



Innovate
UK

Advanced Therapies

Global Business Innovation Programme

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Introduction

The UK medicines manufacturing sector

The UK has a diverse and highly innovative biomanufacturing ecosystem, comprising biologics and advanced therapy manufacturing alongside a strong manufacturing technology provision.

Medicines manufacturing is the largest economic contributor to the UK life sciences sector, accounting for £35.1bn of turnover in 2021 and contributing nearly 45% of the sector's Gross Value Added. The UK ranks third globally for inward investment in life sciences projects and has seen increasing levels of equity finance raised by companies over the last 10 years. It is also home to the third-largest global cluster of cell and gene therapy companies.

The UK has a strong academic research base in life sciences, and the translation of this research is supported by government investment in the Catapult network. This includes the Medicines Discovery Catapult, the Cell and Gene Therapy Catapult, and the Centre for Process Innovation (a High-Value Manufacturing Catapult centre), which hosts the Medicines Manufacturing Innovation Centre and the National Biologics Manufacturing Centre.

The Innovate UK Transforming Medicines Manufacturing programme supports the de-risking of innovative technologies that will transform manufacturing across medicines, vaccines and advanced therapies.

The programme focuses on advanced manufacturing technologies which allow for better, more responsive manufacturing approaches improving productivity, resource and energy efficiency in medicines manufacturing by supporting innovation in flexible, agile, scalable and sustainable manufacturing practices.

Continued investment in life sciences innovation is a key part of the UK Life Sciences Vision, and the UK's International Technology Strategy sets out the importance of strategic international research and innovation collaboration.

UK-Sweden Memorandum of Understanding

In May 2022, the UK and Sweden signed a joint Memorandum of Understanding (MoU) on health and life sciences, highlighting ATMP as a priority. The purpose of the MoU is to promote cooperation across local, regional and national healthcare, research and innovation systems in support of the development of dynamic, effective and attractive life science ecosystems. Cooperation between the UK and Sweden will take place on the principles of equality, reciprocity, mutual benefit, and within the framework of all applicable laws and relevant institutions of both countries.

Cooperation is envisaged in areas that advance medical technologies and techniques that benefit health outcomes in both countries and globally, building on areas of excellence on both sides.



The UK and Sweden have exceptional capability in ATMP technologies and strong government support, endorsed by the Strategic Partnership Agreement signed by Prime Ministers in October 2023. International collaboration has proven invaluable in accelerating the progression of new and emerging technologies, allowing for more diverse ways to look at problems and find solutions. This Global Business Innovation Programme aims to strengthen UK and Swedish relationships and facilitate innovation partnerships.



About us

The Global Business Innovation Programme

The Global Business Innovation Programme (GBIP) helps ambitious UK companies that are developing cutting-edge technologies in key sectors to enter global markets of strategic importance and find international collaboration partners.

Organised by Innovate UK, the intensive three-stage programme:

- Prepares businesses for approaching and operating in market
- Includes a tailored in-country visit, which allows businesses to develop a deeper understanding of the market and facilitates introductions to key partners and contacts from Government, academia and commerce
- Provides ongoing post-visit specialist support to help businesses cement relationships, leverage connections made during the visit, identify partnership opportunities and access R&D funding to drive cross-border collaboration

Innovate UK

Innovate UK is the UK's innovation agency, helping UK businesses to accelerate growth through the development and commercialisation of new products, processes and services, supported by an easy to navigate, agile and inclusive innovation ecosystem.

www.ukri.org/about-us/innovate-uk

Innovate UK EDGE

Innovate UK EDGE is the Business Growth Service offered by Innovate UK. It's network of Innovation and Growth Specialists deliver bespoke support to ambitious innovative businesses to help them grow and scale. The support provided by Innovate UK EDGE is tailored to meet the needs of businesses across all technology sectors and is designed to respond to their evolving needs as they scale and compete globally.

www.innovateukedge.ukri.org



Astral Systems is at the forefront of fusion innovation with their unique reactor design widely regarded as a high-performance, compact and affordable neutron source for producing medical radioisotopes.

With the benefit of £1.2m research grants co-founders Talmon Firestone and Tom Wallace-Smith, leaders in fusion technology developed the novel compact nuclear reactor based on breakthrough fusion physics published by NASA.

Compact fusion-based neutron sources offer enormous potential in allowing communities underserved by the current model of accelerators and fission reactors to be able to produce their own medical radioisotopes on demand, ensuring security of supply, broadening available diagnostic or treatment techniques and improving patient outcomes.

Demonstrating >10x increase in total fusion rate, Astral System's improved reactor design is the MultiState Fusion system. Its technology will play a crucial role in Nuclear Medicine for diagnosis and treatment of life-threatening diseases, such as cancer.

