

# STOCKHOLM UPPSALA LIFE SCIENCE A LEADER IN ATMP MANUFACTURING

### Current landscape of life sciences in Sweden

Driven by advances in biomanufacturing technologies, strong research and development investments, regulatory approvals for novel biologics, and expanding biosimilar adoption, the global biopharmaceutical market size is anticipated to reach USD 741 billion by 2030.<sup>1</sup>

The Stockholm Uppsala region has a strong legacy of being at the forefront of life science research and development, and is globally renowned for its pioneering research and innovation in advanced therapy medicinal products (ATMPs). The region is also becoming established as a leading international hub for companies wishing to establish and expand their biomanufacturing facilities.

In 2024, Sweden exported pharmaceuticals worth USD 18.5 billion, corresponding to 9.4% of the country's total exports, making it the second largest export sector.<sup>2</sup>

As well as being commercially active, Sweden is engaged with the development of new medicines. R&D expenditure in Sweden as a proportion of GDP was 3.6% in 2023<sup>3</sup>, putting it slightly ahead of the US and making it a clear leader in the EU. Moreover, Sweden is highly ranked in terms of pharmaceutical approvals at an international level, and is consistently placed among the top European countries in terms of drug development pipelines. It has an excellent health record system and testing facilities, and is trusted when it comes to conducting clinical trials. Over 450 registered biobanks and a hundred disease-specific national registries covering 20% – 25% of Sweden's population provide extensive, longitudinal data that supports robust real-world studies.

Additionally, "professor's privilege," a system which means that researchers own the IP of their research, inventions or patents, has fostered a commercially engaged academic community that strives to translate groundbreaking science into clinical solutions.

Another major strength of the Swedish biotech industry is the continued collaboration between companies, research facilities and academic institutions. Swedish companies are highly globally connected, with international experts in key advisory and leadership roles. Supported by the government's strategic innovation programmes and vibrant life science hubs, companies are working together to further grow the sector, and Stockholm Uppsala is widely recognised as one of the most innovative and productive areas in the global life science community.

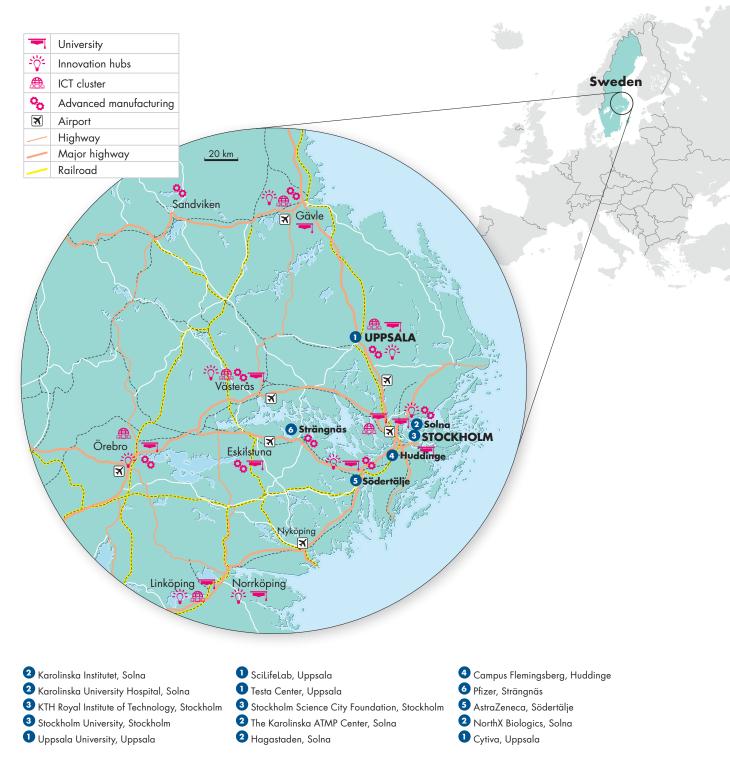
ATMP development is a government priority in Sweden. The foundations for the The Karolinska ATMP Center were laid 50 years ago, and it builds the on the collective strength of Karolinska Institutet and the Karolinska University Hospital. By incorporating all necessary steps of ATMP development within the centre, we can significantly accelerate translational research to provide clinical applications.

