

Innovate UK

Results of Competition: Medicines Manufacturing Round 2: Challenge Fund

Competition Code: 1803_ISCF_ASHN_MEDMANR2

Total available funding is £8,254,414m

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
CRYOGATT SYSTEMS LIMITED	RFID to enable ATMP Manufacturing, Cryogenic Supply Chain Scale-Up and Productivity Gains	£695,862	£487,103
CELL THERAPY CATAPULT LIMITED		£145,005	£145,005
Cranfield University		£172,200	£172,200
Scottish National Blood Transfusion Service		£109,452	£109,452
THERMO ELECTRON LIMITED		£370,326	£222,196

Note: you can see all Innovate UK-funded projects here <https://www.gov.uk/government/publications/innovate-uk-funded-projects>

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Funders Panel Date: 26/06/2018

Project description - provided by applicants

Manufacture of cell and gene therapies (also known as Advanced Therapy Medicinal Products or ATMPs) is highly labour intensive and technically complex requiring a three-phase process: Primary Manufacturing (production), Secondary Manufacturing (storage, packing and distribution) and Final Preparation (delivery and patient administration), which due to the specialist requirements are currently undertaken by different organisations, using different processes, in separate and often geographically remote locations. The manual processes and multiple handling required to produce ATMPs results in low throughput and high costs.

RFID technology is a well-established technology platform in high-volume sectors, such as the automotive industry and Fast Moving Consumer Goods, and is used to facilitate tracking and traceability of individual components, sub-systems and final product within and between sites. However, these systems cannot be simply transferred across to the ATMP industry due to the unique challenges associated with ATMP manufacture, including aspects of product viability, shelf life, batch sizes, cryogenic temperatures required for product storage and complex regulations to ensure patient safety.

This project will develop and demonstrate a full-scale, regulatory compliant, cryogenic RFID system which works across the three stages of ATMP manufacture. The final system will de-risk and overcome a number of critical barriers to enable full and seamless adoption into the ATMP industry.

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FREELINE THERAPEUTICS LIMITED	Development of an Innovative Supply Chain Model to Expedite Delivery of Viral Vector ATIMPs to Clinical Trials	£496,075	£297,645
CELL THERAPY CATAPULT LIMITED		£398,457	£398,457
SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED		£436,011	£261,607

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Project description - provided by applicants

The rapid development of novel treatments called Advanced Therapies, such as cell therapies and gene therapies have required new manufacturing facilities and technologies worldwide. Manufacturing of gene therapy viral vectors for human use requires specialised high-quality manufacturing facilities and there is currently insufficient such capacity in the UK and globally. Reliance on overseas CMOs presents challenges in terms of both capacity and lack of flexibility. The Cell and Gene Therapy Catapult has recently opened its manufacturing centre in Stevenage offering an innovative cost-sharing model for small gene therapy companies, such as Freeline, to establish an internal manufacturing capability for their drug substance. The aim of this project is to further develop the UK based supply chain by establishing an integrated, lean partnership between CGTC-MC and Symbiosis, a UK company that specialises in drug product manufacture (fill finish) for clinical sterile drug products and small volume, niche commercial sterile products.

This collaboration, between Freeline, CGTC-MC and Symbiosis aims to establish an efficient, secure supply chain to reliably deliver viral vector gene therapy drug products to clinical trials. This will speed the pace at which new gene therapies can be made available to patients. The clinical supply chain delivered by this project will provide a foundation on which to deliver commercial supplies of gene therapy products in the future, thus establishing a secure UK-embedded commercial supply chain.

The three UK collaborators will work together to create the new processes and analytical technologies to achieve rapid and seamless transfer of materials between the partners whilst maintaining quality. The project will include alignment of respective quality systems and processes as well as investment in internalising critical quality control tests and establishing new novel rapid methods. Internalising QC will bring about process efficiencies, adding to the security of the supply chain.

The new integrated operating model will be demonstrated with the manufacture and supply of a GMP batch of a Freeline gene therapy drug product to a Phase I/II clinical trial for the treatment of a lysosomal storage disorder. The resulting supply chain and technologies will be translated into standard processes which can be offered by CGT-MC and Symbiosis to other future viral vector customers, thus significantly enhancing the UK viral vector manufacturing capability

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COBRA BIOLOGICS LIMITED	Purification of Adeno-Associated Virus (AAV) by continuous Chromatography	£601,675	£361,005
CELL THERAPY CATAPULT LIMITED		£449,450	£449,450
PALL EUROPE LIMITED		£447,766	£223,883

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Project description - provided by applicants

The project aims to increase yields of Adeno-Associated Viral (AAV) vectors for human gene therapy studies through the improved purification processes and through the adoption of continuous chromatography approaches. The project aims to develop purification processes with improved yields and robustness that can be readily scaled to those required for in-market requirements at a reduced cost of goods than is currently being achieved for these vectors, addressing the critical needs to increase the supply and costs of these medicines.