Astral Systems technology enables governments to alleviate persistent medical radioisotopes shortages and provide nuclear medical independence.

Collaboration opportunities

Astral Systems recognise that Nuclear Medicine is a well-established modality in Sweden. The company is interested to:

- explore the opportunity to establish Sweden's own radionuclide supply capability
- to collaborate with Swedish organisations and universities active in Radiology, Nuclear Medicine and Medical Imaging
- to collaborate on the commercialisation of their technology in the Swedish market



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Deliver Biosciences is pioneering the development of in vivo cell therapies via its proprietary nanoparticle-based platform, making these therapies more affordable, scalable and accessible to all patients in need.

The company's first product focuses on developing in vivo CAR-Ts by modifying immune cells in situ to treat blood cancer patients.

The technology has proved effective in killing cancer cells in vitro and achieves high specificity (over 95%) towards the cells of choice (T-cells) in vivo. This is comparable to viral vectors which achieve 10-50% transduction in vivo.

Given the platform nature of the technology, Deliver Biosciences believes it can bring in vivo cell therapies to potentially treat patients with autoimmune and infectious diseases.

Currently the technology is being validated further in animal models, and Deliver Biosciences is generating a product version that would allow first-in-human trials within 3 years.

Collaboration opportunities

Deliver Biosciences would welcome collaborations in Sweden in these areas:

- academics/companies working in the lipid nanoparticle sector
- companies working with innovative CAR/TCR technologies
- hospitals/centres/clinicians interested in CAR-Ts and in particular, in vivo generation of CAR-Ts
- larger pharmaceutical companies strategic venture arms open to collaboration on advanced therapies



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Exogene is a biotech startup that uses AI to discover novel T-cell receptor (TCR) based treatments for currently untreatable metastatic solid tumours. Exogene is based in the BioEscalator at the heart of Oxford University's biotech innovation hub.

Utilising diffusion and language model architectures, the company's state-of-the-art AI platform is capable of identifying rare, high-affinity TCRs against cancer targets for therapeutic applications. The methodology has received validation through a pilot project with Immunocore, a leading Oxford based TCR drug company and developer of the first FDA approved TCR based drug.

Exogene is also engaging in strategic collaborations with another top UK-based TCR therapy company and with Germany-based Alithea to identify high-affinity TCRs for novel cancer targets.

Since its inception in 2020, the company has secured over £3.5 million through grant funding and private investment.

Collaboration opportunities

Exogene is seeking collaborations in Sweden as follows:

- companies specialising in TCR-based cell therapy OR TCR-based bi-specific therapy development and manufacturing. This is to explore opportunities to discover high-affinity TCRs for a TCR-based therapy Swedish partner
- companies specialising in lipid nanoparticle (LNP)-based drug delivery or viral vector-based drug delivery. This is to explore the possibility of decorating a Swedish partner's drug delivery system with TCRs to make the delivery system highly targeted for cells, such as cancer cells, displaying specific peptide-HLA targets



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Intelligent Lab on Fibre (iLoF) is an innovative company backed by Microsoft Ventures, with groundbreaking technology harnessing photonics and AI, that addresses a critical need in biomanufacturing, specifically in the characterisation of nanoparticle systems for drugs and vaccines delivery.

iLoF's platform offers biotech and pharmaceutical companies a game-changing advantage by enabling real-time, non-destructive and cost-effective monitoring of payload within nanoparticles, while simultaneously determining their size and concentration.

iLoF has compelling evidence supporting their platform's effectiveness in assessing nanoparticle delivery systems, such as liposomes. Currently, the company's primary focus is aligning product features with market needs and engaging with partners and customers to foster business growth. They are also actively exploring new market opportunities.

Collaboration opportunities

iLoF is interested to explore opportunities that harness iLoF's technology and accelerate the development of personalised and controlled nanotreatments including partnerships with:

- research institutes working on diverse nanoformulations
- biotechnology companies developing nanodrugs
- instrument companies developing instruments or platforms for manufacturing nanodrugs

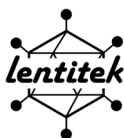


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Lentitek is developing a method to improve both quality and quantity of lentivirus in biomanufacturing.

Lentivirus is the key viral vector for commercial gene-modified cell therapies such as CART, as well as in vivo gene therapy. However, developers often have quality and yield issues making it economically challenging to manufacture the lentivirus vector. A specific issue is the unwanted expression of the payload during manufacture which can cause toxicity-related yield issues or quality concerns if carried over into the final product.

