BioManufacturing Eurocluster for Recovery and Resilience in EU

D2.1 Resilience needs analysis of the Biomanufacturing and Medtech sectors

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Deliverable description	The Resilience needs analysis is a document that includes a critical examination of the results of the Biomanufacturing landscape of the ecosystems that form this consortium, as well as the up-to-date green processes and technologies in the market, a mapping of critical inputs and technologies to foster the introduction of new-to-firm products and services, the identification of SMEs specific difficulties in terms of talent in BMT (Biomanufacturing and MedTech). Data proceed of market research, broads surveys in all of the consortium's regions and conclusions of working groups with KOLs from the biomanufacturing and MedTech fields in the partner regions.
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III. Disclaimer

IV. Executive Summary

The present Deliverable 2.1 “Resilience needs analysis of the Biomanufacturing and MedTech sectors” has been developed within the framework of **WP2 Eurocluster & Ecosystem Building**.

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1. Critical analysis of the results of the Biomanufacturing landscape

1.1. Key aspects, challenges and objectives

The background of the BioMan4R2 (BioManufacturing Eurocluster for Recovery and Resilience in EU) project is aligned with the Annual Single Market (ASM) Report 2021, updated in 2022[1], which highlights the importance of the health sector for the EU citizens and consumers, and points out the current challenges in the Health Single market: lack of skills, lack of reliable intelligence on supply chains, raw material dependencies, technological, political and governance challenge in the health tech field. Along the same lines, BioMan4R2 sees the need to adapt the existing funding in Health Sector for the scaling up of innovation, make biomanufacturing more environmentally sustainable, exploring the new sources of biomedicines production and supporting production capabilities of new vaccines, increase the healthcare capacity (human and financial) and improve the coordination between national and public authorities.

Furthermore, BioMan4R2 recognizes education and talent as a priority in biomanufacturing and MedTech sectors. To assess it, we have launched a survey in all the consortium's regions addressed to SMEs, to identify the main aspects that could be improved related to talent attraction and retention to propose a set of up/re-skilling services. The Panorama of Biomanufacturing Ecosystems in Europe (Biomanufacturing Landscape from here on) was an initiative of EIT Health, co-conducted with EIT Manufacturing and coordinated by the CEBR – Council of European BioRegions, with the support of Biocat, with the objective of exploring the conditions conducive to the emergence, development and industrialisation of disruptive biomanufacturing technologies for advanced therapies or medical technologies in Europe. Launched in October 2021, the report analyses needs and opportunities within the framework of education as well, concluding that the development of a biomanufacturing capacity in Europe

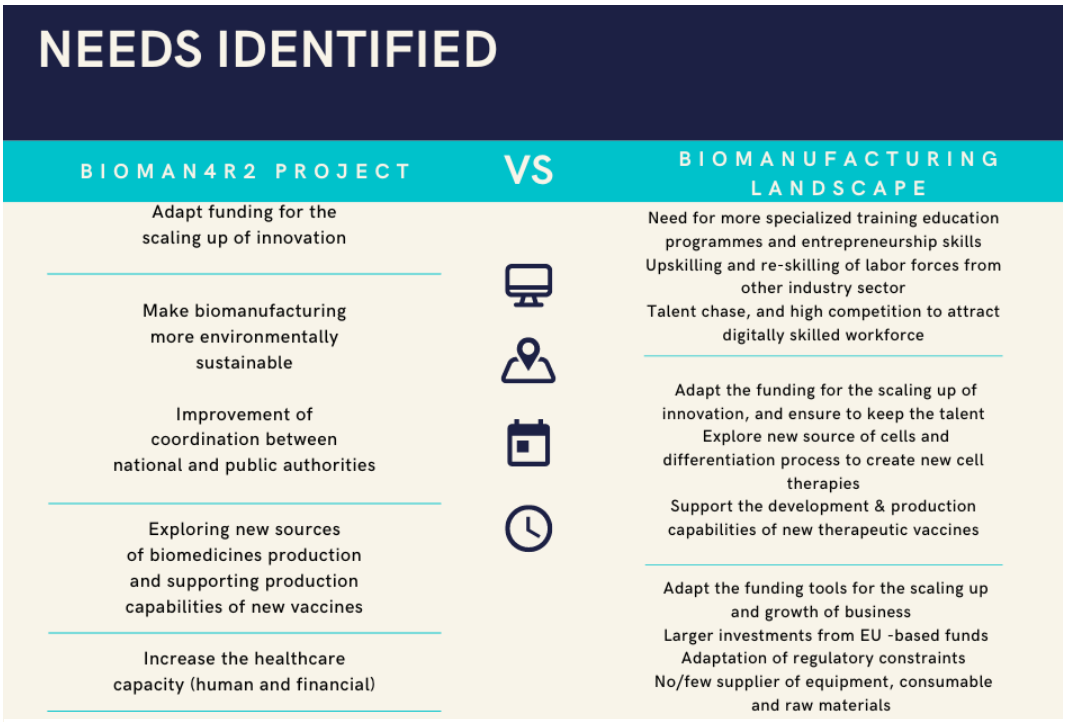

Figure 1: Comparative graph of the needs of the biomanufacturing and medtech sectors identified by the BioMan4R2 project and the Biomanufacturing Landscape Report.

[1] https://single-market-economy.ec.europa.eu/system/files/2023-01/ASMR%202023.pdf

will necessarily require the training of a new type of professionals both seasoned in the challenges of bioproduction 4.0 but also experts in regulatory issues and specific topics.

The main objectives of the Biomanufacturing Landscape analysis conducted by CEBR are:[2]

1. To **validate the relevant barriers** (scientific, technologic, education & skills, environmental, production costs and processes) and enablers for the successful adoption of bioproduction and manufacturing value chain at the European level.
2. **Identify opportunities** in Europe for disruptive technologies which could improve productivity of next generation bio-products, and medical technologies thus improving cost and affordable access to patients.
3. **Outline the potential synergies with European initiatives** to accelerate and expedite integration of innovative technologies and therefore making EU more attractive and resilient for a production in the EU Member States.
4. **Outline the potential opportunities** for harnessing the capital risk co-investments in promising European SMEs on the sector, including CDMOs, therefore making EU Venture Capital Market more attractive, using as an eg. the Venture Centre of Excellence programme to support such a pathway.

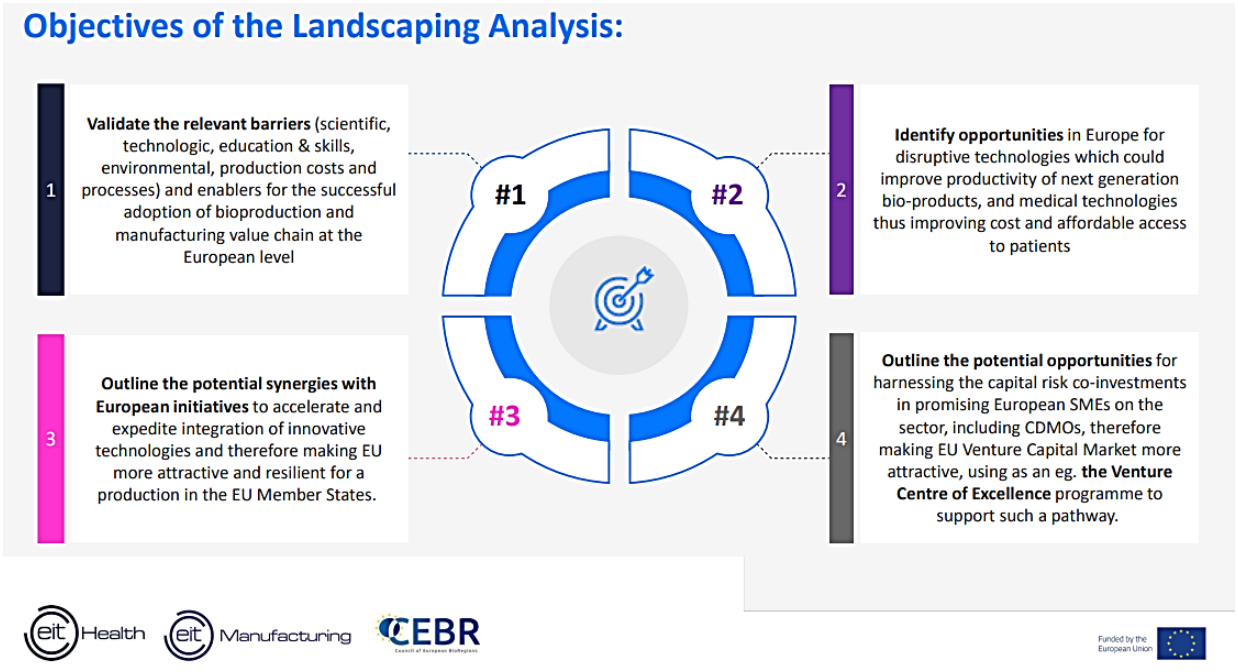

Figure 2: Objectives of the Biomanufacturing Landscape Report conducted by CEBR and EIT Health.

The BioMan4R2 project builds upon the analysis of the current challenges in BMT, taking a more proactive approach by executing activities aimed at directly impacting the ecosystem. The direct objectives of the project are:

NETWORK – to build new collaboration models between European biomanufacturing cluster organisations and other key actors in the field of pharmaceutical / biomedicines manufacturing and MedTech, facilitating value chain interlinkages in the health sector.

[2] https://eithealth.eu/wp-content/uploads/2021/10/Executive-summary-07102021.pdf

GO INTERNATIONAL – to establish services that support partnering opportunities, international trade and investment for European BMT SMEs by facilitating the signature of cooperation agreements between European entities and entities in third countries.

ADOPT – to facilitate implementation and adoption of innovations to the business processes by the BMT SMEs that contribute to SMEs successful green and digital transformation.

TRAIN – a) to improve the skills of the consortium clusters` management to provide more effective up/re-skilling services and attract more talent to BMT; b) to establish services for BMT SMEs to up/reskill their workforce and manage talent.

INNOVATE - to improve and transform the products of BMT in a way that will reduce their dependency on the existing value chains, as well as introduce new innovative products.

1.2. Homogeneity of the information among geographical areas

The Biomanufacturing landscape Report focuses on the conditions conducive to the emergence, development and industrialization of biomanufacturing breakthrough technologies - the production of advanced therapies and the key challenges to be addressed in this area. The wave 1[3] of the study was developed in the following areas: Belgium, France, Germany, the Netherlands, Scandinavia (Finland, Denmark and Sweden) and Spain. [4]

Figure 3: Geographical scope of the first wave of the Landscape Analysis on Biomanufacturing.