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GYROSCOPE THERAPEUTICS LIMITED	A shared scalable suspension platform for cost effective manufacture of novel AAV gene therapies	£524,944	£367,461
CENTRE FOR PROCESS INNOVATION LIMITED		£300,137	£299,637
FREELINE THERAPEUTICS LIMITED		£524,622	£314,773
NHS Blood and Transplant		£149,965	£149,965

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Project description - provided by applicants

The rapid development of Gene Therapy Medicinal Products (GTMPs) requires new manufacturing processes and facilities. Gyroscope Therapeutics Ltd and Freeline Therapeutics Ltd are UK-based SMEs developing gene therapies for different indications but which are both delivered via adeno-associated viral (AAV) vectors. Gyroscope and Freeline intend to co-develop an innovative, suspension-based viral vector manufacturing process, which will provide a shared platform for the manufacture of each company's GTMP products. The major challenge facing commercialisation of gene therapies is the manufacture and supply of products at a commercial scale. Gyroscope and Freeline will develop a proprietary, serum-free, scalable, suspension based manufacturing platform, which will improve product quality, safety, robustness and reduce the costs of goods at commercial scale. Working together with process development specialists at partner organisations the Centre for Clinical Biotechnology (CBC) and the Centre for Process Innovation (CPI), Gyroscope and Freeline will:

1. Establish ways to reduce risk of genetic instability of plasmid starting materials in an integrated approach;
2. Establish a proprietary animal component free and 'chemically defined' suspension cell culture manufacturing process which is scalable and which minimises product heterogeneity while maximising safety, quality and yield;
3. Supply batches of material to confirm comparability of product made using suspension platform material to that produced by current adherent cell culture platforms and so enable process changes to be implemented
4. Generate data to facilitate technology transfer of the developed process at a representative scale to GMP manufacturing facilities for subsequent qualification as a GMP manufacturing process.

Ultimately, a successful outcome will address a significant manufacturing challenge for GTMPs, strengthen the UK position as a leader in scientific innovation, offer scope for investment and employment into UK Pharmaceutical manufacturing and bring healthcare benefits to patients.

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INTRACT PHARMA LIMITED	Development of a Scalable Manufacturing Process for a Novel Oral Infliximab Product using the Soteria Technology	£620,230	£434,161
CENTRE FOR PROCESS INNOVATION LIMITED		£415,687	£415,687
PHARMIDEX PHARMACEUTICAL SERVICES LIMITED		£275,803	£193,062
QUAY PHARMACEUTICALS LIMITED		£161,945	£97,167

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Project description - provided by applicants

Though the monoclonal antibody (mAb), infliximab, is considered a gold-standard treatment for the 300,000 patients in the UK with inflammatory bowel disease (IBD), the compound can only be administered through an inconvenient and often painful injection. In doing so, only less than 1% of the drug reaches the site of disease, limiting the efficacy of the treatment whilst causing a wide range of serious side-effects. Intract Pharma's novel drug delivery technology, Soteria, allows for infliximab to be administered orally, creating a more targeted IBD treatment. In partnership with the Centre for Process Innovation (CPI), Quay Pharmaceuticals and Pharmidex, Intract Pharma will develop, optimise and validate a manufacturing process that enables mAbs to be formulated as an oral solid dosage form, and in turn create a GMP-ready manufacturing protocol for Soteria. So far, mAb therapies have not yet been able to be manufactured for oral administration in both a clinically and commercially viable manner. Therefore, the project will develop new innovative manufacturing approaches in the field of pharmaceutical formulation, particularly with regards to antibody stabilisation and formulation. As a result, this project will not only break new ground in antibody formulation but further develop a therapeutic that could vastly improve the treatment of patients with IBD.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ROSLIN CELL THERAPIES LIMITED	Generation of clinical grade human pluripotent stem cells (iPSCs) using safe mRNA reprogramming strategy	£1,096,815	£767,770
REPROCELL EUROPE LIMITED		£199,116	£119,470

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Project description - provided by applicants

Since their discovery in 2006, induced pluripotent stem cells (iPSC) have demonstrated their importance to disease modelling, drug discovery and regenerative medicine. Using genes/transcription factors associated with embryonic maintenance, 'adult' somatic cells are reprogrammed or induced to an embryonic-like state. This creates cells with the properties of self-renewal and pluripotent potential (meaning they can be used to create any cell type) whilst alleviating the ethical constraints often associated with embryonic derived material. In addition, iPSCs cells may be used for autologous therapies (using the patient's own cells) or, with careful selection of the donor, allow HLA matched, O negative cell banks for multiple recipients (allogeneic therapies which use cells from different donors that are compatible with the immune system of the patient receiving the stem cell therapy).

