our **customer-users** are **qualified staff, laboratory technicians or have the knowledge to carry out tests and interpret the results**.

In the case of human and veterinary health, test results are their 'product', i.e., a clinician charges for tests and forms their diagnosis in reliance in part on their own interpretation of the results.

In industry, test results are information that supports decision-making concerning the quality of products that are being manufactured or produced, or the quantity of an ingredient (such as sugar in must or alcohol, or sulfites in wine) or of a parameter, or to check the quality of a substrate, soil, water or waste, or simply to monitor a process.

BioSystems biotechnology areas



Clinical Testing

In clinical testing, we provide two types of solution: **for humans and for animals.**

Human Clinical Testing

In medicine, we cover clinical biochemistry products, special tests, specific proteins, hormones, autoimmune disease, haemostasis and clotting, electrolytes, haematology, infectious disease, stool analysis.

Users of our products include private laboratories that provide this service directly to members of the public through mutual health insurance companies, laboratories within hospitals, private clinics and laboratories in public hospitals in all medical disciplines, particularly general health.

Users include public and private research centres in universities and centres of excellence in some disciplines in the field of health and medical diagnostics. Those laboratories have varying testing capabilities, ranging from those that process five samples each day to those that process several thousand. The laboratories that use our products are in both developed and developing countries.





Veterinary medicine

In veterinary medicine, as well as the products described for use in human medicine, we also have products for vector-borne diseases, i.e. those caused by a wide variety of infectious agents (bacteria, viruses and parasites) transmitted by insects or arthropods that act as transmitters or host part of the life cycle of the disease agent.

They include ticks, lice, fleas and diptera (mosquitoes, sandflies and flies). Some of these diseases are Zoonotic, which means that they can be transmitted to humans. Examples include Leishmaniasis, Dirofilariasis, Borreliosis, Rickettsiosis and Bartonellosis.

Users of our products include **veterinary clinics and veterinary clinical testing laboratories** for veterinary medicine and welfare and research centres, both public and private, at universities or centres of excellence in any discipline in the field of **veterinary medicine and diagnostics**.

Users also include **livestock farms** and other animal health and welfare companies, **fishing companies and fish farms and regulatory bodies** who need to determine degrees of freshness and deterioration due to bacterial contamination of fish, crustaceans and seafood products.

The diversity of market segments is even greater than with human medicine, ranging from small pet clinics that can do some *in vitro* testing in the clinic (POCT), local and regional veterinary laboratories, large testing laboratories and international reference laboratories that receive samples from all over the country in which they are located, for pets, livestock, and farmed fish.

Industrial Testing

In industrial testing, we provide solutions in three areas: food and drink, agriculture, and environment and bioprocesses.

Food and drink

In the testing of food and drink, we offer, for example, systems to test for sugars, organic acids, polyphenols, ammonium, nitrogen, sulfates, and phosphates for the wine industry, and histamine testing for different types of fish and seafood.

Also tests for sulfites and metal ions in meats, bakery products, allergens and toxins in food, and others.

Our users are involved in **production of food and drink** and include wineries and manufacturers of alcoholic, fermented and distilled drinks, fermented juices and infusions, fruit juices and concentrates, vegetable and other plant juices and purees.

In the **testing of drinks**, in particular in the **wine** industry, BioSystems serves industrial producers of wine, cava, beer (breweries) and distilled fermented products of all kinds, in particular businesses that have in-house testing and do not send samples to outside industry laboratories. In this area we therefore tend to serve medium and large manufacturers.

In terms of **other food industry businesses**, we also serve users of very different sizes and capacities.

Agriculture, environment and bioprocesses

The fields of agriculture and bioprocesses are still in the business development phase and on the one hand target industry users for **agricultural applications and environmental testing** in the area of health and growth and harvest readiness of field crop, and on the other hand users in the **biotechnology industry, research centres and universities**.

These users operate bioprocesses through the cultivation of bacteria, yeasts, principally animal cells, to produce bioproducts such as enzymes, organic acids, aromas and food additives, thickeners and emulsifiers, active ingredients for the pharmaceutical industry such as antigens, antibodies, interferons, interleukins, vaccines, antibiotics, antitumor agents, active ingredients for the cosmetics industry, nucleic acids for DNA and RNA therapy or vaccines, and an endless number of products from a wide variety of biological systems.



What do we buy and where do we buy it?

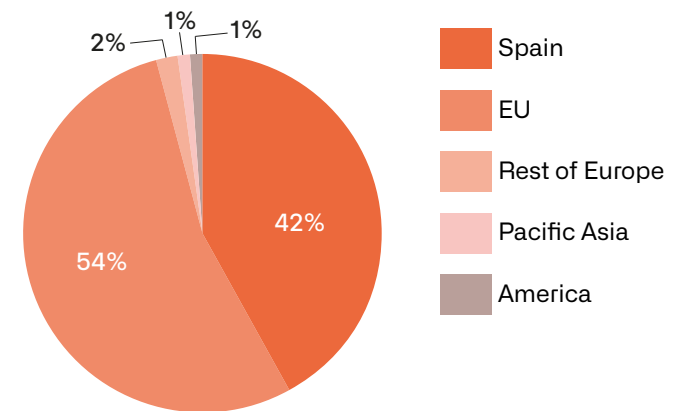
The value chain of the products developed and manufactured at BioSystems is complete and ranges from the procurement of critical **raw materials** for the manufacture of analytical reagents (enzymes and antigens or antibodies) to the assembly of **mechanical**, electrical and optical **components** for the manufacture of analytical instruments (electrical plates, liquid pumps and other components) and operating software for equipment developed *in-house*.

Other raw materials, including **biological or chemical ingredients**, preservatives and lyophilised sera for Controls and Calibrators are purchased from reputable international manufacturers. The chemical and biological ingredients used include alcohol, salts, phosphates, chlorides, and human and animal sera. The production of analytical reagents calls for the use of **plastic and glass** materials for reagent dosing, and **paper and cardboard** for kit assembly.

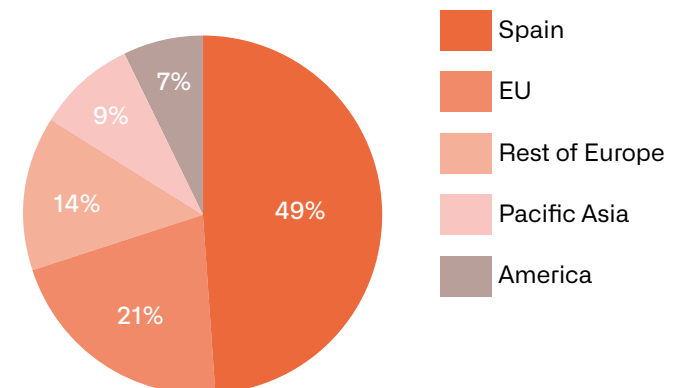
We also purchase mechanical components for our photometers and analyzers. Those components include LEDs, plastic domes, metal structures and integrated circuits, and others. Finally, paper and cardboard are purchased for instrument packaging.

The greater part of our purchases are from suppliers in Spain and the EU, both in terms of number of units and by value. Purchases in Spain and the EU represent 69% of total purchases and 96% of the volume of units used.

Geographic distribution of the volume of units purchased



Geographic distribution of purchases from suppliers in €



Who do we work with?

We realise that working with different bodies and associations, universities and technology centres helps us to improve as a business and enables us to be more responsive in many fields in how we achieve our objectives. For this reason, we work and participate with different business and sectorial associations as well as with universities, entities focused on scientific and technological development or other companies with which we establish projects and synergies that benefit both. There is a list of our principal partnerships and collaborations below:

Associations and sponsorships

We are members of a number of professional and corporate associations and bodies that promote and support business development in the countries in which we operate. Some of the organisations of which we are part are:

- ACCIÓ: Catalan Agency for Enterprise Competitiveness
- CataloniaBio & HealthTech. Body that represents companies in the biomedicine and health sector in Catalonia
- BIOCAT - Bioregion of Catalonia
- ICEX - Spanish Institute for Foreign Trade
- Pimec: employers' association 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 – American Association for Clinical Chemistry
- ACB – The Association for Clinical Biochemistry and Laboratory Medicine
- SEQC: Clinical Chemistry Society of Spain

- ANIAE – National Association of Agronomic and Wine-making Engineers of Chile
- IFU – International Fruit and Vegetable Juice Association
- PMA - Philippine Medical Association
- ICAP – International Consensus on ANA Patterns
- SEEC - Sociedad Española de Enfermedad Celiaca (Celiac 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 and other matters of significance for the carrying on of our business:

- MedTech Europe
- ASCOM – Spanish Compliance Association
- Team PRRC – Person responsible for regulatory compliance

BioSystems, together with its distributors, has also been involved in sponsorship in different countries for participation in trade fairs and congresses for the industries in which it is active.

Strategic collaborations

We have formed and maintain professional collaborations with medical bodies and laboratories for measurement studies and product validation and application verification. Key collaborating centres include:

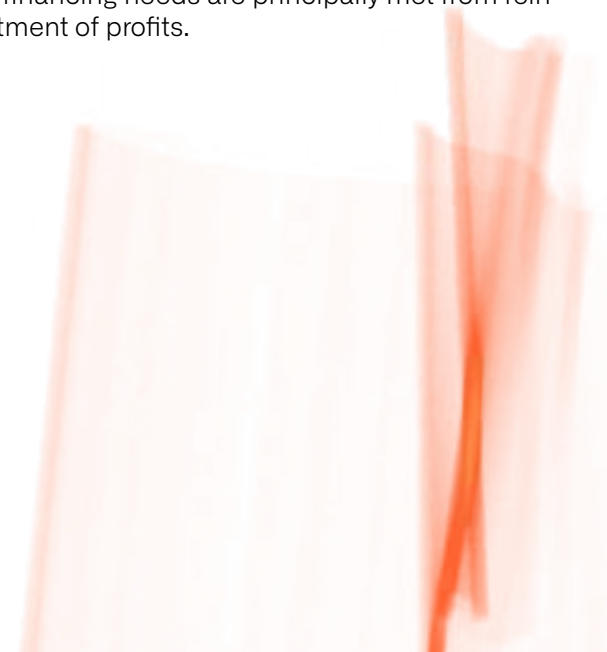
- CATLAB
- Department of Biochemistry and Molecular Biology, Autonomous University of Barcelona
- Bellvitge Institute for Biomedical Research Foundation (IDIBELL)
- Germans Trias i Pujol Hospital, Can Ruti
- Vall d'Hebron Hospital
- Hospital of Santa Creu i Sant Pau Private Foundation
- Reference Laboratory
- AMBAR – Clinical Analysis Barcelona

We also conduct scientific and technological development projects with different businesses, and academic and dissemination activities with different universities and scientific institutions, including:

- LEITAT (Spain)
- Idneo (Spain)
- Magapor (Spain)
- The Australian Wine Research Institute (Australia)
- Protein Production Platform - CIBER -BNN, Universidad Autónoma de Barcelona (Spain)
- Fermentation Pilot Plant, Universidad Autónoma de Barcelona (Spain)
- Marqués de Valdecilla University Hospital - Santander (Spain)
- University of Murcia (Spain)
- University of Guadalajara (Mexico)
- National Autonomous University of Xicoco (Mexico)
- Autonomous University of Baja California (Mexico)

- Pontifical University of Chile
- University of Maltepe (Philippines)
- Saint Luke's Hospital School of Medicine (Philippines)
- Busan National University (Korea)
- Jiangnan University (China)

Finally, BioSystems key partners for the financing of Research and Development projects are the CDTI – Centre for Industrial Technical Development – and the Ministry of Science and Innovation. The rest of our financing needs are principally met from reinvestment of profits.

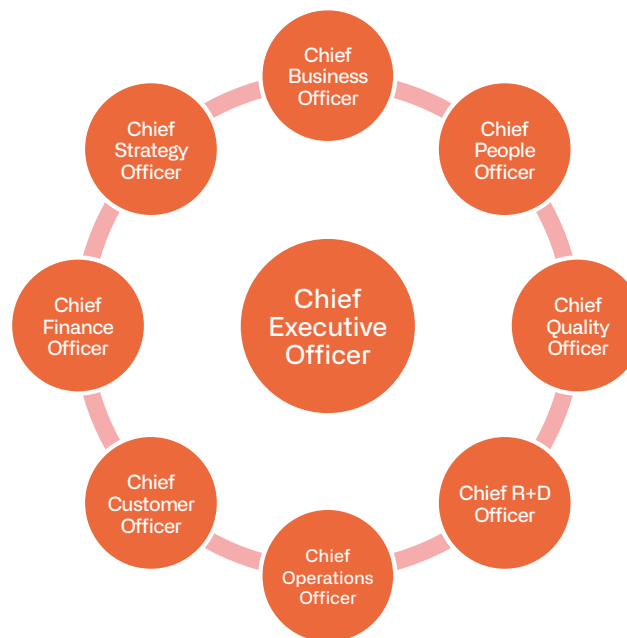


How are we organised?

BioSystems works by **processes and projects**. The different functional areas are coordinated for the implementation of BioSystems strategy and the achievement of our objectives.

The Management and Strategy Team brings together the various BioSystems heads of department. They, together with the CEO, manage BioSystems day-to-day business and execute the strategy in light of the needs and expectations of our stakeholders.

Members of the Management and Strategy Committee



At regular intervals, the Management and Strategy Team with its teams assess stakeholder needs and determines which projects should be carried out. **Projects** are carried out by multidisciplinary groups that include people from different areas and processes.

Process-based work helps us to identify everything we do at BioSystems to bring value to the customer. Processes are implemented across the functional areas of BioSystems. This way of working enables communication among people at BioSystems and facilitates teamwork to achieve our objectives.

This way of working at BioSystems is recorded in a **Process Map** that can be broken down as follows:

- **Central:** focused on generating maximum added value by devising solutions that satisfy our customers and end-users.
- **Management:** to plan, determine and monitor BioSystems targets and to provide adequate resources to achieve those targets.
- **Support:** providing the resources required for all processes to operate effectively and efficiently.

How do we manage risks and opportunities?

The evaluation and management of risks and opportunities is a task that is fundamental to the achievement of our objectives and continuous improvement. Risk evaluation and management is detailed in internal procedures based on ISO 9001 and ISO 31000.

Those responsible for each process, together with the members of their team, are responsible for identifying significant changes in that process that require review of the risks and opportunities identified and their evaluation. Risks and opportunities are reviewed annually and changes in the wider context and stakeholder expectations are evaluated. That is done by the owners of each process with management. Risks and opportunities are assessed under an internal procedure that takes account of their probability and impact.

BioSystems has established a comprehensive suite of actions that are taken to mitigate risks or take advantage of opportunities. Those actions are periodically reviewed by the *Business Process Management* team in order to assess their efficiency and effectiveness, to propose improvements that allow us to address risks and opportunities and to implement actions that promote continuous improvement in the company's processes.

The combination assessments of risk and opportunity on the one hand, and of efficiency and effectiveness on the other, drives out an overall estimate of the residual risk or opportunity. That residual value has to be aligned with the risk tolerance level set by BioSystems.



