INSIDE MEDICON VALLEY

Number 1 | 2022

The Leading Life Science Cluster in the Nordics

World-leading Innovations and Groundbreaking Research

Collaboration Through the Triple Helix Model

Finding the Work-Life Balance

One region with access to two countries

Medicon Valley is the strongest life science cluster in the Nordic countries. The region is spanning eastern Denmark and the southernmost part of Sweden, and is home to a vibrant ecosystem and a deep talent pool underpinned by world-class life science universities and research infrastructure. A competitive business environment and high quality of life in the Nordic makes Medicon Valley an attractive location for both businesses and people.

Nordic innovation is globally recognized, and our life science ecosystem reflects this. In Medicon Valley, we take pride in our rich life science heritage, which spans over a century.

Medicon Valley as a whole is greater than the sum of its parts. It enables synergies and collaborations and is a place to exchange ideas, knowledge, and services. The area bridges borders, disciplines, and the public private divide. A key driver for its success is the massive talent pool in life science, software development, artificial intelligence, machine learning, and tech, which, combined with world-class universities and a unique research infrastructure, creates uniquely fertile soil for new companies to grow and for existing companies to expand.

Whether small or large, Medicon Valley is the perfect location to find your next spark of innovation.

/ Anette Steenberg,
CEO of Medicon Valley Alliance

Ulrika Ringdahl,
CEO of Invest in Skåne

Asbjørn Overgaard,
CEO of Copenhagen Capacity

Medicon Valley by the numbers

- 1,500+ biotech, medtech, healthtech, digital health, and pharma companies with local R&D, including companies using artificial intelligence, machine learning, and quantum computing in developing services and solutions
- 5 global R&D pharmaceutical companies; Ferring, McNeil, Novo Nordisk, Lundbeck and LEO Pharma
- 50,000 employees in the private life science sector
- 9 life science universities with 24,000 life science students
- 14,600 life science researchers
- 6,000 life science and health-related PhD students
- 7 science parks with a major focus on life science
- 10 incubators
- 9 university hospitals (28 hospitals in total)
- New, world-class research facilities ESS ERIC (European Spallation Source) & MAX IV

The survival of devices following EU-MDR and FDAs more stringent scrutiny on clinical data

Watch our video and get a glimpse of what key2compliance is all about!

key2compliance.com

It has been predicted that 50% of all medical device products on the European market will vanish after the MDR curtain has fallen. This produces huge opportunities for companies that are proactive and understand that MDR is not a problem but rather an opportunity.

The biggest impact on life for medical device companies following MDR will be in the clinical evidence that will need to be collected or produced. And there is no time like the present. All devices on the market need to have their post-market-surveillance in place according to MDRA already. Keep in mind, that this is one way to collect further clinical data.

Updated regulations such as the European Commission's MDR, and recent signals from the FDA, mean closer scrutiny of clinical data. As a result, there are more stringent requirements to issue regular, accurate updates including Clinical Evaluation Reports, Post-Market Clinical Follow-Ups, and Period Safety Update Reports. If device manufacturers are not in compliance, they may face both legal and commercial consequences. Be on top of the requirements and you will be one or more steps ahead of your competitors.

If you are uncertain about the value of the clinical data you collected under the MDD, and if you are uncertain about what you will need to produce to be MDR compliant then start with a GAP analysis and updating your clinical evaluation.

It is hard for medical device manufacturers to find the right partner for clinical development. It is not unusual to test pharma competent CROs, both global and local, without receiving the required support that is part of understanding the particulars of the medical device field. There is a huge difference between clinical development in pharma and medical device. Without the correct knowledge any investment in clinical evidence will be in vain. For that reason, in 2020 Key2Compliance decided to start a new business area, Clinical Development. "We did not want to call ourselves a CRO as a lot of medical device and in vitro diagnostic companies unfortunately have bad experience in working with typical pharma CROs", says Jan Hellqvist, CEO at Key2Compliance.

> Our most important asset is our dedicated staff. Our team consists of specialists from all over the world, with long and broad expertise in all aspects of the development of medical devices and in vitro diagnostics. It is the team that makes the difference!
>
> Jan Hellqvist – CEO

One of the usual practices of pharma CROs, include: 30-50% down payment at the signing of the contract, out of scope invoicing, payment according to plan and not according to progress. If a small or mid-size medical device manufacturer contracts a global CRO they will get junior staff with a 30-40% staff turnover, and the person involved in starting your study will not be involved at the end of the study, which is costly both from a relationship and competence aspect. "This is not the way we want to work at Key2Compliance and the reason to why we have decided to call ourselves a Clinical Development partner in medical device and in vitro diagnostics", says Jan Hellqvist.

Key2Compliance have hand-picked an experienced team of device experts forming a full-service team that can support you with your clinical investigation, clinical evaluation, post market clinical follow up, performance study and much more. At the start of a collaboration, we will always recommend doing a GAP analysis to evaluate what you have and to help you develop a regulatory and a clinical strategy to set the road from where you are to success.

"We can support you in fully outsourced projects or work as an integrate part of your team - always with focus and competence needed in your clinical development", says Maria Lindgren, Director Clinical Development. "We have all the skills you need such as Project Leaders, CRMs, CRAs, CTAs, Statisticians, Data Managers, Device Vigilance experts, Medical Advisors and Medical Writers. We have a digital set-up with effective eCRFs, eTMF so all documentation in your investigation is placed safely online" says Maria Lindgren.

Key2Compliance can do both local and global projects through a network of more than 30 000 experienced freelancers. Using a freelancer network instead of a global CRO will save you money, time and give you experienced support where you need it.

Contact us for a discussion about how we can help you reach your road to success.

Key2Compliance is a full-service partner to small and mid-size medical service and in vitro diagnostic companies with services including Quality Assurance, Regulatory, Biological Evaluations & Toxicology, Clinical Development, GxP services and Training & Courses. We also support a large number of pharmaceutical companies with courses and training, custom made competence development, quality assurance and training and consultancy within the entire GxP area.

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• RELY ON US •

Amniotics

Amniotics at a Glance

- Founded in 2015
- HQ in Medicon Village in Lund Sweden
- Based on research at Lund University Stem Cell Center and Skåne University Hospital
- Unique technology platform within mesenchymal stem cells (MSC)
- Own in-house GMP stem cell manufacturing facility with contract manufacturing capacity
- Therapeutic pipeline with lead product to enter phase I/II in 1H 2022
- Listed on NASDAQ First North in Stokholm (ticker sympbol AMNI)

Amniotics offers state-of-the art GMP facility to accelerate the development of novel cell therapies in Greater Copenhagen area

From the get-go, biopharmaceutical company Amniotics in Lund, sets a clear goal, aiming for independence and control of its own value chain. This move, focusing on developing innovative stem cell-based therapeutics, has resulted in a state-of-the-art GMP-facility developed and operating according to the guidelines specific for ATMP. Besides using it for its own production of stem cells for clinical trials and later on for commercial products, the investment has also proved successful in attracting global talent. Amniotics is now assisting academia, hospitals, and industry with sought after technical capabilities in turning promising cell therapy ideas into reality.

Advanced Therapy Medicinal Products (ATMP) is a growing area for development of innovative cell-therapies where effective treatment is currently lacking or insufficient. As the field is expected to grow in the coming years, market potential was part of the rationale for taking a calculated risk and investing in its own production capacity for Amniotics.

- There are a lot of people that know their way around in a lab environment, but there is a lack of knowledge and experience on how to go from R&D to GMP. With our experience, we can be a technology and service provider to those who want to do clinical trials, as well as those who want to start a company, says Jan Talts, Chief Operating Officer at Amniotics.

Providing sought after technical and regulatory expertise

With new facility and the necessary infrastructure in place, Amniotics has attracted attention from the global cell and gene therapy community. Now, the growing Amniotics team is made up of global talent specialized in aseptic production and quality control/assurance. The facility is operated according to the specific GMP for ATMP guidelines (that regulate the development and commercial production of cells, tissues, or genes therapies). With six separate Class B rooms, the facility is large enough for Amniotics to manage parallel tailor-made processes of aseptic manufacturing of products for preclinical and clinical studies.

"We have benefited greatly from our discussions with Amniotics regarding GMP production of our investigational ATMP" says Professor Marlin Parmar at Lund University"

Today, there are only a few approved ATMPs on the global market. The number of clinical trials for cell and gene therapies has increased significantly and this bode well for the future success. Amniotics aims to assist the biopharmaceutical industry, universities, and hospitals with contract manufacturing as well as technical and regulatory advice.

- We have benefited greatly from our discussions with Amniotics regarding GMP production of our investigational ATMP drug prior to our planned clinical trial. Every interaction with them has been very valuable, says Malin Parmar, Professor in Developmental and Regenerative Neurobiology at Lund University and New York Stem Cell Foundation – Robertson investigator.

Open to partnerships in developing stem-cell-based therapies

In the UK, a network of facilities and established collaborations between industry, hospitals and universities is already in place. Though the interest in ATMP is great and growing, also in Europe, there is a shortage of facilities and lack of capacity rooted in a lack of investments here.

"We hope to attract interest to our GMP facility and be the nucleus of a development similar to the network in UK" says Jan Talts, Chief Operating Officer at Amniotics

- With the great number of companies within lifescience, several universities and large hospitals in the Öresund Region/Nordics, we hope to attract interest to our GMP facility and be the nucleus of a development similar to the one in UK. In partnerships, we can collaborate in accelerating and making new innovative life-changing and regenerative treatments available for patients, says Jan Talts, Chief Operating Officer at Amniotics.