To date, most research in iPSCs has been conducted at an early pre-clinical stage; a major challenge is to make the protocols for generating iPSCs suitable for clinical use. Many of the existing protocols require an enormous amount of quality testing because the viruses/genes/transcription factors may integrate into the genome, causing undesirable changes and increasing the risk of tumours if they are not cleared from the cells. mRNA reprogramming avoids these safety concerns as mRNA does not integrate into the genome and remains within the cell for only a short period. However, suitable clinical-grade protocols have not yet been fully developed for the manufacturing processes.

This project proposes a novel strategy for the derivation of clinical iPSCs which have the properties associated with human embryonic stem cells whilst being derived from minimal blood from adults. By using a non-integrating mRNA reprogramming method, the risk of tumour formation usually associated with other methods is avoided.

To make the process economically attractive, manufacturing procedures will be standardised to allow an automated work flow from donor material, reprogramming, iPSC generation and cell-banking. This will allow quicker and safer generation of clinical grade iPSCs for both allogeneic and autologous therapies and provide scope for commercialisation and licensing of the generated cell lines to the biotechnology sector.

Bringing together the expertise of RoslinCT and REPROCELL will provide a step change in the production of clinical grade iPSCs and centre this know-how and manufacturing within the UK.

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SAGETECH MEDICAL EQUIPMENT LIMITED	A Novel Disruptive Production Route to Capture, Extract and Purify Waste Volatile Anaesthetic introducing the first commercially attractive & environmentally beneficial recycled medicines	£1,335,231	£600,854
University of Exeter		£163,428	£163,428

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Project description - provided by applicants

SageTech is developing a pilot project which captures and remanufactures volatile anaesthetic agents. This will reduce both the cost and environmental pollution of anaesthesia in the UK and globally. It will increase access to the most recent anaesthetic agents, improving patient care and theatre efficiency.

SageTech's technology could eventually be integrated into the anaesthetic machine to provide recycling at point of use, as well as into the hospital workflow to provide bulk capture and extraction for recycling as part of the existing volatile agent manufacture market. This holistic approach will ensure that volatile agent recycling is a viable commercial proposition.

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FABRX LIMITED	3D Printing of Pharmaceutical Products for Bespoke Medicinal Delivery	£545,509	£381,856
KATJES FASSIN UK LIMITED		£394,752	£276,326

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Project description - provided by applicants

This innovation is focused on improving the production of solid-dose medicines (tablets). Currently, capially intensive processes are used to produce large volumes of identical tablets. The applicants have identified clear market demand for a flexible point-of-dispensing, manufacturing approach such that bespoke tablet formulations can be produce on a desktop machine. Such an approach can provide greater control of the dose strength enabling medications to be personalised to recipient's needs.

This team is developing such a novel 3D tablet printing "3DP" manufacturing and supply chain. The vision is to produce bespoke doses of personalised medicines. As an example, a long-term goal is to enable production of personalised multi-drug combinations for a patient or defined group of patients with cognitive impairment such that their entire multi-faceted dosage regimen is drastically simplified; such a "polypill", even in a simpler, non-personalised form, has been a long-established goal for dosing to elderly patients but the development is not feasible using standard manufacturing processes. This team's commercial goal is to create the systems and materials which enable production of validated, traceable pharmaceutical products which are suitable for human use, and commercially to establish printing as a pharmaceutical development service to companies researching personalisation of medicines.

Contextually, partner 1 (Katjes Fassin) has developed a food grade 3D printing system. FabRx (the leading pharmaceutical 3D printing specialists) wishes to adopt and modify this system for use in the pharmaceutical sector. The challenge is; 1 -- limited validation of use of the types of food grade materials that form the basis of the 3DP tablets and 2 -- development of the tablet production hardware to provide in-situ confirmation of the table dose (key regulatory requirement).

