Innovate UK

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

Competition Code: 1709_FS_HLS_MEDMANRD1

Total available funding is £1m for Feasibility

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
OXFORD MESTAR LIMITED SEE-THROUGH SCIENTIFIC LIMITED	In-line digital holographic microscopy for automated QC and process control in cell therapy manufacturing	£59,962 £33,331	£41,973 £23,332

Project description - provided by applicants

Recent advances in cell therapy and immunotherapy are changing the face of modern medicine. In particular a new type of treatment -- CAR-T therapy, made from the patient's own immune cells -- is offering new hope to cancer patients. The drawback of these treatments is that they are extraordinarily expensive to produce using current methods and hence are unaffordable to public healthcare systems. Automation is key to making cell therapy manufacturing more efficient and more affordable. One factor holding back progress in this area is that current technologies for process control and monitoring are either inadequte or involve a high level of manual input. The aim of this project is to develop a new type of in-line measurement system that uses the power of digital holographic microscopy to image cells in 3D directly within a bioreactor system. Machine learning software will then interpret the images to generate a rich set of measurements that can be used to optimise the speed and quality of the process in real time. Developing this technology will give UK startups Oxford MEStar and See-Through Scientific a world-beating competitive edge in the rapidly growing CAR-T manufacturing market.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BIOPHARMA PROCESS SYSTEMS LIMITED	FAstLyo: Formulation accelerated freeze-drying by reduced vapour flow resistance (micro-collapse)	£62,860	£44,002
De Montfort University		£29,938	£29,938
ONCOLYTIKA LTD		£7,050	£4,935

Project description - provided by applicants

New medicines/therapies being developed by the pharmaceutical industry and research organizations are increasingly based on some type of biological (rather than chemical) substance, e.g. a large molecule like a protein rather than a small molecule like aspirin. These substances, known collectively as biopharmaceuticals, are significantly more complex to develop and manufacture as a stable and efficacious product than their chemical counter-parts. This increases the demand for new knowledge and understanding to enable the development of these products (for example the composition or formulation of the product) and the associated commercial manufacturing process. Progress in developing new methods and instrumentation which are tailored specifically to the concurrent design of product and process, has been constrained largely by the relatively small market for such instruments and the significant investment that is required to, first test their feasibility, and then develop into a fully validated market offering. The aim of this project is to test the feasibility for developing a new instrument, that has the potential for further development into a high throughput screening tool that will provide the new knowledge required to accelerate and de-risk the development of new product in the fast developing markets for biopharmaceutical, while presenting a unique opportunity for SMEs in the CRO sector and Research Organizations to increase market share and create opportunities for high-skilled employment in this sector.

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Innovate UK

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

Competition Code: 1709_FS_HLS_MEDMANRD1

Total available funding is £1m for Feasibility

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CHAIN BIOTECHNOLOGY LIMITED	Anaerobic Bacterial Spore Therapeutics and their Manufacture	£49,978	£34,985
PORTON BIOPHARMA LIMITED		£24,997	£12,499
SCITECH ENGINEERING LTD		£25,000	£15,000

Project description - provided by applicants

The gut microbiome is a pharmacologically active tissue controlling infection, inflammation, receptor signalling, hormone secretion and central nervous system signalling. These events have significant impacts on patient health and wellbeing (Nature Special Review, June 2012). The importance of the gut microbiome in both health and disease is now widely recognised resulting in an explosion in research, development and pharma investment in new therapeutics, based on live microbes, that can treat chronic gut related diseases. Clostridia are the most prevalent class of microbes in the human large intestine. CHAIN Biotech capitalises on its unique expertise with these bacteria to develop a novel live biotherapeutic for treating inflammatory bowel disease. This product has been validated in pre-clinical tests and we now seek a manufacturing partner that can produce spores for clinical trials. No such facility exists in the UK and this project seeks to address this bottleneck. More specifically, the partners will determine the costs and economic feasibility to build a bespoke spore manufacturing plant in the South East for CHAIN and other SME microbiome and biotech companies.

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Competition Code: 1709_FS_HLS_MEDMANRD1

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BIOMOTI LIMITED	Paclitaxel-loaded biodegradable microparticle production optimised on a microfluidics platform	£21,104	£14,773
CENTRE FOR PROCESS INNOVATION LIMITED		£28,854	£28,854
PHARMIDEX PHARMACEUTICAL SERVICES LIMITED		£49,931	£34,952

