Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
LABXERO LIMITED	CellFlow - Chemical-Free Cell Isolation for Commercial-Scale Cell Therapy Manufacturing	£497,943	£348,560
CELL THERAPY CATAPULT LIMITED		£51,464	£51,464
CELLULAR THERAPEUTICS LTD		£141,204	£98,843
University of Cambridge		£207,481	£207,481

Project description - provided by applicants

Cell-derived products have potential as promising therapeutic approaches for the treatment of a wide range of conditions (e.g. neurodegenerative disorders, cancer, cardiac failure). Cell therapies require large scale supplies of viable cells at high purity levels, driving advancements in cell separation technologies to address downstream processing bottlenecks to achieving high separation efficiency, throughput and sample purity at scale. The key project objectives are to develop, optimise and scale-up a low-cost, chemical-free continuous-flow cell separator/concentrator and demonstrate improved cell extraction efficiency and cell viability in pilot-scale cell therapy manufacturing trials. The proposed innovation lies in proprietary acoustic enhancements for particle manipulation, that provide a cost-effective, contactless, scalable solution for downstream bioprocessing - specifically cell/particle separation/concentration. Ultra low-cost, low energy acoustic methods enable increased throughput, resulting in a step-change beyond state-of-the-art downstream processing techniques. Successful project outcomes will overcome a key biomanufacturing bottleneck, helping to improve commercial viability of the UK Cell Therapy industry, thereby unlocking a sustainable UK bioeconomy.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
TERAVIEW LIMITED	Terahertz real-time release testing for pharmaceutical products	£417,851	£292,496
GLAXOSMITHKLINE PLC		£40,411	£20,206
HUXLEY BERTRAM ENGINEERING LIMITED		£279,608	£195,726
University of Cambridge		£225,317	£225,317

Project description - provided by applicants

The project will develop a new, rapid and non-destructive test instrument for predicting tablet efficacy and performance, based on direct measurements of tablet porosity using terahertz light. In so doing, we expect to contribute to manufacturing efficiency improvements in production of advanced solid dose medicines. Our technology will initially be marketed as a test which can work alongside existing methods (dissolution/disintegration and hardness testing) to improve tablet quality during the design process. The ultimate goal is to act as a real-time, in-line test and feedback mechanism as the industry moves towards Continuous Manufacturing.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
REXGENERO LIMITED	Cost-driven process redesign, automation and scale-out for commercial manufacture of REX-001 therapy	£572,494	£400,746
CELL AND GENE THERAPY CATAPULT		£484,758	£484,758
THERMO ELECTRON LIMITED		£319,167	£191,500
TRAKCEL LIMITED		£415,620	£290,934

Project description - provided by applicants
Rexgenero's lead program (REX-001) is an innovative autologous cell therapy in late-stage development for critical limb ischaemia, a major disease with high unmet medical need. REX-001 is in the last phase of clinical development, but making this potential new treatment available to the many patients who need it is currently limited by the ability to manufacture and deliver sufficient doses in a robust, cost-effective manner, transportation logistics and shelf life. The proposed collaborative project between Rexgenero, the Cell and Gene Therapy Catapult (CGTC), TrakCel and Fisher Bioservices (FBS) will develop a commercial-scale manufacturing process for REX-001 production, with automated needle-to-needle supply chain management and extended shelf life, which is critical to increasing availability to the many patients who are likely to benefit and the usability at the hospital. The Project will enable relocation of Rexgenero's late stage clinical cell therapy manufacture from Spain to the UK's CGTC Catapult Manufacturing Centre in Stevenage, making the UK Rexgenero's manufacturing site for future commercial supply for European markets. Establishing a commercially-viable REX-001 manufacturing process will provide major economic and health benefits to the UK and provide substantial quality of life and health benefits to patients suffering with critical limb ischaemia.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
AUTOLUS LIMITED University College London	Design, Transfer and Qualification of a Commercially-Scalable Process for Viral Vectors	£1,231,489 £478,504	£738,893 £478,504

Project description - provided by applicants

Advanced Therapies have come of age. The spectacular clinical results demonstrated by novel gene-engineered T-cell therapies, with subsequent regulatory approvals in the US, have confirmed the commercial reality of a new class of therapeutics that offer real hope to patients who are bereft of effective treatment options. But behind this hope lies a deep concern that high cost-of-goods and problematical scalability will severely limit patient access to these therapies.