[3] A new wave is under construcition adding more countries to the landscape

[4] https://eithealth.eu/wp-content/uploads/2021/10/Executive-summary-07102021.pdf

Several local bodies were consulted in each geographic area of the study:

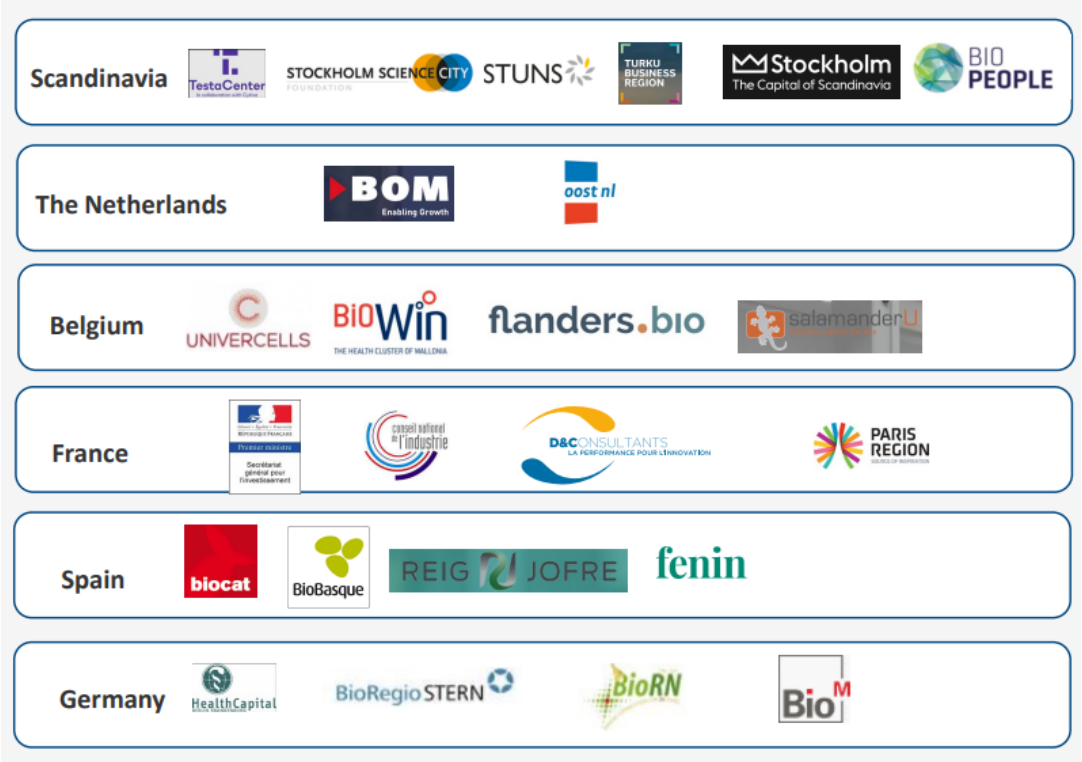

Figure 4: Consulted bodies of the Biomanufacturing landscape.

The consultation process for the report varied among regions, with the number of bodies consulted ranging from 4 to 6. Notably, the Netherlands had a lower representation, with only two organizations providing feedback and it is reflected on the information of this region. Furthermore, the diversity of consulted bodies was not consistent across regions. For instance, while the Netherlands and Germany solely relied on the perspective of life science clusters, which were consulted in all geographic areas, the Scandinavia region included input from testbeds like Testa Center. Meanwhile, Belgium consulted service providers such as SalamanderU and Univercells, France incorporated both government entities and consultants, and Spain added a pharmaceutical industry perspective through the pharma company Reig Jofre.

The Biomanufacturing landscape is a comprehensive source of information that goes beyond just presenting data on the number of companies or clinical trials in various countries. It provides valuable insights into the industry's pain points, success stories, and opportunities.

In addition, the report delved into the key areas that are essential for shaping the future of the biomanufacturing industry. It includes a dedicated section for each region that outlines the challenges and proposes next steps to tackle them. This information is designed to guide decision making and support the efforts to restore EU sovereignty in the bioproduction and medical technology value chain.

1.3. Conclusion

Biomedicines, which include both biotech drugs and small molecules, are poised to play a significant role in the future of the pharmaceutical industry. Currently, they make up at least 20% of the global pharmaceutical market, worth $1,000 billion, and this share is expected to increase to over 50% in the coming years. Today, 40% of all drugs on the market are biotechnology-based, including advanced treatments such as monoclonal antibodies, gene

therapy, cell therapy biologics, and immunotherapy. These drugs are highly complex, relying on cellular and molecular biology, and offer significant value in terms of their mechanisms of action.

A key challenge facing biomedicines is to decrease production costs through advancements in manufacturing processes, while also bringing innovative medical technologies to the market to enhance European competitiveness and sustainability.

The aim of the Biomanufacturing landscape assessment was to uncover the strengths of notable innovation ecosystems in European regions and to identify the drivers of sector growth. The objective was to highlight opportunities for strengthening and connecting these ecosystems to increase Europe's competitiveness. The main conclusions of the report are listed below divided into three pillars: Education, innovation and business.

1.3.1. Education

The growth of biomanufacturing in Europe will need the education and training of new professionals who are well-versed in both the challenges of bioproduction 4.0 and the regulatory requirements and production standards specific to biologics. However, the report indicates that the number of professionals trained in these areas is insufficient to meet the current needs of the sector, and these needs are expected to grow in the future.

To address this challenge, several regions in Europe have established academic programs. It is crucial to emphasize the need for a coordinated effort to bolster European capacities by promoting collaboration and connecting existing educational programs at the national and regional level. This can be achieved through funding programs and by connecting the cluster community, EIT Health, and EIT Manufacturing.

Moreover, the creation of a pan-European alliance for education and innovation, such as an Erasmus+ program, dedicated to bioproduction issues would be highly desirable to coordinate a comprehensive European education and training offering. EIT Health, EIT Manufacturing, and CEBR propose to take on this role by developing and financing programs between European institutions and initiatives, such as the Campus Biotech Digital and the recently established European School of Bioproduction in Belgium.

1.3.2. Innovation

One of the significant challenges facing bioproduction activities in Europe, in addition to market opportunities, is to reduce production costs and enhance process yields while also promoting sustainability. A substantial investment is necessary to overcome these challenges, as many innovative solutions require scaling up and are driven by startups or CDMOs that are struggling to secure funding in Europe.

This is why France and several other member states have proposed the establishment of a Program of Common European Important Interest (PIIEC) to provide substantial budgets to finance large-scale health-related infrastructure projects, particularly production capacities and medical technologies. The PIIEC will also finance the industrialization of innovative bioproduction processes, but only manufacturers and SMEs will be eligible. Academics and clinical research centers wishing to join forces will need to find additional funding to participate. Moreover, it may be challenging for consortium leaders, particularly SMEs, to coordinate such European projects.

Biomanufacturing landscape’s recommendation is to leverage the CEBR, EIT Health and EIT Manufacturing networks as a platform for establishing and monitoring PIIEC projects.

Additionally, KICs could allocate part of their innovation budgets to finance academic and clinical players. It is also crucial to explore further complementarities with other funds such as FEDER (for regional and cross-border initiatives) or Horizon Europe, Next Generation, HERA, and others.

1.3.3. Business

The report highlights the presence of numerous startups and SMEs in the field of bioproduction and medical technologies, but also reveals that most of the large investments in recent years have come from non-European players, particularly in the CDMO sector. To address this, the report suggests offering startups and/or CDMOs financing through the Programme of Common European Important Interest (PIIEC) with privileged access to the European Investment Fund's (EIF), co-investment program in partnership with EIT Health and the Venture Centre of Excellence.

The co-investment program, launched in October 2020, brings together investment and industrial funds in the healthcare sector, with financial support from the European Commission, EIF, and EIT Health. At present, it has a total capacity of co-investments of 1.7 billion euros, which is expected to grow in the coming months through the involvement of additional manufacturers and venture capital funds across all member states.

This program enables European startups or SMEs in the healthcare sector to secure significant funding for their growth and expansion through venture capital companies based in Europe. Additionally, they will have access to acceleration programs offered by EIT Health or EIT Manufacturing, to support their internationalization efforts.

Finally, the report emphasized the critical role of clusters in promoting joint initiatives to strengthen the sector and address value chain disruptions at the EU level. It highlights the key role of cluster organizations in these innovation ecosystems to drive business growth and scale up the industry.[5]

2. Mapping and awareness raising activities about the latest green processes and technologies in the market

2.1. Green Industry

This decade will be crucial for the world to combat the increase in global temperatures and to move towards net-zero emissions. The challenges are significant and the pressure is intense, but this provides a unique opportunity to drive investment in the clean energy sector and the net-zero era.

The European Green Deal solidifies the EU's commitment to a green transition and outlines its goal of reaching net-zero emissions by 2050. The Fit for 55 package[6] provides a specific plan to steer the European economy towards sustainability, with the REPowerEU Plan hastening the shift away from fossil fuels. Together with the Circular Economy Action Plan, these efforts form the basis for the transformation of the EU's industries to be in line with the net-zero era.

The EU is well-equipped to take advantage of the net-zero challenge. Its Single Market-based economic model has driven increased prosperity over recent years. Europe is a leader in innovation, investment in green technologies and the production of sustainable products. It has

[5] https://eithealth.eu/wp-content/uploads/2021/10/Executive-summary-07102021.pdf
[6] https://www.consilium.europa.eu/en/policies/green-deal/fit-for-55-the-eu-plan-for-a-green-transition/

a solid starting point, a highly innovative and trend-setting industry, with growing levels of digitalisation and the capability to produce high-quality products used globally. It has world-renowned scientists and researchers who continuously work on advancing cutting-edge solutions and improving existing technologies.

The EU has demonstrated that the transition to a green economy can enhance competitiveness. The phasing out of Russian fossil fuels has spurred a new industrial revolution aimed at ending the use of fossil fuels. A broad array of net-zero technologies is being developed and adopted across various sectors including transportation, buildings, manufacturing, energy, and even generating new markets. In 2021, the EU's net-zero ecosystem was valued at over 100 billion euros, doubling in value from 2020.[7]

The **Sustainability Green Industry (SGI)**[8] is an initiative aimed at promoting sustainable development in the manufacturing industry. The SGI 4.0 framework integrated Industry 4.0, sustainable manufacturing, and green processes. It is structured into three vertical levels: technological, process, and development, which are connected through the circular economy. The framework also includes a horizontal axis, comprised of three main processes - design, manufacturing, supply chain, and logistics - that are integrated throughout the product's life cycle and the value chain. The development level of the SGI 4.0 framework is focused on sub-goals of sustainability, including organizational and technical sustainability, sustainable manufacturing, and sustainable supply chain and logistics. These sub-goals are intended to

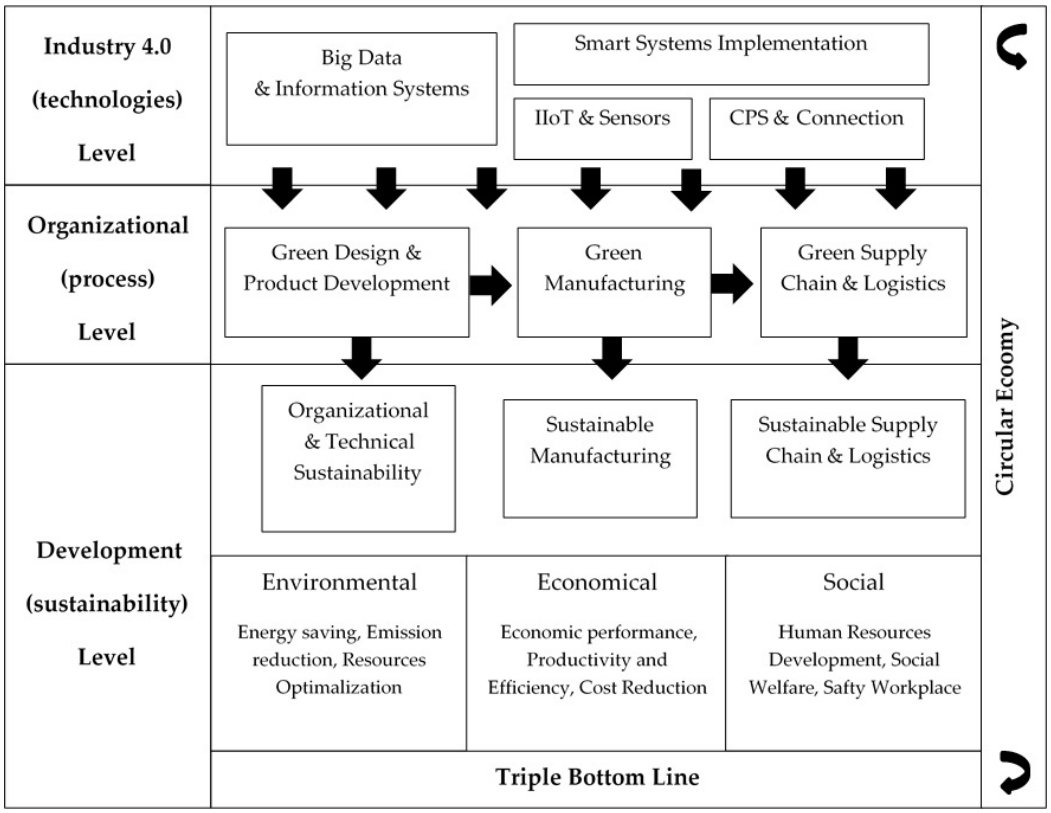

Figure 5: Sustainability Green Industry 4.0 (SGI 4.0) conceptual framework. Source: Vrchota, Jaroslav & Pech, Martin & Rolínek, Ladislav & Bednář, Jiří. (2020). 10.3390/su12155968.