About Amniotics

Amniotics is a biopharma company focusing on mesenchymal stem cells (MSC) from amniotic fluid. The company was born out of the discovery of a novel source of stem cells in full-term amniotic fluid. Based on a decade of research at the internationally recognized Lund University Stem Cell Centre and the Skåne University Hospital in Lund, the company is pioneering the harvesting and propagation of tissue specific neonatal quality mesenchymal stem cells (MSC). These stem cells have unique properties for applications in regenerative medicine. Amniotics also has an, by Läkemedelsverket (Swedish MPA), approved GMP (Good Manufacturing Practice (GMP) manufacturing facility to produce Advanced Therapy Medicinal products Products (ATMPs). With the GMP facilities operational since 2020, Amniotics is now moving into clinical trials with the leading drug candidate, PulmoStem™ and is looking to establish strategic partnerships with researchers and companies that are interested in developing stem-cell-based therapies targeting diseases with high unmet needs. Amniotics has its headquarter in Lund, Sweden.

Learn more at www.amniotics.com

Medicon Valley's innovative life science ecosystem

Medicon Valley is the Nordic's largest life science cluster, dating back to 1997. It is bi-national, situated in what is internationally called the Greater Copenhagen area, or the Öresund Region, with more than 4 million inhabitants. The region is spanning the eastern Danish region of Zealand and the capital, and the Scania Region in southern Sweden.

The companies in the Danish-Swedish Medicon Valley employ more than 50,000 people, with almost a thousand employees border-commuting via the Öresund Bridge every day.

Triple helix

The triple helix is the combination of government agencies, research infrastructure, and business networks creating a holistic approach to life science development in Medicon Valley. Here, work is done in an intensive, integrated, and connected way to help academia and business cooperate, share ideas, innovate, and secure business success. The result is a sophisticated ecosystem focused on the same goal: building a stronger cluster that creates opportunities and reduces time-to-market.

Denmark and Sweden work across the Öresund to build highly advanced research facilities, and Danish and Sweden investment companies join together to create new ideas. Innovation and new startups take shape at universities and science parks in Medicon Valley, bringing together Danish and Swedish expertise. Swedish and Danish companies, organizations, labour forces, capital, and research merge in the Öresund Region's life science sector.

Biotech companies recruit expertise from Skåne. Danish companies list in Sweden with the help of Swedish financial players. Life science companies from Skåne recruit experienced business managers who have been schooled in Denmark's global enterprises. And research groups work across the Öresund to reach joint goals of finding new treatments.

Strengths

One of Medicon Valley's shared Danish-Swedish strengths is that the Medicon Valley region both conduct globally leading research in diabetes, fertility, and cancer. Research is carried out commercially via beacon companies such as Novo Nordisk, Ferring Pharmaceuticals, and Genmab, as well as at universities, where the researchers further boost the region's scientific strong points. Approximately 1,700 cancer researchers, 1,000 diabetes researchers, and 150 reproductive researchers work in the region.

Science parks' and incubators' role in the ecosystem of life science in Medicon Valley

Medicon Village is a science park focused on life science located in Lund with around 170 companies where 2,700 people work daily. At Medicon Village, academia, public sector, and business are all in one place, and the science park creates a stimulating growth environment for ideation and collaboration. Medicon Village was established in 2012 and is owned by the Mats Paulsson Foundation for Research, Innovation and Societal Development. The terms of the foundation stipulate that any surplus must be re-invested in research and innovation, which is a different construction compared to traditional science parks. Medicon Village, which is celebrating its 10th anniversary in 2022, is an integrated part of Lund's innovation district, with close proximity to Lund University, Skåne University Hospital, and research facilities, such as MAX IV and European Spallation Source. Medicon Village is also home to SmiLe Incubator, a non-profit business incubator with a strong track record in supporting start-ups in their growth journey. Petter Hartman, CEO of Medicon Village Innovation, says that we in Scandinavia traditionally have a very strong tradition of innovation-supporting activities and public-private partnerships.

– When you look at the European Commission's innovation index, which measures the power of innovation, Sweden and Denmark always end up in the top. And one of the explanations is the strong expanded innovation support system we have, with science parks, incubators, and accelerators as very important components. There is a very clear ambition to create conditions for companies to be formed based on research at universities.

There are five science parks that are wholly or mostly focused on life science in the Medicon Valley area, and most are directly adjacent to the strongest university areas on both the Swedish and Danish sides. They are all growing and expanding, because the demand for operating in such an environment has increased in recent years. Today, there are about 1,500 companies in science parks in Medicon Valley. In combination with successfully offering start-up programs, scale-up programs, contact with financiers, and business developers, the development of small companies in the region is promoted. The small companies can get advantages from being close to each other and finding partners, exchanging experiences, skills, and services – and thus grow stronger.

> ''We are among the strongest in Europe in creating these innovation environments''

– In the Scanian part of Medicon Valley, it is actually the case that every other life science company is located in a science park, says Petter Hartman.

– It illustrates the important role of science parks. That we are good at generating companies out of universities has generated this strong growth in science parks and the increase in demand. With the help of the universities' tech transfer offices, the natural flow is to move into the science park that is adjacent – there is a straight line from the universities to innovation and commercialization in the science parks.

It has been seen that science parks offer a favorable development for financing for the escalation of the companies, and that the incubators are good at making contacts with investors who choose to invest in local companies. This in combination with strong research as a foundation and a strong entrepreneurial culture has created a high level of credibility around the science parks.

– We are among the strongest in Europe in creating these innovation environments. This is part of the reason why we have received such a high ranking in the European Commission's innovation measurements, Petter Hartman explains.

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Transferred to Denmark and found improved work-life balance

Leticia "Tisha" Boatman is the CEO for Denmark, the Nordics, and the Baltics at Siemens Healthineers, a global medtech company with the ambition to pioneer breakthroughs in healthcare, for everyone, everywhere.

Almost eight years ago she moved from Silicon Valley, USA, to Copenhagen, to manage 650 employees.

– I've been with Siemens for 16 years, and eight years ago I was given an opportunity to transfer to northwestern Europe, and was given the choice of where I wanted to live. Me and my husband looked at convenience of travel, because pre-COVID I travelled all the time, and also at potential for my husband to find a job; he also works in the life science industry, says Tisha Boatman.

They were moving with an almost two-year-old and a five-year-old, so it had to be a good move for the family.

– That was part of leaving the global job I used to be in; I was tired of the kids playing "mommy goes on a business trip" - I wanted to be more locally focused, and I wanted a good quality of life.

Tisha Boatman explains that there is a big difference in work-life balance between Silicon Valley and Denmark:

– In Silicon Valley it was a very competitive environment. All managers are expected to work the longest hours, you have to come in first in the morning and leave last, and that's not the expectations here. In Denmark you almost look down upon workaholics - there is a big difference there. And here, as CEO, I'm not expected to do everything and drive everything. I'm expected to care for my team, while of course keeping an eye on the business, but the lack of hierarchy in the Nordics means that I see employees stepping up much more. There is more openness to hearing ideas from all different parts of the organization, and I appreciate that.

When it comes to family life, Tisha Boatman also says that Denmark is better in terms of maternity and paternity leave, child care, and the clear expectations that men carry as much weight as women.

– My husband always felt that way, but in practical terms it's harder in the US, the environment isn't there for it. He took two weeks off when our babies were born, and people were like "Wow, you took two weeks off to help!"

The situation for the children is also different in Denmark compared to Silicon Valley:

– The fact that Denmark has subsidized programs for kids, for arts and sports and science – that's very expensive in Silicon Valley. That results in a small group of elite kids who can do that sort of thing – they don't have the broader horizon for kids, there is a huge difference in how kids grow up. To have enrichment activities at a reasonable price, and also the fact that it is very safe here. I can put my 12-year-old on the train to cheerleading; in Silicon Valley I would have had to pay someone to drive her. There is no public transit that is in any way safe for people under 16, there is a huge difference in safety in general.

Tisha Boatman summarizes:

– As a working parent, it's a lot easier here. The culture really supports dual income. The norm is that both parents work, which is not the case in the US. The system with child care and after-school activities, it really facilitates balance.

The Boatman family at the American Chamber of Commerce Denmark Family Thanksgiving Dinner at the Copenhagen Marriott Hotel. Tisha Boatman is the Chairwoman of the Board at AmCham Denmark.

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Kushagr Punyani enjoys the Nordic open collaborations

When moving from India to Sweden, Kushagr Pynyani found life easier. Less stressful both at work and overall in society, and an openness in the work culture creates results.

He is the founder and Chief Scientific Officer at Spermosens, and also one of the founders of Diagonal Bio. Spermosens, founded in 2018, focuses on solutions to male infertility problems, with a groundbreaking new approach to analyzing sperm. "Kush" Punyani explains:

– Male infertility is very relevant, and there is lack of good diagnostics. Today all diagnosing of sperm is done microscopically, it's all about the shape, size, and how they move. We took a different approach, where we don't have to rely on optics at all. We are working on developing a diagnostic device where we look at infertility from a functional aspect, how the sperm do their job and bind to an egg cell.

The technology used is a special electrochemical biosensor:

– We produce the JUNO and ZP3 proteins that egg cells usually produce and put them on an electrochemical sensor. We then allow the sperms to bind and measure the response electronically. The embryologist can then decide which kind of IVF treatment is suitable for the couple.

– It is known that male and female factors share equal responsibility in terms of infertility. 3.2 million IVF cycles run every year, and unfortunately, they have a poor success rate of 15–20%, Kush Punyani explains. He came up with the initial concept for Spermosens when he was an undergraduate in New Delhi, India, in 2011. In 2014, he moved to Lund in Sweden after applying for an open position at Lund University:

– I didn't come to Sweden for Sweden, but for the science. It was a very good group that I was excited about, Kush Punyani says with a laugh.

He sees many differences between India and Sweden:

– It's not as stressful here, and the lifestyle is easier. You don't have to fight for simple things here. In Delhi there's a lot of people, it's very crowded, a lot of traffic, and there are resource limitations since it's a developing country. So when I moved here, it was just an easier lifestyle, and on top of that the work environment is much more relaxed. The focus is on the process and learning, and then results happen – it's not so goal oriented; the speed of working is more relaxed.