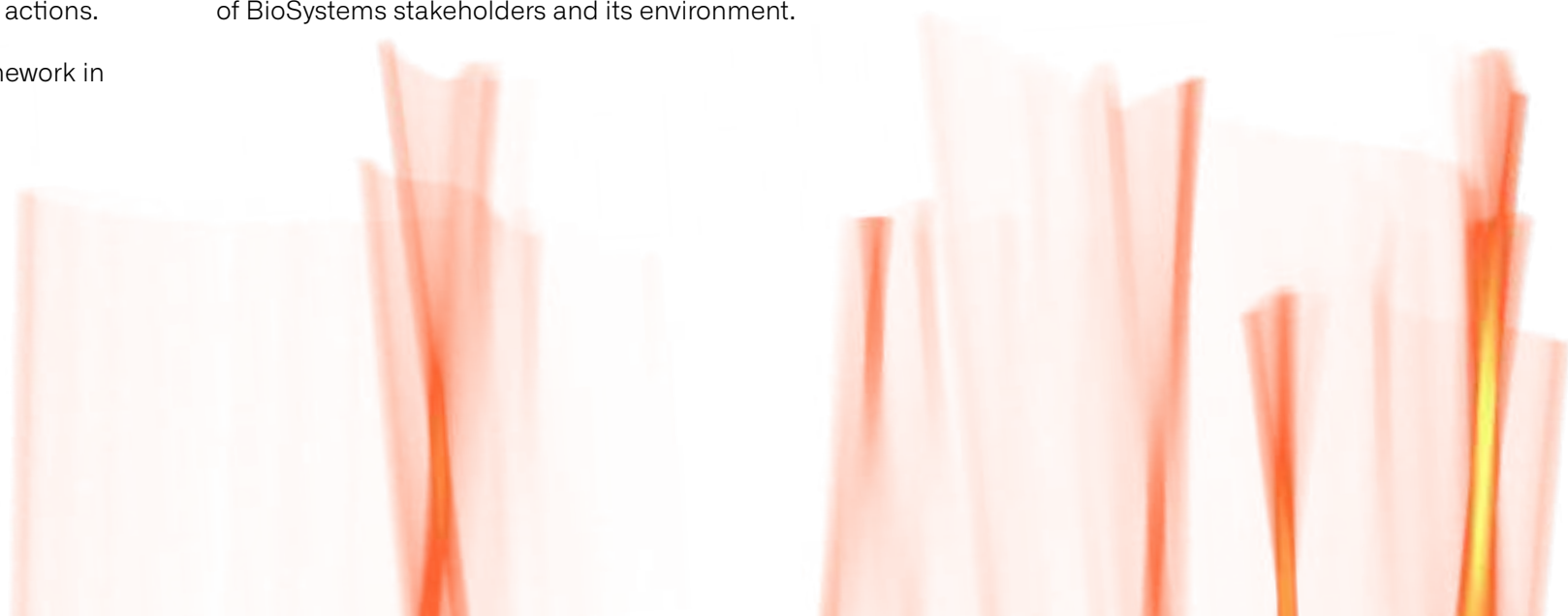
Principles of BioSystems risk management

Our assessment and management of risk is based on the following principles:

- Leadership and allocation of sufficient resources to identify and handle risks and opportunities.
- Integration of risk assessment and management in the company's strategic processes.
- Simplicity and uniformity in process management to avoid risks happening.
- Periodic review of risks and opportunities and the efficiency and effectiveness of mitigation and management actions.
- Segregation of functions in mitigation actions.
- Determination of a risk tolerance framework in line with our business and objectives.

We have identified the following classes of risks and opportunities:

- Financial: related to cashflows or that can affect financial outturns.
- Operational: related to the normal operation of BioSystems processes.
- Strategic: impact on implementation of the strategy of the business.
- Regulatory: related to extensions or changes in applicable laws.
- People and environment: affect the expectations of BioSystems stakeholders and its environment.





Sustainability at BioSystems

For BioSystems, sustainability is a way of managing resources aimed at meeting current needs without jeopardising future needs. That requires focus not only on economic development, but also on social issues and care for the environment.

Sustainability, therefore, is much more than green energy. It is about rethinking a broad set of ways of doing things, such as transportation, electricity consumption, waste generation, our habits, our work environment and the impact we have on the community and the environment. Whilst it is true that we have always worked with a focus on sustainability, in 2021 we decided to take a step forward and set up a permanent sustainability work team focused on three objectives:

- To make sustainability an overarching principle underlying decision-making in all areas of BioSystems, involving all people and stakeholders across the whole business.
- Understanding the impact of our business in a broad sense: assessing aspects such as governance, the environment, our products, people and the community.
- To reduce our negative impact and enhance our positive impact by promoting a sustainable transformation among partners, suppliers, customers and wider society, being a driver of change.

In that way, BioSystems sustainability team works to train and raise awareness of sustainability, coordinate improvement measures and projects, monitor impact and distribute information about our progress on sustainability.

To do so, we focus on three areas: **business management, environment and facilities, and people and community.**







The Sustainable Development Goals (SDGs)

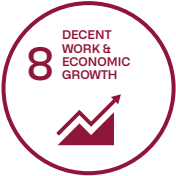




The Sustainable Development Goals are a common framework for action to end poverty, protect the planet and improve the lives of people around the world. That common framework is composed of 17 goals adopted in 2015 by the Member States of the United Nations. Those 17 objectives are broken down into 169 specific goals that allow us to plan concrete actions to bring them about.

BioSystems understands the essential role that business has in achieving those objectives. Aware of the importance of each and every one of them, BioSystems wanted to identify the goals that were directly relevant to our business or business model and goals to which we can contribute at an operational level through voluntary steps within our scope of action.



How do we affect each SDG?

	SDGs	Contribution
Business model	 <p>3 HEALTH & WELLNESS</p>	<ul style="list-style-type: none"> • BioSystems contributes to the improvement of people's health and well-being from the field of clinical diagnostics and from food and veterinary monitoring. • Our products help to diagnose disease and test foods. • BioSystems mission is to provide analytical solutions to help improve health and wellbeing.
	 <p>9 INDUSTRY, INNOVATION & INFRASTRUCTURE</p>	<ul style="list-style-type: none"> • BioSystems encompasses the entire value chain, from R&D to product marketing and sales. • We invested 160,456€ in R&Di. • 92% of sales are of products manufactured at BioSystems.
Operational contribution	 <p>4 QUALITY EDUCATION</p>	<ul style="list-style-type: none"> • At BioSystems we have a clear commitment to the education and training of staff. • We have platforms for the continuous training of all BioSystems people in Spain, France and Italy. Access to information and training relevant to person's needs is basic to personal development. The human resources function advises teams to hold the courses that can add the greatest value to projects. • In 2021, more than 4,200 hours were devoted to training. The staff who spent the most time on training were managers and technicians, with 39% and 30%, respectively, of the total number of training hours. • We also work with universities to train people through internships at the business.
	 <p>7 AFFORDABLE & CLEAN ENERGY</p>	<ul style="list-style-type: none"> • Since 2020, all the energy used at BioSystems Spain, the group's main plant, comes from renewable sources. • In 2021, we began to assess the installation of solar panels on the roof of the BioSystems Barcelona plant. It would provide energy savings of 5% of energy – Installation of solar panels in Barcelona, the group's main plant.

	SDGs	Contribution
		<ul style="list-style-type: none"> • BioSystems scrupulously complies with employment law in the countries in which it operates to ensure decent jobs and economic growth. • In 2021, we hired 21 people below 30 years of age and 3 people over 50 years of age, promoting the employability of young people and people over 50. • In 2021, there was a 21% increase in full-time staff.
		<ul style="list-style-type: none"> • Respect for diversity is a core value under the BioSystems Code of Conduct. • The Equality Plan implemented at BioSystems Spain showed that there is no evidence of a gender pay gap. • During 2021, areas for improvement in this area have been identified and, from 2022, BioSystems will work with the Eurofirms Foundation's 2022 8M challenge, which aims to incorporate 1,000 women with special abilities into the world of work to improve their employability.
<p>Operational contribution</p>		<ul style="list-style-type: none"> • Since 2019, BioSystems has had an instrument reuse system in place. Thanks to the cooperation of our customers, we are able to recover disused instruments, recondition them and put them back on the market at a price that reflects their prior use. • We monitor water consumption and adopt measures to prevent water wastage.
		<ul style="list-style-type: none"> • Since 2020, BioSystems Spain has a criminal compliance model and a Compliance Committee responsible for ensuring regulatory compliance and respect for human rights. • BioSystems has an Reporting Channel that allows anonymous reporting of any suspected irregularity or behaviour in breach of our Code of Conduct.
		<ul style="list-style-type: none"> • BioSystems works and participates with different associations to achieve common objectives. • In 2021, BioSystems participated in CataloniaBio's Shared Value programme for the identification of common sustainable development objectives within the Healthcare cluster.



Compliance

Support of and respect for Human Rights

As a global company in biotechnology, we are subject to a multitude of different regulations and laws. We base our relationships with all stakeholders and partners on respect and transparency, with compliance as core. That is why legal compliance and respect for human rights is one of the pillars of our Code of Conduct.

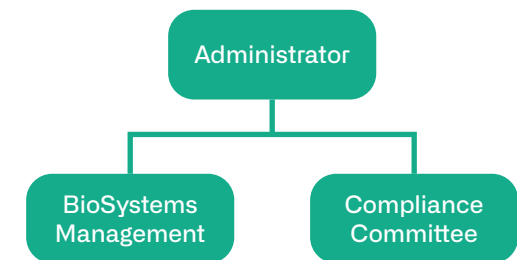
In that way, the company's owners, administration and management, who promote a culture of compliance at all levels, have given the company the means to ensure legal compliance. Similarly, our relationships with government bodies and international organisations are conducted transparently and collaboratively in accordance with the requirements and terms and conditions in each case.

That is why BioSystems has been developing its compliance model since 2020 under which the Compliance Committee ensures oversight, monitoring and control. The Compliance model is currently focused on the business of BioSystems Spain, the business that carries on the majority most of the Group's industrial and commercial activity. Despite that, we want to implement that model in the other Group companies over the next few years.

The Compliance Committee is multidisciplinary and its members are chosen by BioSystems Board of Directors to perform the Compliance function, i.e. to identify, prevent and detect the principal compliance risks, to foster and develop the compliance culture within BioSystems, and to resolve doubts or questions arising in relation to regulatory compliance. In order to safeguard the independence and autonomy of its decisions, the Compliance Committee reports directly to the Administrator and has an annual budget to carry out its duties. The activity of the Compliance Committee is currently principally focused on the identification and management of criminal compliance risks, including respect for human rights and the management of the Whistleblower Channel, as described the rules of the Compliance Committee.

In order to keep current and trained in relation Compliance, the Committee is assisted by external advisors from Tornos | Criminal Defence & Compliance. BioSystems is an associate member of ASCOM (Spanish Compliance Association).

Relationship of the Compliance Committee with the Administrator



Roles of the Compliance Committee



Compliance environment

Our compliance structure is based on three main pillars:

Code of Conduct

2020 saw the approval of BioSystems new Code of Conduct, which sets out the culture, values and behaviour that are expected of every member of our community, who are required to observe the Code and receive annual training in relation to the Code. The Code of Conduct is available to everyone in the BioSystems Group through the BioSap intranet.

Our Code of Conduct sets out our way of doing things, with priority for wellbeing and respect for others.

The Code of Conduct provides for disciplinary measures for non-compliance, in accordance with the system set out in the Collective Bargaining Agreement.

The Code of Conduct also includes policies and protocols to give effect to the company's commitment to regulatory compliance.

Whistleblower Channel

We have an anonymous confidential channel for the reporting of potential non-compliance. The channel can be used in three ways:

- Co-Resol: using the Co-Resol app with the code BIOSYSTEMS, a person can communicate with any member of the Compliance Committee with anonymously or giving their name. The confidentiality and privacy of any conversations will be respected at all times.
- By surface mail to the following address:
Compliance Committee - BioSystems C/Costa Brava 30, planta 6^a 08030 Barcelona
- In a private conversation with a member of the Compliance Committee.

Criminal compliance model

The Criminal Compliance Model regulates and oversees the most significant elements of the organisation and management with appropriate oversight and monitoring measures to prevent and detect the occurrence of unlawful actions within BioSystems.

The model includes:

- Analysis of criminal risk under the relevant laws of Spain.
- Measures for the prevention, detection and response to the commission of illegal acts.
- Description of principal Compliance activities.

The Code was approved by the Administrator in September 2020 and is regularly reviewed.

Respect for Human Rights

At BioSystems, people are our focus. Respect for each person is fundamental and underlies our firm commitment to respect the Human Rights recognised in the Universal Declaration of Human Rights and the human rights declared by the International Labor Organisation, including rejection of any form of child or forced labour at any level in our value chain.

That is why our Code of Conduct includes the protection of Human Rights as one of our basic principles. Respect for different cultures, human wellbeing, care for the environment and respect for the law are among the basic principles observed in our group of companies.

We also have a Whistleblower Channel so that the people within the Group can easily make confidential, anonymous reports of the existence of a potential breach.



Compliance Activity 2021

Compliance activity is focused on identifying risks and implementing measures to mitigate those risks; disseminating the Code of Conduct and the model and providing relevant training and managing the Whistleblower Channel. All of this affects all members of the company in a transversal manner.

The Compliance Committee meets regularly to organise compliance activity and besides everyday discussions with the Administrator, holds at least two meetings each year to take review progress on the fulfilment of objectives and monitoring of the Compliance budget.

In 2021, we identified several issues that led to revisions to BioSystems compliance model. In particular:

- The revision of the BioSystems Process Map: we have updated the identification of risks and opportunities to reflect the new Process Map.
- Consistent risk management: we have modified the Compliance risk management model to align it with the management of the company's other risks to avoid duplication of risk assessment models.
- Upcoming entry into force of Directive (EU) 2019/1937 of 23 October 2019 on the protection of persons who report breaches of Union law: we have checked that the Reporting Channel is compliant with the directive and ISO 37002 on whistleblowing management systems.
- Review of new ISO 37301 on compliance management systems: we have reviewed the standard to identify areas for improvement in our compliance systems.
- Analysis of new laws and amendments to the Criminal Code: specifically, we assessed the possible effects of Organic Law 06/2021, Organic Law 09/2021 and Organic Law 08/2021 and did not identify any material changes that affect the identification and assessment of our compliance risks.



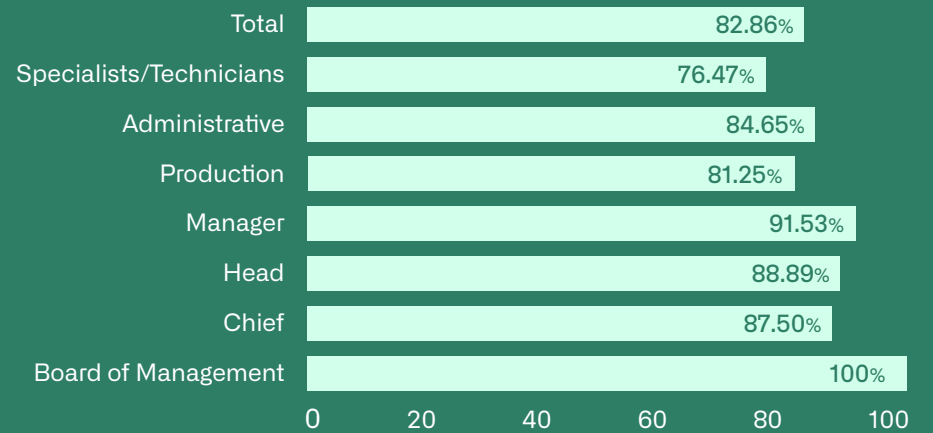
Training and awareness-raising on the model

In 2021 we held a number of training sessions on the Code of Conduct and Compliance in BioSystems Spain. For some of those sessions we worked with our external advisor, Tornos I Criminal Defence & Compliance.