[7] A Green Deal Industrial Plan for the Net-Zero Age, European Commission

[8] https://sgieurope.org/news/the-eu-green-deal-must-drive-the-eu-industrial-strategy-says-sgi-europe/?from=home&anchor=latest

achieve the three main outcomes of sustainability - environmental, economic, and social - through the concept of the triple bottom line.[9]

2.2. Green technologies and processes

Green processes and technologies aim to reduce the environmental impact of industrial processes and products, by using renewable resources, reducing waste, and minimizing emissions. They play a critical role in promoting sustainability by improving resource efficiency and reducing the carbon footprint of industries, thus contributing to the transition towards a low-carbon and circular economy.

Green Manufacturing refers to the production of the goods in an environmentally friendly manner. This involves reducing waste and pollution during the manufacturing process, conserving resources, and using renewable energy sources and "clean technologies".[10]

Here is a list of the latest green technologies:

Renewable energy sources

The industry is currently in the transition to renewable energy sources such as solar, wind and hydro power. A crucial aspect of green technology is the ability to store renewable energy on a large scale for extended periods of time at an affordable cost. Scientists and engineers are developing solutions to store the excess of energy generated from renewable sources for future use. Here are some of the most promising methods for storing renewable energy[11]:

- **Batteries:** Lithium-ion batteries are the most widely used storage solution. in which the anode and cathode store lithium. They work by storing lithium ions in an anode and cathode, while an electrolyte carries the ions between the anode and cathode to power devices and recharge the battery using renewable energy. However, there are some drawbacks to this technology, including energy loss over time, high production costs, negative environmental impacts from extracting raw materials, and the fact that not all energy is retained during the charging process.
- **Pumped hydro energy storage** is a form of energy storage that involves using excess energy to pump water from a lower reservoir to an upper reservoir. When energy is needed, the water is released back to the lower reservoir and the falling water drives a turbine, generating electricity. This type of energy storage is one of the most mature and established technologies, with a long history of use and a large installed base globally. PHES has high energy density and long life cycles, making it well-suited for large-scale energy storage. The main disadvantage of PHES is the need for large reservoirs and a source of water, which can be challenging in some locations.
- **Pumped thermal elecctricity storage** is a form of thermal energy storage that utilizes the differences in temperature between hot and cold storage media to store and release energy. In PTES systems, excess electricity is used to heat a storage medium, such as molten salts, to a high temperature. When energy is needed, the hot storage medium is used to generate steam, which drives a turbine to produce electricity. The cooled storage medium is then pumped back to the heat source to be reheated and the cycle

[9] https://encyclopedia.pub/entry/1556
[10] *Cai et al.*, 2021 https://www.mdpi.com/books/book/4382
[11] https://www.livescience.com/renewable-energy-storage

repeats. PTES has a relatively high energy density and long cycle life, making it a promising technology for large-scale energy storage. However, the high operating temperatures and the need for specialized heat exchangers and pumps can make PTES systems more complex and expensive than some other energy storage technologies.

- **Gravity energy storage** uses gravitational potential energy to store and release energy. In a gravity energy storage system, energy is stored by lifting a heavy object, such as a weight or water, to a high elevation. When energy is needed, the object is allowed to fall back to its original position, generating electricity through a turbine or generator. Gravity energy storage systems have the advantage of being relatively simple and low-maintenance, with no need for batteries or other complex components. However, they also have limited energy density compared to other forms of energy storage and require a large amount of space for the storage of the heavy object. Additionally, the initial cost of lifting the object to the high elevation can be substantial, making gravity energy storage a less practical solution for many applications.
- **Compressed air energy storage** During periods of excess electricity on the grid due to low demand, a compressed air energy storage plant can compress air and store it underground in a cavern. When demand is high, the stored air is released to recover the energy.
- **Hydrogen storage** Hydrogen serves as a chemical energy storage method. Electricity is transformed into hydrogen through electrolysis, which splits water into hydrogen and oxygen. The stored hydrogen can be stored and then used as fuel for generating electricity, or it can power hydrogen vehicles to lower greenhouse gas emissions from transportation.

Bioremediation

Industrial water is utilized in various processes, such as manufacturing, processing, washing, dilution, cooling, or transporting a product. In the pharmaceutical industries, water acts either as a direct medium or solvent, as an indirect cleaning tool for equipment or as an essential raw material used to produce dosages. Bioremediation is a cost-effective and economically viable method for cleaning contaminated sites through natural biological (microbe) activity. Bacteria, fungi, or plants with the ability to degrade, detoxify, or neutralize toxins, can be utilized. In some cases, microorganisms may already be present on the site or introduced to the trated material, using bioreactors as an example. Bioremediation techniques, with their versatility and potential, can provide a sustainable solution for wastewater management in the pharmaceutical industry, reducing its ecotoxicological impact.[12]

Biosequestration

Biosequestration, which involves removing CO_2 from the atmosphere and storing it in the carbon pools of specific habitats, such as above ground biomass, roots and soil, is a promising field. Algae have a CO_2 fixation efficiency estimated to be 10 to 50 times higher than that of terrestrial plants and are being examined as a potential source of renewable energy.[13]

[12] A comprehensive study of bioremediation for pharmaceutical wastewater treatment, 2022.
[13] The Bio Revolution: Innovations transforming economies, societies, and our lives. McKinsey Global Institute. May 13, 2020

Carbon capture and storage

Carbon Capture and Storage (CCS) is a technique to decrease carbon emissions which could play a crucial role in addressing global warming. The process consists of three steps: capturing the CO2 generated during power generation or industrial processes by separating it from other gases, transporting it, and finally storing it deep underground in geological formations.[14]

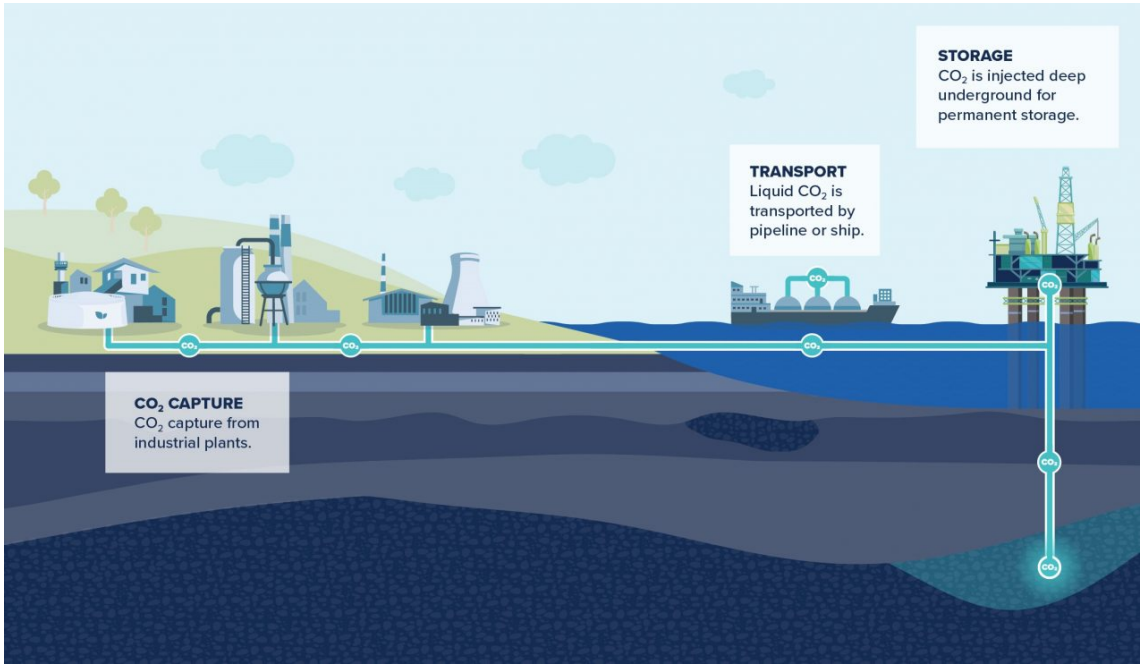

Figure 6: Process of Carbon capture and storage. Source: Global CCS Institute.

Carbon tracking software

Carbon tracking is a method for measuring and monitoring carbon emissions from both direct and indirect sources. It enables businesses to quantify the greenhouse gas emissions produced from all their business operations and provides a clear understanding of their carbon footprint and the most effective opportunities for reducing it.[15]

Clean Chimneys

Manufacturing companies produce significant amounts of emissions. Some manufacturers are addressing this issue through cleaner production methods, but they may also capture and clean their exhaust as it is emitted. For instance, a high-tech chimney in China functions as an air purifier instead of a contributor to pollution. The chimney is engineered to remove particles with a mass of less than 2.5 micrometers, known as PM2.5, which are dangerous to human health and increase the risk of cardiovascular mortality. This technology can be implemented instead of traditional exhaust systems or placed in high-pollution areas to clean exhaust from multiple sources.[16]

[14] https://www.nationalgrid.com/stories/energy-explained/what-is-ccs-how-does-it-work
[15] https://greenly.earth/en-gb/blog/company-guide/why-carbon-tracking-is-essential-to-stay-accountable
[16] https://www.digitaltrends.com/cool-tech/china-pollution-sucking-chimney/

Energy self-sufficient buildings

Energy self-sufficiency refers to the proportion of energy that is generated and consumed over a given period of time. An energy self-sufficiency ratio equal to one indicates that the amount of energy generated during that time period is equal to the amount of energy consumed.

To maximize the energy self-sufficient building ratio, the following two main objectives must be achieved:

1. To maximize the energy self-sufficient building ratio, the first step is to minimize the energy demand within the building. This can be achieved by:

- ✓ Using highly efficient electrical appliances, which can reduce energy use by around 20-30% compared to less efficient ones.
- ✓ Installing motion and occupancy sensors, which can detect when residents are present in the building and adjust the use of lighting, heating, and cooling accordingly, resulting in energy savings of up to 20-40%.
- ✓ Implementing smart building/home energy management systems and optimization algorithms, which can control and schedule the power consumption of appliances and equipment, reducing energy waste and increasing the overall efficiency of the building.

