Innovate UK

Results of Competition: Analytical technologies for biopharmaceuticals
Competition Code: 1509_CRD2_HVM_AATBP

Total available funding for this competition was £3,402,284 from Innovate UK

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
GlaxoSmithKline Research and Development Ltd Cell Therapy Catapult LGC Ltd	RaSTA (Rapid Sterility Testing Approach)	£992,842	£634,526
Project description - provided by applicants			
Current safety methods for product release such as the compendial sterility test are inadequate for a largenumber of autologous cell and gene therapy products due to their short shelf life. This problem is exacerbatedby the long complex manufacturing processes during which microbial contamination can occur. As a resultsterility testing has to be performed during manufacture and the products released with an element of risk.This project, led by GSK and supported by the Cell Therapy Catapult and LGC, will address this issue bydeveloping a rapid sterility test (<1hr) based on a novel technology to allow real time product release. Theproject will also develop a high sensitivity approaches which will quantify live and dead microbial contaminantsfor in-process testing and be used to validate the readout of the rapid sterility test. These technologies will be amajor innovation for the field and will provide a much needed technical solution to allow cell and genetherapies to be tested for safety prior to their use.			

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: Analytical technologies for biopharmaceuticals
Competition Code: 1509_CRD2_HVM_AATBP

Total available funding for this competition was £3,402,284 from Innovate UK

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
Malvern Instruments Ltd Paraytec Ltd University Of Central Lancashire Centre for Process Innovation Ltd GlaxoSmithKline PLC Fujifilm Diosynth Biotechnologies UK Ltd Medimmune Ltd	Towards a condensed screening platform for aggregation profiling	£1,032,915	£598,349

Project description - provided by applicants

Biotherapeutic drugs are an increasingly important class of new medicines and their effective action in thetherapeutic treatment of disease has attracted interest from both academic and industry sectors. Despite theoverwhelming benefits to patients, the availability of these drugs at point-of-care is inextricably linked to theiraffordability. Currently, the costs associated with the development and production of safe and effectivebiotherapeutic drugs are extremely high, and such costs must ultimately be passed on in the final drug product.One of the major risk areas in drug development is the occurrence of bundles of drug molecules known asaggregates, which can result in unwanted side-effects in patients or in a reduction of therapeutic effectiveness.This project brings together biopharmaceutical companies, academic research leaders and developers ofscientific instruments in order to produce novel sensors that can improve the detection of drug aggregatesthroughout the drug development process. With this novel analytical technology, we aim to attenuate the risksassociated with aggregation to ensure the delivery of safe and cost-effective drugs in 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: **Analytical technologies for biopharmaceuticals**
Competition Code: **1509_CRD2_HVM_AATBP**

Total available funding for this competition was £3,402,284 from Innovate UK

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
GEA Process Engineering Ltd Bluefrog Design Ltd IS-Instruments Ltd Ocean Optics B.V. CPI Innovation Services Ltd OncoLytika Ltd National Institute for Biological Standards and Control (NIBSC) Fraunhofer UK Research Ltd De Montfort University Nottingham University	AtlasBio - Analytical Technologies for the Lyophilization and Stabilization of Biopharmaceuticals	£1,143,541	£804,931

Project description - provided by applicants
The AtlasBio project will strengthen the UK knowledge base in science and engineering in the areas of freeze-drying product and process development, & influence the future directions and strategy in biopharmaceutical product and freeze-drying process development. The need is for new measurement technology for concurrent product and process design and the development of more efficient continuous processes, moving away from batch and increasing process efficiency and reducing waste.The project aims to develop and demonstrate scalable PAT to support freeze drying of biologics in order to support (i) scale up of batch freeze-drying (from high-throughput formulation screening to process development and scale-up), (ii) development of freeze drying processes for next generation biopharma products, by designing more robust, scalable processes via the in situ evaluation of interactions between critical material attributes and critical process parameters, thereby enabling (a) drying efficiencies (drying rate), and (b) the development and implementation of continuous freeze-drying methods.

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: Analytical technologies for biopharmaceuticals
Competition Code: 1509_CRD2_HVM_AATBP

Total available funding for this competition was £3,402,284 from Innovate UK

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
Celltech R&D Ltd Applied Photophysics Ltd Centre for Process Innovation Ltd	Practical application of Circular Dichroism for biopharmaceuticals	£321,609	£231,155
Project description - provided by applicants			
Circular dichroism (CD) spectroscopy is an analytical technique routinely used in the biopharmaceutical industry to study the effects of manufacturing, formulation, and storage conditions on protein conformation and stability. The difficulty in data interpretation of CD is limited to demonstrating conformational comparability after a manufacturing/formulation change using qualitative assessments of overlaid spectra, which is fundamentally subjective and prone to error. This project will standardise data collection and analysis and build model based approaches for quantitative analysis of Higher Order Structure using CD. The data collected will allow for the generation of platform models and data sets to widen the application of CD into bioprocess development.			

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: Analytical technologies for biopharmaceuticals
Competition Code: 1509_CRD2_HVM_AATBP

Total available funding for this competition was £3,402,284 from Innovate UK

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
Applied Photophysics Ltd Centre for Process Innovation Ltd Medimmune Ltd University of Cambridge	Biopharmaceutical HOS analysis by automated fast hydrogen deuterium exchange	£837,597	£614,374
Project description - provided by applicants			
Knowledge of a biopharmaceutical product's higher order structure (HOS) and conformational dynamics, andhow these relate to it's mode of action and/or degradation, are central to enable effective and streamlinedbiopharmaceutical development through QbD-based approaches. Hydrogen deuterium exchange massspectrometry (HDX MS) is a technique increasingly used to characterise the HOS of peptide and proteintherapeutics. HDX MS can determine structural perturbations in a protein that elicit changes in conformationaldynamics or solvent accessibility. Commercial implementation of automated HDX MS analysis, has greatlyincreased the utility of HDX MS in the biopharmaceutical industry for HOS analysis. But there are limitationswith these systems where unstructured or highly dynamic, solvent exposed protein regions are not able to bedifferentiated or analysed. This team propose to develop a system that will allow routine analyse of theseproteins and peptides with HDX MS.			

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