He also thinks it's very different in terms of hierarchy:

– Sweden is as flat as it gets, and India is as top-heavy as it can be, there is a very big difference. A welcome one, of course!

Since moving to Sweden, Kush Punyani has started several companies:

– Spermosens is one of the first companies that I founded, and after that it's been a few more. In April 2020, right after COVID-19 entered Sweden, we started Diagonal Bio, which is developing a PCR alternative for diagnostics of infectious diseases. Diagonal Bio has also benefited a lot from this open culture. The fact that we were welcomed to Lund University with open arms to do experiments and research – within two weeks we had a company with a first proof of concept.

– In Medicon Valley there are so many collaborations between universities and industry, the general quality of research happening at the universities is high and relevant from a global perspective. There is openness to discussion, which is something I definitely enjoy. I didn't finish my PhD, but still I managed to found startups and lead them. It's a result of open collaboration and that there is infrastructure available for entrepreneurship.

Du ärvde din mormors humor, kärlek till jazz och

Få vet att typ 2-diabetes beror lika mycket på arv och miljö som livsstil. Detta skapar fördomar som komplicerar vardagen med sjukdomen. Ingen person med typ 2-diabetes är den andra lik. Men alla förtjänar ett liv med långsiktig hälsa. Utan komplikationer.
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Carolin Clausen appreciates the lean Scandinavian organizational culture

Carolin Clausen is Crop Science Country Commercial Lead Nordics & Managing Director at Bayer Denmark. Her origin is German, and she has been with Bayer for 12 years in various roles across divisions.

After starting with assignments in the pharma division, she moved on to the finance and strategy department in Crop Science, where she investigated global growth opportunities and investments in agriculture. With Bayer being the leader in agriculture in most markets, she gained a broad overview of agricultural challenges and needs and could specifically liaise with adjacent industry partners that would help to shape the future of sustainable and digitalized farming. She then took on a more operational role, being the lead of business strategy for Mediterranean countries and Africa. Being based in Barcelona, she describes her assignment as a fantastic opportunity to deep-dive and learn about markets and cultures in and beyond Europe:

– My personal aim and motivation is to change things where we can. I am specifically interested in the digital uptake in agriculture, as this provides a lot of opportunities to establish a data-driven, intelligent way of using agricultural products. My assignments in various countries and now specifically in the Nordics, being known as the frontrunners in innovation, provides the perfect opportunity to test and engage in various pilots, Carolin Clausen says.

– Therefore, when I received the opportunity to move to the beautiful city of Copenhagen, it felt like the perfect place to be, although it was a bit of a climate shock coming from Barcelona, she laughs.

"It's just different"

When asked if she prefers to work in Germany or Spain compared to Denmark, she says:

– You can't say if it's better or worse, it's just different, which specifically shows pointing to the Nordic culture. Here in the Nordics, you can really feel and breathe the innovative climate in the way people are thinking and approaching problems and solutions. You can see that both at a company and customer level; there is a huge technological and digital adaptation rate.

– In addition, I personally appreciate the very lean organizational culture, which allows a very lean and fast decision-making. Hierarchical thinking is not appreciated, which leads to a very dynamic and encouraging company culture.

With Bayer being situated in Medicon Valley, Carolin Clausen only sees advantages:

– In general, it is important as a life science company to show a presence in such an important cluster of innovation. It is important to say "Hey, we are here, Bayer would like to participate and contribute in driving innovation!" However, it should not only be about "showing presence". Real advantages occur when bringing people from various companies together to drive diversity and foster a life science culture. Today, we have already installed common sports groups and joined lunches to embrace the positive spirit, that the innovative culture provides, and, of course, we would welcome further activities that allow and strengthen collaboration.

Medicon Valley's high-ranking universities

Universities in the Medicon Valley area are standing strong against international competition. Three of the region's universities are included on the annual QS World University Rankings of the world's top 100 universities: University of Copenhagen, Lund University, and the Technical University of Denmark. The number of students in life sciences is around 27,000 - in the medical, science, and engineering faculties. Multiple smaller universities and colleges in the region also offer education in the life sciences, for example Malmö University, Kristianstad University, and Roskilde University.

The Greater Copenhagen area is home to 4,4 million inhabitants and is uniquely positioned for performing groundbreaking research and successful innovation. It boasts 17 institutions of higher education, with University of Copenhagen and Lund University regularly ranked among the world's top 100 higher education institutions. Here, cutting-edge research and education exists in almost all scientific areas, including life sciences, material sciences, research on climate change, and sustainability, but also human rights and economics and management. This is done by 14,000 researchers and 150,000 students that are being prepared for careers on a global scale, perhaps starting within one of the 17 research parks and incubators that exist within the region.

– Erik Renström, Professor and Vice-Chancellor at Lund University

The life science ecosystem in the region is developing fast these years, and the coherence between academia, clinics, and the whole life science industry innovation ecosystem is being enforced. More early stages ideas are being developed and financed, more companies are seeing daylight – and with the help from strong private foundations, public funding, and private companies, the flow of knowledge from academia into society seems to increase to benefit and increase the region's innovation capacity.

– Trine Winterø, Vice Dean of Innovation and External Relations at University of Copenhagen

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World-leading research

In Medicon Valley, there is pioneering research going on in several life science fields on both the Swedish and Danish sides of the strait. Some of the particular areas with ground-breaking results are diabetes, oncology, inflammation, reproduction and fertility, stem cells, neuroscience, microbiome, diagnostics, and precision medicine.

World-class research is matched by top-notch facilities with knowledge-sharing networks, advanced medical record databases, comprehensive health registers, and support organizations. Medicon Valley is a great location for conducting clinical trials because of the access to the health-care system and unique health registers and biobanks. For example, the regional biobank for Skåne is one of six biobanks in Sweden, where there are a total of 24.2 million samples.

Diabetes

Medicon Valley is a globally leading center for diabetes research. There are strong research teams at hospitals, universities, research centers, and companies in both Denmark and Sweden. The Danish company Novo Nordisk goes back to 1923 and is a pioneer when it comes to insulin production and now manufactures 50% of all insulin produced worldwide. Novo Nordisk also develops new and modern drugs for treating diabetes.

Cancer

Cancer research is Europe's fastest and largest growing field. In Medicon Valley there are more than 25 organizations that are focusing on cancer research, with collectively over 75 therapeutic compounds in the pipeline, and there are frequent collaborations between individual researchers and research groups across the Öresund strait.

Lund University has a strategic center for clinical cancer research, which brings together researchers from diverse fields, such as nanotechnology, proteomics, cancer genetics, and tumor cell biology to develop novel cancer treatments and diagnostics. One of the programs at Lund University brings together several different facets of cancer biology into a multifocal approach where early diagnosis, patient stratification, targeted therapies, and resilience are studied by collaborators from different scientific disciplines.

Inflammation and autoimmune diseases

Over 20 pioneering companies in Medicon Valley are working in the field of inflammation and autoimmune diseases, as well as many research groups.

Lund University has had a lot of commercial success in this area; from developed treatments for allergic asthma to infection control. Here, industry works with academia to create a synergy, resulting in one of the most respected centers for inflammation study, prevention, and treatment in the world.

There are also several research groups conducting research within the area in Denmark.

Neuroscience

Applied neuroscience is another area where Medicon Valley is considered a world leader. Although the volume of organizations in the

region is small, there are over 60 compounds in development.

A few examples are The Wallenberg Neuroscience Center, which focuses on understanding neurodegenerative diseases such as Alzheimer's, Huntington's and Parkinson's diseases, and an epilepsy center that has been established in Lund, where advancements are being achieved through strong cooperation with other universities and industry leaders within Medicon Valley. The Brain Research and Integrative Neuroscience Laboratory (BRAINlab) at the University of Copenhagen is aimed at understanding normal, pathological, and adaptive brain functioning at both molecular and systems level, and The Center for Neuropsychiatric Schizophrenia Research (CNSR) conducts multidisciplinary neuropsychiatric research.

Stem cells

In the field of stem cell and developmental biology, the research covers developing stem cells, cell replacement, and gene therapy. Both Lund University and the University of Copenhagen have stem cell centers. The one in Lund is both a stand-alone research center and an essential part of other research areas and projects, with the aim of pioneering advancements in new cell therapies, particularly for treating diseases that currently have no treatment options. The Danish center covers both basic stem cell biology and strategic translational stem cell research and therapy.

Reproduction and fertility

Reproductive research is conducted at Medicon Valley universities, hospitals, and companies. Ferring Pharmaceutical's largest research facility is situated in Copenhagen.

Many of the research environments throughout the region are part of the collaborative project ReproUnion 2.0, which has been active in various iterations for more than 10 years.

Microbiome

In Medicon Valley there are more than 80 companies, organizations, and institutions working actively within the field of the microbiome. The region's industry, academia, and clinical environments collaborate across disciplines to bridge basic and applied science, and to establish causalities and generate knowledge. All efforts have the ultimate purpose of enabling microbiome-based innovations for the benefit of health and the environment.

Precision medicine

Precision medicine marks a paradigm shift in treatment, from "one size fits all" to a model with stratification of patients into groups, based on biological information and biomarkers at the molecular level, to match the right treatment to the right patients.

The MAX IV synchrotron source in Lund is one integral part in developing precision medicine.

World-leading facilities with endless possibilities

The synchrotron facility MAX IV opened in Lund, Sweden, in 2016, and in 2027 the neutron source ESS will start its operations.

Jimmy Binderup Andersen is Head of Innovation and Industry at ESS, European Spallation Source. He is excited and eager about ensuring taking full advantage of the possibilities of ESS and MAX IV, the two big research facilities in Lund, Sweden:

– It's important that all the different involved stakeholders in the region prepare for the opportunities to come, he explains.