A critical component of these therapies is a recombinant viral vector capable of effectively transducing the T-cells and enabling the expression of novel anti-tumour receptors. Unfortunately, the current technologies to manufacture these vectors at commercial scales are not fit for purpose. This project will combine leading academic expertise and the commercial imperative of a UK Biotech company to create innovative and scalable viral vector processes that will facilitate patient access to Advanced Therapies.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: **Medicines Manufacturing Round 1: Challenge Fund - CRD**

Competition Code: **1709_CRD_HLS_MEDMANRD1**

Total available funding is £14m

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
SYNPROMICS LTD LONZA BIOLOGICS PLC	Development of a novel inducible expression system for the manufacture of therapeutic proteins from CHO cells.	£103,688 £131,288	£72,582 £65,644

Project description - provided by applicants
Production of biopharmaceuticals that are toxic or have detrimental effects on the growth of the host cell line is very challenging. To overcome this challenge researchers have developed a number of promoters allowing control of protein expression during the bioproduction process. The primary aim of that research was to enable a 2-step bioprocessing platform to be developed whereby the expression of the gene of interest is switched on after sufficient biomass has been obtained or a gene that has negative effects on DSP or product quality can be silenced. This type of process is particularly attractive for the production of difficult to express or toxic proteins where expression is deleterious to the cell or where host cell protens co-purify with the final product and complicate purification strategies. However, to date these promoters have proven to have insufficient control for the task with leaky expression observed or the need for multiple rounds of transfection and cell line selection to achieve the requisite control. Ideally the activity of those promoters should be inducible/repressible by a stress stimulus (chemical or physical) during the production process and allow tight control over the expression levels to ensure maximum productivity and high quality of the final product. To this end Synpromics has used its proprietary technology to develop new synthetic inducible/repressible systems that have demonstrated exquisite control of gene expression. These systems offer significant advantages over the currently available systems as they are small in size, can be driven from one plasmid, offer fine tuning of gene expression, are driven by physiological or chemical stimulus that are non-toxic and are therefore ideal for improving productivity and minimising costs during bioproduction in CHO cells. Using these novel gene expression control tools Synpromics and Lonza will embark on an 18 month exemplification program to validate the use of these control tools in a GMP environment using well characterized model proteins. Once validated in an industrially relevant situation, these tools will then be used to design a process for a therapeutic construct and a manufacturing process will be developed. In addition to this outcome, the validation of Synpromics's control tools will increase the flexibility of bioproduction and offer the industry new powerful tools with which to increase the number and type of proteins that can be produced from CHO cells.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: **Medicines Manufacturing Round 1: Challenge Fund - CRD**

Competition Code: **1709_CRD_HLS_MEDMANRD1**

Total available funding is £14m

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
CAMENA BIOSCIENCE LIMITED	Rapid Metabolite Analyser for Medicines Manufacture	£1,276,527	£893,569
CENTRE FOR PROCESS INNOVATION LIMITED		£353,531	£353,531
GLAXOSMITHKLINE PLC		£0	£0

Project description - provided by applicants
Many modern medicines are no longer produced in chemistry labs, but instead in big bio-reactors where cells produce the medicines (aka biotherapeutics). This is similar to what happens when beer is brewed or yoghurt is made. Like any living organism, different strains of cells vary subtly with some much more effective at making high quality medicines than others. Thus it is important to select the best cell line for the medicine you are trying to produce. In addition, when growing cells it is important to regularly check that they are healthy and have the right levels of nutrients to ensure that a high quality medicine is produced at highest possible yield. An excellent parameter to monitor the health of these cell cultures is a diverse group of chemicals known as metabolites. These include nutrients (vitamins, sugars, amino acids, fats), but also metabolic by-products (like lactate) or toxins. Currently, whilst they are promising treatments, biotherapeutics are expensive to manufacture, thus are a big drain on a country's medicines budget. The close and repeated monitoring of multiple metabolites in cell culture processes could significantly improve the efficiency and cost of manufacturing biotherapeutics and avoid costly culture failures, enabling better medicines to be produced more cheaply, ultimately benefitting patients. Despite the noted advantages of metabolite monitoring, only a few are measured at present and at infrequent points in the process. This is because current measurement instruments are very expensive to purchase, each test is expensive, the machines are difficult to operate and slow in giving results. Our solution is to develop a breakthrough metabolite analyser that overcomes the above drawbacks. Our analyser will be able to quickly measure many different metabolites in one sample. Importantly it will be easy to use and much cheaper to purchase and run. This will make it usable at many stages of medicines manufacture, ultimately leading to new medicines reaching more patients.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
IPSEN BIOPHARM LIMITED	Novel production process for a highly potent recombinant protein using doggybone DNA (dbDNA) vector and cell free expression technology	£443,241	£221,621
CENTRE FOR PROCESS INNOVATION LIMITED		£353,510	£353,510
TOUCHLIGHT GENETICS LIMITED		£419,535	£293,675