2. To maximize energy production from renewable sources, the following steps should be taken:

- ✓ Installing solar panels, wind turbines, or other renewable energy technologies on rooftops, facades, or windows. This can help to generate clean energy on-site, reduce reliance on the grid, and lower energy bills.
- ✓ Implementing energy storage systems to store excess energy generated by renewable sources for later use. This can help to balance energy supply and demand and provide backup power during outages.
- ✓ Using highly efficient renewable energy technologies that can maximize energy production from a given surface area, such as concentrated solar power systems or small wind turbines.
- ✓ Employing optimization algorithms to determine the most effective renewable energy technology and system configuration for a particular building or location. This can help to minimize costs, reduce payback periods, and maximize energy production.

By adopting these strategies, buildings can increase their energy self-sufficiency and reduce their environmental impact by relying on clean and renewable energy sources.[17]

Fiber Solar Lighting

Fiber solar lighting systems can transport sunlight to parts of a building that are away from windows. Some European companies have been working on improving this technology. It basically eliminates the need for electric lights during the day and is especially useful for high-rise office buildings. Not only is it green, but it's also healthier for workers to bring sunlight into all corners of an office.[18]

[17] https://smartgrid.ieee.org/bulletins/april-2020/steps-toward-smart-energy-self-sufficient-buildings
[18] https://www.forbes.com/sites/forbestechcouncil/2022/02/17/12-industry-experts-share-potentially-powerful-green-technologies-and-initiatives/?sh=1d4a2a2f6ab9

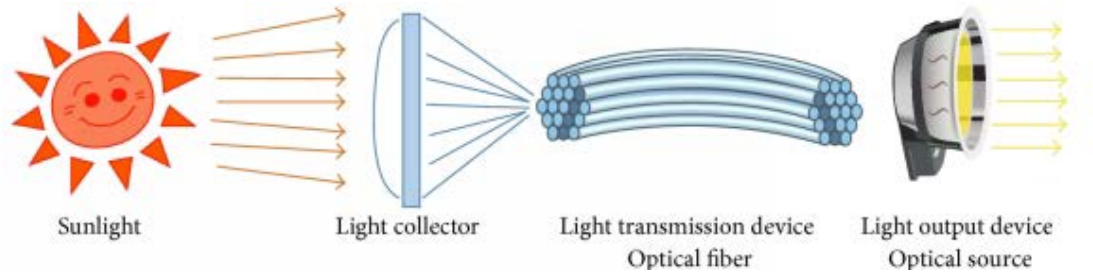

Figure 7: Schematic diagram of the solar optical lighting system. Source: Qin et al., 2015

Continuous pharmaceutical manufacturing

Continuous pharmaceutical manufacturing sees a drug taken from its base ingredients to the final product with no need to stop during production. This means there is no need to shut down equipment and no down time as the product is created. Continuous pharmaceutical manufacturing is more time-efficient, reduces energy needs, helps to increase productivity and reduces the amount of overall waste. The risk of human error is also reduced because continuous processing means fewer people are involved in the production process from start to finish. Many have inquired about issues that may arise in the case of a recall using the continuous manufacturing method, but worries can be quickly put aside by using lot numbers.[19]

Big data and information systems

In the context of using information systems for big data analytics, this component of the framework facilitates the efficient processing of vast amounts of data that are stored both on local servers and on the Internet in the Cloud, using cutting-edge real-time information systems. These information systems and data serve as the foundation of intelligent factories, which are integrated with ERP systems and visualized using sophisticated business intelligence technologies. This enables users to conveniently access the data through a web browser and a software client, allowing them to analyze and derive insights from the data virtually from anywhere.

Big data analysis can offer valuable insights into our impact on the environment. By identifying patterns in the data, we can better understand how our behavior affects the planet. These patterns can reveal opportunities to encourage more sustainable practices or highlight areas where our actions are causing harm, such as leaking toxins, expending excessive energy, or wasting water.

This is in line with the United Nations' Sustainable Development Goals, which recognize the potential of big data to contribute to progress towards sustainability. By leveraging the power of big data, individuals and organizations can take significant steps towards achieving a more sustainable future for all.[20]

Closed-loop manufacturing systems

Closed-loop manufacturing is a process where companies plan their production cycles to continuously gather data on their products' performance back into the production cycle. To achieve this, they set Key Performance Indicators (KPIs) from the outset and put in place robust

[19] https://www.generalkinematics.com/blog/batch-vs-continuous-pharmaceutical-manufacturing/
[20] https://www2.deloitte.com/nl/nl/blog/sustainability/2022/big-data-big-environmental-impact.html

systems to monitor and collect readings. As products go through the stages of implementation, production, and release, measurements are taken, adjustments made, and KPIs reset, starting the loop over again.

This process is closely linked to the Industrial Internet of Things (IIoT), as the data used to inform the next cycle of R&D and manufacturing comes directly from the product itself, in addition to connected devices, sensors, applications, and controllers. By utilizing IIoT and closed-loop manufacturing, companies can gain valuable insights into how their products are performing in the real world. This enables companies to be more efficient, effective, and responsive to customer needs while reducing waste and minimizing their impact on the environment.[21]

Industrial Internet of Things (IIoT) and sensors

Industrial Internet of Things (IIoT) refers to technologies such as sensors and switches that act as a source of information for a control system. The Technical devices convert the data measured (such as temperature, pressure, etc) into a signal that is transmitted and processed remotely. The ability of IIoT devices to communicate with each other through Cyber-Physical Systems (CPS) enables them to receive and transmit information seamlessly.

IIoT and sensors play a crucial role in promoting sustainability in manufacturing. They can monitor and control the usage of water and fuel in production processes, as well as the consumption of electricity. Sensors can detect when an area is unoccupied and automatically turn off the lighting in that area. These applications of IIoT and sensors help reduce waste, save energy, and promote more sustainable manufacturing practices. By leveraging IIoT and sensors, companies can improve their environmental performance, increase their operational efficiency, and reduce costs.

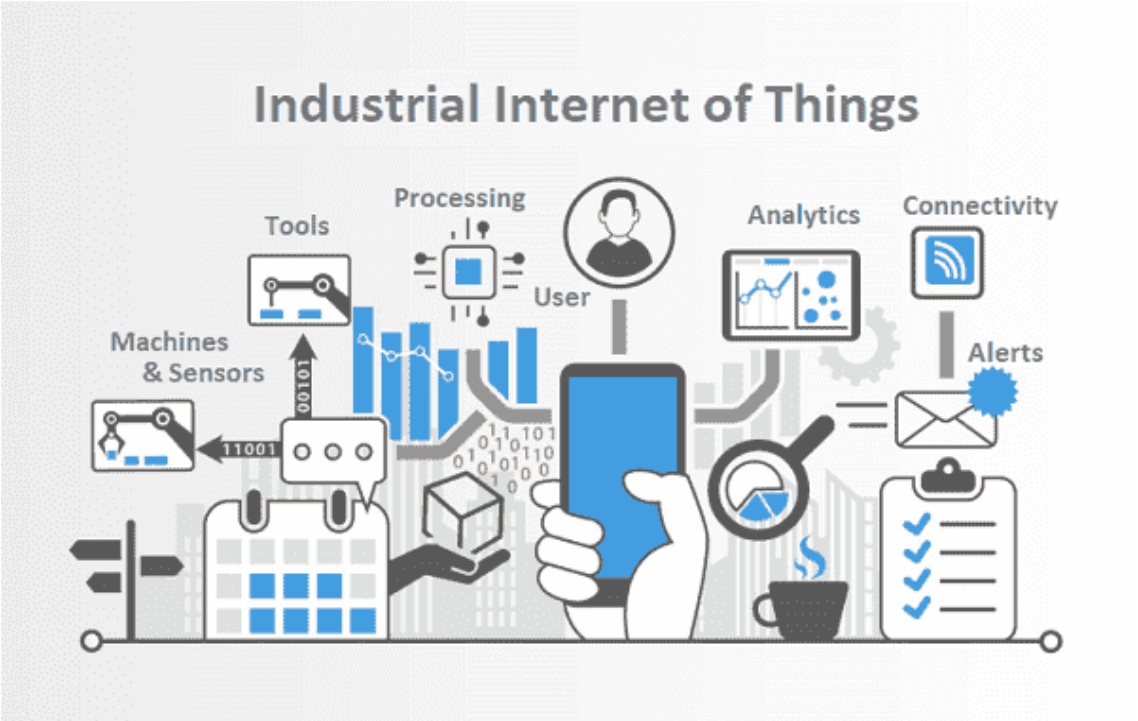

Figure 8: Industrial Internet of Things (IIoT). Source: connectingindustry.com

[21] https://www.ptc.com/en/blogs/iiot/top-5-benefits-of-closed-loop-manufacturing

CPS and Connection

in the field of development using CAD tools, augmented (AR) and virtual reality (VR) and in logistics in various CRM (customer relationship management) and SCM (supply chain managmeent) applications.

The foundation of the modern production units is the collaboration of independent control units, such as computers, that can make autonomous decisions, manage technological processes, and operate as full and independent members of complex production systems. This intelligent connection (Bluetooth, RFID, Z-Wave, Zigbee, WiFi, etc.) of various products and devices, provides new functions and capabilities that enhance productivity and connect the virtual world with people.

The ultimate goal of this integration is to bridge the gap between the physical and digital worlds in the production process through Digital Twin technologies. In development, CAD tools, augmented reality (AR), and virtual reality (VR) are utilized to optimize the design process, while in logistics, various customer relationship management (CRM) and supply chain management (SCM) applications are employed to streamline operations.

Cloud Computing

Traditional computing methods typically require significant physical infrastructure to operate, including a large number of computing devices and associated hardware. The manufacturing and shipping of these components can contribute to a significant amount of pollution, and the operation of these devices consumes a substantial amount of energy. In contrast, cloud computing offers a more sustainable alternative by reducing the amount of physical hardware required to operate. This not only reduces the amount of pollution generated by the manufacturing and shipping of computing equipment, but also lowers the energy consumption associated with running these devices. [22]

Smart grid technologies

Smart grid technologies are to self-sufficient systems that utilize controls, computers, automation, and equipment to quickly identify and solve problems while adapting to constantly changing demand. By working together, these technologies can reduce the need for manual labor and help ensure the delivery of sustainable, reliable, safe, and high-quality electricity to all consumers.[23]

3. Technologies to foster the introduction of new-to-firm products or services

Visualization technologies and digital twins

By utilizing visualization technologies such as virtual reality (VR), augmented reality (AR), and 3-D printing, the pace and flexibility of research and development efforts can be greatly improved. Instead of spending several weeks constructing a physical prototype, designers can create a VR prototype in just a few days. With appropriate tools, teams with varying areas of expertise can make changes to the prototypes more quickly, and can estimate the cost implications of design

[22] https://blueandgreentomorrow.com/environment/9-technologies-making-industries-greener/
[23] https://www.smartgrid.gov/the_smart_grid/smart_grid.html

improvements in real time. The efficient use of VR can significantly reduce the time and cost of research and development, resulting in up to 10 to 15 percent reduction in both measures, while also enhancing product performance.

However, traditional established companies often face challenges in extracting and utilizing insights from data generated by their products in use. These companies manufacture multiple versions of their products, which may be customized to meet specific regional requirements. Consequently, it becomes difficult to keep track of all these product variations. Additionally, when these companies need to release software updates for their products, they face difficulties in ensuring that these updates work with every version of their product.