– ESS will be operational in 2027, and it is planned to enable world-leading neutron science. To be world leading doesn't really mean anything right away, but with excellent science opportunities there is no limit to how far we can go. People usually say that the sky is the limit, but we don't know what the limit is here!

We are talking to Jimmy Binderup Andersen on a business trip to the startup and innovation village in Hamburg, just 30 meters from the DESY synchrotron, similar to MAX IV.

''People usually say that the sky is the limit, but we don't know what the limit is here!''

– An innovative ecosystem is needed, where we can work together, share data, and be innovative together. In Hamburg they've built such an ecosystem for years – they are used to it. And in France, they also work together in an innovation setup. They are doing it around the world, and it should be done here too. ESS and MAX IV are physically situated side by side, but it's clear that you need to do more than have the scientific facilities to create impact for the region. Why not be ambitious?

To make innovative ecosystems work, they need to be sustainable, Jimmy Binderup Andersen says:

– I have analysed successful innovative ecosystems around the world, to see how they work and how they can be made sustainable without needing continuous funding from the state or EU et cetera, how corporates, entrepreneurs, governments, academia, and venture

capitalists can work together.

– In Europe, venture capital is often lacking, and there is a need to practice on being able to sustain innovative ecosystems. At ESS I am working on these topics, but it is not our core business – we will contribute to innovative ecosystems and help make them sustainable in the best way we can – being a part and supporting – but we can't do it alone.

Jimmy Binderup Andersen dreams of the Science Village Scandinavia evolving into a substantial innovation ecosystem, with facilities where scientists can work and cooperate:

– You normally don't stay on the instrument stations for very long; you maybe work there for a few hours, but you need to do pre-tests and prepare your samples in labs, and after the sessions with the facilities there are vast amounts of data to be processed and post-analysis of samples to be performed. It calls for a setup where we can cooperate, listen, help, and suggest solutions. "This molecular vehicle can carry insulin into our bodies, can it carry something else as well?" Create momentum for the things that can be done by ESS and MAX IV. I'm impressed every day when I walk through the gates to ESS! But ESS and MAX IV are "just" very big scientific tools that need to be used to create scientific and societal value. We need to make them and the science accessible for big companies and small companies, experienced companies and less experienced, involve organizations like Medicon Valley and others, give them different channels to see what they can be used for, and create value for society. Let's work together to get the most out of this!

MAX IV – where the invisible becomes visible

The MAX laboratory at Lund's University has been successful for 35 years, and in 2016 a new significant step was taken with the opening of MAX IV. When it is fully operational it will be able to welcome more than 2,000 scientists from around the world annually.

Brightness and world-class experimental stations

The MAX IV laboratory is one of the world's brightest synchrotrons and Sweden's most significant investment in research infrastructure of all time. Researchers travel to MAX IV from all around the world to perform experiments at the various experiment stations, the beamlines. MAX IV has 16 funded beamlines. Today, 14 beamlines supply light for research, while two are still under construction.

A wide range of research areas

At MAX IV, research is conducted on everything from components for electronics to catalysts and in environmental science. Some recent publications include artificial wood with tailor-made and reproducible properties, ultra-strong steel for lighter and more sustainable transport, energy storage, cloud formation affecting climate models, and insights into Alzheimer's disease, antibiotic resistance, and cancer.

High-quality light provides excellent opportunities

Because the light produced at MAX IV is of high quality, researchers can see more details and do types of experiments that could not be performed before. It gives us the opportunity to learn about materials closer to actual and dynamic conditions in, for example, an industrial process or inside a cell.

ESS opens life sciences to neutrons

Thanks to a collaboration of 13 countries, one of the world's most powerful neutron sources is being built in Lund, Sweden, with its data center in Copenhagen, Denmark.

European Spallation Source, a collaboration of 13 countries, are cooperating to build and operate one of the world's most powerful neutron sources. ESS is being built in Lund and with Data Management and Software Centre in Copenhagen. The investment is done with one leg on each side of Öresund in the midst of the strong Medicon Valley. There is a good reason why this is so. Life science research faces numerous challenges in the study of biological processes that occur on the atomic to cellular scale, such as large macromolecular complexes, the function of water in enzyme mechanisms and drug-substrate-product binding, and the role of biological macromolecules in membranes. Neutrons are ideal probes for the study of biological samples as they are very sensitive to hydrogen-rich materials.

With unparalleled neutron flux and sophisticated support facilities, ESS will open the field of life sciences to neutrons and make an entirely new set of scientific experiments possible. There are several instruments that will be either dedicated to or excellent for life science studies, from single-crystal diffractometers to small-angle neutron scattering instruments. The ESS Data Management and Software Centre designs, develops, and supports the ESS scientific data pipeline, including experiment control, data acquisition, data curation, scientific web applications, data reduction, data analysis and modelling, data systems, and data centre operation. With operations starting in 2027, the position for Medicon Valley as a hub for life science will be strengthened.

Precision Medicine at the forefront

There is a paradigm shift about to happen in treatment, from a ''one size fits all'' view to precision medicine. That is about the stratification of patients into groups, based on biological information and biomarkers at the molecular level, to match the right treatment to the right patients.

In the last 15 years, the cost of mapping a human genome has fallen from USD 100 million to below USD 1,000, enabling a paradigm shift in treatments.

Medicon Valley is at the forefront in the field, with Sweden ranking first in European funding awarded to advanced therapy developing companies between 2014 and 2019. Skåne is one of five precision medicine hotspots in Sweden with more than one fourth of the companies.

Sweden's health care system, where every Swede carries a personal identification number for all healthcare documentation and the country having extensive biobanks with 24.2 million samples, combined with the latest available technologies are factors contributing to major research achievements.

Some multiple precision medicine initiatives in Skåne

GMS, Genomic Medicine Sweden, is coordinated by Region Skåne in close collaboration with Karolinska Institute in Stockholm. GMS was founded in 2018 with the aim of translating innovation in genomics into clinical practice and implementing a sustainable infrastructure for precision medicine in Sweden.

CTG, Center for Translational Genomics, works closely with the Center of Molecular Diagnostics (CMD) at the Division of Laboratory Medicine at Region Skåne, to offer expertise and service in genomic technologies to facilitate clinical implementation of new diagnostic assays within healthcare.

At Lund University, precision medicine research is done at the Stem Cell Center and Wallenberg Centre for Molecular Medicine. More than 20 independent groups are specializing in stem cells from different organ systems to develop novel cell therapies through holistic understanding of genetic pathways regulating stem cell fate decisions.

Marianne Holst
EVP Regulatory & Safety Operations
info@LINKMedical.eu

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Developing and producing bacteria of the highest quality

Chr. Hansen is a part of the regional microbiome ecosystem in Medicon Valley. Having produced beneficial bacteria for food supplements for decades, the company is now a strong contributor in the microbiome science field.

Adam Baker is Director of Science, Microbiome, at Chr. Hansen, the Danish global bioscience company that develops natural solutions for nutritional, pharmaceutical, and agricultural industries, with the goal of creating a more sustainable future.

– I work with understanding the science behind individual products in food supplements and developing the science, looking mainly at how bacteria can influence your health, Adam Baker says.

– The probiotics, or beneficial bacteria, that we sell at Chr. Hansen, we've sold them for decades. For example, some yoghurts that you buy in the supermarket have them. But microbiome is a new science area, and it means that science is catching up with how good for our health these bacteria are.

Chr. Hansen works with microbiome in several different ways. The biggest division is Food Cultures & Enzymes, where they make dairy products, like yoghurt that can contain probiotic bacteria. The second is the Human Health area, and Adam Baker explains:

– There we focus specifically on delivering bacteria for health benefits. The third area where we work with microbiome is understanding the science of microbiome and how we can treat diseases with bacteria. And to produce them for medicines we have a company that's spun out: Bacthera, which is developing and producing bacteria of the highest manufacturing quality so that partners can come in and develop them to produce high quality medicines to treat people. It's a very new science.

Adam Baker moved from England to Denmark 14 years ago for family reasons and says that when he came to Copenhagen after having worked in the field of cancer and complex diseases, it wasn't that easy to find a job, even though human health is a strong focus area in Copenhagen.

– It was difficult to get a job in Denmark in the field I was in; it wasn't quite open to international staff.

But he thinks that Medicon Valley having become a strong science and research hub has made it more open:

– It's a slightly interesting twist: I now have five different nationalities working in my group. I think this microbiome center and hub is allowing Denmark and Sweden to become a more international environment. It's very beneficial for what Chr. Hansen is doing. We produce food supplement products, but with Medicon Valley being a very important, concentrated center for science, research, and clinical research, which is also for production of food supplements and medicines, we have a whole ecosystem. We don't just have research, we don't just have clinical science – we have all of those things. It's very powerful.

A leading hub for microbiome research

The EU-funded Microbiome Signature Project aims to strengthen Medicon Valley as one the world's leading microbiome research hubs.

The microbiome is comprised of microorganisms (or microbiota) that live on and inside the human body. Research in the microbiome is a relatively new interdisciplinary field that takes place across several established research fields. It has gained high interest in recent years due to its links to a number of conditions, ranging from inflammatory bowel disease to diabetes, multiple sclerosis, rheumatoid arthritis, and certain types of cancer. Hopefully, research in the microbiome field can lead to breakthrough treatments of these diseases.

Close collaboration between researchers, clinics, life science companies, and private investors is crucial to enhance the knowledge in the microbiome field so that we can better understand the role of the microbiome in our health, which will lead to research and products that benefit health outcomes.

For the past 2.5 years, the Microbiome Signature Project, jointly led by Medicon Valley Alliance, Copenhagen Capacity, and Invest in Skåne, has strengthened the exposure, collaboration and engagement of the microbiome ecosystem in Medicon Valley, the life science cluster of the Greater Copenhagen Region.