Knut Steffensen Director, Karolinska ATMP Center



## The Stockholm Uppsala region

The region's life science cluster includes major facilities in Stockholm, Uppsala, Södertälje, Strängnäs and Solna, and thriving life science hubs, for example in Hagastaden and Flemingsberg. Half of all life science employees in Sweden are based in the region, and it is home to Swedish multinational companies such as **Elekta**, **Bristish-Swedish AstraZeneca**, and global brands including **Pfizer**, **Johnson & Johnson** and **Cytiva**. Within the region there are five universities with significant life science activities, three university hospitals, and essential authorities such as the Medical Products Agency, the Public Health Agency and the European Centre for Disease Prevention and Control (ECDC).



## World leading research facilities

Well over half of Sweden's biotech and pharma companies are spin-offs from academia or healthcare, reflecting the country's strong academic ties.

**Karolinska University Hospital** was ranked fifth in the world in 2025 and number one in Europe, based on its ability to deliver the highest quality patient care, conduct critical research, and attract top talent. It works in close collaboration with the medical university **Karolinska Institutet**, which conducts world-leading basic, translational, and clinical research. Together, the two are celebrated for groundbreaking research and their role in awarding the Nobel Prize in Physiology or Medicine.

Other universities that are of great importance to industry include **KTH Royal Institute of Technology**, **Stockholm University**, and **Uppsala University**.

**SciLifeLab** is an institution for the advancement of molecular biosciences in Sweden, funded as a national research infrastructure by the Swedish government. It is one of Europe's leading research centres for molecular bioscience.

**The Testa Center** is an initiative between the Swedish government and Cytiva to secure the growth of the life science industry and its manufacturing capabilities. It is an open access innovation hub, available for academic researchers, startups and SMEs, as well

as large industry from all over the world. Users have access to industry-standard labs, state-of-the-art, infrastructure and expertise. Labs are equipped with pilot-scale biomanufacturing platforms and cutting-edge equipment for cell cultivation, harvest and purification unit operations in a controlled non-GMP environment.

#### Stockholm Science City Foundation (SSCi)

was established in 1990 to strengthen collaboration between the universities, industry and healthcare providers, and to promote the redevelopment of the surrounding area for life science companies. From 2009-2024, the number of companies almost tripled, from 59 to 175 companies. Through seminars, workshops, panel discussions and reports, it assists knowledge transfer, and facilitates cooperation locally, nationally, and globally.

#### ATMP Sweden and The Karolinska ATMP

**Center** (see Page 11) are central contact points both nationally and internationally to accelerate patient access to safe and effective medicines based on recombinant genes, live cells and/or tissue engineering. They work to facilitate R&D in the sector, increase international collaborations, and provide capacity for industrial development and manufacture of ATMPs. Together with similar regional organisations, their mission is to ensure that Sweden maintains its position as a world leader in development and implementation of advanced therapies.

Whenever you do something new, there are elements that you have done before. With an **experienced ecosystem and highly skilled research groups** that collaborate with industry, success is more likely.

> Janet Hoogstraate CEO, NorthX Biologics





### Thriving life science hubs

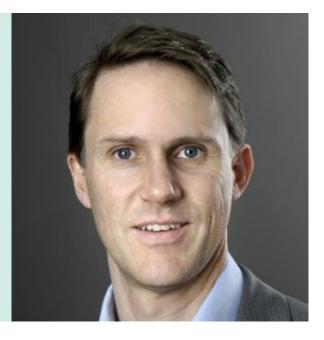
Property owners have a good understanding of the needs of life science companies, and with flexible lab space, conference facilities, co-working spaces, meeting rooms and cafes, it is easy to meet and build on each other's ideas.

**Hagastaden** is new district of Stockholm, developed from an old station into a vibrant life science ecosystem. Global companies such as Astra Zeneca, Pfizer, MSD, Abbot and Bayer have chosen to locate here, together with a large number of small innovative startups. A key advantage is the proximity of Karolinska Institutet, Karolinska University Hospital, KTH and Stockholm University, all of which are within walking distance of each other. It is also close to the city centre and to relevant authorities, tech, information and financial districts.

Significant investment is also being made in life science properties at **Uppsala** and at **Campus Flemingsberg** in Huddinge (in connection with the Karolinska University Hospital).

#### Sweden has a significant legacy of supporting stem cell research, with institutions like the Karolinska Institute playing a key role. At our facility in Campus Flemingsberg we have all the necessary tech functions including process development, analytical development, GMP manufacturing quality control and quality assurance.

Johan Rugfelt COO, SmartCella



# Advantages of the Stockholm Uppsala region for biomanufacturing

As well as providing a diverse talent pool, the Stockholm region offers stable and productive operating conditions and access to exceptional physical infrastructure through its network of roads, ports, and power grid systems.