To overcome these challenges, some established companies have adopted the use of "digital twins," which are virtual replicas of physical products. By integrating product information, including software and hardware configurations, and performance metrics with real-time data on product usage and performance over its entire lifespan, companies can monitor issues and identify unmet customer needs with precision. Such insights can lead to innovative breakthroughs in product design, as well as significant cost and time savings related to activities like maintenance, product recalls, regulatory compliance, and manufacturing process optimization. Moreover, before implementing software updates on actual products, incumbents can test fixes and new functions on their digital twins..

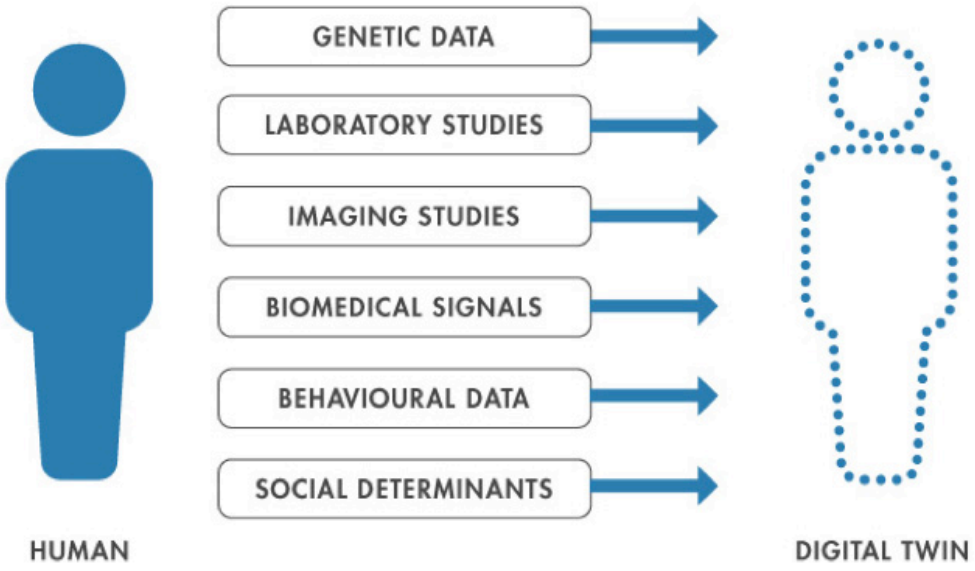

Figure 9: Digital Twin of a Human. All these data are combined into a single virtual representation of a patient, so a more complete picture of the medical history of the patient is available to support decision making. Source: MathWorks

Virtual-reality hackathon

With the goal of overcoming outdated assumptions, a series of hackathons are organized by companies to create a new version of their product. Various departments are brought together in a physical or virtual room to utilize a VR prototype that underwent multiple rounds of review and refinement. Companies include their prototype along with competitor models in the VR environment, enabling direct comparisons that would have been challenging in the physical world. The cross-functional team make adjustments to the prototype in real-time as suggestions for improvement arose. This use of VR technology not only accelerates the design process, but

also facilitates the rapid resolution of problems and the development of new capabilities, such as agile teamwork, by inviting relevant departments to hack the virtual prototype simultaneously.[24]

Open Innovation Forum

The Open Innovation Forum is a program that allows companies to share their innovation challenges and get proposals from research groups and centers. It is a great opportunity to meet the right collaborator to tackle your innovation challenges

The Open Innovation Forum program allows companies to share their innovation challenges and receive proposals from research groups and centers. This program presents an excellent opportunity for companies to identify suitable partners to help address their innovation challenges..[25]

4. Identification of SMEs specific difficulties in terms of talent in BMT

4.1. Consortium

The consortium is composed of experienced partners such as:

Turku Science Park (TSP) - Finland

Turku Science Park Ltd (TScP) is an independent and impartial expert company which has promoted business operations of SME companies based on leading know-how for more than 30 years in Turku region. The mission of TScP is strictly linked on the performance of enterprises to improve their capacity to succeed in business and operations generally, specifically in international markets. TScP Ltd is owned by the City of Turku and acts as a strategic partner for universities and companies, both start-ups and fully operational small companies which are seeking growth and new business opportunities. Turku Science Park Ltd coordinates activities of HealthTurku cluster, which is the strongest cluster in life sciences field in Finland. It represents more than half of Finnish bio-industry. Within HealthTurku the Health Campus Turku network of three universities and Turku Science Park Ltd work in collaboration to promote the business operations of companies. HealthTurku in figures:

a) Employment effect around 6000 industrial jobs (appr. 20 % of industrial workforce in Turku);
b) 75 % of Finnish pharma export and 50% of Finnish in vitro diagnostic export comes from Turku;
c) More than 130 life science companies in the region.

BioRegion of Catalonia (Biocat) - Spain

Founded in 2006, Biocat brings together the life sciences and healthcare innovation community in Catalonia, an ecosystem that includes over 1300 companies of which 98% are SMEs. The organisation is a Partner of EITHealth, Board member of CEBR and partner of the European Infrastructure EATRIS for the Personalised Medicine flagship project Eatris-Plus. Biocat has a dedicated team of 20 professionals of life sciences, experts in international relations, innovation, science diplomacy and economy. Biocat runs a complete portfolio of acceleration and innovation programs, mentoring, networking and access to funding, promotes training and talent

[24] https://www.mckinsey.com/capabilities/operations/our-insights/accelerating-product-development-the-tools-you-need-now

[25] https://www.openinnovationforum.cat/

development actions and runs a series of strategic projects to connect the ecosystem's stakeholders and help the Catalan BioRegion take a qualitative leap forward both nationally and internationally (with a large network of partners abroad). Biocat's governing bodies gather a representation of the regional and local governments, academia, hospitals, sectorial entities, SMEs associations and industry organisations. Biocat runs the Catalan Life Sciences Database that gathers the players from the Catalan Life Sciences ecosystems, by sector including the name of the company, description of services, contact details, etc., based on Biocat's internally-used software where detailed data about the players and projects active in the Catalan BioRegion and beyond are gathered for their use in daily actions.

Medicen – Paris region, France

Medicen is the lifescience cluster located in Paris that aims to foster and develop Health Innovative solutions. We are the trusted third-party connecting all the stakeholders: half of the academic research in life sciences, chemistry and digital health in France, the largest European hospital network APHP and a network of healthcare clusters in France and in Europe. Medicen is composed by more than 500 members among clinics, hospitals, large companies, and SMEs covering all the value chain with biotech, medtech and digital health and a special focus on Diagnostic solutions and techno-therapies and Data collection (Data Hub Medicen Initiative).

Council of European Bioregions (CEBR) - EU/Belgium

The European Council of Bioregions is a membership-driven network of life science clusters and regional ecosystems across Europe, representing over 40 subscription members and hundreds of cluster partners across the world. Together, we represent and support a critical mass of SMEs, and hundreds of universities and research centres. Since 2020, involved together with the European Clusters Alliance in COVID task force leaded by DG Grow. Currently working on a smart, dynamic map for detection of disruptions in Vaccines and therapeutics Value Chain for DG Grow, linked to the development of HERA.

BioRegio STERN (STERN) - Germany

BioRegio STERN Management GmbH offers inter-municipal funding to stimulate the economy for a region with 248 towns and local authorities and a total of 3.3 million inhabitants. At the heart of the cluster are 120 medtech companies, with more than 12,000 employees, and 110 biotech companies, employing over 4,000 staff. The more than 1,000 engineering companies – around 40 of which are already active in the life sciences – are increasingly important. All in all, some 18,000 jobs have been created in the region's life sciences sector. The STERN BioRegion has just under 400 "members", the majority of which are SMEs (55%). Large companies (3%), universities and research institutes (18%) and other organisations (24%) are also represented. The funding for BioRegio STERN Management GmbH is made up of 20% from the public purse, 75% from shareholder contributions and 5% from sales revenue. To date, the region's 110 biotech companies have secured investment totalling EUR 1.2 billion and funding of EUR 120 million from the German federal government alone. The team at BioRegio STERN Management GmbH has helped 75 businesses with the start-up process since the company was founded, creating over 2,000 jobs.

LifeTecZone (LTZ) - The Netherlands

LifeTecZone is a foundation in the South of The Netherlands focussing on Lifesciences and Medical Technology SME's. LifetecZONe is a community, where around 100 SME's meet, are coached, getting informed about latest trends and are connected to other collaboration partners. LifetecZone is steered by a board of directors. The Brabant Development Agency (BOM) and LifetecZone are connected and work together to improve the services towards the

SME's. LifeTecZoNe is managed by a program coordinator, who is talking to the companies regurlarly, and knows what the main hurdles and challenges are of the SME's and entrepreneurs. With this knowledge, programs and projects are build, to bring the SME's in the region to a next level. BOM and LifetecZone together cover the region of North-Brabant with over 400 companies in Health, and more than 10.000 jobs. Bringing companies to the next level and help them to grow is day – to -day business. LifetecZone gained a bronze label for cluster management excellence. BOM and LifetecZone have a lot of experience in European programs, and are member of CEBR.

Górnośląski Akcelerator Przedsiębiorczości Rynkowej sp. z o.o. (GAPR) - Poland

GAPR is a dynamically operating institution of the business environment. For 20 years, GAPR has been conducting intensive activities for science, business and local government. It creates favourable conditions for the creation of new companies and the development of existing enterprises. The company has a unique set of resources, thanks to which support for companies can be comprehensive. 100 - Completed EU projects 1000 - Completed consulting services 5200 - Trained people 250 mln - PLN granted financial support. GAPR is a Coordinator of MedSilesia Cluster. MedSilesia Cluster consists of 108 innovative companies, R&D units, hospitals, healthcare facilities and universities. We offer a broad range of products from the field of rehabilitation, surgery and orthopedic tools, diagnostic equipment, cardiology and other medical areas – according to our wide range of Cluster Members. Support of the experienced, knowledgeable and renowned research and development institutions allows us to provide high quality medical products. Cluster cooperates with numerous institutions and initiatives, implementing projects and ventures affecting the potential of its members.

Figure 10: BioMan4R2 consortium geographical scope

4.2. Surveying the ecosystem players

The BioMan4R2 consortium has conducted a comprehensive survey across all partners' regions in order to identify **the specific difficulties in terms of talent in the biomanufacturing and medtech sectors**. As the biomanufacturing landscape identified the needs for more specialized training education programmes, upskilling and re-skilling of labor forces from other industry sector, talent chase, and high competition to attract digitally skilled workforce (digital twins, simulators, virtual & augmented reality and for the education system to include more entrepreneuship skills lessons.

The goal here was to determine the extent of these gaps and recommend a range of upskilling and reskilling services. Each partner has sent out a survey composed of 9 questions addressing the target group's opinion on talent needs: where are the main gaps in their companies? In which areas could specific training help overcome those gaps? What do they think would help attract and retain talent?

Each cluster had to survey their target players, especially SMEs of the biomanufacturing and medtech sectors, to analyze the specific difficulties in terms of talent on their ecosystems' industries.

As the leader of the Work package 2, Biocat's team shared a template proposition to the consortium to be sent out to the target groups after validation. 9 questions were agreed at the partnership level to evaluate the challenges related to talent.

Each cluster had to:

1. Identify its target groups
2. Send out the survey to the target groups
3. Collect and monitor the results
4. Biocat prepared a digest of the key inputs to be shared

4.3. Global results and key findings of the survey

The survey received a total of 66 responses. Of these, 28 respondents were from the biotech and pharma sector, 39 from medtech, and 2 from other categories (university and consultancy) (Fig. 11). Additionally, 29 of the respondents were micro enterprises (with less than 10 employees), 23 were small companies (with 11-50 employees), 11 were medium-sized companies (with 51-250 employees), and 3 were large enterprises (with more than 250 employees) (Fig. 11).