Project description - provided by applicants
Cancer is the second leading cause of global mortality with over 8,000,000 deaths worldwide (WHO, 2015) and 163,444 in the UK (CRUK, 2014). There continues to be large unmet clinical need for patients with certain cancers such as ovarian where median survival is only 3 years. These survival rates have not changed for the past 3 decades. BioMoti, in a new alliance with Pharmidex and the CPI, is developing the Oncojan(tm) platform to overcome current limitations. Oncojans(tm) are a new class of precision sustained therapeutics that are loaded in biodegradable microparticles and target CD95L on tumours. CD95L is overexpressed on cells of the tumour bulk and vasculature (but not on healthy tissue) where it promotes proliferation, metastasis and immune evasion. BMT101 is the Oncojan(tm) based lead candidate that is the chemotherapy loaded into biodegradable microparticles surface modified with CD95R to target CD95L. This proposal aims to build on exciting pilot data showing that BMT101 results in remarkable preclinical activity; 65-fold reduction in tumour burden, doubling of median survival and loss of toxicity compared to the Taxol(r) standard-of-care chemotherapy in ovarian cancer. One major barrier to progressing the technology to a successful commercial outcome is the ability to controllably manufacture microparticles with desirable attributes at a meaningful scale. This includes reliably producing microparticles with high paclitaxel loadings at a specific and monodisperse size. For this project, we will study the feasibility of developing a scalable protocol for the reproducible manufacture of BMT101 formulation with desirable attributes using microfluidics technology. We will verify that produced formulations maintain high efficacy in vitro and in vivo as seen in early pilot studies. The aim is to provide a clear route for the future manufacture of regulatory compliant material for clinical trials. Positive project outcomes will enable commercial investment to support future formal development of BMT101 for the benefit of patients in the highly unmet ovarian cancer indication. It is likely the same formulation could be used in further poorly treated indications such as triple negative breast or oesophageal cancer.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ANGLO BIOPHARMA LIMITED	mAb manufacturing for future subunit vaccine platform	£30,334	£21,234
ABSOLUTE ANTIBODY LIMITED		£39,109	£27,376
University of Reading		£29,401	£29,401

Project description - provided by applicants
Anglo Biopharma Limited is a UK based British biotech startup. It is using advanced molecular and synthetic biology techniques to rapidly generate new candidate vaccines for protection against emerging and outbreak infections that could spread worldwide. A major problem for dealing with outbreaks such as Ebola, SARS and Zika is that existing vaccines are slow and complex to produce, and so it can take many years to develop a new vaccine against emerging infections. Each vaccine requires a different factory design. Anglo Biopharma's approach is to produce 'subunit' vaccines which are specially engineered using a standard protein 'backbone' that can give good protection from a single, simple and highly purified component. This type of vaccine is highly suitable for rapid manufacture using existing factories that were developed to produce a type of medicine called 'therapeutic antibody'. Drugs like Herceptin are 'magic bullet' drugs that can specifically target certain diseases such as cancer. The manufacturing methods used to make these have not yet been applied to vaccine production. Anglo's first target is Middle Eastern Respiratory Syndrome (MERS). MERS is an emerging infectious disease related to SARS that was described by the director of the World Health Organisation (WHO) as a a threat to the entire world" because of the concern over its potential to rapidly spread beyond the Middle East across the world. So far, Anglo has produced new "subunit" vaccine candidates using research production facilities, but not yet used clinical grade manufacturing methods to produce these MERS vaccine candidates. Anglo Biopharma has joined with project partner Absolute Antibody, another UK based and rapidly growing company, is expert in the rapid manufacture of antibodies for clinical diagnostics and researchers. These two UK SMEs have teamed up with the University of Reading who will provide expertise in testing vaccine candidates. In this project, the team will test whether the latest antibody manufacturing methods are suitable for production of novel MERS vaccine candidates, and compare the effectiveness of vaccines produced using two different production methods. This will demonstrate feasibility of rapid production of high quality clinical grade vaccine using a method that is ideal for dealing with global outbreaks of new infections."

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

Competition Code: 1709_FS_HLS_MEDMANRD1

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
N4 PHARMA UK LIMITED MEDIMMUNE LIMITED	Manufacturing process development for Nuvec nanoparticles for the delivery of therapeutic Papilloma Virus (HPV) nucleic acid vaccines	£63,435 £0	£44,405 £0

Project description - provided by applicants
Human Papilloma Virus (HPV) has been implicated in a range of cancers. Currently, a prophylactic vaccine is prescribed for adolescent girls with a view to prevent infection by HPV. However, this preventative vaccine does not have a therapeutic effect on malignancies developed as a result of HPV infection. In this regard, the use of nucleic acid vaccines for treatment of HPV related cancers has been considered, for which the proposed strategy is to induce antigen specific immune response to cancer cells in the body. As for many systems of this type the challenge is to deliver the plasmid DNA (pDNA) or messenger RNA (mRNA) effectively to antigen presenting cells, with a view to stimulating recognition and destruction of cancerous cells by the immune system. The challenge for pDNA vaccine delivery relates to the availability of suitable and safe non-viral vectors which have high loading capacity for pDNA and mRNA and are able to recruit antigen presenting cells to the site of injection, but do not elicit an excessive inflammatory response. In this regard, N4 Pharma have developed a novel vector (Nuvec), which has been demonstrated to provide high nucleic acid loading capacity and transfection in in-vitro and in-vivo experiments. This 9 month feasibility project will explore the manufacture of a prototype nanomedicine product using N4 Pharma's Nuvec system for delivery of a therapeutic HPV nucleic acid vaccine. It will focus on the design of a process for manufacturing Nuvec nanoparticles optimally loaded with pDNA and modified mRNA encoding antigens specific to HPV related malignancies. This will include evaluation of strategies for maximising loadings and reducing the levels of free nucleic acids in the formulation.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ADDED SCIENTIFIC LIMITED XAARJET LIMITED	Printed Pills: Inkjet printing for pharmaceutical applications	£52,856 £17,248	£36,999 £8,624
Project description - provided by applicants			
Additive Manufacturing (aka 3D Printing) offers the pharmaceutical industry significant opportunities to create novel products with unique benefits for patients. However, there is a major challenge in demonstrating the viability and scalability of using ink jet printheads. This project aims to overcome these challenges, and build confidence in the potential opportunities for ink jet technology in the pharmaceutical industry.			