– Our Microbiome Summit attracted more than 600 participants across some 60+ countries, three new companies have opened offices in the region, and the project's talent campaigns have attracted more than 65 foreign talents to move here, says Sarah Lidé, Senior Strategy & Project Manager at Medicon Valley Alliance and the Project Manager for the Microbiome Signature Project.

Cloud-based services to enhance research output and collaborations

Ledidi is set out to equip Health and Life Science researchers with more efficient tools in their quest of providing valuable insights and knowledge that will improve health on a global scale.

– Though many other areas have moved forward using new and innovative technology, researchers to a large degree are still stuck with old fashioned, on-premises solutions that are neither efficient, nor user-friendly", says Einar Martin Aandahl CEO of Ledidi – a Science- and software company established in Oslo.

Based on their self-experienced frustration from health research, the doctors and researchers of Ledidi joined forces with a group of IT-engineers with high expertise inn cloud computing. The result is Ledidi Core, an all-in-one, cloud-based research platform that covers the entire research workflow from study design, data capture and structuring, analysis, and graphical presentation. Analyses are done real-time without the need for manual re-structuring and preparation of the raw data.

– Researchers need to be able to securely collect, process and share data across organisations and borders," says Aandahl and points out that existing solutions do not facilitate data sharing and collaborative workflows well enough.

Better research with more collaboration

The COVID-19 pandemic has been a brutal reminder of how dependent we are on efficient and collaborative efforts within research and science. Health is not limited along national borders, and to be able to respond efficiently to health threats, international collaboration is crucial.

– In a pandemic situation, it is important to quickly and seamlessly set up collaborations",
says Aandahl.

During the pandemic, Ledidi Core has been used in Norwegian hospitals for Covid studies - with good results and positive feedback. Ledidi helped several studies get fast up and running, and enabled researchers and clinicians from all the Norwegian hospitals to contribute to collaborative studies.

Research collaborations are important also outside of a global health crisis.

– Today, there are increasing demands for collaboration in research", Hanne Valeur, Chief Communication Officer of Ledidi, explains. "By collaborating researchers are able to provide larger and richer datasets to draw solid conclusions."

There is often a requirement for collaboration to obtain funding for studies - both across organizations and disciplines.

– These demands points to the fact that collaboration provides better research and deeper insights," says Valeur.

– But to achieve true collaboration, we need tools that actually make collaborations work," Aandahl underlines.

Today, many research collaborations are limited to collecting data in a joint database, but the data is not available for analysis and further use for most of the collaborators.

– We wanted to make a platform where all collaborators can contribute through the whole workflow – from study design to analysis and interpretation of results. This makes collaborations more attractive for all parties."

Einar Martin Aandahl and Hanne Valeur from Ledidi.

All you need is a browser

Moving the scientific tools to the cloud, with a user-friendly interface, also make advanced scientific tools available to more researchers, even in low-resource settings.

– All you need to run complicated studies is a browser and an internet connection," says Valeur. "The user-friendly interface makes the researchers independent of local IT-support and programmers to set up a database. With Ledidi Core, the researchers are able to do it all on their own."

Ledidi envisions that their products will enable more research in Low- and middle-income countries and make it easier to run collaborations across countries independent of resource levels.

– Imagine the impact if we are able to lower the threshold for doing research on a global scale," Valeur concludes.

Visit www.ledidi.com to learn more about Ledidi.

ledidi

Infection Control – crucial for our future

The primary aim of infection control is to prevent infections from spreading- and healthcare-associated infections (HAI) from emerging. HAI is a global health challenge, growing with the increasing antimicrobial resistance (AMR).

Many experts claim that AMR will be the next pandemic, diminishing the tools available today to prevent and treat infections. Innovation and implementation of new solutions to combat AMF, HAI, and pandemics in the future is therefore of the highest importance.

Sweden is in the forefront against antibiotic resistance, having successfully contained the use of antibiotics to a level lower than most EU countries. There is also a low level of antibiotic-resistant bacteria.

In Skåne, there are over 60 companies active in the field of infection control. Since 2018, more than SEK 270 million has been allocated in research funding for over 75 infection control projects. Also, more than SEK 25 billion has been invested in the world-class infrastructures MAX IV and ESS with applications for life science and infectious diseases.

With Skåne being a part of Medicon Valley, there are countless opportunities for collaborations between companies, hospitals, research facilities, incubators, and science parks. The networking organization Medicon Valley Alliance connects the region's triple helix of universities, healthcare, and companies.

An investment of SEK 12 billion in Skåne University Hospital in Malmö will give it state-of-the-art flexible facilities and solely single-patient rooms with bathrooms included to reduce spread of infections and improve overall hygiene, a centrally located sterile technical center that cleans, disinfects, and sterilizes instruments, high ventilation standard in all clinical areas, and improved transformation flows through culverts between buildings to guarantee patient safety and fulfill collaborative needs. This will be completed in 2025.

Focus areas

Some examples of focus areas in Skåne:

Wound care is one industry stronghold. There is a strong setup of innovative companies within the wound care segment, several of which are spinouts from research at Lund University.

Sepsis is being fought with cross-sector initiatives and innovative industrial actors with medical devices and pharmaceuticals for treatment of sepsis.

There is a strong triple helix engagement in the emerging infection control opportunity microbiome. Microbiome is a relatively new area with the opportunity to profoundly influence prevention and treatment of infectious diseases. Over 80 organizations within the triple helix are working actively within microbiome in Medicon Valley, making it one of the leading ecosystems in the world in the field.

Significant initiatives were also taken during the COVID-19 pandemic within clinical research, adaptation of research, rapid industry response, and a COVID symptom-tracking app.

Infection control projects

A few examples of ongoing or recent research projects within the infection control field are:

- Identification of drug targets in infectious diseases, with the aim to address the molecular mechanisms involved at each stage of the infectious process.
- The role of complement inhibitors in infectious diseases and immune regulation, which aims to understand how bacteria manipulates the immune system and how that can be used to design vaccine candidates and treatments.
- Spatiotemporal gene expression in secondary lymphoid tissue during hyperacute HIV infection, with the objective to identify key virus-host interactions in early infections.
- Novel strategies to avoid and treat infection with antibiotic resistant bacteria, which aims to create a world-leading research environment within infectious diseases and antibiotic resistance.
- Fighting infection and inflammation by utilizing innate immunity, combining our bodies' defense mechanisms with technologies in drug design and therapy development to develop new anti-infective therapeutic concepts.
- Prevention of surgical site infection after vascular surgery – multicenter randomized controlled trials, aiming to study virulence mechanisms with the long-term goal to define new antimicrobial treatment strategies.

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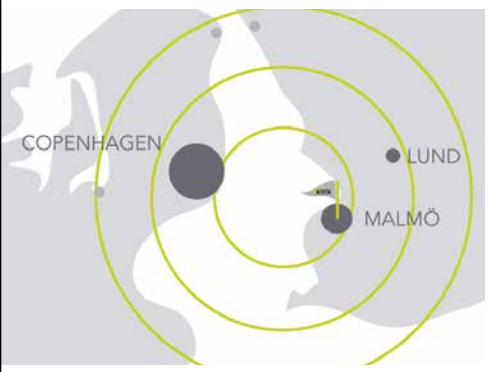

The Science Park in Malmö, in the center of Greater Copenhagen and in the heart of Medicon Valley.

An ecosystem in diabetes

- Diabetes Samverkan Sverige (*Diabetes Alliance Sweden*) – project management
- World Diabetes Day – organizer
- Diabetes Center – process initiation, collaboration between healthcare, academia and business
- LUDC Lund University's Diabetes Center – close partners
- Diabetes Focus Team – support for SMEs
- The Medeon Prize – focus on diabetes, awarded annually

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Trial Nation offers a single, national entry point for life science companies, patient organizations, and clinical researchers wishing to sponsor, participate in, and conduct clinical trials in Denmark. Trial Nation is the result of strong and continuous governmental support of the Danish life science sector.

Marianne Pilgaard, CEO of Trial Nation, says:

– Across public and private partners, we have jointly created, cultivated, and refined a unique ecosystem, which makes it attractive for foreign pharmaceutical companies to conduct clinical trials in Denmark. We have succeeded to such an extent that we have managed to set one of the highest standards for public–private cooperation, which means that foreign countries look at us with appreciation. And this is the case because we have managed to define a common ambition, take on a shared responsibility, work towards a common goal, and create great results for the benefit of patients, hospitals, businesses, and communities.

Clinical trials and clinical studies on medicinal products and medical devices help to ensure that the already skilled physicians and healthcare professionals are at the forefront of new research, new methods, and new treatments. This means that patients with rare hereditary, chronic, and life-threatening diseases benefit from both the process and the results.

– That is exactly what clinical trials and clinical research are all about – offering the best possible treatment to patients, Marianne Pilgaard says.

At the same time, research-intensive companies help create more jobs and thus act as beacons of the economy. This applies not only to pharmaceutical companies, but also to the medical technology industry, which contributes significantly to both exports and the economy in general.

– We are in a very strong position internationally because we can account for our patients from cradle to grave, Marianne Pilgaard says.

– We have highly educated and qualified employees in all posts in the healthcare sector. Everything is generally done at a high level, and the quality of the data we provide is thus very high.

Clinical research and clinical trials are essential to the healthcare system being able to develop new therapies and create a better foundation for nursing, care, curing, diagnostics, methodology development et cetera. This benefits patients and the overall quality of healthcare and is essential for patients getting treatment that is up to date and in line with international standards.

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Clinical trials for the good of both patients and society

Clinical trials are an absolute necessity in the development of new medicines and medical devices. They are a prerequisite for market approval and for CE marking of medical devices.