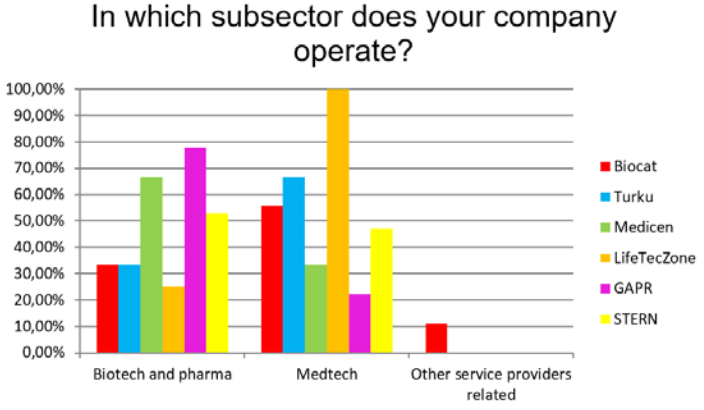

Figure 10: Percentage of respondents according to the sector and partner's region.

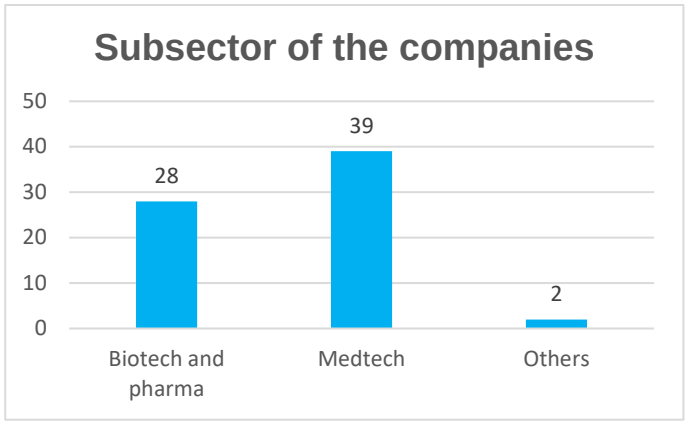

Figure 11: Number of respondents according to their sector.

4.3.1. Key similarities

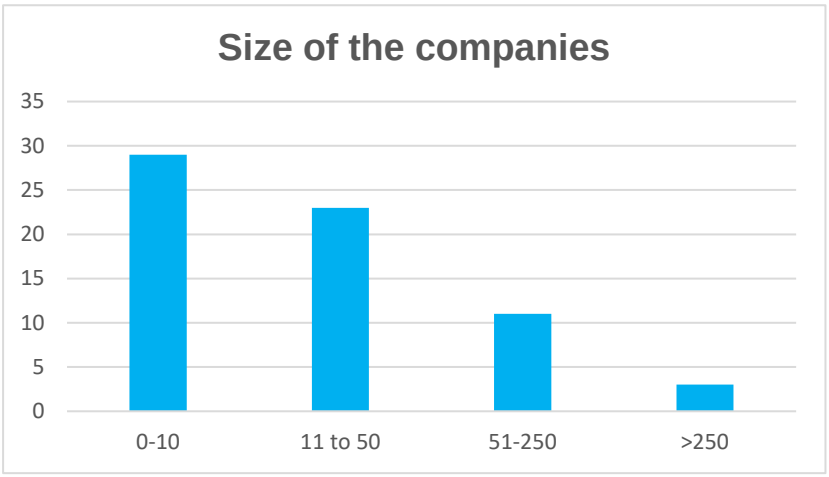

Figure 12: Number of respondents according to the size of their companies.

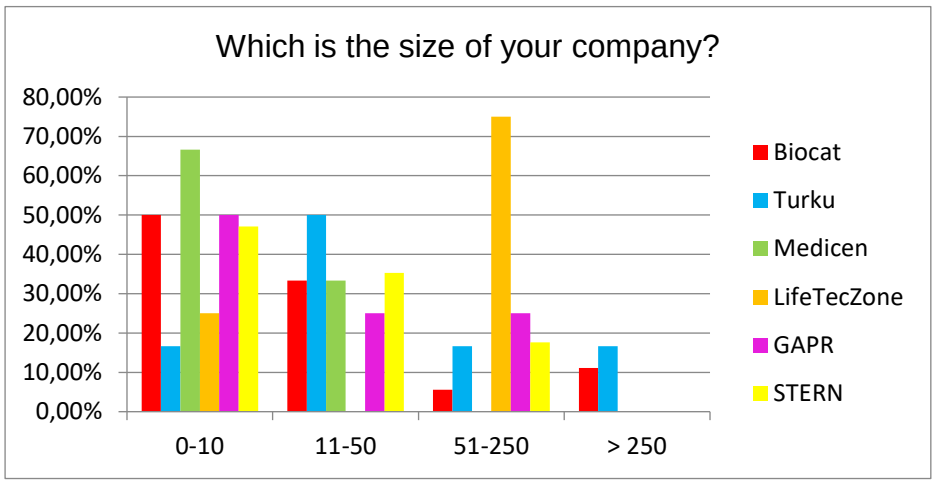

Figure 13: Percentage of respondents according to the sector and partner's region.

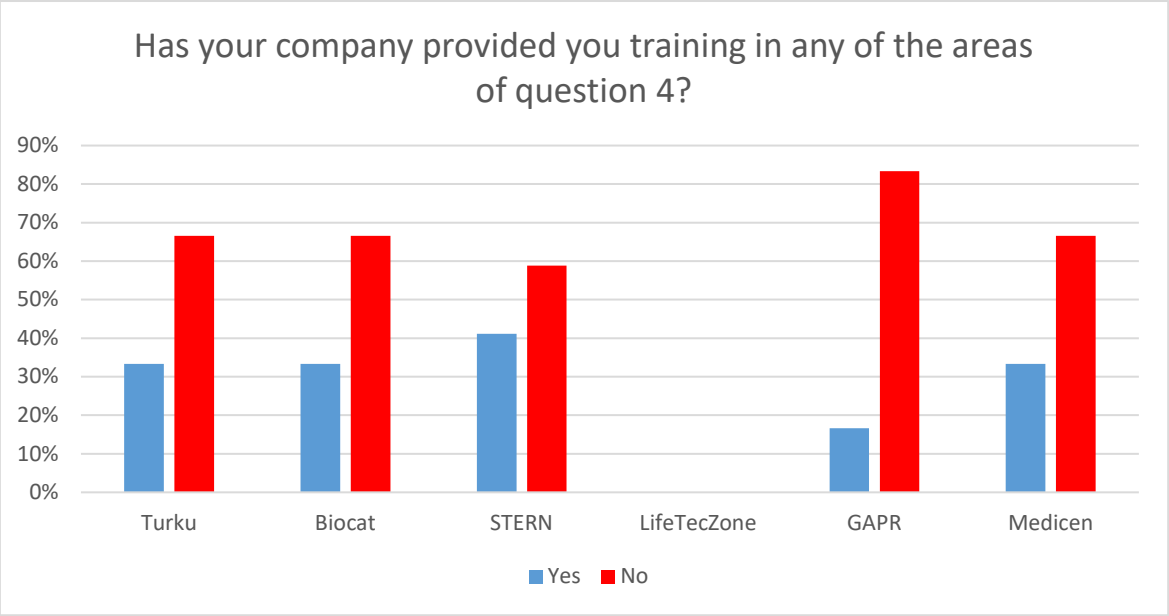

Figure 14: Question 5 of the survey: Has your company provided you training in any of the areas of question 4?

The majority of regions concur that their companies are not providing adequate training in the essential areas necessary to bridge the existing gaps, as reported by most surveyed players (Fig. 14).

Additionally, there is a belief that SMEs lack the resources required to conduct these training sessions (Fig. 15). Consequently, the main gaps identified in the BMT sector in the majority of the regions are two: **talent and funding** (Fig. 15).

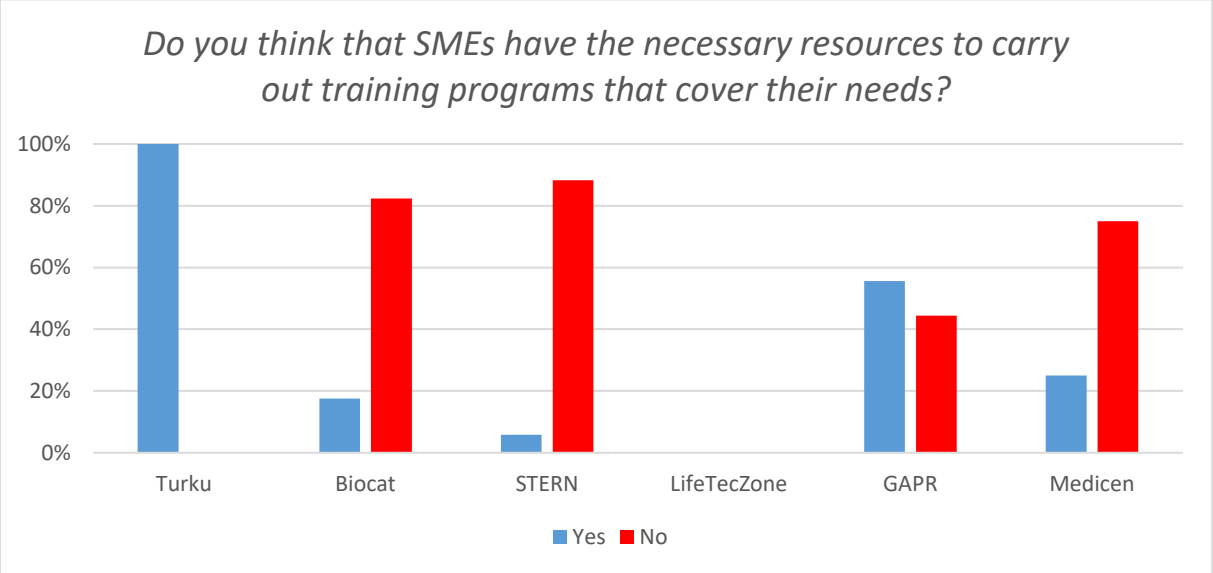

Figure 15: Question 6 of the survey: Do you think that SMEs have the necessary resources to carry out training programs that cover their needs?