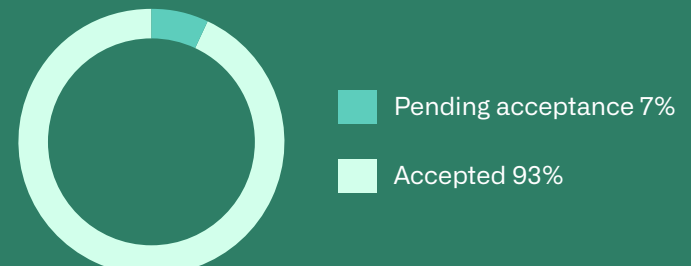
83% of those working at BioSystems Spain during 2021 received training on the Code of Conduct and Compliance. In addition, 93% of those people read and accepted our Code of Conduct and 91% accepted the Whistleblower Channel procedure.

Code of Conduct training is included in the welcome pack and forms part of the onboarding process. Our policies are available on the company's intranet.

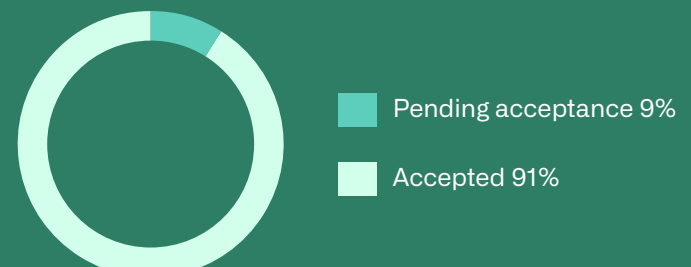
Percentage of people trained by role



Acceptance of the Code of Conduct



Acceptance of the Reporting Channel procedure



The Whistleblower Channel

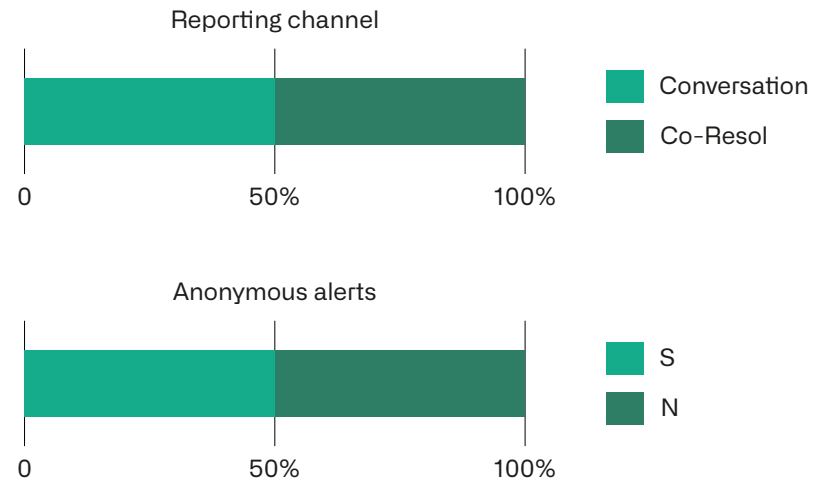
2021 was the first year in which a confidential anonymous open Whistleblower Channel was made available to everyone at BioSystems. The Reporting Channel allows concerns to be reported in three ways:

- By mail.
- In conversation with any member of the Compliance Committee.
- Co-Resol.

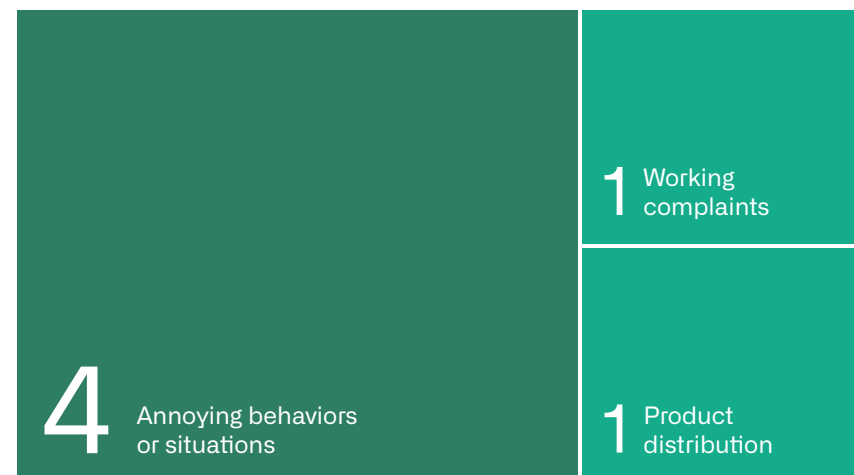
We do not tolerate retaliation of any kind against people who make good faith reports of breaches of any part of our Code of Conduct, including breaches of the law and infringements of internal rules.

In 2021 we received a total of six reports. They were all handled in accordance with our internal procedures. Adequate investigation was undertaken for the appropriate corrective action to be taken. None of the reports received concerned violations of human rights, fraud, corruption, bribery or money laundering.

Percentage of use of reporting channel and anonymous reports received



Classification of reports by subject



Measures against corruption, bribery and money laundering

Our Compliance system and Code of Conduct clearly prohibit any actions related to corruption, bribery or money laundering. Our fight against such actions is based on three pillars:

Prevention

We train our staff and make it clear that we do not accept such practices. BioSystems Compliance system has also assessed corruption, bribery and money laundering risks and has identified the situations of highest risk and the principal mitigations. In our business and industry, we have not identified any activities that present significant risks of corruption, bribery or money laundering.

We base our relationships with third parties on trust and transparency, because we firmly believe that it makes them stronger and more enduring. That is why we always try to get to know our business partners and we want them to know us so that we can communicate our values and ways of working. We do not have relationships with entities or individuals who do not respect those values or ways of working.

Detection

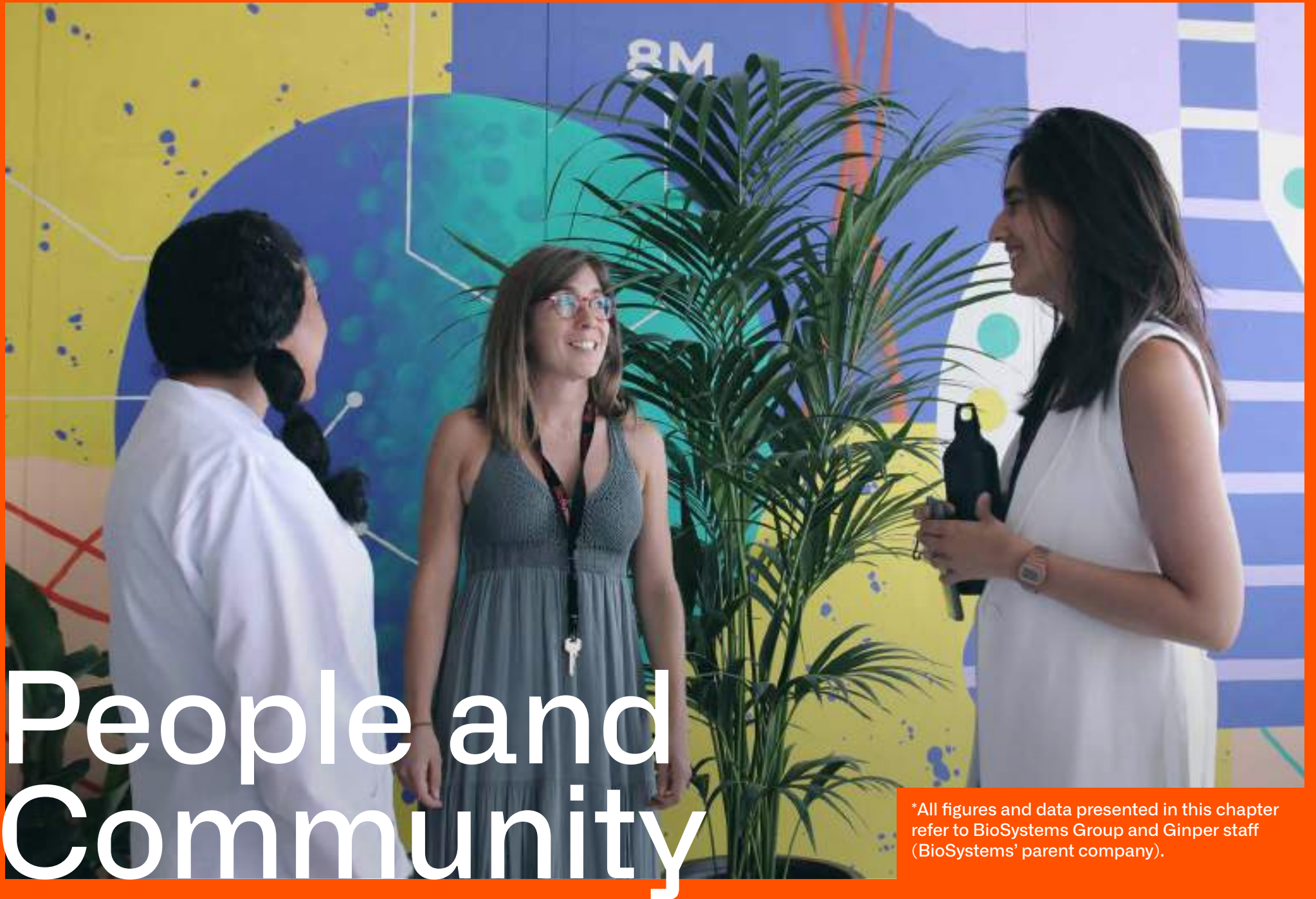
The *Financial Controls* department periodically reviews the company's transactions. The company also has mitigation measures in place to detect possible untoward situations, including financial controls to maintain cash flow traceability.

Finally, we have a Whistleblower Channel to report any suspected non-compliance or suspicious behaviour.

Response

We have internal procedures to investigate suspicious situations and the monitoring of any remedial measures. The Code of Conduct also provides for sanctions in accordance with the industry's collective bargaining agreement against people who breach the BioSystems Compliance system.





People and Community

*All figures and data presented in this chapter refer to BioSystems Group and Ginper staff (BioSystems' parent company).

People management

Each of the processes we carry out is the work of people who give of their best and grow continuously to respond among other things to all stakeholders. Our treatment of people and the way we deal with everyone is something that sets us apart and that we value above everything.

We strive to balance the wellbeing of the people working in our project and the productivity of the project. That is why ensuring equality and diversity through policies, guidance and other management tools are fundamental. We also seek to provide fresh challenges so that people can grow within the community and achieve their career goals.

People are our essence

Their ideas, values and attitudes have created a culture that unites us and sets us apart. An attitude to life and work that evolves by nourishing itself with the spirit of all of us who are part of this community.





Policies on social and people-related issues

- Quality Policy.
- *Hiring Process*.
- Onboarding process for new hires. For people on temporary contracts, we have a condensed onboarding process, with more virtual training.
- Equality Plan.
- Procedure for training and capabilities of staff during people's *Journey*.
- *Follow-up* programme: support for permanent staff during *On-Boarding* in their first four months at the company. There are monthly meetings to discuss the training plan and to give and receive feedback.
- *Mentoring* programme for new permanent hires.
- *Off-Boarding* procedure.
- Flexible content based on role, self-management skills and trust.
- Open discussions with team leaders over the course of the year where constructive *feedback* is given to support development.

Principal risks and actions

We carry out an annual review of the risks associated with the personal development of members of our community in order to work towards our objectives in the most effective way. We ask ourselves what difficulties we may have in attracting new staff, how to support people in their working lives and how to ensure the necessary balance of people's knowledge, skills and attitudes. In 2021, the principal risks or difficulties in achieving our people development objectives were related to the following areas:

Training and professional development

We continuously improve training plans to ensure the personal and professional development of all our people.

Overburdened and unmotivated staff

We have introduced more flexibility in working hours which makes it easier to achieve a work-life balance and helps people to give maximum value as the main source of personal motivation.

Health and safety

Compliance with health and safety law is always important COVID-19 has made it even more important.

Care for people

We try to support everybody and to understand and meet their needs. Overarching, transparent communication is key to this work.

Proactivity and responsibility

To encourage people to take the initiative and think critically to implement team projects that help us to improve day by day.





Our commitments to the team

We are a responsible and inclusive company in which we take care of the wellbeing of our teams and the individual members of those teams who make them up in a culture that promotes excellence at work in an optimal working environment.

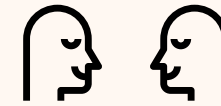
Trust, flexibility and personal responsibility are part of our culture and we hope that everyone will feel committed. We base our relationships on trust and transparency.

We embrace diversity and communicate with the whole organisation in a spirit of respect and honesty. We give and receive constructive *feedback* at all levels so that people can grow both professionally and personally.

Our work is organised by projects and processes. Consequently, effective teamwork is essential to the achievement of our objectives. We are proactive and committed to our staff. We provide an environment in which they can develop their personal initiative and leadership.



Respect



Confidence



Generosity



Initiative



Individual
responsibility



Communication



Teamwork



Honesty



Critical thinking

The psychological and personal effects of COVID-19

We felt the impact of COVID-19 across the whole Group. New ways of working and managing teams were implemented to address the pandemic. The safety of our people and their emotional wellbeing and the continuity and growth of the business, sustaining supply to customers, were the priorities. Despite everything, the pandemic helped us to quickly adopt ways of working that make us more responsiveness and flexible. We have made progress in digitisation and remote working, with the obvious benefits they can bring to people and their environment.

To safeguard health and safety, measures were adopted in 2020 and retained in 2021, having shown themselves effective:

Preventive measures

The principal measure was the obligatory wearing of face coverings, the review of space requirements, signage, eating in shifts and increased remote working.

Detection measures




Taking people's temperature before they were admitted to premises; testing as required through the service offered by our work-related injury insurer.

Response measures




Self-isolation of groups of direct Covid contacts and assistance for those affected persons in managing illness-related absences.

COVID-19 Procedure







In these cases:

 <p>Have symptoms</p>	 <p>Test positive for COVID-19</p>	 <p>Have a temperature $\geq 37.5^\circ$ at the entrance of BioS</p>
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You should:

 <p>Stay home</p>	 <p>Contact your CAP (Primary Care Center) to receive instructions</p>	 <p>Inform the Health committee after speaking with the CAP</p>
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Any doubt?