In addition to that, there are more perspectives:

– From the patient's perspective, clinical studies can be an opportunity to get to test new treatments that are potentially better than the existing ones. And from the healthcare perspective, it is important to be involved in clinical studies of new drugs and medical devices early on, in order to gain knowledge about how they work and contribute to the evaluation of the products. It can also be a gateway to becoming the first country to have access to the new drug when it is approved, explains Ulf Malmqvist, Director at Clinical Studies Sweden-Forum South, Skåne University hospital.

– But it is worth remembering that only about one in ten clinically tested drugs is approved; many perish along the way for various reasons. But no matter what, clinical trials are also important from a regional business perspective. In addition to the potential value for the patients and healthcare sector, clinical studies generate qualified jobs within the life science sector, tax revenues, and thus value for society.

At Clinical Studies Sweden-Forum South, around 35 experts in clinical studies work to offer research support and services in statistics, project management, quality assurance, and regulatory support. The support is primarily provided to healthcare professionals and academia, to help planning, conducting, and reporting of clinical studies. The Clinical Trial Unit at Forum South provide services to industry and academia, with phase 1 studies on both patients and healthy volunteers. The operation is accredited by the Medical Products Agency and handles all types of First in Human studies.

”Only about one in ten clinically tested drugs is approved”

Ulf Malmqvist says:

– Another of our tasks is helping companies get access to the healthcare system for product development. Clinical Studies Sweden offers life science companies and researchers assistance with both Country/Early Feasibilities and Site Feasibilities. Once the company has decided to carry out the study, we mediate contacts and are responsible for a smooth agreement process – all agreements on clinical trials between Region Skåne and the industry go through us.

During Q2, 2022, Clinical Studies Sweden will launch its own website for clinical studies in Sweden, to market Sweden as a clinical trials nation.

– We believe that it is important to collaborate nationally on clinical trials, to be able to reach patients all over the country and in the long run the whole Nordic region – collaboration can increase our appeal. Here, in the Öresund Region alone, we have a relatively large patient base if we can collaborate across Öresund and send patients in both directions over the bridge.

Work has begun to overcome the structural obstacles that exist for cooperation between Sweden and Denmark:

– One of the things that need to be solved is how ordinary care in addition to that which is study-specific is to be paid if the patient comes from another country, and that needs a pragmatic solution by our respective politicians on both sides of Öresund. We believe that when this is up and running, approximately the same number of patients will be sent in both directions and make it a zero-sum game. We are now trying to calculate costs of ordinary care and how many patients we might be talking about, says Ulf Malmqvist.

ReproUnion is giving new hope to couples with reproductive problems

As many as 16–25% of all couples in the Nordics are experiencing reproductive problems. Infertility has been recognized as a disease by the WHO, but despite revolutionary developments in the techniques for assisted reproduction, the success rate per treatment is still below 30%.

The Swedish-Danish ReproUnion has for the past 10 years conducted fertility collaboration across borders and disciplines between academia, hospitals, and industry.

The aim is to understand the underlying reasons of infertility and to personalize and improve fertility treatment, while also working on preventive initiatives to ensure that the society and young people are equipped with the right information to make informed choices about family planning.

Aleksander Giwercman, professor at Lund University, is one of the founders of ReproUnion. In 1999, he moved from Denmark to Malmö, Sweden, but continued to collaborate with a former urologist colleague from Denmark. They started talking about ways to strengthen integration in the field of reproduction in the Öresund Region, and in 2009 they found Interreg, the European Regional Development Fund, for Öresund-Kattegat-Skagerrak. When visiting their offices to learn more, they met Petter Hartman, who was very supportive of their idea and helped them apply for funds. A group of clinic managers and research group leaders from Sweden and Denmark were gathered, and in March 2010 they were granted €1 million from Interreg together with €1 million as own co-funding for a three-year project.

One important issue for ReproUnion was letting patients in both Sweden and Denmark benefit from medical specialties from both sides of the border. Together with Region Skåne and Region Hovedstaden, a patient mobility agreement was agreed upon, which lets Danish patients with certain highly specialized reproductive issues get treatment in Sweden, and vice versa.

– One example is that in Malmö at that time, we had many women willing to donate eggs to involuntarily childless couples, while the queues were long in Denmark. So instead of having to wait for years in Denmark they could come to Malmö for treatment, Aleksander Giwercman says.

– And to Copenhagen, pieces of ovaries for freezing could come in from all over Denmark. Why shouldn't they be able to come from Skåne as well?

With inspiration from Petter Hartman, a new Interreg €4 million grant was awarded for the following two years, and in, 2014 ReproUnion came in contact with Medicon Valley Alliance (MVA), which also works for strengthening integration in the life science area in the region. In one meeting, Petter Hartman was invited to talk about Interreg, which led to him being headhunted to MVA, which he subsequently became the CEO of.

With the connection to MVA, the bars were raised, and the third time

ReproUnion applied for funds they were granted €12 million, and the industry started getting involved, with Ferring Pharmaceuticals becoming a partner.

Aleksander Giwercman recalls:

– We had a lot of PhD projects in the field of reproduction; I think we had 25 different projects. But we started thinking: it was great to have many, but it was a bit scattered. When the ambition is to become world-leading, maybe we should focus on some parts and not all of them?

So ReproUnion defined five major global reproductive challenges, of great individual and social concern:

1. Improve human male fertility
2. Optimize reproductive health outcomes
3. Secure female ovarian function
4. Prevent infertility-related morbidity
5. Raise fertility awareness

Eva Hoffmann, Professor of Functional Genomics and Reproductive Health at University of Copenhagen, and Scientific Coordinator for ReproUnion, explains:

– There are three parts: woman, man and future child. There is still limited knowledge about why women become less fertile with age, even though we now live to be around 85. We are also looking at infertility as a marker for disease. There are some trajectories: young men under 40 with erectile dysfunction often, within a few years, get diagnosed with cardiac disorder as well. It's a marker for later things to come. Early onset of menopause means a high risk for cardiac problems, osteoporosis and dementia. And we are also doing preventative measures for fertility awareness in the population, to get societal impact and changes to structures at large.

More than 50 professors and researchers in the ReproUnion partnership collaborate across borders and disciplines to drive research in the underlying reasons and optimized fertility treatments. Eva Hoffman continues:

– We are very focused on research, but we are also close to clinical treatment and implementation. The reason we are successful is that there is great capacity between the different regions and universities and a good management structure at MVA in terms of skillset and capacity. Ferring Pharmaceuticals also plays a big part, predominantly they contribute with funding, as well as Interreg. We have a public-private partnership, which is very relevant and works so well in creating synergy between academia, society, and clinical implementation. All this requires long-term vision and multidisciplinary teams, new technology, and international collaborations.

In 2021, ReproUnion also received €2.3 million to research the impact of COVID-19 on reproductive health. EU/Interreg, Region Hovedstaden, Region Skåne, and Ferring are supporting ReproUnion with €2.3 million to research whether the Coronavirus SARS-CoV-2 has an impact on reproductive systems, both the male reproductive organs and the female reproductive system, if it can be sexually transmitted, and if it can affect the fetus or new-born child.

Accelerating the green transformation

The Chemical Engineer Per Falholt has a long history in the world of Danish bioproduction. After 32 years at Novozymes he left his position as Chief Scientific Officer in 2016 to focus on startup companies and board positions, to help develop the business.

– Besides being a scientist, I've always had the interest of creating interest for science among young people, Per Falholt says.

– The latest startup company, where I'm fully engaged, is 21st.BIO, and that is my fifth startup. Four of them are still alive and three are doing really well; we are in a good spot with fantastic technology.

21st.BIO is a scaling hub. Many innovative small companies neither have the knowledge nor the means for scaling up, and that's where 21st.BIO comes in as a world-class technical delivery partner. They are focused on recombinant proteins and peptides and food and materials replacement chemicals, with Novozymes as technology partner.

– We managed to get a sizeable funding for 21st.BIO right before Christmas, for using biology for green transformation, Per Falholt explains.

– We got funding up to DKK 640 million to build infrastructure: a research facility and a scaling facility in Kalundborg on the west side of Zealand, and labs in Copenhagen and California. To get a flying start, we managed to get a deal with Novozymes to the right to use their technology in fields not competing with theirs.

This opens up for producing new proteins for food like meat, milk, and eggs as well as other materials, such as replacing oil with other components to make biodegradable plastics – all in a sustainable way.

– We don't expect to replace all animals, but feeding the world in a less polluting system, biotechnology is one of the tools that can do this. In Denmark and the south of Sweden we have a really strong tradition of using fermentation to produce lots of stuff, not just pharmaceuticals like insulin, but also beer! From microbes and fermentation we can produce milk exactly like from the cow – instead of the cow producing milk protein, we can produce it in a lab and in the future shape a new green industry born out of Medicon Valley.

Per Falholt continues:

– One of the reasons we started 21st.BIO was that we could literally see hundreds, if not thousands, of companies trying to do the transformation, but not knowing how to scale it. They can do a little bit in their labs, but to build a factory to make proteins for millions is another thing entirely. We can make a big difference at 21st.BIO. We are planning to build laboratories, one in Denmark and one in California, and a scaling facility in Kalundborg to make tons – we can help small companies come to market faster, and thus accelerate the green transformation.

– Being in Medicon Valley gives us access to competence, a flow of young, talented, and super-skilled people who understand exactly what is needed. If we hadn't started 21st.BIO, it would have happened in the US or China instead, and I think it's better to have it in Medicon Valley. The skills, competences, and infrastructure are all here.

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THE DECADE TO DELIVER BY ACCELERATING SUSTAINABLE INNOVATION

TECHNIA has a dedicated, global Life Sciences team of more than 50 consultants.

Our mission is to Make Product Creation Sustainable in the Life Sciences industry.