Moreover, the significance of biomanufacturing to Sweden as a whole means that the sector receives consistent strategic government investments and support, in addition to major private investments in production facilities. In August 2024 it was announced that AstraZeneca will invest USD135 million to expand the manufacturing operations footprint of its site in Södertälje near Stockholm by 50%. Pfizer also recently invested approximately USD 25 million to expand its production facility in Strängnäs to enhance capacity and produce a broader range of drugs and vaccines. And NorthX Biologics expanded its infrastructure in July 2023 with a biomanufacturing unit in Solna for production in mammalian systems.

Sweden is consistently ranked among the most sustainable countries in the world, with a strong focus on renewable energy and environmental protection.



#### In 2024 Sweden was ranked second in the Global Innovation Index<sup>4</sup>, fourth for competitiveness in the IMD World Talent Ranking<sup>5</sup>, and second in the SDSN Sustainable Development Report.<sup>6</sup>

When you locate a site here, it's sustainable, it is low in carbon dioxide emissions. **So if you are planning a facility that's environmentally conscious, Sweden is the ideal location.** 

Mats Karlsson Supply Chain Director, Pfizer



## Welcome to Stockholm

The region is renowned as one of the most innovative and productive areas in the global life science community. Stockholm Business Region is the official investment promotion agency and has been providing free advice to help companies establish and build their businesses in the region for more than 20 years. To be part of our success story in life sciences and see how we can help your business grow, contact Ylva Hultman Life Science in Stockholm – A market overview.



#### References

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## Behind the Stockholm Uppsala region's excellent biomanufacturing capabilities are determined, inquisitive minds who are driven to make a difference.



**Mats Karlsson** of Pfizer explains: "Taking into account resources, infrastructure and sustainability, it's a really great area. This is where the magic happens in pharma and biotech. Innovation is a buzzword and there are many different kinds of innovation hubs in the area.

"Proximity to universities and to other life science companies is a key factor. There's a golden triangle of pharmaceutical businesses – Stockholm, Uppsala and Strängnäs (where Pfizer's production facilities are located) – which are only an hour apart by car or train. The region is home to global companies and also to many smaller companies that are growing and developing new technologies. Staff can move between the different companies, and this facilitates the sharing of knowledge and skills, and encourages innovation."

Or, as **Janet Hoogstraate**, CEO NorthX Biologics puts it: "The region has a long heritage of life sciences – the focus is always on innovation. There is expertise here... right from the early stages, all the way to regulatory

These individuals are also willing to collaborate. Hoogstraate notes that



while Pfizer and AstraZeneca are, of course, giants in pharma with their own portfolios of drugs, they actively work alongside smaller players, particularly when it comes to technology advances and targeted education in "process development and production". Jesper Hedberg, CEO of the Testa Center, agrees: "We do have people

approval and commercial manufacturing."

**Jesper Hedberg**, CEO of the Testa Center, agrees: "We do have people who help our members over the whole ecosystem – all the way from academics, to startups, mid-size and even large, drug-producing companies with sites like AstraZeneca and Pfizer."

According to Hedberg, the presence of support networks, like those offered by the Testa Center, is vital for emerging companies' journeys across what he describes as the "Valley of Death".

"Projects at an early stage often demonstrate potential. But then they need to scale," he says. "Since the start of 2018, we have run maybe 100 projects and many of them have shown great success in commercialising and also being able to grow with the market."

**Pia Sjögren**, Director of Technology at Pfizer, highlights the region's proximity to universities as one of its core strengths. "The leading universities in Stockholm and Uppsala are keen to cooperate with local businesses, and we can find the talent we need at all levels," she says. "We hear from other countries that sometimes it's extremely difficult to find the right competences, but we don't really see that here.

"The pharmaceutical sector is historically very important for Sweden. The government is proud of what has been achieved here, and keen to promote the continued success of life science companies in the region. Local authorities do all they can to support startups and larger companies, and are always willing to listen to the industry. In the region, we have a strong track record of building new facilities and delivering on time and on budget."





SmartCella is a global biotech company pioneering advanced therapy development and novel delivery platforms for targeted therapies. It is built on globally renowned science and research from Karolinska Institutet. The team of 80 employees from 27 nations consists of scientists, visionary innovators, and experienced business leaders, all dedicated to shaping the future of targeted therapies and delivering life-changing treatments to patients.

SmartCella combines novel delivery platforms, such as the Extroducer<sup>®</sup>, an endovascular delivery device that enables direct injection to hard-to-reach organs and tissues, with state-of-the-art development and manufacturing of regenerative medicines. In 2024 it obtained approval from the Swedish Medicinal Products Agency for GMP manufacturing and quality control testing of cell therapies, and the company raised 50 million euros to accelerate growth and commercialisation of both its delivery platforms, and cell and mRNA operations.