 <ul style="list-style-type: none"> • What do I have to do if I have been in contact with a suspected case who is awaiting a COVID test result? • What do I have to do if a classmate has tested positive in my child's class and I am waiting for the result of the COVID test? • Am I a covid close contact? • Etc. 	 <p>Contact:</p> <p>Health committee: comitesalud@biosystems.es</p> <p>Catalan Health Authorities: 061</p> <p>Your Primary Care Center (CAP)</p>	<p><i>cuida't</i> </p>   
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The people behind our success

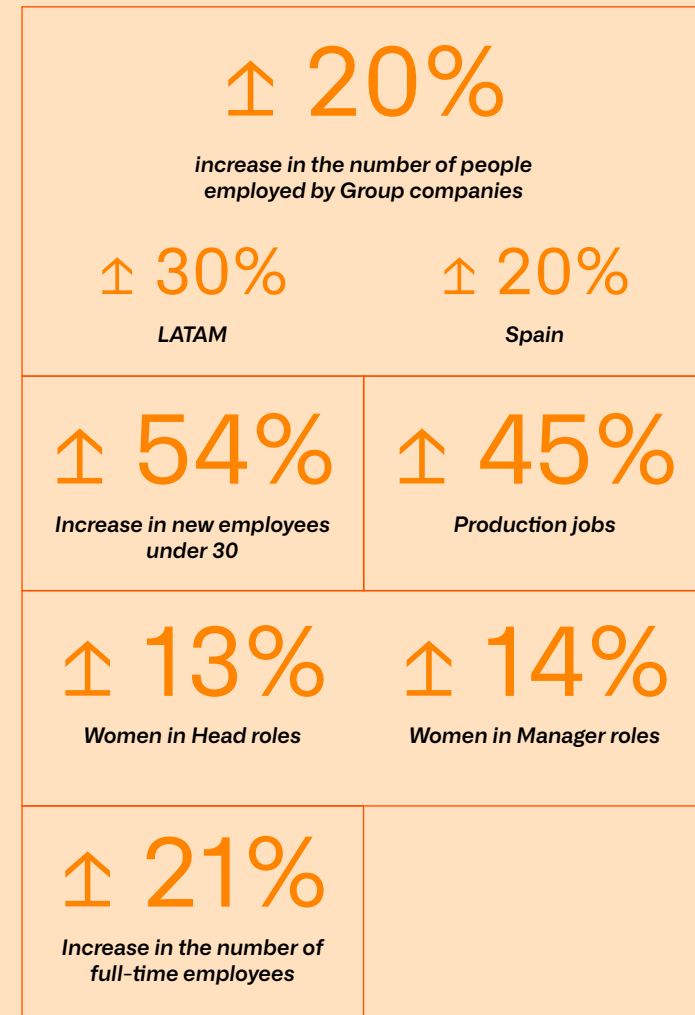
As at December 31, 2021, the BioSystems community consisted of more than 600 people from a total of 17 business, including Group companies, affiliates and representative offices around the globe.

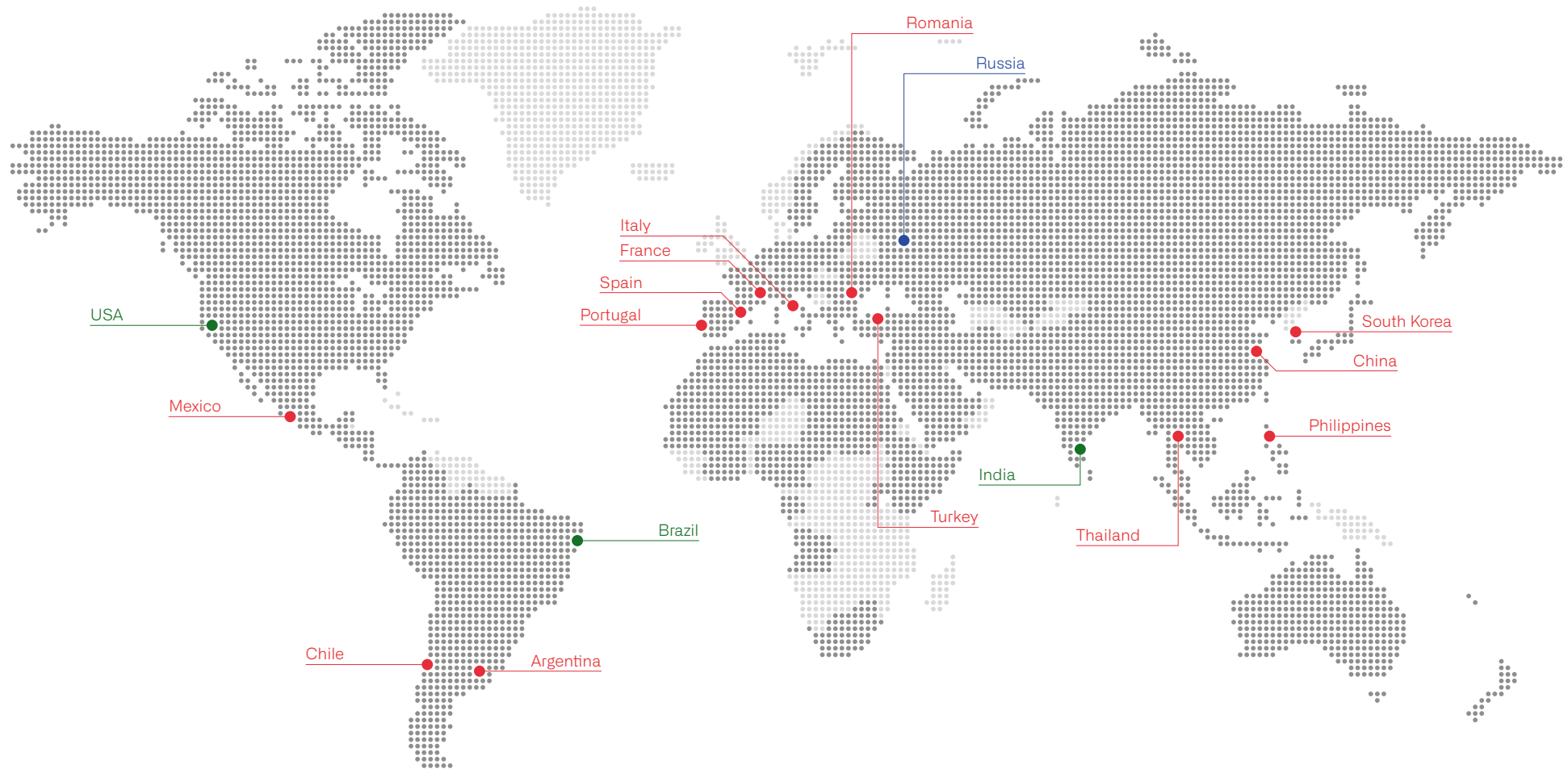
Of those more than 600 people, 492 were employed by Group companies, an increase of 20% over the previous year. This increase is mainly evident in Latin America (\pm 30%) and Spain (\pm 20%).

The increase in new hires under 30 years of age (\pm 54%) in all geographic areas is a sign of our commitment to bringing young people into the workforce. Production jobs increased strongly (\pm 45%), showing a clear relationship between the company's growth and increase in manufacturing capacity. Those jobs have been filled equally by men (\pm 23%) and women (\pm 16%) in all geographic areas, with notable increases in women, principally in Spain and Chile.

In the course of 2021, representation of women in *Head* roles increased to 9 (\pm 13%) and to 49 in *Manager* roles (\pm 14%). Finally, the increase in full-time employees (\pm 21%) should be noted as a reflection of the company's clear commitment to decent work and economic growth (SDG 8).

People have always been a priority for BioSystems, which has had a sustained commitment to employment. In the course of 2020, in the middle of the pandemic, BioSystems submitted a Covid furlough plan in Spain which was approved by the government but not activated or implemented. No furlough applications were submitted by other Group companies for 2020 or 2021.





13

Companies
+3 joint ventures
+1 representative office

110

Distributors

+600

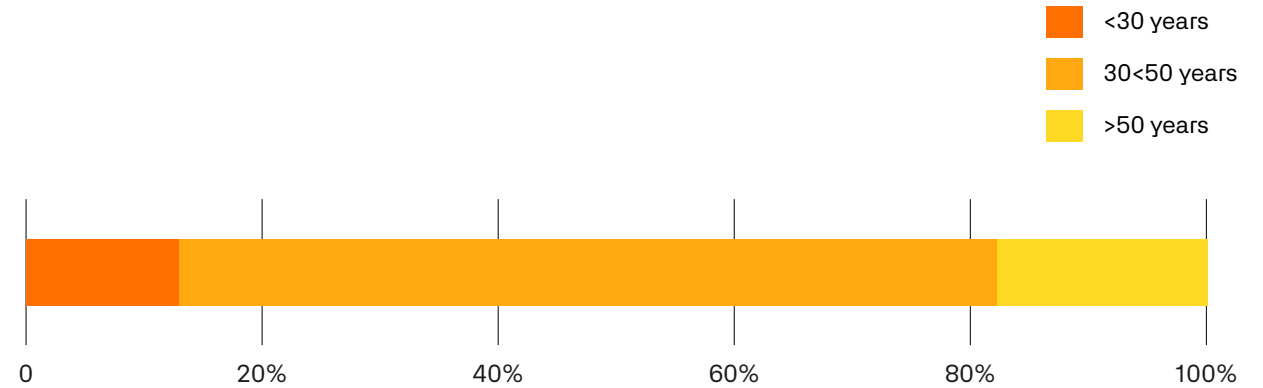
People at your service

+25,000

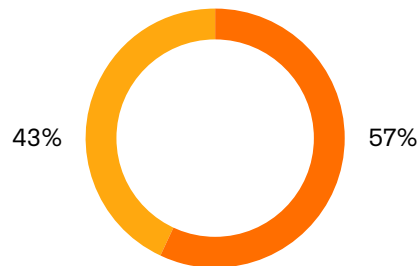
Users

Diversity and inclusion

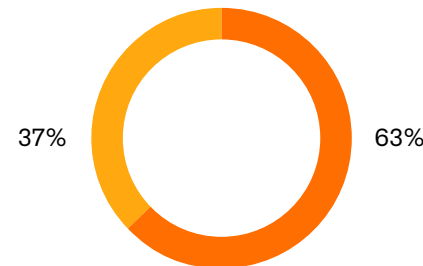
The Group embraces diversity and sees it as an opportunity for growth and enrichment. Diverse teams in which people can take the initiative and find their own voice allow different ways of seeing things and different opinions to coexist. Transparent, respectful communication in diversity is key to fostering new ways of thinking and working that drive learning and overall personal and professional growth.



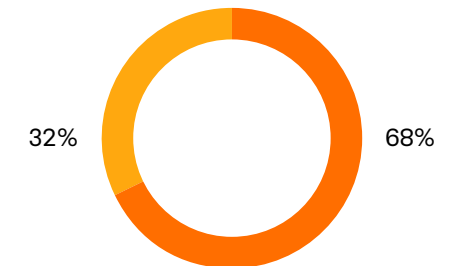
Distribution by age band



Proportions of men and women in the 480 workers in group companies



Distribution of men and women in management positions



Distribution of men and women in Head roles

Equality in the workplace

BioSystems Spain has an Equality Plan that was developed in the course of 2021 that will be in place until 2025. The Plan sets out the principles that govern our actions in relation to gender equality and equal treatment and opportunities in access to employment, training and promotion, and terms of employment.

Out of commitment to the principle of non-discrimination and equality and as required by the Equality Act (Law 3/2007 of March 22), the company is committed to a series of actions over the next three years that reflect the basic principles set out in its Code of Conduct. The objectives are as follows:

- Raising awareness of the Equality Plan.
- Appointment of the Equality Negotiating Committee and the Equality Agent.
- A gender-balanced workforce.
- To demonstrate the organisation's commitment to ensuring equal opportunities and non-discrimination in recruitment.
- To progress in implementing mechanisms and systems that ensure equal pay in the organisation.
- To ensure that internal promotion and professional development processes respect equal opportunities.
- To train and equip staff with tools to enable them to work towards equality of opportunity.
- Flexibility and work-life balance measures that support the right to work-life balance.
- To raise awareness of measures to prevent gender-based and sexual harassment.
- To promote the use of non-sexist and non-discriminatory language in the organisation's documentation and communications.

So as to identify opportunities for improvement for inclusion in the Equality Plan, BioSystems Spain employees were asked to complete a questionnaire during 2021 to gather information on their perceptions of equal opportunities within the organisation.

Some 42% of the workforce in Spain responded (the questionnaire was sent to 272 and 112 responses were provided). Of the respondents, 54% were women and 46% were men.

The results have allowed us to identify significant factors that give rise to differences in pay:

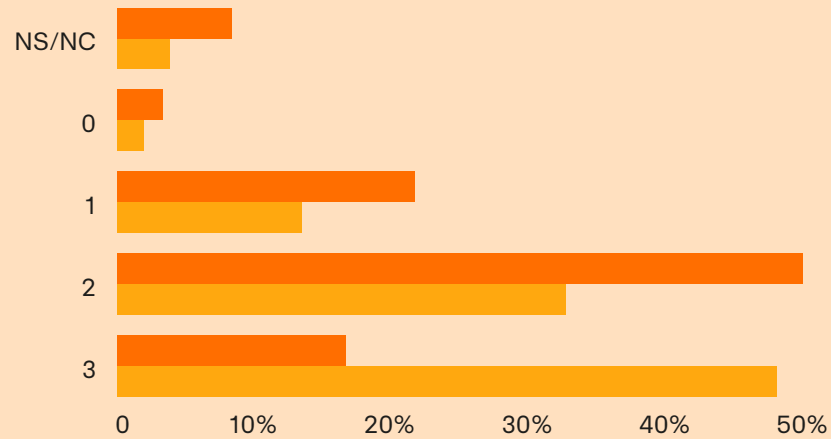
- High number of single-person posts.
- The absence of a job evaluation system.

Finally, it should be noted that we have not found a gender-based pay gap. In addition, people have a positive view of the measures taken by the company to raise awareness of equality and work-life balance.

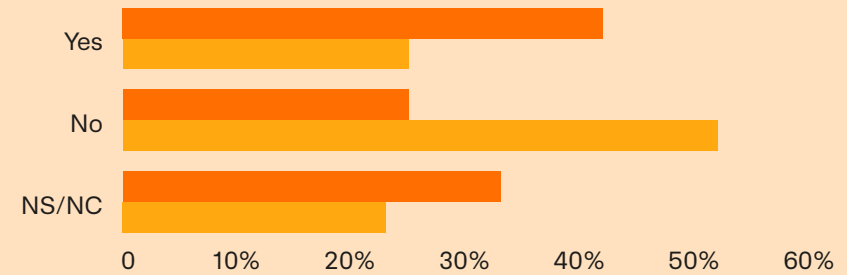
Main results of the questionnaire



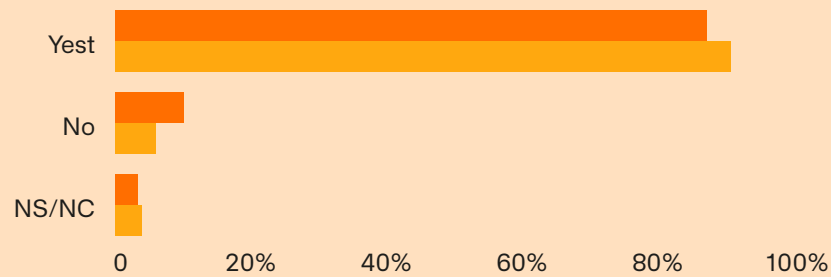
Assesses the company's level of awareness of equality:



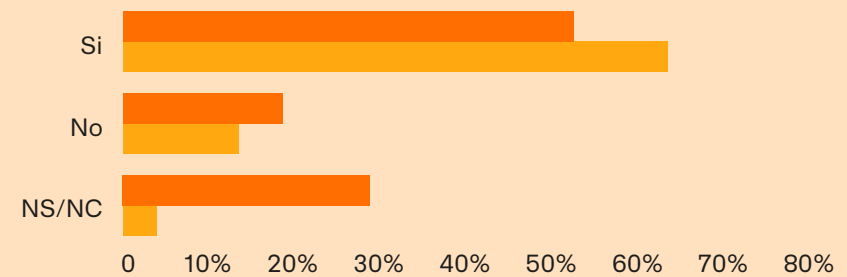
Do you think there are inequalities between men and women?