> *"We have less than 10 years to radically change the way we consume and produce just about everything. This is the decade to deliver on the UN Sustainable Development Goals. Incremental change is no longer an option."*
>
> **Alice Steenland, Chief Sustainability Officer, Dassault Systèmes**

Sustainable Innovation

The recent 2021 UN Climate Change Conference (COP26) once again reminded everyone of the importance to fight climate change, and facilitated important discussions on how sustainable measures can tackle it. Meanwhile, the Life Sciences PLM Innovation Forum gathered leading Medical Device and BioPharma industry experts from across the world to share pioneering knowledge, with the joint mission to accelerate sustainable innovation, ensuring healthy lives and well-being for all.

The Future of Life Sciences

When it comes to sustainability, the challenges faced by the Life Sciences sector are very similar to the challenges faced by other industries. Managing the lifecycle of information is critical to driving true sustainability and positive environmental impacts.

PLM (Product Lifecycle Management) is a proven solution in the Life Sciences industry, allowing businesses to reduce time-to-market by making the product development process much more efficient, whilst at the same time ensuring regulatory compliance.

TECHNIA supports sustainable business value with more than 30 years of experience implementing, customizing, and maintaining PLM solutions. With a dedicated, global Life Sciences team of more than 50 consultants, our mission is to Make Product Creation Sustainable in the Life Sciences industry by turning regulatory complexity into a sustainable competitive advantage. Our domain specific knowledge, best practices and industry solutions are critical to supporting, guiding and challenging our customers, while providing the Life Sciences community with regular networking opportunities at global events, customer advisory boards, webinars and more.

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Would you like to know more about the value of PLM? Our PLM Value Assessment is beneficial for any business looking to gain valuable insights into their PLM journey, regardless of how far they have come.

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Empowering Nordic healthcare companies

HealthTech Nordic is the largest community for healthtech companies in the Nordics. In Medicon Valley, 128 companies are members, offering a variety of world-class healthtech solutions that empower individual patients as well as healthcare professionals.

128 Swedish and Danish healthtech companies in Medicon Valley are organized in the initiative HealthTech Nordic. A majority of the Scanian healthtech companies are part of the initiative together with a significant proportion of the Danish, and along with the other Nordic countries HealthTech Nordic brings together 315 companies in the sector.

Christer Månsson works with business development at Invest in Skåne, and a big part of his job is finding investors for the members and helping them with international business opportunities.

– Our organization provides assistance to the member companies with fast-track funding, investment networks, events, and international reach and business development, Christer Månsson explains.

Healthtech is a relatively young industry that has developed in the last decade. HealthTech Nordic's definition of healthtech is:

Any solution that may contribute to the paradigm shift in healthcare through digitalization in a wide sense is healthtech. It's about providing affordable tools to people all over the world for wider prevention, earlier diagnosis, and better treatment. From artificial intelligence to information technology, we include any digitalization and connected health solution in our definition of healthtech.

The healthtech companies in Medicon Valley are active in diagnosis, therapeutics, prevention, and rehabilitation in chronic diseases, cardiovascular diseases, oncology, unhealthy lifestyle, mental illness,

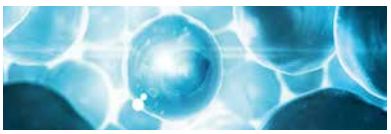
and female health – but also in support systems for healthcare staff and elderly care. The companies range from startup companies to small and medium-sized enterprises.

Most member companies are in the fast growth phase, which means that they have a strong focus on investments and sales, national as well as international, in addition to the development of clinical trials, organization and technology. Most of them focus on B2B, although there are some examples of companies that target consumers directly.

Some of the member companies use medical technology devices, which makes the boundaries towards the medtech industry somewhat blurred. Some of the technologies used are imaging, sensors and measurements, medical software, e-health, and data analytics. Some even use AI and virtual reality.

Christer Månsson says:

– Digitalization of the health sector creates completely new possibilities for new solutions, which will benefit patients all over the spectrum. And Medicon Valley has a leading role!



SYNCSENSE's new VR solution transforms exercising

With a proprietary, intelligent, AI-driven motion sensor and a VR platform, SYNCSENSE aims to transform exercise equipment into engaging and adaptive exergaming experiences that prevent and treat diseases related to physical inactivity and aging.

Simon Bruntse Andersen stood witness to the final stages of his grandparents' lives as they withered away in their hospital beds. Although now a long time ago, it has had a lasting impact and has helped shape him to think of ways to mitigate the damage institutionalizations have on the fragile and elderly.

Together with fellow student Steen Petersen, who is an experienced physical therapist and software developer – and supported by a grant from EIT Health in May, 2020, Simon and Steen started developing a VR exercise prototype – a solution connecting people to nature outside, with a special focus on elderly in nursing homes and hospitals. This VR intervention activates the body, brain, and mind while giving patients an escape; allowing them to move their bodies and simultaneously be transported virtually outside, with various sceneries to pick from.

The initial prototype was co-created with Herlev & Gentofte Hospital. Following that, prototyping started in co-creation with nursing homes and rehab centers. The product was launched in the Danish market at the end of 2020, with evidence conducted from several pilot tests in hospitals, nursing homes, and rehab centers.

Statistics show that in Denmark, elderly in hospitals spend 70-90% of their in-hospital time in bed, which weakens bones, muscles and cardio-vascular system, and also leads to boredom and loss of motivation. This has both physical and mental consequences and makes it harder to recover.

SYNCSENSE has applied for a patent on the motivation-enhancing exercise system, which is a combination of software and hardware.

Living Labs has now been established in hospitals, rehab centers, and nursing homes both in Denmark and Sweden, and co-creation continues with leading partners. SYNCSENSE has acquired accolades both internationally and nationally. This means that Johnson & Johnson Innovation named SYNCSENSE as an awardee in the NAM Health Longevity Quick-Fire Challenge, and in Denmark, SYNCSENSE has also been nominated Entrepreneur of the year in the category of Social Entrepreneurship & Future Impact by Ernst & Young, Den Sociale Kapitalfond, and Danske Bank Growth & Impact. Furthermore, and recently, SYNCSENSE won the Danish AI Award, organized by AI Denmark and their university collaborators, thereby being celebrated as one of the leading SMEs in the application of AI.

– With a proprietary, intelligent, AI-driven motion sensor and a VR platform, we are the first solution of its kind in the world transforming exercise equipment into engaging and adaptive exergaming experiences. As of today, we have validated our product on the Danish market and are about to cross international borders. We are seeking the right strategic partnership/distributor to accelerate the development and prevalence of our life-enhancing solution, says Simon Bruntse Andersen.

Early detection of stroke creates big wins

Every four minutes, someone in Sweden suffers a stroke. Today, stroke is a curable disease, but the treatment effect is highly time-dependent – every minute matters.

Uman Sense has developed Stroke Alarm, a wearable solution for early detection of stroke. It increases the chance for the user to receive timely curative treatment in the event of a stroke. Stroke Alarm consists of two bracelets and a mobile app.

Uman Sense is a medtech innovation company, a spin-off from Lund University, and a part of SmiLe Incubator in Lund.

Stroke is a source of huge suffering, and the consequences cost the Swedish society SEK 18 billion every year. During the last decade, healthcare has developed effective, minimally-invasive procedures that drastically increase the chances of recovery – if the treatment is given in time.

– Today, we can effectively treat even the most difficult cases. Unfortunately, many patients arrive too late. We are unable to translate technological advances into success for those patients, says Johan Wassélius, Senior Interventional Neuroradiologist and associate Professor at Skåne University Hospital and founder of Uman Sense.

To improve the odds for early and successful treatment, Uman Sense has developed Stroke Alarm, a wearable medical device for detecting stroke onset.

– Stroke Alarm helps those living with an increased stroke risk by alerting neighbors, family, or friends in the event of a stroke. It is a unique product that is easily integrated into people's everyday lives, says Cecilia Belfrage, CEO and founder of Uman Sense.

Every minute counts

The opportunity to treat stroke more effectively presents major economic benefits for healthcare and society. For the individual receiving treatment, it brings hope of being able to continue life as before.

– It is wonderful to experience patients who arrive paralyzed and muted by their stroke recover right in front of our eyes after the treatment. 10 years ago, they would have faced lifelong disability. Today, we can see stroke patients walking out of the hospital the day after treatment. I want as many stroke patients as possible to get access to this medical breakthrough – but for that to become a reality, every minute counts, says Johan Wassélius.

HealthTech and Digital Health

Curaizon is a company delivering data-driven drug adherence solutions that merge novel push notification technologies with big data and artificial intelligence. The aim is to be the leading provider of adherence tech across the primary care and pharmaceutical sectors, helping patients achieve better health outcomes and wellbeing, while reducing the burden that non-adherence places upon healthcare providers and pharmaceutical companies.

Curaizon was started in the UK in 2015 and has since moved its headquarters to Copenhagen. Nicholas James Rumble, CEO of Curaizon, explains that the decision was made for a number of reasons, including but not limited to: availability and lower cost of skilled labour, proximity to technical partners, quality of life, business-friendly environment, R&D incentives and lower cost of office space compared to London.

– Copenhagen punches above its weight in the field of life sciences and being part of Medicon Valley is doubly advantageous as it has created an environment where policy makers and stakeholders are engaged in the development and evolution of innovation that will change the face of healthcare. Market access and product testing is encouraged, and, because of the high levels of technological proficiency combined with the willingness to be a first mover in the area of medtech, Copenhagen is set to become a world leader in this space.

Investing in Medicon Valley

As soon as Enbiosis Biotechnology found out about Medicon Valley, their interest was raised. Today, they have offices in Copenhagen. Asgard Therapeutics was founded by scientists at Lund University, and being located in Medicon Valley helped them create a successful business out of their groundbreaking cancer research.