Johan Rugfelt, COO, and Ricardo Baptista, CTO and Head of Procella, discuss how the company has developed, and the advantages of growing a biotech company in the Stockholm region.

Johan Rugfelt: SmartCella is located in Campus Flemingsberg close to Karolinska University Hospital, Karolinska Institutet and Novum. Novum is a major centre for ATMP companies; it offers, flexible spaces for small and medium sized companies, plus all the infrastructure that they require, such as clean rooms and labs. The local municipalities are very supportive and hold regular meeting to see if they can facilitate further development. SmartCella is a relatively large company and has its own facilities, occupying 4,000m<sup>2</sup> including development labs, a GMP manufacturing suite and QC lab. We are keen to collaborate with other companies within the Swedish ecosystem and the global industry.

Although the company was founded in 2014, its main activity started in 2018. The 'Targeted Delivery' business unit has a medical device solution for delivering cell therapies and other types of payloads directly to any organ in the body. The Extroducer® already has a European patent and FDA approval, and three clinical studies using the device will start in 2025. One of these is a gene therapy project with an external partner, which is using the Extroducer® to deliver a regenerative gene therapy for refractory angina. It's a multicentre Phase II study involving sites in several EU countries and the US. There's also a planned study in pancreatic cancer patients, in which chemotherapy is injected into the tumour inside the pancreas, rather than systemic treatment with chemotherapy which only delivers a tiny part of the treatment to the tumour. This means that although we deliver a fraction of the dose, a much large amount of the drug reaches the tumour compared to standard delivery methods.



Johan Rugfelt (left), COO, and Ricardo Baptista (right), CTO and Head of Procella, discuss how the company has developed, and the advantages of growing a biotech company in the Stockholm region.



**Ricardo Baptista:** Regenerative Medicine is SmartCella's other business unit, which has two segments – Cell Therapies and mRNA Therapeutics.

Our pipeline focuses on allogenic Regenerative Medicines produced from human pluripotent stem cells (PSCs), which have the capacity for unlimited selfrenewal and the ability to generate (almost) any cell type of the human body. Our current therapeutic focus is on heart failure and Parkinson's disease.

Our first product, SMART01 is cardiac progenitor cells to treat advanced heart failure. PSCs are differentiated in vitro to cardiac progenitor cells with a proprietary differentiation protocol and cells are the delivered as single cells directly to the heart using the Extroducer. In pre-clinical studies, SMART01 cells reduced the infarct size and attenuated decline in cardiac function in minipigs. We have initiated the GMP manufacturing campaign to support a Phase I/IIa clinical trial in the UK and in Sweden.

Professor Johan Ericson (Karolinska Institutet) and his team have developed a novel method to differentiate PSCs into midbrain dopaminergic neurons (mDA neurons) with improved efficiency and yield in therapeutic mDA neurons after transplantation. We have built upon Ericson's work to develop our SMART02 programme – this is an example of 'professor's privilege in action'. Our SMART02 product is cryopreserved allogeneic human ventral midbrain progenitor dopamine producing cells (mDAs) derived from PSCs. Grafted cell preparations have shown exceptional therapeutic performance in preclinical transplantation studies in parkinsonian rat model, suggesting potential to become a best-in-class cell product. In addition, we focus on mRNA therapeutics. We have a programme in osteoarthritis in early-translational stage with promising data in small animal disease models, showing potential for cartilage regeneration and pain relief.

Johan Rugfelt: Sweden has a significant legacy of supporting stem cell research, with institutions like the Karolinska Institute playing a key role. All our technologies and all the IP that we own has been acquired from professors at Karolinska Institutet – this includes the endovascular catheter-the Extroducer, the SMART01 cardiac progenitor programme, and the SMART02 Parkinson's project. We work closely with their researchers and are planning to do many of our clinical studies in Sweden. We also recruit highly skilled process engineers from KTH Royal Institute of Technology as well as scientists and researchers from Karolinska Institutet.