Project description - provided by applicants

Toxic medicines are becoming a major focus of the pharmaceutical industry, as high potency products need minimal amounts to dose patients and so material requirements are low. However, the associated risks of working with these toxic products can make their development problematic, and traditional manufacturing routes are often unsuitable. This project will examine using cell free expression to produce a botulinum toxin from a "doggybone DNA" (dbDNA) vector. The project will develop a closed loop system for producing dbDNA, and screen a wide range of conditions to optimise a cell free expression system, for enclosed processing of toxins to negate the health and safety risks and technical yield limitations associated with high potency biopharmaceutical production. The project is a collaboration led by Ipsen Biopharm, involving Touchlight Genetics and the Centre for Process Innovation.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
ARC TRINOVA LIMITED University of Nottingham	Flow-inova: Innovation in manufacturing medicines	£1,399,996 £599,932	£839,998 £599,932

Project description - provided by applicants
The nature of small molecule drug substance manufacturing demand is changing in response to the development of new and more targeted pharmaceutical treatments. Small molecule drug substances are becoming generally more complex in nature, more potent, and as a consequence the drug substance requirements for a candidate drug, both through the clinical development phase, and at commercial launch, has reduced significantly. The future emphasis for drug substance manufacture will be on new manufacturing technologies which can be can be introduced to handle increasing complex chemistries, where manufacturing inventories need to be kept low, where product purity needs to be maximized, where manufacturing throughput and efficiency are maintained at high level, where the technology can be aligned with the ethical and economic desire to minimize reagent, catalyst, and solvent usage as part of a GREEN and where the manufacturing technologies can be rapidly switched over to cope with low batch numbers, but increasing numbers of discreet manufacturing stages. There is therefore a clear, and as yet unmet need, for the implementation of a flexible modular manufacturing technology platform which can facilitate the above. Our vision for this project is the development of a continuous, modular manufacturing technology platform which will enable ARCINOVA to be a leading player in the development, scaleup and manufacture of new small molecule drugs. The project will focus on the development of new innovative continuous manufacturing technologies which can be rapidly transferred from proof of concept to a commercial scale asset. Initially a number of key technology areas will be chosen for development. These areas will be chosen on the basis of expected technical need from ARCINOVA, and on the basis of demonstrated expertise from the academic partner (University of Nottingham). The project outcome will enable the consortium to demonstrate operating feasibility of world first innovative continuous production tools, and will establish ARCINOVA as a world leader in defining continuous modular manufacturing technology for the support of new chemical entities (NCEs) development, scale up and manufacture

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: Medicines Manufacturing Round 1: Challenge Fund - CRD

Competition Code: 1709_CRD_HLS_MEDMANRD1

Total available funding is £14m

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
MEIRAGTX UK II LIMITED	Development and implementation of a next-generation commercial gene therapy manufacturing platform	£732,083	£512,458
SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED		£340,510	£238,357
TOUCHLIGHT GENETICS LIMITED		£799,260	£559,482

Project description - provided by applicants

MeiraGTx, Touchlight Genetics and Symbiosis Pharmaceutical Services are collaborating to develop an improved Adeno-associated virus manufacturing process. The process will be improved through a number of different routes to deliver a cost effective large-scale bioreactor manufacturing process for the production of AAV gene therapies

Through our collaborative bioreactor development program we will achieve:

An increased yield of infectious AAV particles sufficient to enable the transition of gene therapies from niche to more first line therapy and higher dose indications
A serum free process -- reducing regulatory risk, adventitious agent testing costs, and a source of variability
A synthetic DNA transduction method -- removes common blockages in the manufacturing supply chain, reduces COGs, reducing regulatory risk, reduction in adventitious agent testing costs, and a source of variability
A lower cost of goods due to improved process efficiency, represented by a higher product output from the same GMP suite time

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: **Medicines Manufacturing Round 1: Challenge Fund - CRD**

Competition Code: **1709_CRD_HLS_MEDMANRD1**

Total available funding is £14m

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
RENEURON GROUP PLC	Multi-donor allogeneic human retinal progenitor cell therapy (hRPC) 4sight	£483,427	£290,056
CELL THERAPY CATAPULT LIMITED		£300,140	£300,140
ROSLIN CELL THERAPIES LIMITED		£917,880	£642,516
University College London		£298,261	£298,261