Does the company support work-life balance?



Do women and men have the same opportunities for promotion and/or development within the business?



Diversity and discrimination

The inclusion of people with different abilities is something that we promote and foster every day. We have specific training in that regard for the people responsible for recruitment. We promote internally to promote people's awareness of diversity within the business through training and information, to share first-person accounts, the use of inclusive language and shared endeavours with employment diversity charitable bodies.

Eurofirms Foundation 8M Challenge

We have joined the Eurofirms Foundation's 8M Challenge, whose aim is to enable 1.000 women with different skills to join the workforce through an employability programme.

We have given scholarships to three unemployed women with different skills to take part in the Eurofirms Foundation programme and so improve their skills and self-confidence in recruitment processes.

BioSystems Spain currently employs five people with different skills (one woman and four men). In the other Group companies, there is no record of staff with different skills.



BioSystems is committed to the principles in its Code of Conduct aimed at protecting human rights, respect for different cultures and creating a working environment free of discrimination and harassment to ensure the wellbeing of all BioSystems people.

Support for personal and professional development

The people at BioSystems have aptitudes and qualities whose common denominator is our values and culture, that determine what the organisation is like and how it acts.

We defend, communicate and promote those values through our People Support Map (MAP) which is available to everyone, through training, individualised support in some situations, two-way feedback and other socially significant actions.



Support for people

Over 2021, we made a number of changes to continue to improve our *On-Boarding* process. Some of the most significant are:

- Changes to the contractual procedure.
- Improvements in the virtual recruitment platforms: BioSystems uses LinkedIn for recruitment and selection.
- More complete selection processes with Visiotalent to attract talent through videos to motivate people in the process.
- BioSmentoring: when people join the business, they are assigned a mentor to support them on their path in the company.
- *Follow-up* programme: guidance during the first four months after a person joins BioSystems.

A total of **101 people** were hired in 2021, 62 men and 39 women.



Training as a bridge to leadership

We want everyone in the community to be able to develop and have their best career. We are our own best trailblazer for our careers and professional achievement. Training is now an essential part of the path to professional development. Teams can identify training opportunities each year and submit them to team coordinators for possible inclusion in the training plan.

The company has a number of virtual tools that ensure continuous training for everyone. An example is the *GoodHabit* platform, which offers constant access to information and training in a variety of fields chosen by each participant choice as basic provision for people's professional development. BioSystems Spain also has the *Plural Sight* tool for technical software training.

Alongside those platforms, yearly training sessions are held to deepen knowledge of concepts that are important to the performance of people's duties. That training includes matters such as Compliance, Code of Conduct, Quality and others matters concerning the technology used in our products, such as: technical service apps, analyser functionality, interpretation of Prevecal reports, etc.

As a consequence of COVID-19, most of the training over the last two years has been given remotely through digital platforms. However, we are gradually returning to in-person training to increase exchange among participants, subject to the maximum capacity under the law and the preventive measures in our Covid Procedure.

By the close of 2021, more than 4,200 hours had been spent in training, as against 2,200 hours in 2020. The difference is the result of the difficulties caused by the pandemic and the time taken to adapt to the new circumstances. The staff who spent the most time in training were managers and technicians, with 39% and 30% respectively of the total number of training hours.



Training for new recruits

Development from the moment people join. They receive training in many areas to introduce them to the company's culture and its way of working in tasks and processes that are relevant to them. Training is provided by the different areas or departments of BioSystems Spain. Principally the following:

1. *People Culture Communication*: transmission of the culture, mission, vision and values of the BioSystems project.
2. *Business Process Management*: introduction to the BioSystems Process Map.
3. *Compliance* and Code of Conduct.
4. Quality Management System.
5. ITC resource management.
6. *Facilities Management*: sustainability and infrastructure management.

New hires in Spain follow the BioSmentoring programme, in which each new joiner has an allocated mentor for both work-related and social and emotional support to support them while they get used to the firm during their first few months.

A mentor or facilitator is a person who guides and supports a new joiner during *On-Boarding*. The mentor can tell them what they need to know and give any advice that may be needed:

- Clarify the requirements of tasks or processes.
- Show where to obtain basic office supplies and workspaces.
- Explain the company's internal guidance and culture.
- Share general knowledge about the company.
- Involve them in workplace social activities.
- Follow-up for actions.
- Open dialogue.

Technical and specific training

At a global level and for all group companies, technical product training is provided throughout the year. Other specific training is provided in function of the needs of members of teams. Discussions are held annually with managers to plan training.

From the perspective of the company, the purpose of training is ensure that everyone is fully equipped to provide leadership and share leadership with others to allow them to grow professionally and deal with all their work-related professional, maximizing creativity, responsiveness and freedom in carrying out their duties.

Internship programmes

The BioSacademy internship programme aims to identify and capture talent for different areas of the company to join the workforce in Spain in due course. BioSystems Philippines has a *Trainee* programme for junior positions that may become senior positions.



BioSystems

human - centred biotech

Quality of employment

The pay gap in the Group

As part of our responsibility for equal pay, we are committed to equal pay that ensures equal opportunity regardless of gender. The company's Equality Plan sets out actions to monitor pay from a gender perspective.

The gross or unadjusted wage gap is the percentage difference between men's and women's gross pay per hour worked. For our suite of businesses, we calculate the pay gap as average additional male pay over average female pay divided by average male pay.

The Group's wage gap was **18%** in 2021 and 23% in 2020, across all businesses, all levels of staff and both permanent and short-term staff. That represents a 5% year-on-year improvement. In senior roles, (*Chief and Head*), the pay gap was stable at 13% in 2021 and 2020.

The pay gap in BioSystems Spain is **15%** for 2021 and 17% for 2020.

Although it is true that the overall figure is decreasing from year to year, the 2021 pay gap underlines the need to continue to work in this area.

Continued progress towards meeting the company's commitment to genuine equality under the 2022-2025 Equality Plan, the company is taking steps to promote employment of the under-represented sex. There is training on equal opportunities and work-life balance and flexible working.

Remuneration system

Our compensation system is intended to offer fair, attractive terms and conditions so that people can develop personally and professionally. That is why pay at BioSystems is competitive and market-driven. The compensation system flexes in function of the geographic location of each Group business. A typical compensation package breaks down as follows:

- Fixed salary based on performance, skills and work experience.
- Variable compensation in the form of measurable bonuses or incentives linked to the achievement of objectives, set in advance with each person to motivate them to be productive and improve their level of performance.

- Flexible compensation programme in Spain: flexible compensation plan for people with one year of seniority in the company. The plan includes tax benefits for public transportation, childcare services, restaurants, additional mutual health insurance and training.

We internally review competitiveness of our salaries annually to ensure that salaries are in line with the market.

Conventions and Committees

As a worldwide business, we are subject to the requirements of a number of legal systems. Group companies as well as complying with the minimum standards of the Declaration of Human Rights and International Labor Organisation conventions, we comply with employment laws in each jurisdiction in which we carry on business.

In some jurisdictions, we are required to create committees for worker representation that staff are free to join. We have such committees in companies in Spain and Mexico. In Spain, the company is subject to the General Chemical Industry Collective Agreement because it has manufacturing facilities.

In the BioSystems Group, 78% (100% in Spain and 100% in Mexico) of employees are covered by collective bargaining agreements.

Employee Wellbeing

We organise activities to improve employee relations and interpersonal communication and to create an atmosphere that gives people with moments of rest, fun, downtime and constructive leisure. In Spain, such activities include the following:

- **Yoga and mindfulness:** having healthy daily habits helps us to improve our health and wellbeing. The practice of yoga and *mindfulness* encourages a healthy lifestyle.
- **Paddle tennis and table tennis:** there are teams and championships for these two sports.
- **Hiking trips:** exploring hiking routes and paths.
- **Athletics:** taking part in races organised by the community.

It has been difficult to sustain those activities over the last two years due to Covid-related restrictions. However, there have been sessions with lower permitted attendance and we are determined to go fully back to the way it was before.



Occupational health and safety

Caring for people also means safeguarding their health and safety at work, taking all the steps required to protect them.

Our Health and Safety teams play an important role within the organisation and are responsible for identifying and assessing potential hazards and risks. At the same time, preventive measures and safety programmes are introduced to eliminate, manage and reduce risks in order to continuously improve the workplace.

Communication, exchange of information, participation and consultation with these teams are key to ensuring that each and every employee is aware of the company's objectives in terms of risk prevention. Health and Safety activities reach all levels of the organisation to ensure universal commitment to safe behaviour that is not harmful to health.

The Management of BioSystems Spain is responsible for compliance with the requirements of the Health and Safety at Work Act (Law 31/1995).

Management delegates functions in this area to the Health and Safety Committee which is in constant communication with everybody who has any queries or who request assistance. We also use rely on the External Risk Prevention Service for the management and assessment of risks in addition to risk prevention measures.

In 2021 we faced major challenges from the Health and Safety point of view, due to the ongoing COVID-19 pandemic. We have had to adapt and have been working on the appropriate responsive risk prevention measures in light of national, regional and local laws. That work has been carried out with full respect for the company's commitments to the people in the BioSystems project.

Our commitment to Health and Safety commitment has been strengthened, focusing objectives on carrying on business in a safe environment that is not harmful to health through the work of the Health and Safety Committee and the External Risk Prevention Service (Valora Prevención).



Absence

We have a set of indicators that show detailed break-downs of levels of absence so that we can take steps to reduce the impact of some reasons for absence and improve the health and wellbeing of all. Those steps include:

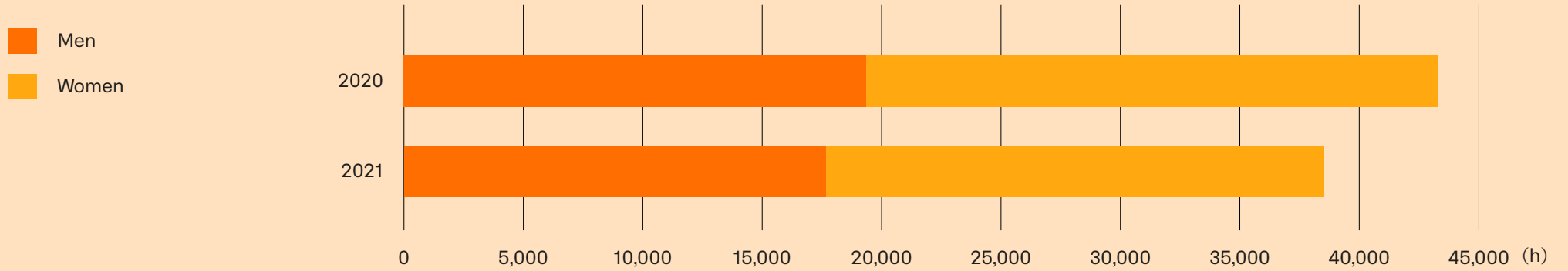
- Mutual accident insurance company.
- Regular issue of personal protective equipment (PPE).
- Regular checks of the safety and use of work-related equipment.
- Signage for risks, correct storage, evacuation routes and exits that are not obstructed and are properly signposted.
- Training and working procedures.
- Work-related accident procedure.
- Fire drills.
- Coordinating with other firms that carry out activities in the company's facilities.

The number of absence hours fell to 38,554 in 2021 compared to 43,314 in 2020. From that total, 26,815 hours of absence were due to a common illness (30,850 in 2020), 10,507 hours of absence were due to maternity and paternity leave (12,144 in 2020), and the remaining 1,232 hours of absence were due to work-related accidents (320 hours in 2020).

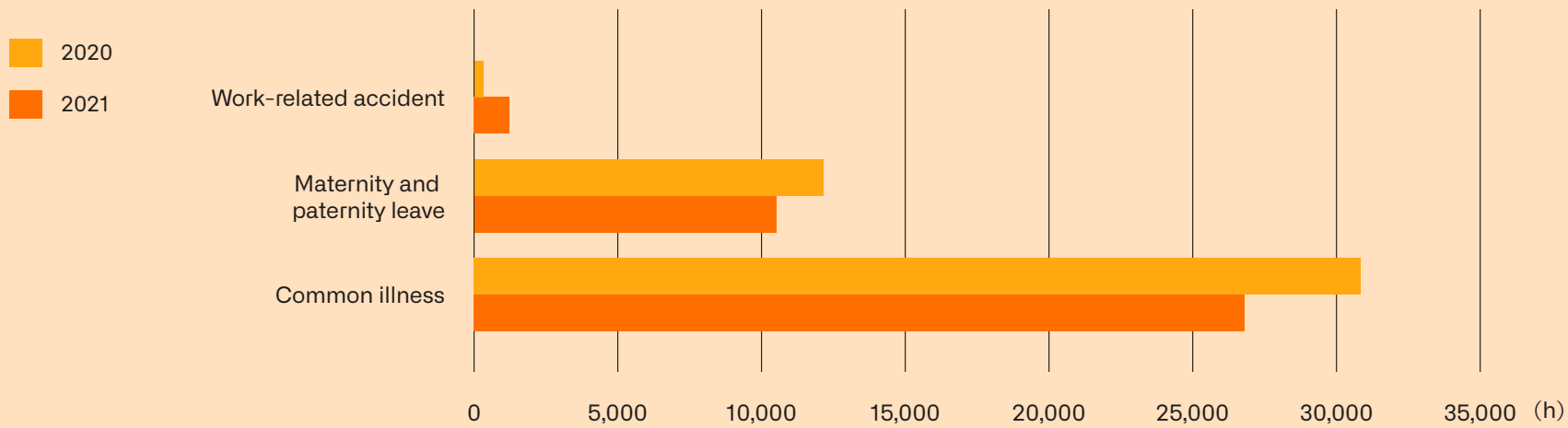
The pandemic had a notable effect on the level of absence for common illnesses, with increases of 29% from 2019 to 2020; and 23% from 2019 to 2021. By gender, of the 38,554 total hours in 2021, 20,886 hours were for women and 17,668 hours were for men. Of the 43,314 hours in 2020, 23,958 hours were for women and 19,356 hours were for men.



Absence hours in 2021 by gender



Reasons for absence



Work-life balance and time management

As stated in our Equality Plan and Code of Conduct, we foster a culture that respects the balance between work and personal life, so that everybody can combine their life with their work.

Flexible working

Since 2020, we have 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, people and processes.