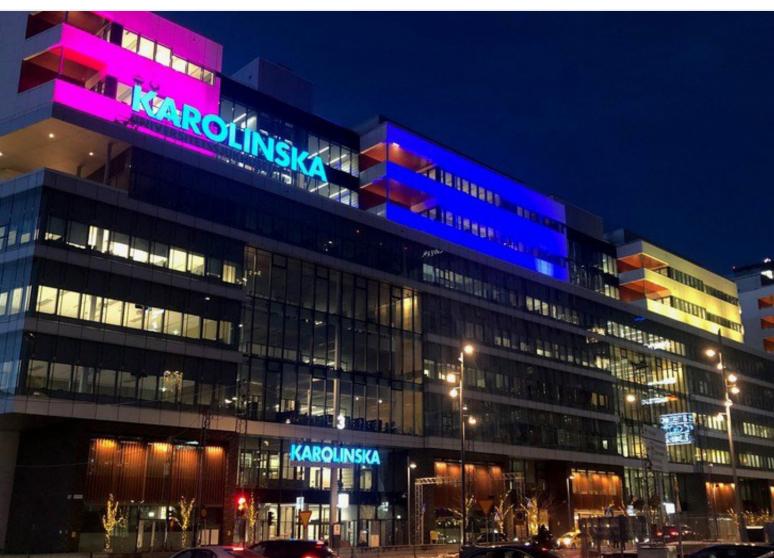
At our facility we have all the necessary tech functions including process development, analytical development, GMP manufacturing, quality control and quality assurance, supply chain. ProCella's manufacturing authorisation and GMP certification from the Swedish Medicinal Product Agency signifies the ability to start clinical production of cell-based therapies for clinical studies, for the manufacture of internal therapeutic developments in both pre-clincal and clinical development phases.

Our business model for the regenerative medicine area is to be a bridge from early science to Phase I. The focus is on early development and preparing for scale up and clinical trials, but we partner with Big Pharma to take the projects into Phase II and III and to commercialisation.

## The Karolinska ATMP Center

The Karolinska ATMP Center is a joint venture between Karolinska Institutet and Karolinska University Hospital. It is tasked with consolidating ATMP operations based on cells, genes or tissues to enhance the development and implementation of innovative therapies.

ATMP development is a government priority in Sweden. This means that in addition to regional networks there are several national projects for specific aspects of ATMP research, regulatory policy development, clinical development and healthcare implementation. The foundations for the Karolinska ATMP Center were laid 50 years ago with the Medical Unit for Cell Therapy and Allogeneic Stem Cell Transplantation. It is now working to forge stronger, closer ties with public sector players and pharmaceutical companies within Sweden and around the globe.



Knut Steffensen took over as director of the ATMP Center in November 2024. His extensive experience of basic research at molecular level and practical knowledge of the very latest ATMP drugs from the industry gives him a broad overview of what's required to take discoveries in basic research all the way to new cell and gene therapy (CGT)-based drugs.





**Knut Steffensen:** The centre builds the on the collective strength of Karolinska Institutet and the Karolinska University Hospital, both of which are internationally renowned for excellence in research and healthcare. Our aim is that by incorporating all necessary steps of ATMP development within the centre, we can significantly accelerate translational research to provide clinical applications. Structuring everything within the umbrella organisation helps to streamline development and save time and money.

All Swedish researchers as well as companies developing CGT are welcome to our pre-GMP and manufacturing facility at the Karolinska ATMP Center. Here we can also connect researchers and companies to experienced clinicians with expertise within a broad range of conditions, including rare diseases, and we also offer regulatory support to perform clinical studies and develop market strategies.

Our centre aims to contribute to the development of the Swedish ATMP ecosystem, hence fostering good relations with the various stakeholders is vital. For instance, we have a very successful collaboration with Uppsala ATMP Center and we collaborate with companies such as NorthX and Testa Center, utilising complementary resources and competences. Moreover, we're looking internationally – in particular to collaborate with European countries to become more competitive and where university hospitals aim to develop their own manufacturing facilities.

We're also exploring opportunities to work with pharmaceutical companies in this dynamic field and we are keen to develop co-operative research and development agreements with pharma. Such collaborations are important because the complementary resources within academia and industry can speed up translational research into clinical applications, and finally new treatment options for patients. In the future, I envisage that collaboration between universities, hospitals and industry will be necessary in order to succeed. We need to collaborate, not compete, to ensure that all patient groups will gain access to new CGTs. Technological development within CGT is moving at a fast pace and decentralised manufacturing may become more common. Collaboration between academia, industry and policymakers as well as across boarders will become increasingly important.

As a nation, Sweden is gearing up to be prepared for the future of CGT and Karolinska ATMP Center aims to be at the forefront of ATMP readiness and development by accelerating in-house research to clinical application, but also by extensive collaboration at all levels. By working together, we are all stronger.

Stockholm Uppsala Life Science Cluster

## Interested in knowing more or exploring this region further, get in touch!

We are the official business and destination development agency for the City of Stockholm, responsible for the international promotion and strategic development of the city. We are dedicated to promoting and developing our city as an attractive and sustainable destination for business, international investors, talent and visitors.



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