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Innovate UK

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

Competition Code: **1709_FS_HLS_MEDMANRD1**

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
TECEXEC LIMITED	Active and passive Ingredient wet Milling (AIM)	£99,385	£69,570

Project description - provided by applicants
This project evaluates the feasibility of applying ConCor wet milling technology to the dispersion and deagglomeration of nanomaterials and the production of nano emulsions within the Pharmaceutical Industry. Whilst the importance of the application of active and passive nanomaterials within the Pharmaceutical industry has been identified, many applications are still at an early stage of development. Technology road-mapping indicates that one key process area is the efficient and effective dispersion of nanomaterials at industrial scales. Often presented as powders, nanomaterials tend to form agglomerates of primary particles, mainly due to van der Waals' forces, that are orders of magnitude larger than the primary particles. These need to be dispersed back down to primary particle sizes if the effects of the nanomaterials are to be exploited and then evenly distributed within the target product. Nano scale emulsions are another area of increasing interest, as many delivery systems include insoluble APIs in liquid form, e.g. anaesthetic emulsions, and these can benefit from droplet size reduction. This requires similar approaches to particle dispersions as the problem of inter particulate forces are common to both. Whilst sonication and media milling have been used at smaller scales, and high pressure homogenisers and high shear mixers at larger scales, there are clear drawbacks to the use of these technologies. As an alternative, ConCor technology has been demonstrated to provide a number of benefits over a range of nanomaterials. This project aims to test the feasibility of applying ConCor technology to meet this need within the Pharmaceutical Industry by designing and building a small-scale hygienic system and testing it on up to 3 material systems. In addition to the results obtained during the project, the resultant ConCor system will be made available for further testing and demonstrations at the end of the project.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
RENEURON LIMITED National Instiute for Biological Standards and Control	Single Cell Transcriptome Profiling for Advanced Cell Therapy Manufacturing Process Monitoring	£74,997 £24,998	£44,998 £24,998

Project description - provided by applicants
Our project is a collaboration between ReNeuron Ltd, a well-established British stem cell therapy company and the Department of Advanced Therapies at the National Institute for Biological Standards and Control. ReNeuron has created an immortalised neural stem cell line called CTX, which is presently undergoing clinical trials as a transplant treatment for stroke and ischaemia (damage to the limbs similar to that caused by stroke in the brain) and also for exosomes (nano-scale particles produced by the CTX cells) as therapeutics in their own right. Stem cells such as CTX are capable of differentiating into other cell types found in the body; this is why there is so much interest in them as potential therapeutics for many otherwise hard-to-treat conditions. However, this presents difficulties: unlike a preparation of a standard small molecule drug, each preparation of stem cells is unique, being a constantly changing, dynamic living thing that responds to its environment. This presents challenges with confirming the efficacy of each cell population, and with ensuring that changes to manufacturing protocols, for example, when they are scaled up to produce large cell batches of a size suitable for treating significant numbers of patients, do not introduce untoward changes in the cell populations. It is now possible, using a technique called scRNAseq (single cell RNA sequencing) to identify all of the genes expressed in a single cell, for large numbers (hundreds to thousands) of individual cells. This allows us to create the most fine-grained profile of a cell population, identify subpopulations in the stem cell population, and explore differences between different batches of nominally the same cell type prepared at different times or by different methods. We will compare our CTX neural stem cell line with similar sister cell lines, human pluripotent" stem cell lines including reprogrammed CTX cells, and stem cells of different types such as mesenchymal stem cells (MSCs) derived in turn from CTX-derived pluripotent stem cells. Cross-comparing these results with current assays for therapeutic activity or phenotype will allow us to distinguish the therapeutic subpopulations from "passenger" cell types, to rationally optimise protocols for cell preparation, and most importantly confirm unequivocally that our stem cell therapies are safe and effective to the patient."

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BIOTOOLOMICS LIMITED	Very efficient platform purification process for gene therapy medicines using innovative chromatography technology	£95,826	£67,078
Project description - provided by applicants			
Gene therapy has formed one of the most advanced medical technology in the modern precision medicine area. It has shown some unique advantages in curing certain diseases. There is a growing demand of high quality viral medicines to be manufactured with efficient and cost-effective processes. This feasibility study project proposes a much efficient purification process to address the technical challenges facing this emerging market.			

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