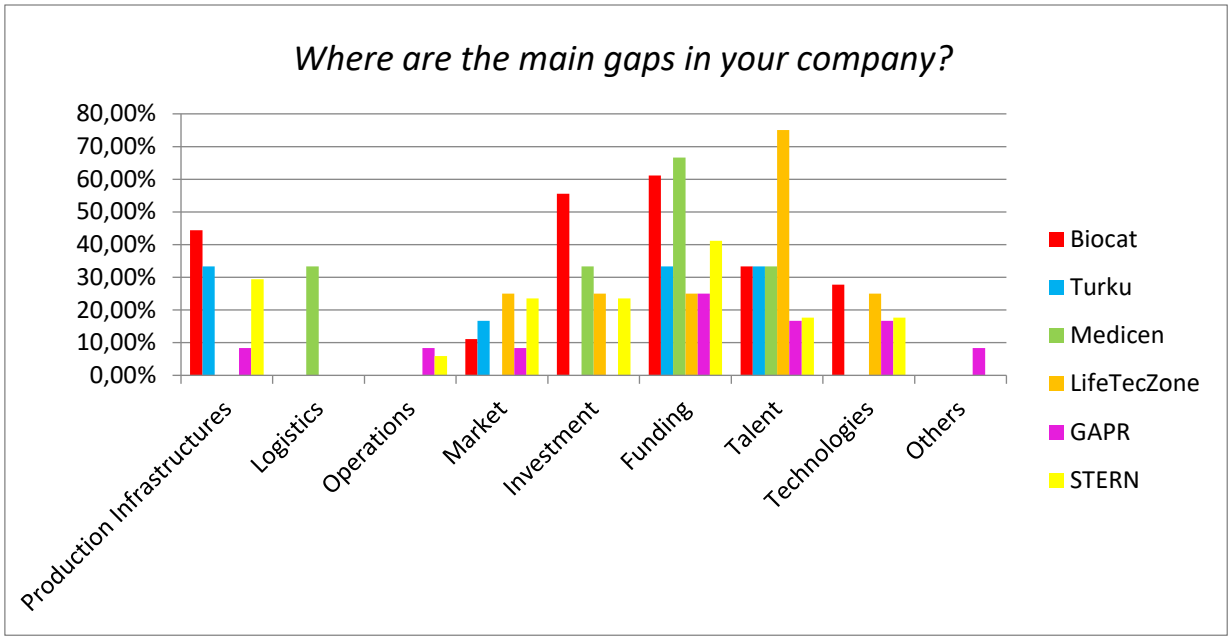

Figure 16: Question 3 of the survey: Where are the main gaps in your company?

Respondents of all regions agree that the **attraction and retention of talent** is a problem in the BMT sector (Figure 16).

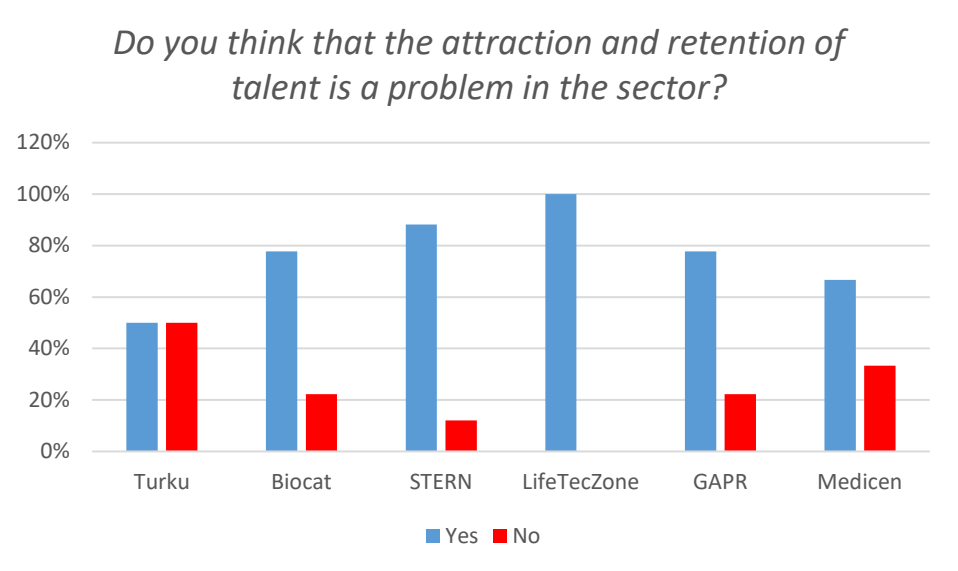

Figure 17: Question 7 of the survey: Do you think that the attraction and retention of talent is a problem in the sector?

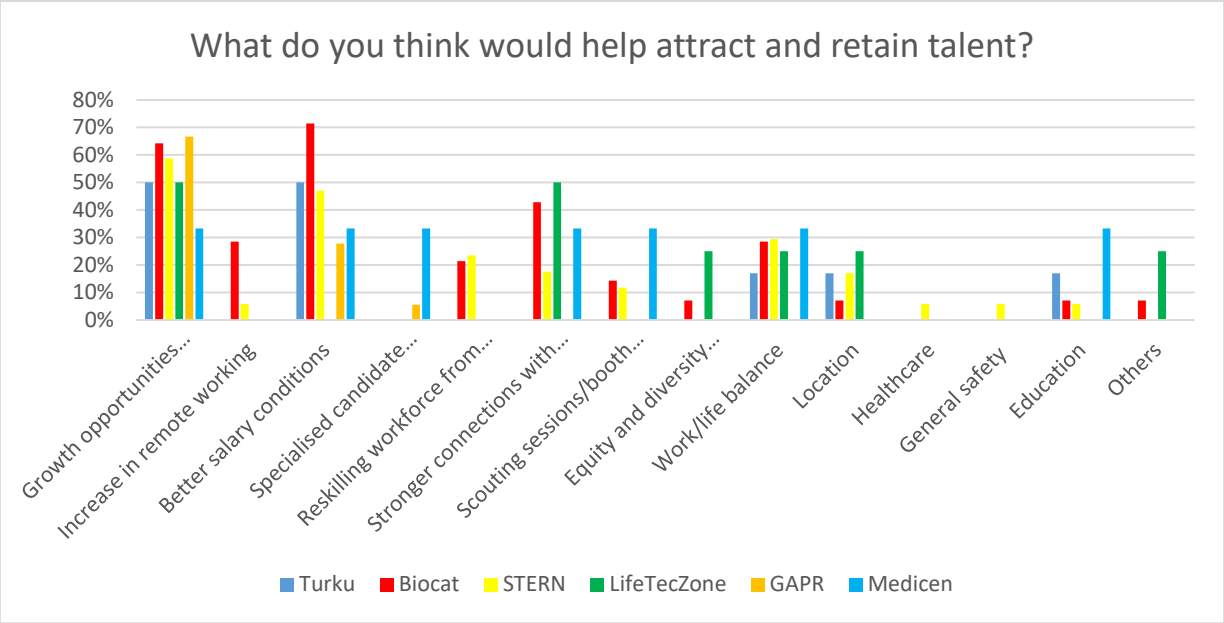

Figure 18: Question 8 of the survey: What do you think would help attract and retain talent?

According to the players surveyed, common factors that could aid in attracting and retaining talent include **growth opportunities within the company, improved salary conditions, and strengthened connections with academia** (Fig. 18).

The majority of people that answered the survey from the 6 regions believe it is a good idea to create an Erasmus+ or some other EU-level training program dedicated to aspects of innovation or development of sectoral skills, as the Biomanufacturing landscape conducted by CEBR and EITHealth suggested. Furthermore, other ideas arised such as trainings of european networking in engineering, agile methodologies applied to biomanufacturing or medtech start-ups, utilisation of digital tools and artificial intelligence (Fig. 19).

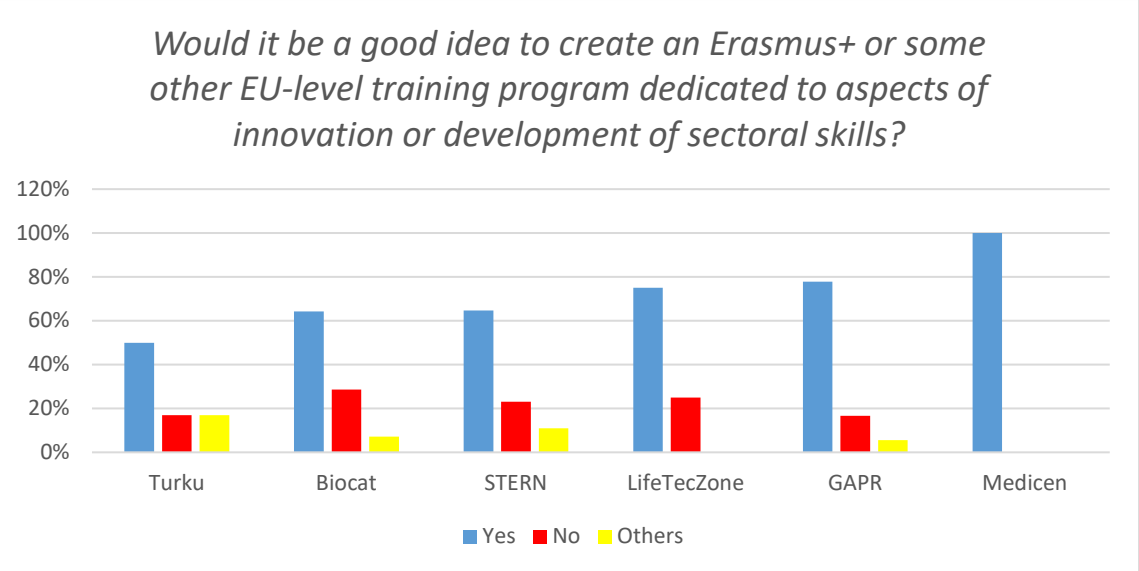

Figure 19: Question 9 of the survey: Would it be a good idea to create an Erasmus+ or some other EU-level training program dedicated to aspects of innovation or development of sectoral skills?

A vast majority of respondents across all six regions surveyed expressed their support for the creation of an Erasmus+ or similar EU-level training program focused on innovation and the development of sector-specific skills, as suggested by the CEBR and EITHealth Biomanufacturing

landscape report. Additionally, respondents proposed several other ideas, including training in European networking for engineering, applying agile methodologies to biomanufacturing or medtech startups, utilizing digital tools and artificial intelligence.

4.3.2 Key differences

The responses regarding the areas in which specific training could help in overcoming the identified gaps were diverse. One area commonly identified across most surveyed regions was **access to market for new products**. **Regulatory compliance, scaling up production, and Lean Methodology** were also among the main training needs identified. In addition, players selected big data and artificial intelligence, digital transformation, product development, and new technologies and processes as other areas in which specific training could help bridge these gaps (Fig. 17).

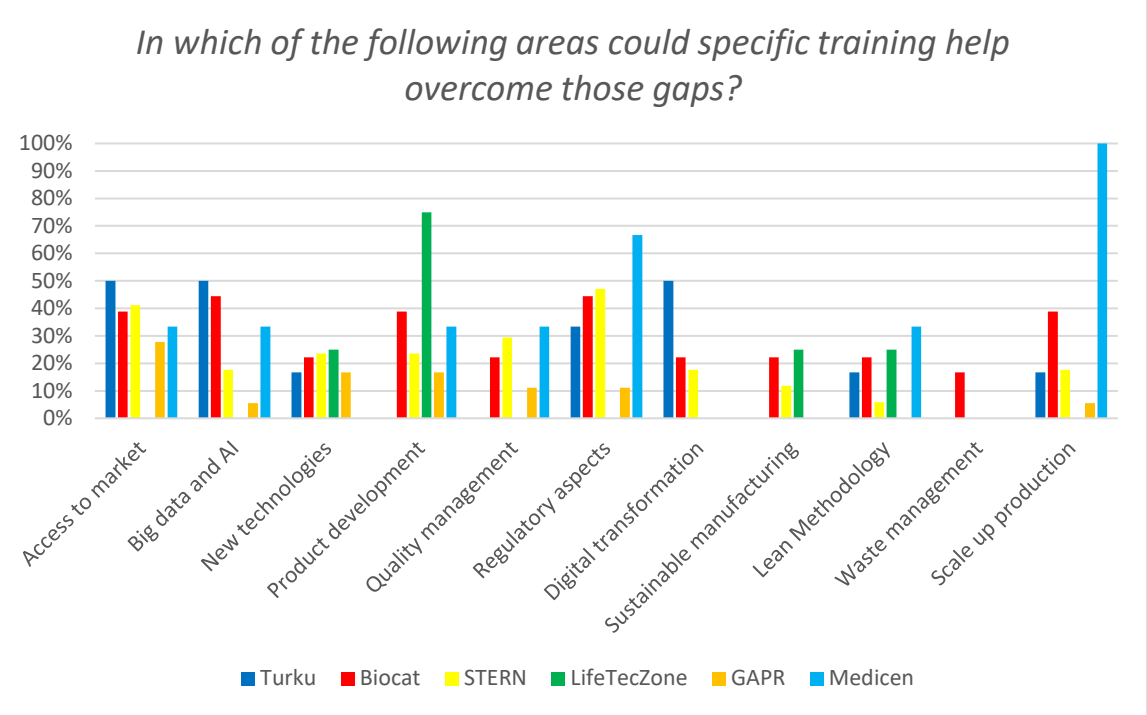

Figure 20: Question 4 of the survey: In which of the following areas could specific training help overcome those gaps?