Lentitek's novel promoter technology can significantly reduce, and in some cases eliminate, the breakthrough expression of the payload during manufacture, leading to improved quality and/or yield of the final product.

The company has successfully demonstrated that its technology will produce an infective virus that can transduce target cells in an indistinguishable manner from the current state-of-the-art production systems.

Benefitting from Scottish Enterprise funding in 2021, and supported by collaborations

at UCL, Cell and Gene Therapy Catapult, and Virocell, Lentitek has demonstrated its novel approach can manufacture viable, infective lentivirus with clinically relevant CAR payloads. Earlier this year the company raised £250,000 to further prove the technology in application and with customer applications.

Lentitek is looking to partner with alpha-trial customers facing yield and quality issues in lentivirus manufacture with a view to licensing the technology in 2025.

The company is led by Adam Inche, who has 15+ years' experience in ATMP biomanufacturing working in strategic roles for Merck KGaA, Symbiosis and PathoQuest.

Collaboration opportunities

Lentitek is looking to engage with developers or manufacturers in Sweden who are working with lentivirus:

- in gene-modified cell therapies
- in in-vivo gene therapy applications
- in the manufacturing process



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microfluidx

MicrofluidX is an Advanced Therapy manufacturing platform company developing a highly adaptable and scalable bioprocessing platform for cell and gene therapy manufacture.

The Cyto Engine™ is built upon the company's proprietary planar bioreactor technology and is underpinned by a family of unique planar bioreactors which enable increased process data collection and crucially maintain the same cellular microenvironment from very small to large manufacturing volumes. This allows therapy developers to connect their earliest learnings on cell biology in R&D to cell behaviour in manufacturing and enables faster translation of therapies to the clinic and generates large datasets, needed to drive a more adaptive manufacturing approach to accommodate the biological variability of starting material.

MicrofluidX's mission is to make complex precision medicines more accessible to patients across the globe by disrupting the current advanced therapy development process, providing scalable, fully automated platforms that can be used in early research and seamlessly scaled up and out to intensify and industrialise GMP manufacturing.

Collaboration opportunities

MicrofluidX's objectives in Sweden are to:

- build knowledge of the Swedish cell and gene therapy ecosystem
- connect with cell therapy developers
- explore future collaborative grant opportunities
- meet institutional and strategic investors within the ecosystem
- receive input on the platform and technologies from potential users
- connect with potential testers of the platform and technologies
- explore the potential for Sweden to be microfluidx's EU operations base



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ReproGO

ReproGo is a pioneering Deep Tech startup from Queen's University Belfast, specialising in advanced stem cell technology, with a focus on eco-friendly biomanufacturing practices for cell reprogramming and differentiation.

ReproGo targets vascular and cardiovascular diseases, with their patent-pending technique for the efficient creation of vascular cells and advanced organoids. The company's technology significantly reduces or eliminates the need for animal testing, providing treatments for vascular diseases by treating their root cause, not just the symptom.

ReproGo's stem cell-derived vascular cells offer exceptional purity, longevity in cell culture and boast cost-effectiveness and sustainability advantages over traditional cell therapies.

The company aims to revolutionise regenerative medicine with a patient-centric, ethical, and sustainable approach.

Collaboration opportunities

ReproGo is seeking to collaborate with partners that have:

- specialised knowledge of sustainable cell therapies
- cutting-edge facilities developing these therapies
- equipment in green bio sourcing, banking, and automation, which align with the company's ethos



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Founded in 2018, Rinri Therapeutics Ltd is a therapeutic discovery and development company working on hearing loss. Supported by the Boehringer Ingelheim Venture Fund, UCB Ventures, Pioneer Group and the University of Sheffield, Rinri Therapeutics is developing innovative first-in-class stem cell-derived therapies to address the unmet needs of patients with sensorineural hearing loss (SNHL).

The company's lead product, Rincell-1, is targeted explicitly at auditory neuron-related SNHL (AN-SNHL). There are no disease-modifying therapeutics for sensorineural hearing loss (SNHL). Hearing aids and cochlear implants are the gold-standard treatments, but they cannot restore normal hearing and are entirely ineffective for AN-SNHL, leaving millions of patients with poor healthcare outcomes.

Rincell-1 addresses this by replacing the damaged auditory neurons within the cochlea, regenerating the cytoarchitecture and connections of the inner ear and restoring hearing.

Rincell-1 is in late preclinical development with a clear path to clinical trial in 2025 and two further pipeline products in early preclinical development.