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

Blank calendar

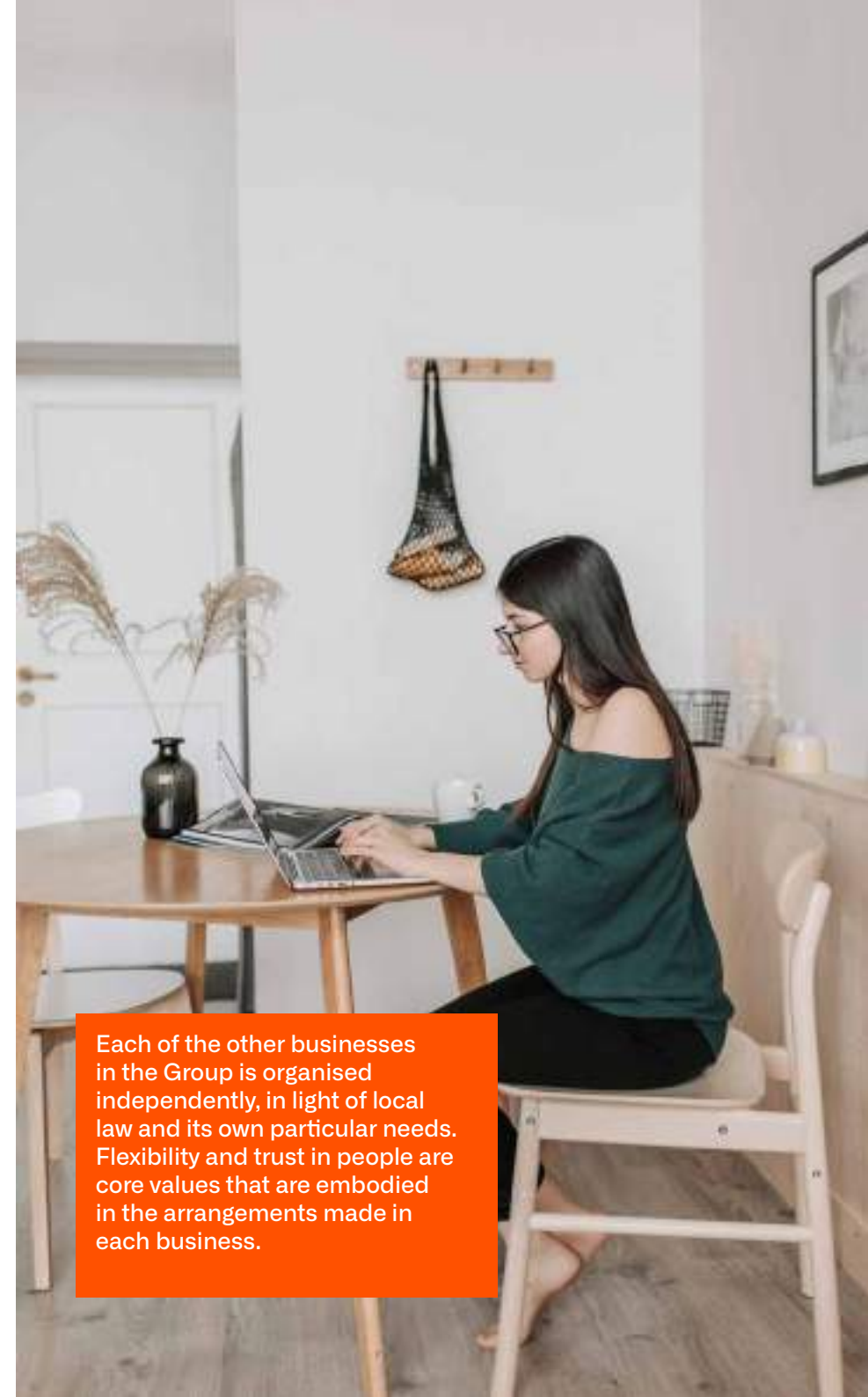
Our employees have a blank holiday calendar where they can manage their days off in consultation with the team they work in and in function of the allowance set under the collective bargaining agreement.

This blank calendar is based on freedom, trust, personal responsibility and leadership, to make the process as efficient as it can be and give broad latitude for achieving work-life balance.

Remote working

We have implemented the infrastructure and resources to enable remote working, subject to the requirements of each process and in agreement with each team.

It has been decided to keep all our existing workspaces. Each individual can therefore determine with their team which is more effective – remote working or physical attendance.



Each of the other businesses in the Group is organised independently, in light of local law and its own particular needs. Flexibility and trust in people are core values that are embodied in the arrangements made in each business.

Commitment to society

We maintain our commitment to have a positive impact on the environments and communities in which BioSystems is present, strengthening the competitiveness of the company and setting ourselves apart from other businesses.

Being local, being close to people and taking advantage of the opportunities that the environment provides are things that we work towards in an active way in the communities in which we are present.

In line with the company's mission to improving health and wellbeing, BioSystems takes part in community and charitable activities that go beyond the company's business and its bottom line. Total contributions to foundations and non-for-profits during 2021 amounted to 17,862.90€. The initiatives supported include:

Laia Foundation

Through our Indian partner company (BioSystems BDPL), BioSystems has been working since 2018 each year with the Laia Foundation, an organisation that promotes the social and economic development of communities at risk of exclusion in southern India.

Vicente Ferrer Foundation (VVF)

BioSystems BDPL supports the VVF at their hospital laboratories in Anantanpur, India. In addition, a portion of BioSystems India (BDPL) profit is donated each year.

Group ¾

Group ¾ was formed in 2006. It is a charity formed by BioSystems Spain to support families in difficult social situations in two parts of the city of Barcelona. Biosystems supports the Group with an annual donation and by allowing its projects to be publicised within the business.

Projects include "The solidarity sandwich" once a month or the gift of cosmetics from Idesco (part of the Ginper Group) during the Christmas and summer campaigns. BioSystems has a direct relationship with the Carmelite nuns of Roquetes and the Sisters of Charity of Raval, and is involved in different activities depending on the needs of the families who come to those two centres, for example: donations for rent, food, and school supplies for children.

Eurofirms

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

Donation to the Sabadell animal shelter

In the form of animal feed and veterinary medicines.





Tracking metrics

The figures shown in the tables in this section are for all people within Ginper, to BioSystems Spain and to subsidiaries more than 50% owned. The tables show all individuals under existing contracts in the company. The averages are only for 2021.

Year-end data

Headcount as of December 31 by geographic area

	2021	%	2020	%
Spain	351	72%	293	72%
Rest of Europe	35	7%	29	7%
Asia	50	10%	45	11%
LATAM	56	11%	43	10%
TOTAL	492		410	

Workforce by age range

	2021	2020
Up to 30	60	39
31-50	342	281
Above 50	90	90
TOTAL	492	410

Year-end data

Workforce by role and gender

	2021	2020
Chief	8	9
Head	29	28
Manager	120	105
Production	158	109
Technical	139	123
Administration	38	36
TOTAL	492	410

Workforce by country and gender (2021)

	Men	Women	Total
Argentina	1	1	2
Chile	9	7	16
Spain	202	149	351
France	2	1	3
Italy	3	1	4
South Korea	7	5	12
Mexico	20	18	38
Philippines	13	14	27
Portugal	2	1	3
Romania	12	9	21
Thailand	4	7	11
Turkey	3	1	4
TOTAL	278	214	492

Workforce by country and gender (2020)

	Men	Women	Total
Argentina	1	1	2
Chile	6	5	11
Spain	166	127	293
France	2	1	3
Italy	3	-	3
South Korea	6	5	11
Mexico	13	17	30
Philippines	12	13	25
Portugal	2	1	3
Romania	10	8	18
Thailand	3	6	9
Turkey	2	-	2
TOTAL	226	184	410

Year-end data

Workforce by country and age group (2021):

	Up to 30	31-50	Above 50	Total
Argentina	-	1	1	2
Chile	2	10	4	16
Spain	34	244	73	351
France	-	2	1	3
Italy	2	2	-	4
South Korea	1	10	1	12
Mexico	4	29	5	38
Philippines	10	17	-	27
Portugal	-	2	1	3
Romania	4	14	3	21
Thailand	2	8	1	11
Turkey	1	3	-	4
TOTAL	60	342	90	492

Workforce by country and age group (2020):

	Up to 30	31-50	Above 50	Total
Argentina	-	1	1	2
Chile	1	7	3	11
Spain	19	200	74	293
France	-	2	1	3
Italy	1	2	-	3
South Korea	1	9	1	11
Mexico	4	21	5	30
Philippines	9	16	-	25
Portugal	-	2	1	3
Romania	3	12	3	18
Thailand	1	7	1	9
Turkey	-	2	-	2
TOTAL	39	281	90	410

Year-end data

Workforce by gender and type of contract (2021):

	Permanent	Temporary	Total
Men	247	31	278
Women	186	28	214
TOTAL	433	59	492

Workforce by age group and type of contract (2021)

	Permanent	Temporary	Total
Up to 30	52	8	60
31-50	292	50	342
Above 50	89	1	90
TOTAL	433	59	492

Workforce by role type of contract (2021)

	Permanent	Temporary	Total
Chief	8	-	8
Head	29	-	29
Manager	120	-	120
Production	111	47	158
Technical	129	10	139
Administration	36	2	38
TOTAL	433	59	492

Workforce by gender and type of contract (2020):

	Permanent	Temporary	Total
Men	226	-	226
Women	175	9	184
TOTAL	401	9	410

Workforce by age group and type of contract (2020)

	Permanent	Temporary	Total
Up to 30	37	2	39
31-50	274	7	281
Above 50	90	-	90
TOTAL	401	9	410

Workforce by role type of contract (2020)

	Permanent	Temporary	Total
Chief	9	-	9
Head	28	-	28
Manager	105	-	105
Production	104	5	109
Technical	119	4	139
Administration	36	-	36
TOTAL	401	9	410

Year-end data

Workforce by gender and full/part-time (2021)

	Full-time	Part-time	Total
Men	273	5	278
Women	203	11	214
TOTAL	476	16	492

Workforce by age group and full/part-time (2021)

	Full-time	Part-time	Total
Up to 30	59	1	60
31-50	329	13	342
Above 50	88	2	90
TOTAL	476	16	492

Workforce by role and full/part-time (2021)

	Full-time	Part-time	Total
Chief	8	-	8
Head	28	1	29
Manager	119	1	120
Production	151	7	158
Technical	136	3	139
Administration	34	4	38
TOTAL	476	16	492

Workforce by gender and full/part-time (2020)

	Full-time	Part-time	Total
Men	223	3	226
Women	172	12	184
TOTAL	395	15	410

Workforce by age group and full/part-time (2020)

	Full-time	Part-time	Total
Up to 30	39	-	39
31-50	268	13	281
Above 50	88	2	90
TOTAL	395	15	410

Workforce by role and full/part-time (2020)

	Full-time	Part-time	Total
Chief	9	-	9
Head	27	1	28
Manager	104	1	105
Production	103	6	109
Technical	121	2	123
Administration	31	5	36
TOTAL	395	15	410

Year-end data

Dismissals by role

	2021	2020
Chief	1	-
Head	-	1
Manager	6	10
Production	5	4
Technical	1	-
Administration	-	-
TOTAL	13	15

Dismissals by gender

	2021	2020
Men	7	12
Women	6	3
TOTAL	13	15

Dismissals by age range

	2021	2020
Up to 30	1	2
31-50	9	8
Above 50	3	5
TOTAL	13	15

Averages

The average number of employees has been calculated in FTEs (*Full Time Equivalent*) on the basis of contracted hours and the time worked by each person during in the course of 2021 (full working day for one year equates to 1 FTE).

		2021				
		Permanent		Temporary		
		Full-time	Part-time	Full-time	Part-time	TOTAL
Men	Up to 30	20	-	3	1	262
	31-50	167	4	13	-	
	Above 50	54	-	-	-	
Women	Up to 30	25	-	3	-	200
	31-50	112	5	15	-	
	Above 50	37	2	1	-	

		2021			
		Permanent		Temporary	
		Full-time	Part-time	Full-time	Part-time
Chief		8	-	-	-
Head		27	1	-	-
Manager		116	1	-	-
Production		105	5	26	1
Technical		123	3	7	-
Administration		36	2	1	-

Average pay

The pay shown in the tables is for people working in the company as of December 31, 2021 and 2020, respectively; it has been calculated as annualised averages in gross data including fixed salary and any variable remuneration. Salaries have been converted to euros using the following fixed rates:

Country	Rate 2021	Rate 2020
Argentina	0.009825	0.01236
Chile	0.001181	0.0011
Spain	1	1
France	1	1
Italy	1	1
South Korea	0.00074	0.00074
Mexico	0.04202	0.04061
Philippines	0.017286	0.01762
Portugal	1	1
Romania	0.20348	0.20673
Thailand	0.02663	0.02783
Turkey	0.09587	0.1242

Average pay by gender

	2021	2020
Men	34,674€	38,115€
Women	28,270€	29,518€

Average pay by age bands

	2021	2020
Up to 30	21,735€	20,110€
31-50	30,181€	32,605€
Above 50	45,146€	45,544€

Average pay by geographic area

	2021	2020
Spain	37,042€	40,530€
Rest of Europe	24,857€	26,969€
Asia	16,365€	15,491€
LATAM	17,839€	16,071€

Average pay

Average pay by role

	2021	2020
Chief	109,196€	110,938€
Head	65,271€	64,556€
Manager	36,958€	39,214€
Production	24,454€	27,177€
Technical	26,946€	26,653€
Administration	23,119€	23,459€

Training

Training time by role

	2021	2020
Chief	107	21
Head	172	168
Manager	1,644	795
Production	602	175
Technical	1,264	820
Administration	425	220
TOTAL	4,214	2,198

Accident rates

For both Ginper and the BioSystems Group, the principal measures of accident rates are shown for Spain. In the rest of the BioSystems Group companies no accidents were reported.

	2021		2020	
	Men	Women	Men	Women
Number of accidents with sick leave	5	-	3	1
Frequency (*)	10.27	-	7.58	3.10
Severity (**)	0.32	-	0.10	0.03

* Frequency: (Accidents / Hours worked^{***}) x 10⁶

** Severity: (Days lost / hours worked^{***}) x 10³

*** Hours worked: Annual 1,752 hours under the Collective Bargaining Agreement multiplied by the total number of men and women in 2020 and 2021 across companies in the BioSystems Group and Ginper.

	2021		2020	
	Men	Women	Men	Women
No sick leave	1	-	1	-
Medical leave	5	-	3	1
In transit	-	1	2	-

No occupational illnesses were reported declared in 2021.



Environment

Diversity in resource consumption and waste management

Because the Biosystems Group companies are active in 17 countries and they vary greatly in size, their structures are also very varied. There are businesses that have headquarters, like the Barcelona facility with a total surface area of 17,500 m², while others have only one office, with teams spread throughout their country of operation. That means that information related to resources consumed and waste generated is non-comparable and in some cases there is no information available.

BioSystems production activities, which have the greatest environmental impact, are mainly carried out in BioSystems Spain, with the exception of some processes carried out in India by our affiliate. Other group companies are mainly involved in product distribution. Consequently, although we consider all BioSystems companies, most of the data in this section refer exclusively to BioSystems Spain.

BioSystems Spain has trained specialist staff to manage environmental risks.



Risk and opportunity management



Governance

Environmental risks and opportunities are managed by *Facilities Management*. The department brings together teams working in Health and Safety, and Environment. BioSystems Spain and our Indian affiliate have specialists to undertake these specific tasks. In the other BioSystems companies, these tasks are carried out by administrative staff. These people are in direct communication with the BioSystems Management and Strategy Team and Country Managers.

In 2021, BioSystems started working with a multidisciplinary team to develop its approach to sustainability. BioSystems management participates directly in the team.

Risks and opportunities identified

The identification and management of environmental risks follows the same process as overall risk management process at BioSystems. In terms of the environment, we identify compliance, people and environmental risks and opportunities. We assess the probability and possible impact of those risks. Likelihood of occurrence is assessed on the basis of the frequency of the activity in which the risk could occur and its occurrence in the organisation. Impact assessment takes into account financial, operational, compliance, strategic, human and environmental consequences. Having evaluated the risks and opportunities, we identify mitigations of risks and steps to take advantage of opportunities.

Our risk analysis has not identified any impacts of the business in terms of light or noise pollution. The principal risks recognised relate to management of waste generated in production. Those risks are themselves principally related to compliance and operations.

Environmental damage

Deliberate or negligent direct or indirect emissions that may contaminate the environment in possible breach of the law concerning waste management and the operation of facilities in which hazardous activities are carried out.

Disposal of products

Failure by the business to dispose of product/inventory as required by law.