4.4. Focus Groups

As part of the Task 2.1 of Resilience Needs Analysis and mapping of Actors for the SME support Programme, the consorium conducted direct interviews and focus (working) groups with KOLs from the biomanufacturing and medtech fields.

The meetings took place on February 2023 (8th Feb Biomanufacturing group, 9th Feb MedtTech group).

In both cases, the format of the meeting was the same: a presentation of BioMan4R2 delivered by Biocat to a group of 6 KOLs from the public and private value chains of the BTM sector and a foresight analysis actively involving the participants in the discussion, exchange and reflection on current challenges of the Biomanufacturing and MedTech sectors at Regional, National and European level.

The participants differentiated between the dynamics od the pharmaceutical industry and the biotech industry, being in the latter the capacities and innovative ideas are mainly found in Europe. Some conclusions might be found as a SWOT in the following table. See the full report on the Focus Groups as an Annex to this deliverable.

Strengths	Weaknesses	Opportunities	Threats
BIOMANUFACTURING			
- Industrial fabric at regional level, strong in some regions - Europe generates products with excellent quality and safety	- The EU is slow with respect to other regions such as the USA (inefficient dynamics) - Lack of own (bioengineering) equipment	- Change of Mindset: knowledge is NOT enough. Opportunities will come from strengthening the Innovation chain all along - Investing in productive capacities	- Leaving production for other regions - Bottlenecks in production - Professionals leaving the regions of origin and deploying the industry of top talent
MEDTECH			
- Efficient use of resources - Qualified Talent from universities - Competitive products and with good quality - The strict regulatory framework is can also be seen as a strength, as the products in Europe have high quality and safety properties	- Void in entrepreneurship knowledge in the health sector -Lack of production capacity (chain supply) - - Large industries become outdated due to the obstacles they encounter in innovative new products	- Medical staff involved in new medtech products to be used in hospitals. - Entrepreneurship education and training programmes - Prioritizing core subjects and the supply chain for the healthcare sector - delayed application of the MDR and making regulations more flexible - Mentoring new startups, incubators, and SMEs, and helping them to be competitive in the market and find their gap in the market - Decentralized production chain.	- Talent draining - limited capacity to react to market demands - Complex regulations limit the capacity to evolve into a sustainable and innovative industry - Investor oligopoly

Focus Groups Challenges for the Bio-Manufacturing and Medical Technologies Sector

Action funded by:

Funded by the European Union

INDEX

1. CONTEXT

At the start of both focus groups some general data and context of the sector (both in Europe and Catalonia) was shared with attendees for kicking off the discussion.

1.1. Bio-Manufacturing Sector

General Data:

- 2021 total occupation of the pharmaceutical industries in EFPIA countries is of 840 000 people.

- EFPIA members invested 41.5 bn€ in R&D, with an 4% average growth over the last 5 years.

- Sales forecast for the EU in 2025 is of 296 bn€.

Current status: The sector has nowadays a high dependence on Asia.

- Up to the mid-90s USA, EU and Japan produced 90% of the principal active pharmaceutical ingredients (APIs)

- Nowadays China is the second provider of APIs and antibiotics to the EU27 (in volume). The last European factory producing acetaminophen (paracetamol) was closed in 2008.

- There are projects in Europe working to move production outside of Asia (e.g. Sanofi)

- Europe needs to strengthen the resilience of its chain of production and manufacturing, for example by providing incentives to diversify providers of critical components, chemicals and other raw materials needed for production.

Contribution to European Economy:

- Biotechnologies and life sciences contribute to modernizing the European industry.

- Biologic products are used in a diverse range of industrial sectors: such as healthcare, pharmaceutics, animal health, textile, chemistry, plastics, paper, food, and animal feedstock.

- Biotechnology helps the EU Economy to grow, contributes to job creation, and supports a sustainable development, public health and environment.

1.2. Medical Technologies Sector

General Data:

- The medical technologies sector employs more than 730 000 people in Europe

- Europe has more than 32 000 companies working on medical technologies, 95% of which are SMEs

- Market size is estimated to be 150 000 million Euro

Current status: The sector has nowadays a high dependence on Asia.

- Europe needs to strengthen the resilience of its chain of production and manufacturing, for example by providing incentives to diversify the providers of critical components, chemicals and other raw materials needed for production.

Contribution to European Economy:

- Medical technologies are aimed at saving lives, at improving the health of the population and contributing to a sustainable healthcare provision.

- Through innovation this industry gives value to patients, healthcare providers, healthcare systems and the society as a whole. It is also contributing to the European economic growth and employment.

2. FOCUS GROUPS

2.1. Composition of the focus groups

FOCUS GROUP 1	FOCUS GROUP 2
Date: 8th February	Date: 9th February
Attendees: Anaïs Le Corvec, CEBR David Resina, Bioingenium Päivi Linna, Bioingenium Isabel Amat, Reig Jofre Olga Durany, GAT Biosciences Francesc Gòdia, UAB Andreu Soldevila, LeanBioPro and Syna Therapeutics	Attendees: Alfons Carnicero, Able Human Motion Jordi Martorell, Aortyx Eva García, Wivi Vision Javier Selva, CataloniaBio & HealthTech Sofia Ferreira, Heecap Marta Guardiola, MiWEndo Solutions
	

2.2. Structure of the focus groups

The focus groups were two-hour sessions aimed at addressing questions related with three main areas:

- Defining the current challenges of the biomanufacturing and medical technologies sectors in Catalonia

- Identifying the actors and actions that can play a role in addressing those challenges

- Talent management

The two meetings happened in the format of conversations and debate triggered by open questions.

3. ANALYSIS and RESULTS

In terms of Biomanufacturing though there is agreement with regards APIs, attendees emphasized the strong position of Europe in other fronts like the monoclonal antibodies production.

With regards the Medical Technologies sector in Catalonia, there was consensus in defining it as highly efficient, with good public investment at initial stages, with access to excellent training and talent, and developing relevant products.

3.1. Challenges

Both groups made reference to a series of challenges and provided suggestions to address them:

BIOMANUFACTURING.
Innovation: - Innovation goes beyond knowledge generation and into production to create value and generate solutions - Incremental innovation should also be accepted in existing financial mechanisms and with adjusted reference pricing. **Raw materials and equipment provision / supply chain:** - High dependency on a small group of providers - Invest in local bioengineering **Policymaking aspects:** - Institutional support through specific local strategic projects including appropriate funding and involving the private sector **Financial aspects:** - Funding should be available for all stages of the production, not only for early phases (going up to GMP production) - Invest in production capacity and big industrial projects - Pricing and budgeting should be revisited and aligned with the rest of Europe **Regulatory framework:** - need to harmonise and expedite. Going country per country for approval slows processes and even prevent market entry **Connect with other ecosystem actors:** - build on the Industrial network, connect with pharma (a very traditional sector in Catalonia) **Value chain:** - Manufacturing has a limited role in the local value creation chain **Education**: - coordinate with academia to overcome the negative perception of working for the industry

- improve the connections academia and industry

MEDICAL TECHNOLOGIES.
Innovation: - support the transition from prototypes to scaling up production **Raw materials provision / supply chain:** **-** Delayed deliveries in electronic components due to global shortages and distribution bottlenecks - Prioritise supplying the healthcare sector before other sectors - Enable secure recycling of part of the materials (also moving towards sustainability) **Policymaking aspects:** - Public pricing policies: revisit to focus on value-based procurement and not best price (low prices give no return to providers and disincentivise participation in public tenders) **Financial aspects:** - Investors ecosystem – enable other actors to enter the local system - Invest in MVP and PoC, funding personnel costs - Invest in the development of prototypes - Invest in early validations to facilitate market access and acceptance - Give favourable conditions to start-ups for them to stay and not leave to other EU regions **Regulatory framework:** - Streamline and facilitate access - Revisit MDR certifications (access to SMEs, resources, etc) **Connect with other ecosystem actors:** - Promote innovation amongst healthcare providers (doctors, nurses, etc) - Enable professionals to be able to contribute to the trials, tests and innovation related work in healthcare environments, that is reducing their workload. **Education**: - Advanced entrepreneurship training (not only commercial but also on other relevant aspects) - Use suitable mentoring strategies to support start-ups

3.2. Actors

There is general agreement in the two focus groups that:

- in spite of the existing challenges, the local ecosystem is progressing.

- there is a need for coordinated efforts across quadruple-helix actors to consider the whole innovation value chain as strategic (and not only the early stages of development), engaging both public and private sectors.

ACTORS considered and suggested actions
Biomanufacturing and Medical Technologies sector: - put the focus on value-based pricings and budgeting

- strengthen the connections between local actors (pharma, start-ups, universities and research centres, healthcare providers, etc)

Public agencies:
- include competitive and selective funding for start-ups and service providers
- include biomanufacturing as a funding priority
- consider later stages of innovation for targeted funding actions (scale-up)

Government:
- push for a local strategic plan that coordinates all actors
- revise pricing for public tenders
- use clusters and networks to facilitate adoption of innovations

Regulatory agencies:
- work towards facilitation and process streamlining (move to an EU regulatory framework similar to the US one)

Healthcare providers:
- promote innovation as part of their activities, facilitating participation

Education:
- complement the technical education with entrepreneurial and managerial know-how and mentoring
- improve the connections academia-industry to facilitate access to talent

3.3. Talent Management

There is consensus in the two focus groups that young professionals are well-trained and very capable but that it is challenging to retain talent due to the difficulty to compete in terms of salaries and career progression.

As mentioned above, suggestions to overcome this included: improving the coordination between universities and industry, the promotion of professional opportunities at the different educational levels, the addition of entrepreneurial training in the academic curricula, and the inclusion of mentoring programs.

4. QUALITY ASSESSMENT OF THE FOCUS GROUPS

Overall, attendees welcomed the opportunity to meet up with peers and discuss about challenges and experiences. Many expressed the need to have more shared spaces. Also, all valued the opportunity to contribute to the assessment of the ecosystem and thanked the organizers for the initiative.

	General		Focus Grup 1		Focus Grup 2	
	AV.	MEDIAN	AV.	MEDIAN	AV.	MEDIAN
The session has been in line with my personal expectations	4,8	5	4,7	5	5,0	5
The session has been in line with my professional expectations	4,6	5	4,5	4,5	4,8	5
The session format has been easy to follow	4,9	5	4,8	5	5,0	5
Suitable space and location	4,9	5	4,8	5	5,0	5
Facilitators have been clear and provided sufficient information	4,9	5	4,8	5	5,0	5