Enbiosis Biotechnology sees the future of personal healthcare in microbiome. The company had offices in the UK, Netherlands, Turkey and Ukraine when they chose to establish in Denmark and become an MVA member. The company's activity in Denmark focuses on science-based R&D and knowledge-intensive activities. It was thanks to Copenhagen Capacity's proactive approach that Enbiosis first heard of Medicon Valley's life science industry in general, and the microbiome R&D in particular, Ömer Özkan says.

CEO Ömer Özkan explains why they chose Copenhagen:

– Prior to Copenhagen Capacity reaching out to us, we had not even considered the possibility of investing in Denmark. We were considering Berlin in Germany and Boston/San-Francisco in the US. However, as we learned more about Greater Copenhagen's life sciences industry, we were very impressed and attracted by a number of factors, such as the access to innovative environment, specific knowledge, competences, R&D, clusters, partners, and technology. We have also considered factors like the ease of doing business, quality of life, availability of highly skilled labour and political stability. Since we are a biotechnology company, interested in human microbiome, drug discovery, nutrition, and probiotic development, we were also attracted by the opportunity to join the Microbiome network for Medicon Valley Alliance members. Having considered all this information, we decided to establish a branch office in Copenhagen. Copenhagen Capacity has made this decision easy for us, by introducing us to the community, helping us establish a virtual office in Symbion and become a member of Medicon Valley Alliance.

Asgard Therapeutics enjoyed the benefits of Medicon Valley

Asgard Therapeutics is a biotech company aiming to develop a new generation of cancer immunotherapies. The Lund-based startup found crucial support in Medicon Valley during its initial stages, much thanks to a boosted profile by Invest in Skåne which helped bring in €6 million in a capital funding round.

Founded in 2018, Asgard Therapeutics grew out of a research project in cellular reprogramming at Lund University among the Portuguese co-founders Christiana Pires, Fábio Rosa, and Filipe Pereira. They are working on a unique gene therapy approach where the identity of cancer cells is reprogrammed to induce an attack from the body's immune system against themselves, named TrojanDC. What makes the technique so groundbreaking is that while other immunotherapies for cancer typically focus on stimulating certain cells of the immune system to fight the disease, the innovation behind Trojan DC targets cancer cells themselves, still with the goal of provoking an immune response, but by making the cancer cells much more noticeable to a patient's immune system.

But being able to create breakthrough biotech doesn't automatically mean that you'll be able to build a successful business. Thankfully, there are advantages to launching a startup in Medicon Valley. Asgard's founders did not only receive support in applying for early grants, but they also received assistance with everything from accounting to legal advice for registering a business through Lund University Innovation and LU Holding. The team won several awards and grants, and eventually joined one of the region's life science incubators, SmiLe, all of which helped ease early financial risks. The company also became part of Invest in Skåne's Biotech pipeline, highlighting the company to potential investors.

– In other places, if you want to start a company, you need to set up your own lab from scratch. It takes a lot of money. It's also more risky to set up all the infrastructure alone, says Pires.

– To be in Skåne, within Medicon Valley, but also looking outside gives us good visibility, she concludes.

A Unique Role in the Life Science Ecosystem

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About us

Medicon Valley is all about collaboration to combine strengths in order to reach the best results. In this magazine, Medicon Valley Alliance, Invest in Skåne, and Copenhagen Capacity has collaborated to highlight some of the companies, organizations, healthcare providers, and academic institutes in the life science cluster Medicon Valley, who are all working to build a better future.

Medicon Valley Alliance

Medicon Valley Alliance (MVA) is a Danish-Swedish networking organization for the entire life science community in eastern Denmark and southern Sweden. It functions as a non-profit membership organization, with over 300 members representing the region's triple helix, including universities, hospitals, human life science businesses, regional governments, and service providers.

MVA creates value for its members by co-hosting, launching, and driving meetings, networks, seminars, conferences, and projects that strengthen the collaboration, networking, and knowledge-sharing in the region's life science community, create critical mass, and help realizing the full potential of Medicon Valley.

/Anette Steenberg,
CEO of Medicon Valley Alliance

Invest in Skåne

Invest in Skåne is the official trade and investment promotion agency for the southernmost part of Sweden. Its mission is to proactively promote the area to attract international investments and assist local businesses in expanding to international markets.

The overall goal is to contribute to the sustainable economic development of Skåne, so that it can become a hub for international business opportunities, new technology developments, and the latest innovations.

Invest in Skåne helps international companies establish and expand in Skåne, and helps local businesses grow with international opportunities.

/Ulrika Ringdahl,
CEO of Invest in Skåne

Copenhagen Capacity

Copenhagen Capacity is the official organization for investment promotion and economic development in Medicon Valley.

Copenhagen Capacity assists foreign businesses, investors, and talent in identifying and capitalizing on business opportunities in the region. Foreign-owned companies who want to establish or invest in the region can get help with information gathering and analysis, business establishment, and expansion and business development.

/Asbjørn Overgaard,
CEO of Copenhagen Capacity

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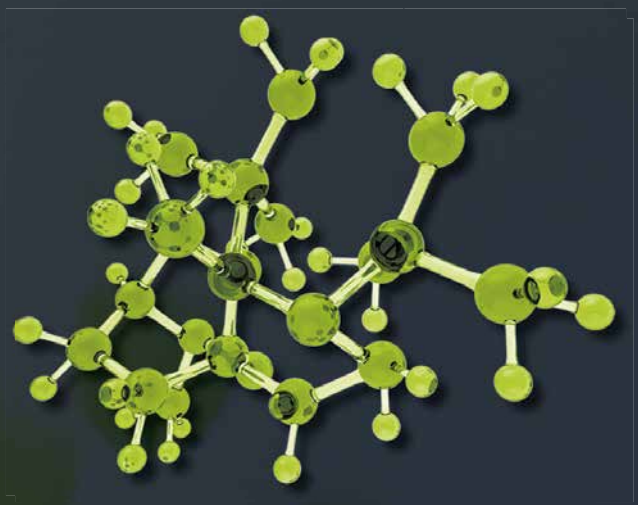

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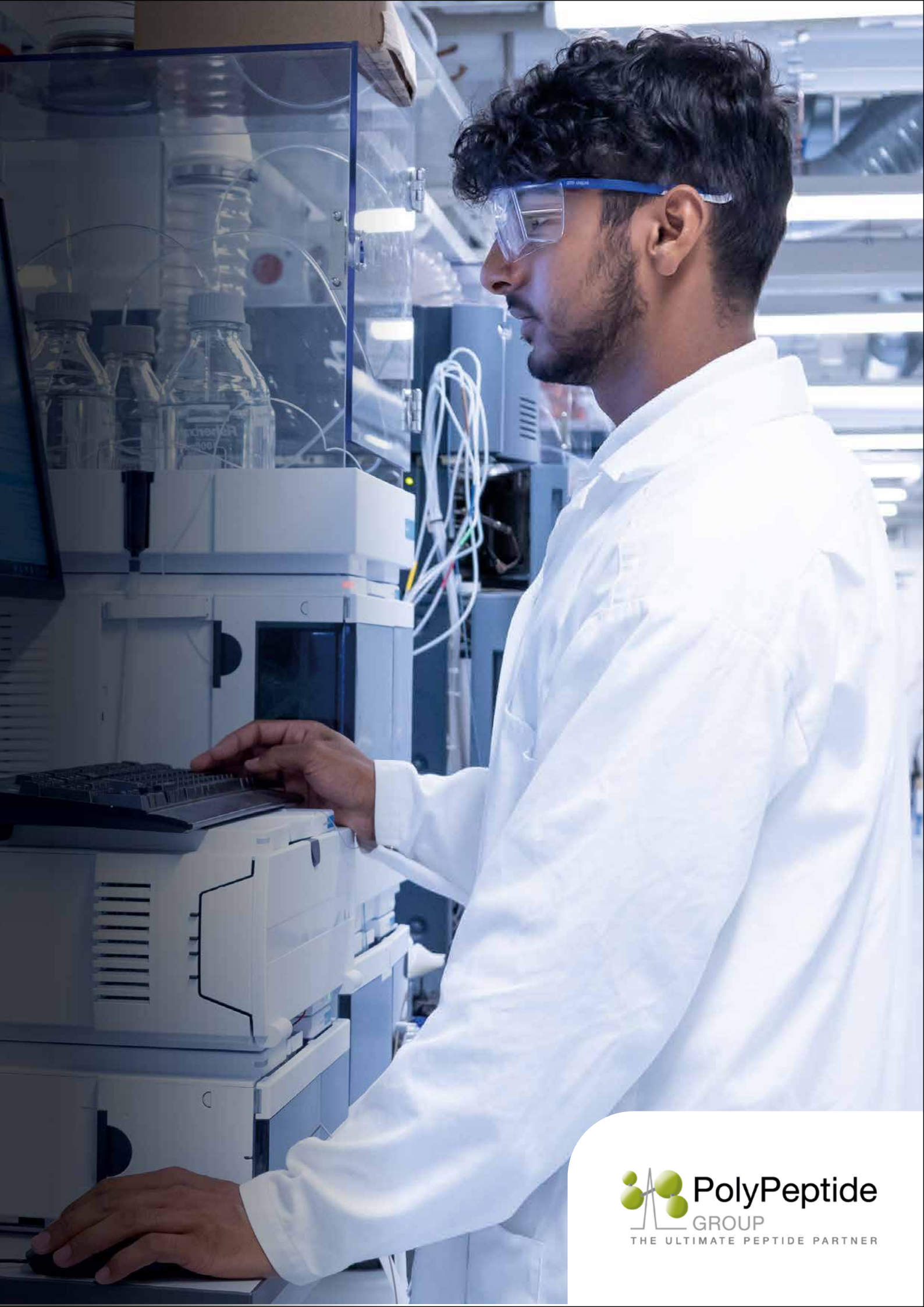

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