Natural phenomena that affect the company

The risk that the company will fail to plan for uncontrollable events (e.g., earthquake, toxic clouds, flooding, severe weather), so as to impair the company's ability to sustain critical operations and provide essential products and services, or give rise to additional costs of operation.



Risks and opportunities identified

We are currently implementing a number of measures to address the risks identified. For example, we regularly review our obligations under environmental law, we review our waste disposal procedures, we perform maintenance to our water treatment plant and on the company's assets in general. We have emergency response plans to ensure worker safety and continuity of operation.

In terms of opportunities, we have identified the following opportunities related to people and the environment:

Access to environmentally conscious external suppliers

Energy efficiency certification is advantageous to participation in public procurement processes and the formation relationships with suppliers who are aware of such measures.

To take advantage of that opportunity, we explored possible new energy certification to create alliances with new suppliers and to be able to exploit new business opportunities.



Environmental management

We have known for years, that to improve health and wellbeing we must minimise our impact on the environment. Because we understand the impact that our business can have on the environment, we seek to minimise that impact. We have internal procedures to ensure efficient resource management. Operating procedures prescribe in detail how to manage waste generated by processes. We have three procedures that address environmental issues.

Management of statutory environmental management obligations

This procedure gathers together all the statutory requirements that affect the company in relation to the environment and provides guidance as to how to meet them. Those environmental relate both to permits for activities and to waste and water treatment.

Waste disposal

This procedure details the types of waste generated by the business and the obligations of individuals in the course of the generation, treatment, collection and disposal of waste.

Waste water treatment

This procedure describes the operation of the wastewater treatment system.

Beyond written procedures, we have a two-pronged approach to environmental issues. We first identify and comply with the legal obligations that apply to our business. Second, we bear in mind the environmental impact in decision-making so that we can take steps to improve and minimise our impact. That is why for several years we have been making decisions aimed at reducing water stress, minimizing the use of non-renewable energy and making changes to our products and their packaging to reduce our environmental impact.

BioSystems is not required to take out Environmental Liability insurance under Law 26/2007 on Environmental Liability. Further, since there is no identified a material risk of environmental contamination, there is no cover for accidental contamination in the company's civil liability policies.



Circular economy and waste prevention and management

We strive to consume raw materials efficiently in order to manage production costs whilst ensuring good product quality. Our business generates different types of waste, depending on the quantity and type of products manufactured.

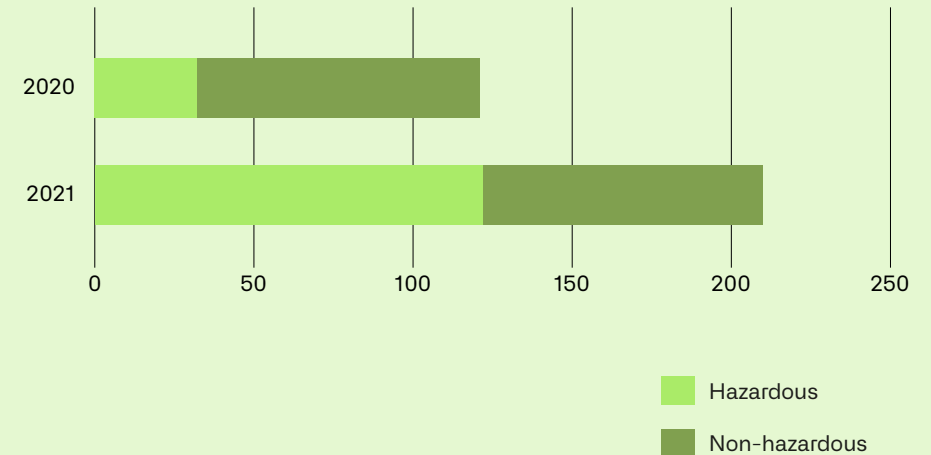
BioSystems Spain's plant has a wastewater treatment plant that treats wastewater from production before its discharge into the public sewage system. In 2021, 23.8% by mass of waste generated is liquid waste from equipment cleaning; in 2020 the figure was 58.5%. The increase in waste generation between 2020 and 2021 is largely due to the non-hazardous waste generated by the return to on-site working.

Waste reduction measures taken are:

- Optimise the use of raw materials and cleaning chemicals in the production process.
- Improve waste segregation and recycling.
- To reduce the environmental impact of containers and packaging through measures to reduce plastic and paper used in each kit.
- Implement a system for the reuse of out of use equipment through reconditioning and market use at a price that reflects its condition.

Most of the waste generated requires special treatment as hazardous waste under the classification of the Waste Agency of Catalonia.

Tonnes of hazardous and non-hazardous waste generated



GHG emissions and sustainable use of resources

Emissions

Emissions are classified into three groups:

SCOPE 1

Direct emissions:

Directly generated by the business, such as the consumption of natural resources and gas emissions.

SCOPE 2

Indirect emissions:

The consumption of electricity and other external energy sources.

SCOPE 3

Other indirect emissions:

Transportation of goods, travel and movement of people, and waste treatment and recovery.

Under Scope 1 emissions, we have identified fuel consumption by the company's own fleet and diesel consumption by the boiler used to heat water in the freeze-drying processes. In total we have calculated that in 2021 we generated 266.45 tonnes of CO₂. Under Scope 2 emissions, from 2020 all energy purchased at BioSystems Spain will come from renewable energy sources. The switch to renewable energy consumption in 2021 is estimated to have generated savings of approximately 270 tonnes of CO₂. However, for other BioSystems companies we have calculated a total of 95 tonnes of CO₂ (*market based*).

Finally, for the time being, we have not taken any actions to monitor or offset Scope 3 emissions indirectly caused by our business.



Measures to adapt to of climate change

Installation of solar panels

During 2021, we commenced the process with Endesa for the installation of solar panels at the BioSystems Spain building. The panels will allow us to generate approximately 5% of the electricity consumed by the company off-grid.

Remote working

As a consequence of the COVID-19 pandemic, remote working by agreement with members of each unit or department has become a possibility. Remote working has led to reduced ability to travel and led to lower of Scope 3 emissions generated by the people who work in Group companies.

Installation of bicycle parking

There is bicycle parking at BioSystems Spain's offices people who want to use their bikes.

As at now, we have not adopted specific voluntary targets for the reduction of greenhouse gas emissions. Even so, in addition to the measures mentioned above, BioSystems not only encourages the efficient use of resources, but also promotes the use of public transport cards available through our flexible remuneration plan. Those measures help us to work together to reduce our emissions of greenhouse gas and thus to reduce our impact on climate change.



Electrical power

BioSystems energy consumption is very unevenly distributed. In that regard, 90% of the electricity consumed in 2021 was consumed in BioSystems Spain. In 2021, 100% of that electricity will come from renewable sources.

The total electrical energy consumed in Spain was 1,881.45 MWh. The energy consumed by the other companies that have a physical headquarters and consequently can monitor electricity consumption was 208.79 MWh, which represents 10% of the total electricity consumption.

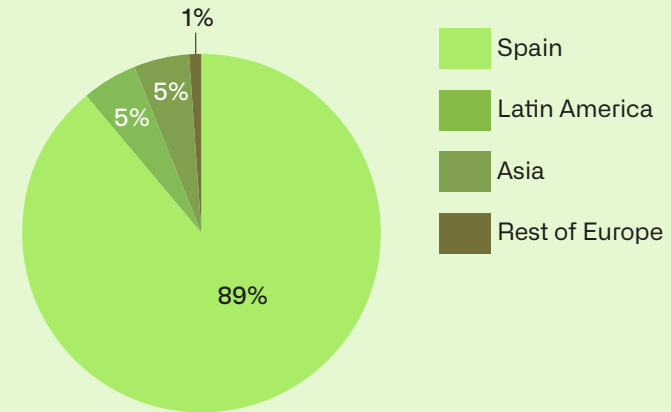
As a result of energy saving measures adopted in recent years, and despite the growth in the turnover of the business, energy consumption is on a clear downward trend. BioSystems Spain consumed about 2,117 MWh in 2015 compared to the current 1,881 MWh.

Energy saving measures

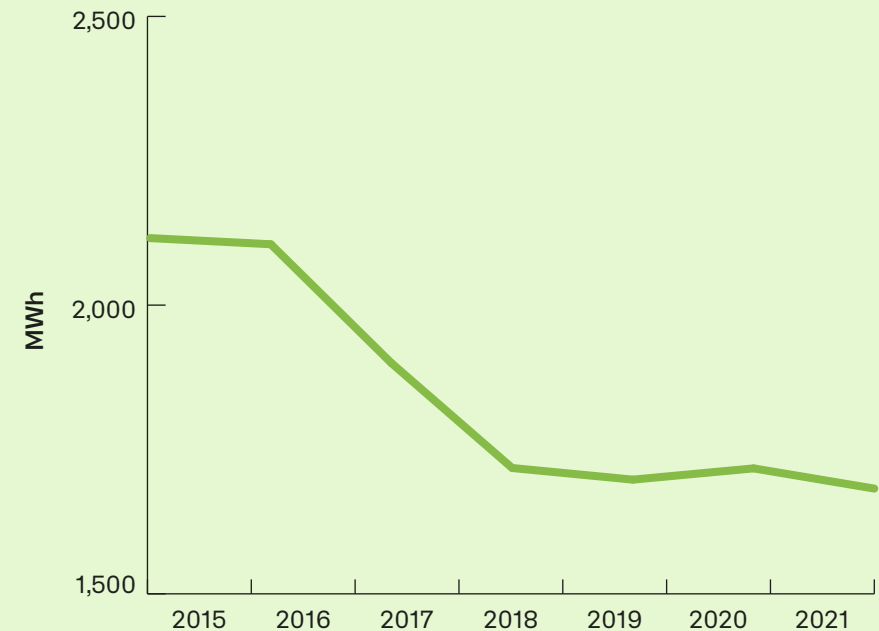
BioSystems Spain has taken a number of steps to reduce energy consumption. In 2019, we clad the facades of the main building with an air gap. We also invested in improving the insulation of the building by installing double-glazing. In 2020 we replaced all the lighting in the business with LED lights.

An 184,092€ investment is planned to install photovoltaic panels in the course of 2022, which will allow us to self-generate approximately 5% of the electricity consumed in Barcelona.

Distribution of energy consumption at BioSystems



Trends in energy consumption at BioSystems



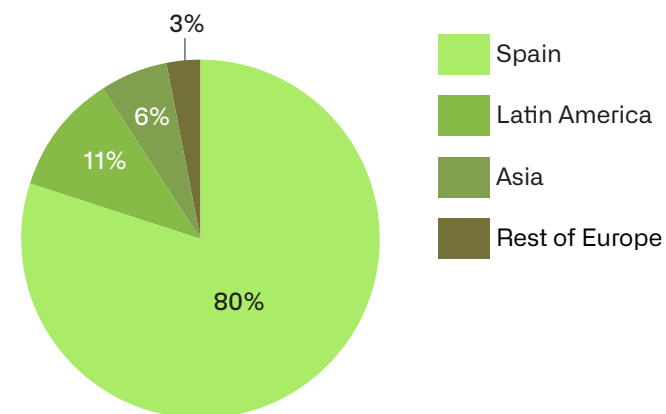
Water

Water is essential to the production of a large part of BioSystems products. That is why we have for many years focused on being more efficient in our use of water and very careful in its treatment.

The bulk of our water consumption occurs at our headquarters in Spain, where the production of reagents takes place. However, as in the case of electricity, for some of our companies we do not have figures for water consumption because it is not paid for in some countries or because our offices are within a shared office building.

BioSystems Spain has a wastewater treatment plant (WWTP) at its manufacturing plant in Barcelona where chemical waste from the manufacturing process is concentrated by evaporation process further treatment in authorised waste treatment plants. This plant processes all water from our production processes, so that no hazardous waste is discharged into the public sewerage system.

Percentage of water consumption in Spain and other BioSystems companies



Recent initiatives with environmental impact

Product de-listing

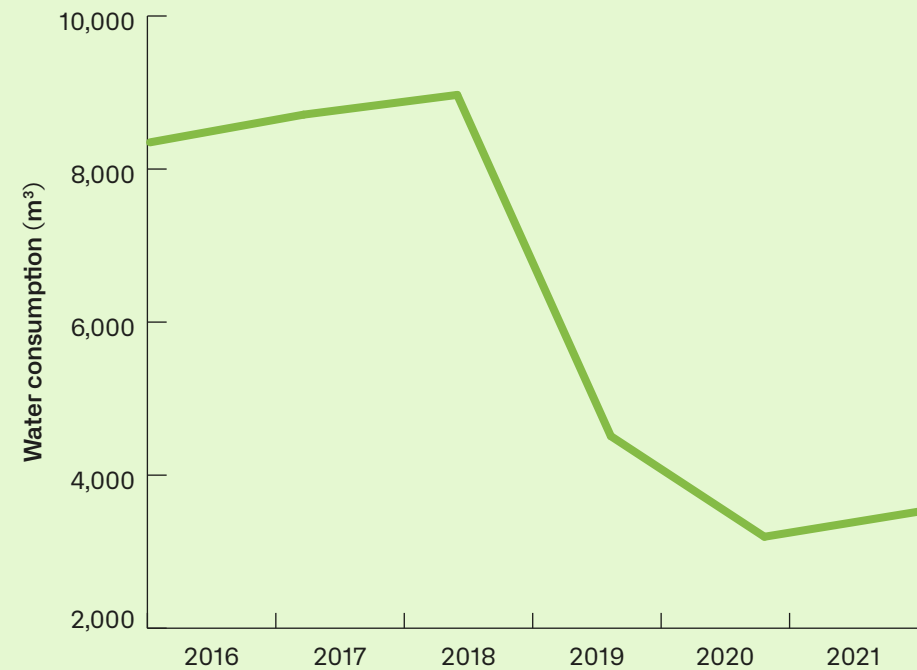
In 2018, we decided to de-list glycated haemoglobin chromatography (CRO - HbA1C). It was the principal product in the chromatography line. By discontinuing the product, we are able to reduce water consumption and the generation of phosphate waste.

As a result, water consumption has been reduced by 50,447 m³ from 2018 to 2021. Conversely, turnover has increased from around 45M€ to 70M€.

Reuse of osmosis water for the freeze-dryer

Since the end of 2020, the cooling system for the compressors of the two freeze-dryers has been changed from mains water to a closed water circuit. As average water consumption for each process was 2 m³ per hour and the average process time is 24 hours, the average water savings per process is 48 m³. 162 freeze-drying processes were carried out in 2021, giving total water savings of 7,800 m³.

Trends in water consumption in BioSystems Spain





Tracking metrics

We monitor environmental matters with the greatest impact. We monitor water and electricity consumption at our manufacturing plants and waste generation.