Project description - provided by applicants
ReNeuron is a biotechnology company that is experienced in developing cell therapy treatments for degenerative diseases such as stroke rehabilitation and diseases of the retina, such as retinitis pigmentosa (RP), for which there are no known treatments. In RP, the light detecting photoreceptor cells in the eye die gradually over a period of time, and the ultimate consequence to the patient is vision loss. Our own preclinical scientific research shows that it is possible to either protect these photoreceptor cells from dying and/or replace the lost photoreceptors by injecting similar cells, from donated eye tissue, that are grown in culture in the laboratory. ReNeuron is currently conducting Phase I/II clinical studies in RP. The hRPC cells may have efficacy in many different retinal degenerative diseases of the eye, therefore, ReNeuron has ambitions to extend the use of hRPC into multiple indications. For our cell treatment therapy to fully exploit the market potential in the long term, we need to be able to make cells on an industrial scale, and we, therefore, need to be able to characterise and select more eye tissue donations. We must always ensure the quality and comparability of the hRPC cells during these clinical trials and when we eventually supply the market. Therefore, in this project our intention is to make new banks of cell product from different donors, and, develop scientifically validated assays to demonstrate that the cells that are produced from each donor have the same biological properties as the first cell product, and that these properties are maintained during the cell expansion that is part of the manufacturing process. These assays are essential to develop as they will form the basis of Quality Control of the cell product for use in humans, just like with other medicines. We have formed a consortium that will bring together expertise in all of the relevant areas that are needed to make this project a success. The UK has a strong position in developing cell therapies and the current project will add to strengthening this position. Also, if the project is successful, we will set the standards for the manufacture of multi-donor cell based therapies into the future.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results

Innovate UK

Results of Competition: **Medicines Manufacturing Round 1: Challenge Fund - CRD**

Competition Code: **1709_CRD_HLS_MEDMANRD1**

Total available funding is £14m

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
PHICO THERAPEUTICS LIMITED	Development of Manufacturing Process of Engineered-Phage for IV administration in P.aeruginosa infections	£1,885,916	£1,320,141
GE HEALTHCARE UK LIMITED		£0	£0
THE CLINICAL TRIAL COMPANY LTD		£99,997	£69,998

Project description - provided by applicants
Phico is a biotechnology company developing a novel platform technology, SASPject, to treat infections, particularly those due to antibiotic resistant bacteria. Phico is developing an intravenous SASPject, PT3.8 targeted against Pseudomonas aeruginosa which causes 10% of all hospital infections and is a major cause of hospital acquired and ventilator associated pneumonia where it causes a very high rate of mortality. There are globally limited options for manufacturing novel engineered-biologicals, particularly phage-based, such as SASPject, resulting in significant barriers to the development of these drugs, ultimately limiting patient options for treatment. To address this need, outside of this grant Phico is developing its own internal Good Manufacturing Practice (GMP) capabilities for process optimisation and manufacture of future SASPject platform products in the UK. The grant objectives are: *Optimise the development of the manufacturing process for PT3.8 to increase the yield, thereby ensuring commercially viable cost of goods, and develop a purification method that ensures the product is fit for intravenous use in humans. *Scale up and provision of a 15L engineering batch of material for GLP-toxicology studies, exemplifying Phico's facility, thereby supporting its GMP accreditation As well as underpinning and optimizing manufacture of Phico's first intravenous product, this project will form the foundation for exemplifing the UK's first GMP manufacturing capability suitable for GMP manufacturing of bacteriophage-based therapeutics which will ultimately support production of the Phase 1 and later clinical batches for PT3.8 clinical development. This will ensure future manufacturing capacity and sustainability for Phico's lead product and future product pipeline, providing a solution to the major barrier to fulfilling Phico's pipeline manufacturing requirements. Longer-term, Phico plans to make its manufacturing capabilities available for rental to other biotechnology companies when not in use by Phico, enabling other companies to conduct manufacturing in the UK, retaining knowledge of manufacturing processes in-house and in the UK. Phico will work with two collaborators on the grant: The Clinical Trial Company will provide a Qualified Person to set up and oversee the Quality Assurance system to support PT3.8 manufacture, oversee and release the engineering batch of PT3.8 ensuring it will ultimately underpin a Phase 1 batch for approval by the UK's Medicines and Healthcare products Regulatory Agency (MHRA); Second collaborator, GE Healthcare UK Ltd have a Manufacture of Investigational Medicinal Product Licence in the UK for manufacture of medicines and will be providing advice and guidance throughout the project.

Note: you can see all Innovate UK-funded projects here
https://www.gov.uk/government/publications/innovate-uk-funded-projects Use the Competition Code given above to search for this competition's results