Collaboration opportunities

Rinri Therapeutics is seeking to:

- engage with stakeholders in Sweden which will be invaluable in building rinri's global strategy as they progress towards a first-in-human clinical trial in the UK
- improving their understanding of the Swedish regulatory framework
- identifying potential development partners
- meet fellow advanced therapy developers to discuss common challenges and potential solutions



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StemBond Technologies, a spin-out from the University of Cambridge, has developed innovative technology that enhances and regulates cellular function by manipulating the mechanical environment.

StemBond hydrogels are non-toxic, cost-effective, scalable, animal-free and GMP-compliant. Patents are pending in the US and EU. StemBond hydrogels have been shown to improve the function of a variety of cells ex vivo, including stem cells, neurons, and immune cells.

The company is now developing a groundbreaking technology based on their hydrogel platform, designed to enhance Chimeric Antigen Receptor (CAR) T cell activation and expansion. The company is now developing a groundbreaking technology based on their hydrogel platform, designed to enhance Chimeric Antigen Receptor (CAR) T cell activation and expansion. This offers a unique advantage by enabling comprehensive CAR T cell activation while mitigating cell exhaustion, a significant challenge with existing products resulting in a critical bottleneck for clinical investigation.

This offers a unique advantage by enabling comprehensive CAR T cell activation while mitigating cell exhaustion, a significant challenge with existing products resulting in a critical bottleneck for clinical investigation. StemBond's approach will substantially increase the pool of functional CAR T cells, enhancing their in vivo efficacy and facilitating faster, more effective treatments for patients.

Collaboration opportunities

StemBond's objectives in Sweden are to:

- engage with early-stage developers
- consider ways in which they can integrate their cutting-edge technologies with initiatives in Sweden
- forge meaningful relationships with Swedish biotechnology companies at the forefront of immunotherapy innovation



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Stratosvir is an early-stage company funded by Deep Science Ventures, angel investors and Cancer Research UK, working on a next-generation viral immunotherapy platform technology. Stratosvir is currently raising its Seed round.

Advanced cancer patients currently have limited treatment options, often associated with side-effects, poor quality of life and a high burden on caregivers and treatment costs. Badly needed therapeutic options require a multi-pronged approach to overcome treatment resistance and disease spread.

Stratosvir is developing a proprietary viral immunotherapy platform that has proven safe in the clinic and is made suitable for intravenous delivery and repeat dosing. This platform technology forms the basis of a product portfolio, each able to deliver tumour type-specific medicinal payloads from within the tumour, resulting in a high local concentration. Together with the intrinsic anti-tumour effect of the virus, this will achieve a novel, effective and well-tolerated combination therapy.

Collaboration opportunities

In Sweden, Stratosvir is aiming to:

- engage with peers interested in repurposing or co-developing biologics deemed suitable for virus-mediated intratumoural delivery
- explore the Swedish ecosystem for opportunities in co-development or manufacturing of its viral technology



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UNICORN^{bio}

Unicorn Biotechnologies provides cell culture automation and scale-up solutions, starting with stem cell (ES/iPSC) processes.

Unicorn's modular systems enable the reliable production of difficult-to-grow cell types by delivering streamlined process control via an integrated biomarker, sensor-driven analytics system. End-to-end workflow automation provides 24/7 operating capability with minimal operator intervention.

In R&D, Unicorn Biotechnologies helps:

- free up a teams' time by automating the laborious process of cell culture
- develop robust, digitised benchtop processes that reduce variability and batch failures

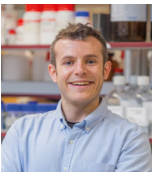
In developing GMP manufacturing processes, Unicorn Biotechnologies helps:

- remove tedious and risky tech transfers by instantly transferring digitised protocols from unit to unit
- manage all process control and batch records in a digitised GMP-compliant format
- save space and reduce manufacturing costs when scaling through clinical trials and commercial production

Collaboration opportunities

Unicorn Biotechnologies is keen to:

- establish a Swedish partner in their early access programme
- seek feedback on Unicorn Biotechnologies prototype systems
- build an understanding of the Swedish ATMP community
- working together with a Swedish partner, access the broader EU stem cell therapy ecosystem



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Leading the visit



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Louise has worked on the Global Business Innovation Programmes since 2018 and has successfully led twelve Global Business Innovation Programmes to target countries and supported over 200 companies to achieve their international ambitions. Louise is a qualified barrister and solicitor and previously specialised in criminal law and dispute resolution.

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Sarah provides specialist support and preparation to UK businesses with international ambitions. Prior to joining Innovate UK EDGE she held postings with the UK diplomatic service in the Middle East, Africa and Latin America and led Embassy teams in Iraq, Mexico, Jordan, and the Dominican Republic and became Head of Post in Monterrey, Mexico. In the UK, Sarah continues to help UK companies maximise their growth in new international markets.

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