Consumption of raw materials

RM used	2021	2020
Electronic components and equipment for photometers and analysers (units)	1,531,050	1,372,400
Organic solvents (L)	13,473	12,134
Metal components for photometers and analysers (units)	12,410	11,100
Plastic components for photometers and analysers (units)	11,900	10,700
Inorganic compounds	3,042	2,729
Serum (L)	1,225	1,107
Phosphates (kg)	868	785
Buffers (kg)	481	441
Culture media (L)	255	234
Detergents (kg)	190	170
Latex microparticles (L)	138	124
Organic solvents (kg)	119	107
Resins (kg)	58	55

Tracking metrics

Electricity

Monthly electricity consumption (kWh)

	2021	2020
Spain	1,881,451	1,711,722
Asia	95,945	92,890
LATAM	83,141	82,222
Rest of Europe	29,703	27,629
TOTAL	2,090,240	1,914,463

Water

Water consumption (L)

	2021	2020
Spain	3,522,000	2,663,000
Asia	294,380	268,195
LATAM	480,120	480,120
Rest of Europe	124,000	114,400
TOTAL	4,420,500	3,525,715

CO₂

CO₂ savings

	2021	2020
Electricity consumption BioSystems Spain	1,881,451.00	1,711,721
Emission factor*	0.144	0.138
kg CO ₂ saved at BioSystems Spain	270,928.94	236,217.64

*Emission factor for electricity generation in the electrical system in Spain obtained from Red Eléctrica de España.

CO₂ generated (T)

Emissions calculated under GHG Protocol.

	2021
Scope 1*	266.45
Scope 2 ** (market based)	95.00
Scope 2 ** (location based)	365.93
Scope 3	No data

* Diesel consumption in our transport fleet has been calculated by multiplying fuel expenditure by 124.52 euro cents per litre, on the basis of the Fuel and Fuel Prices Report, 2020-2021 Comparison issued by the Ministry for Ecological Transition and Demographic Challenge. The diesel consumption of the transport fleet and Diesel C consumption by our boiler have been multiplied by the following emission factors to produce an emissions figure:

- Diesel: 2.46 kg CO₂/L. Source: Practical guide for calculating GHG emissions. April 2021 version from Oficina Catalana de Canvi Climàtic (OCCC) (Office for Climate Change of Catalonia).
- Diesel C: 2.87 kg CO₂/L. Source: Emission factors; carbon footprint register, offsetting and carbon dioxide absorption projects. April 2021 version from the Ministry for Ecological Transition and Demographic Challenge.

**Scope 2 emissions have been calculated using the emission factors for electricity generation for the electricity system of each country of operation. Because in Spain we purchase electricity with a Guaranteed Source (GdO), emissions calculated using the *Market Based* method are significantly lower emissions calculated using the *Location Based* method.

Waste

Hazardous / Non-hazardous	Waste	2021 T	2020 T
Hazardous	Rejected electrical and electronic equipment with hazardous components	1	0.7
	Batteries and accumulators	0.04	0.02
	Concentrated liquid waste from cleaning of equipment	50	71
	Non-halogenated organic solvents	11	3
	Chemically contaminated packaging	8	5
	Absorbents and filters for chemical contaminants	0.60	0.60
	Laboratory chemical waste	11	2
	Sanitary wastes	8	7
Non-hazardous	Scrap	0.10	0.01
	Plastic containers	40	2
	Cardboard and office paper	55	13
	General waste	27	17
TOTAL		211.74	121.33



Product

Quality management

BioSystems is committed to having in place the processes and resources to ensure the quality of its products and services and the satisfaction of all their users. It is also committed to complying with the worldwide requirements for each industry in which it is active and to identifying risks, opportunities and areas for improvement. Those commitments all BioSystems to determine quality objectives and to take the steps to achieve those objectives.

BioSystems commitments are stated in its Code of Conduct as part of the company's culture; we are fully aware of our duties to all stakeholders, society in general and the environment.

All of the company's processes are subject to quality and safety standards, particularly those directly involved in the design, development, manufacture, marketing and review of marketed product.

We have a Quality Policy, which sets out the mission, vision, culture and strategy of the company and states its principles concerning people development, customer and user satisfaction, compliance with quality requirements under a robust Quality Management System, research, development and innovation focused on the user and the identification of risks, opportunities and areas for improvement.

The BioSystems Spain Quality Management System covers all processes and operations of the company and includes the procedures required to ensure that all individuals are qualified to correctly perform their assigned duties. The System also contains procedures, policies, work guidance and other quality documents that facilitate the performance and understanding of work on a day-to-day basis and formalise the way the company works.

BioSystems regularly reviews its Quality Management System, both internally and externally, through different types of audits. Review includes processes, risks and opportunities and areas for improvement arising, key quality indicators and legal compliance status. The targets set by BioSystems on a regular basis are also monitored and assessed.

Quality control at BioSystems

Product quality is a key element of the company's good practice, embedded in organisational processes, and is a core value of the company's culture. Consequently, matters such as the adequate preparation and training of people, product design, and traceability of processes and products are actively monitored. Materials are also monitored at every stage of the supply chain to ensure the quality, safety and efficacy of our products.

That monitoring is part of the Quality System and is developed continuously with the support of key performance and quality indicators.



Basic Principles of the Quality Management System (QMS)

The principles on which the QMS is based are:

- Customer focus.
- Leadership capacity.
- Commitment of people.
- Process-centred approach.
- Improvement (ISO 9001) and maintenance of efficiency (ISO 13485). Improvement does not in any case lead to a lower degree of legal compliance.
- Evidence-based decision making.
- Stakeholder relationship management.

All this is shown in:

- The documentation and/or system used.
- Records of implementation.
- Audits that demonstrate the adequacy and effectiveness of the QMS.

QMS Scope

The QMS covers the design and development, manufacture, distribution, installation and after-sales service activities of BioSystems analytical solutions for:

- Human and veterinary clinical testing.
- Agri-food industrial testing.
- Bioprocess monitoring.



Relationships with suppliers

BioSystems uses suppliers evaluated or approved by the person responsible for the product or owner of the process, with support and follow-up from the Quality Control Department in order to confirm the technical, operational and management capabilities of suppliers, particularly suppliers who provide materials or services that may affect the quality of the company's products. Continuous evaluation of suppliers is an obligation of the departments involved in production and of the Purchasing and Quality Department.

The company has internal procedures that set out the criteria for the evaluation and selection of suppliers of raw materials, services and finished product from other manufacturers. Likewise, supplier re-evaluation procedures are also carried out to ensure the correct follow-up and compliance of suppliers. In the case of raw materials and services, supplier selection process is determined by how critical the relevant supply would be to production process and quality of raw materials.

For finished product from other manufacturers, how critical a supply would be is determined by legal requirements.

The selection and initial approval of suppliers is part of the product design and development process. For finished product, supplier approval is affected by legal requirements concerning the placing of products on the market and market requirements, as assessed by the Customer and/or Business Area.

The selection and evaluation of providers is principally based on the quality of the service requirements, the quality of the product received and the supplier's Quality Management System (ISO 9001, ISO 13485 or standard questionnaire sent by BioSystems for evaluation of the supplier's QMS). Social and environmental matters are not taken into account in the evaluation of suppliers at this time.



Continuous evaluation criteria

BioSystems Spain has annual supplier evaluation procedures that assess a number of matters. Supplier evaluation is focused on suppliers of raw materials and services that are ingredients of or affect BioSystems products and suppliers of finished product from other manufacturers ready for market use. The criteria for supplier evaluation are as follows:

- **Quality of raw materials or services:** used to evaluate the raw material or service. Quality is checked on inspection at reception by Quality Control.
- **Service:** an assessment of the supplier in terms of delays, errors, packaging integrity or defects not related to product quality in deliveries. Applies to all suppliers.
- **Quality System:** an assessment of the supplier's quality system. Suppliers are approved when they score above 70% for each of the criteria evaluated. A score of less than 70% for any criterion leads to disqualification of the supplier.
- **RoHS:** An assessment of the compliance by a supplier/product for any electrical or electronic equipment (EEE), equipment, sub-assembly, cable, component or *spare part* that contains or may contain substances restricted under the law relating to RoHS.

Account is also taken of any incidents involving the supplier or their product that are significant and require consideration. In that case, any incident is reviewed with all parties involved in the process/product affected by the incident.

These criteria apply to raw materials for the manufacture of *in vitro* diagnostic (IVD) medical devices and to non-IVD products (Food & Drink or Veterinary). Different legal requirements apply to the marketing and sale of finished product from other manufacturers, depending on whether a product is an IVD product.

BioSystems has management and monitoring tools for these assessments:

Type of supplier	Favourable assessment	Unfavourable assessment
Conditioning material	17	-
Raw material	161	1
Finished product	3	-
Product for distribution	36	-
Semi-finished product	3	-
GENERAL TOTAL	220	1



Customer relations

BioSystems products and services are subject to a very strict legal regime in order to foster, assure and ensure the transparency, safety and quality of all its products, principally in healthcare and clinical medicine. As stated in the BioSystems Quality Policy and Code of Conduct, our mission is to contribute to the improvement of health and wellbeing. As such, the company is strongly committed to compliance with all standards and laws that govern the safety of the staff with whom it interacts.

Operation and safety

Under BioSystems Quality Policy and Quality Management System, all appropriate monitoring is carried out to ensure that the quality of the products marketed and distributed meets internal and external specifications, whether market-driven, operational or regulatory. That monitoring is carried out on products and processes.

The information is recorded as required by any relevant standard, as evidence of good practice, transparency and traceability of all activities affecting or affected by internal (design, operational, quality) and external (continuous contact with the customer) processes.



Customer feedback

Suggestions, queries and complaints from laboratories, hospitals, health-care professionals and other users, are received through a BioSystems digital platform for requests, queries, suggestions or incident reports. All Biosystems Group customers have access to the platform for response to cases, queries or incidents). They can also be reported or notified through the BioSystems website.

Once a request has been logged, the Customer, Design, Production and Quality Departments work together to respond as quickly and efficiently as possible.

That process gives us a good overview of the strengths and weaknesses of our products and services through market monitoring indicators for each product or service. To complete the picture, a customer satisfaction survey issued under BioSystems internal procedures.

Product claims/batches issued (%)	2021	2020
Reagents (2.8 million reagents/year)	1.2	1.5
Analysers (approx. 100,000 analysers/year)	1.1	1.2
GENERAL TOTAL	1.2	1.4



Product recall

BioSystems has product recall procedures. Those procedures are part of the Quality Management System and are internally and externally auditable to confirm their effectiveness and legal compliance.

Our complaint and product recall systems include procedures for notifying Health Authorities and healthcare professionals about the potential risks of a recalled product if there health monitoring issues. The company has a customer support centre to notify any incident in the market that may compromise safety in use.

In such cases, all group companies, distributors and customers collaborate to identify a non-compliant product released to the market, remove it and replace it as efficiently as possible, with the aim of reducing the risk of shortages of product in laboratories.

There were no product recalls in 2021.

BioSystems has a Medical Device Technical Manager under its license to operate and a Person Responsible for Regulatory Compliance (PRRC), as required by Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices, to establish and maintain procedures to identify and monitor adverse events that could affect the safety of patients and users of IVD medical devices. That is directly related to the withdrawal of product from the market.

Health surveillance system

BioSystems has not had any health surveillance cases for more than five years.



Documentation issued with products

Labelling and Instructions for Use

The information that BioSystems includes in its Instructions for Use (IFU) and labels for IVD medical devices is regulated by the European Union relation to In Vitro Diagnostic Medical Devices. For the balance of non-IVD products, some harmonised symbols under IVD Standards are used, such as lot number, expiry symbol and commercial reference.

Hazard or warning signs with their warnings or notices are also shown on the IFU and labelling for the protection of the user in the handling of products, under REACH and CLP Regulations and the standards for accompanying Product Information, ISO 15223 and ISO 18113. Any limitations or contraindications are also indicated in the Instructions for Use, together with any risk mitigating actions, as indicated in ISO 14971 on the risk management of medical devices.

Promotional material

All promotional, information or communication materials developed by BioSystems in relation to a product, the company or its processes, are reviewed by the parties involved, with final approval by the Quality Control Department. The information included a product's promotional material must in all circumstances match its Instructions for Use, as required by applicable standards and laws in force. Those materials also comply with BioSystems internal policies and procedures, and industry codes. The information provided by the company is therefore always truthful, reliable, complete and balanced.

List of materials (catalogues, product brochures, etc.) approved in the last two years:

2021	2020
156	120



External Certifications and Licenses

BioSystems has the following certifications and licenses for the design, manufacture, marketing and after-sales follow-up of its 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: Provider of Inter-comparison programmes (Prevecal).
- Prior License for Operation of medical devices.
- License for the manufacture and importation of animal health products.



Quality audits

Internal and external audits are carried out at BioSystems Spain to verify that the Quality Management System functions as intended and is legally compliant:

- **Internal:** the annual audit programme determines the internal audits to be carried out, processes, requirements, etc. Two internal audits were conducted in 2021:
 - Quality audit under ISO 9001, 13485 and regulatory requirements, covering all BioSystems processes. Quality audit is carried out by a team of internal auditors who operate independently of those involved in each process. Findings are shared with those responsible for the processes involved and with management.
 - Internal audit of the Prevecal Management System, under ISO 17043. Such audit is carried out by a competent internal auditor who is independent of Prevecal activities who reports the outcome to the Prevecal coordinating group, those responsible for the audited processes and management.
- **External:** to maintain the certifications and accreditations, audits are carried out by the awarding bodies. Three external audits were carried out in 2021:
 - Audit of the Prevecal management system under ISO 17043 (for Prevecal programmes) by ENAC.
 - Audit of the quality management system under ISO 9001 by TUV Rheinland.
 - Audit of the quality management system under ISO 13485 (1st stage) by TUV Rheinland.

Historically, audits and inspections of BioSystems have had a favourable outcome, reflecting its commitment to the safety and quality of its products. In 2021, no incidents related to regulatory non-compliance, fines or official notifications have been identified in this regard.



Research and Development

Innovation is one of our strategic pillars. BioSystems is not concerned only about innovating in product development to keep up to date with scientific and technological advances, but also to innovate in new processes and introduce process to enhance effectiveness, efficiency and competitiveness by generating ideas that can provide services or products and bring us closer to our customers by offering them a user experience that ensures that they will want to work with us again, and so achieve the intended outcome.

We seek to stay ahead of the market by offering solutions that adapt to our customers' needs and demands. We seek to improve the efficiency of all our operations and internal processes. We focus on ensuring that we have the best possible staff to achieve our aims under the seal of the BioSystems brand around the world.

We can therefore assure you that R&Di is just one more part of our value chain, which includes other relevant activities such as operations, business development, customer care and other support activities. Our R&Di strategy is based on a comprehensive approach using through multiple processes and projects. Each team, in their work area, has the freedom and the duty to innovate in the processes in which they participate towards a common goal: to improve user experience.



More sustainable products

BioSystems Spain is part of various projects aimed at positive change in our environmental impact – making and marketing products that are more sustainable and less harmful to the environment. The following projects started in 2021:

- **Design of a web portal for product documentation:**
In the course of 2021, work was carried out to implement a web portal to host product documentation. The portal is intended to host product-related documentation to enable users to view the documentation remotely and where allowed by law and user capability, dispense with paper copies. The digitisation of these documents reduces the consumption of paper, ink and waste and facilitates access to information by users who have adequate Internet access.
- **Substitution of expanded polystyrene with paper in product packaging:**
Expanded polystyrene is a foamed plastic material with good sterility and temperature maintenance qualities. Expanded polystyrene can be very useful for the thermal insulation of buildings and improve their energy efficiency. Despite that, expanded polystyrene has a high environmental impact because it takes more than 500 years to break down and in many cases it is not possible to recycle or reuse due to contamination with other materials.

Consequently, BioSystems will replace the expanded polystyrene used as a filler in our packaging to protect our products during transport with paper as of July 2020, except for products that have very strict temperature maintenance requirements.



Patents and trademarks

BioSystems protects the intellectual property rights in all its products around the world and the value of its brand, which identifies us in the market as a global, innovative, proactive business whose essence is people.