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ASTON PARTICLE TECHNOLOGIES LIMITED	A Novel and Improved Commercially Viable, Cost - Effective Manufacturing Process for Fixed Dose Combination Dry Powder Inhaler Formulations	£464,778	£325,345
QUEST HEALTHCARE LIMITED		£90,835	£63,584

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Project description - provided by applicants

At the present time there are few, if any, manufacturing processes for particle surface modification that do not adversely affect the innate properties of the core particles. State-of-the-art blending technologies for DPIs, e.g. high shear or turbula mixing, often are unsuitable for processing poorly stable APIs and even when suitable, create highly variable product outputs. This becomes even more complex when combinations containing more than one API are to be created. This project is targeted to deliver improved and commercially viable cost-effective processes for manufacture of formulations of small molecule APIs that are already available as Fixed Dose Combination (FDC) DPI medicines. These products have proven to be very difficult to turn into generic medicines until now. Aston Particle Technologies (APT) Ltd. has created a novel dry particle coating process, newly trademarked as APT-Hale(tm), which could be a game-changer in this regard. The process has many unique characteristics which have been confirmed with single API formulations. It operates at ambient temperature, requires the use of no volatile organic compounds (VOCs) or solvents, generates no heat and causes no particle attrition. It can handle APIs with problematic properties, such as high charge / high charge retentiveness, high cohesivity or acute moisture sensitivity. It can be applied equally to poorly stable APIs as to those that are robust. It has already been successfully used with readily available 'off the shelf' APIs and excipients with no pre-treatment. The process operates through control of a small number of critical processing parameters which create a fluidised state in dry nitrogen, in which every fine particle is firstly fully wetted by the dispersion gas and then adsorbed onto the coarser carrier particles. It is a primary aim of this project to validate the broad applicability of the process by creating FDC DPI formulations that can be progressed as credible substitutable generics for the market-leading, innovator products. In doing so, a range of established, off patent APIs will be investigated in combination. Application of this simple and relatively 'easy to implement' platform for development and scale up could eventually lead to registration of a suite of generic FDC inhalers that will meet the requirements of prescriber, payer and patient alike. If this project is successful, this platform technology will be utilised in the longer term not only in the development of generic combination formulations but also of those containing new chemical entities.

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MIKOTA LTD	Extraction and purification of a novel hemocyanin through implementation of new technologies.	£115,504	£80,853
Cardiff University		£21,388	£21,388

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Project description - provided by applicants

Mikota Ltd is looking to build on early investigative work into hemocyanin from the blood of the slipper limpet, an invasive, non-native species to UK shores. Having successfully identified hemocyanin proteins in the limpets as well as drafted and tested a basic extraction protocol, Mikota now aims to scale up production of this hemocyanin to a commercial level. As well as scaling up production, we will focus on perfecting a storage method for the finished product that will preserve the viability of the hemocyanin for long term storage.

This work is being undertaken in collaboration with Cardiff University, with their work packages being led by Dr Mark Young and Prof Thomas Wirth. In support of Cardiff University work, and Mikota's helping young people prepare for the work place, Mikota is funding 3 Professional Year students to be placed at Cardiff University.

By scaling up this process Mikota will deliver a new sustainable medical grade hemocyanin sourced locally from an invasive species to the UK, that has significant value in the anticancer, vaccine and immunotherapy markets.

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MEDHERANT LIMITED	First steps in scaling up Medherant's transdermal patch manufacturing capabilities to cGMP	£76,608	£53,626

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Project description - provided by applicants

Medherant seeks to become the world's leading developer of transdermal drug products and has the technology platform, scientific expertise and R&D capabilities to do so. We are developing our own best-in-class products to out-license to global pharma marketing partners alongside offering contract formulation services for companies seeking to develop novel transdermal products using our unique TEPI patch platform technology.

Medherant has a global exclusive licence to a truly revolutionary suite of adhesive polymers developed by Bostik S.A. which allow the formulation of a much wider range of drugs at much higher loadings than existing adhesives and with better rates flux across the skin. Our TEPI patches also have excellent consumer benefits such as strong adhesion, they are waterproof and easy to remove and they don't leave unsightly black marks.

We have developed a novel patent pending system which enables us to perform high-throughput skin permeation studies which in turn allows us to formulate and test novel patch products in a fraction of the usual time seen within the industry. Such advantages have already been leveraged to attract interest from pharmaceutical companies across the globe and we have already successfully completed feasibility studies for a large European company and one of Japan's largest transdermal pharma companies.

Our services are in demand - we are in contract negotiations for feasibility studies with a number of large international companies and are in serious discussions with other potential clients with whom we hope to fill our R&D capacity for 2018\ . We have recently installed our own pilot-scale in-line patch manufacturing plant (January 2018) and have already successfully produced patches of our own ibuprofen patch and a batch of patches for our Japanese client which are being used in pre-clinical studies.

To meet our own future demands and commercial ambitions and to expand our service offering to clients for our formulation services we now need to expand our in-house manufacturing capabilities and to start the process of upgrading those facilities to produce clinical grade materials. This funding will support the expansion of our current formulation and production capabilities and to plan the future work necessary for us to obtain the GMP certification which will allow us to manufacture patch materials suitable for clinical trials.

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