Developing commercially-successful Pharmaceutical products and processes

Accelerate the development, scale-up and commercialisation of your novel biologics across multiple processes and modalities.

CPI – a trusted partner to support the development of your strategy, technology, process and product

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CPI is an independent, deep-tech innovation centre addressing the global challenges and opportunities of society, industry and the environment

We help companies to develop, prove, scale-up, and commercialise their disruptive and transformative novel innovations - within key Pharmaceutical markets

- **Biologics**
- **Oligonucleotides and mRNA**
- **Microbiome and Phage**

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CPI has the expertise, capabilities and connections to define and develop strong solutions for the Pharma market

700+
Members of staff

500+
Scientists and engineers

Expertise in development and scale-up (biologics, small molecules and complex medicines), formulation, process optimisation and sustainable and digital manufacturing.

Business founded in **2004**

Celebrating **20** years of innovation

£3 billion
Unlocked private investment into R&D&I

Industry network
Senior leaders across major Pharma and BigTech

$300 million
in innovation facilities

Supporting innovation and scale-up in multiple modalities: Including protein-based biologics, gene therapies, nucleic acids, microbiome and phage.

Improving your processes: Net-zero, digital transformation including PAT, and process intensification and continuous processing.

CATAPULT High Value Manufacturing

Founding member of the UK's High Value Manufacturing Catapult

1500 R&D&I projects delivered

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The drug development process

Research → Discovery → Pre-clinical → Clinical → Commercial on patent → Commercial off patent

Medicine manufacturing innovation and development

Antibodies	Digital Transformation
Therapeutic Proteins	Sustainability
Viral Vectors	Oral solid dose
mRNA	Nanomedicines
Oligonucleotides	Microbiome and Phage

Commercial drug manufacturing

Core CPI capability

Non-core CPI capability

What value does CPI bring to Pharma?

Protect

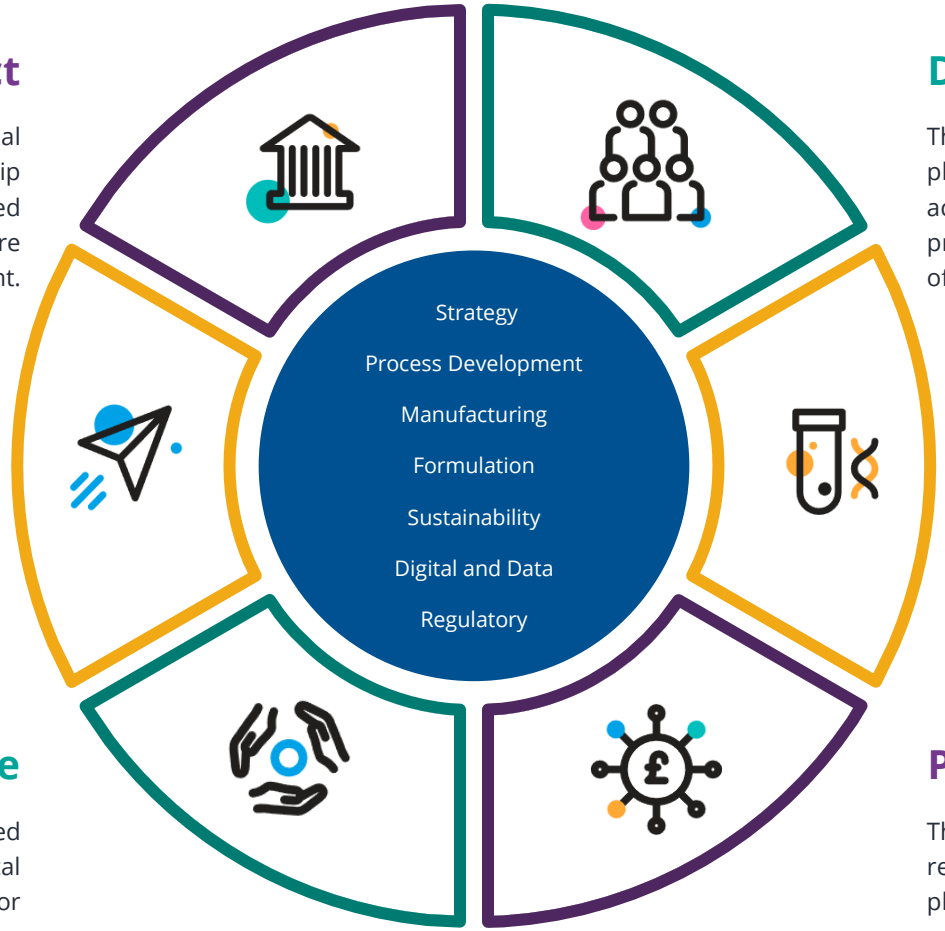
CPI's unique approach to intellectual property means you retain full ownership and freedom to operate, without being tied into specific processes or limited in future development.

Streamline

Complex approval processes, ensuring compliance with evolving FDA, EMA, or MHRA requirements through CPI's regulatory experts. Allowing you to focus on advancing your medicines and pharmaceutical innovations.

Secure

The financing and strategic alliances needed to bring your medicine or pharmaceutical innovation to market. Whether it's for funding, corporate investment or acquisition, CPI can help.



Demonstrate

The benefits of your medicine or pharmaceutical innovation faster by accelerating development, scale-up and progress to market leveraging the expertise of CPI's scientists and engineers.

Evidence

The manufacturability and scalability of your medicine with CPI's expertise in process development and scale up, digital modelling, formulations and characterisation.

Prove

The commercial viability and investment readiness of your medicine or pharmaceutical innovation through CPI's process expertise and supply chain experience.

Our capabilities

Deep expertise in medicines manufacturing innovation, digital technologies and sustainable production

Biologics

Accelerating the development and scale-up of biologics and advanced therapies

- Biologics – development and scale up of recombinant proteins and antibodies
- Viral vectors – scale-up and characterisation for gene therapies
- Microbiome and Phage therapies – process development, optimisation and characterisation
- Formulation– supporting clinical and commercial readiness

Oligonucleotides and mRNA medicines

Supporting innovation, scale-up and GMP-manufacture for oligonucleotide and mRNA medicines

- Oligonucleotides – ASO and siRNA
- mRNA-LNP – mRNA synthesis, encapsulation and characterisation
- Process innovation – scalable, sustainable manufacturing processes
- Analytical testing – advanced characterisation and quality control

Formulation and Process Optimisation

Innovating and optimising formulation and manufacturing processes for complex pharmaceuticals

- Formulation – oral solid dose, biologics and complex medicines
- Process design and optimisation – batch and continuous processing
- Digital tools – modelling, simulation and advanced control
- Sustainability – green chemistry, sustainable manufacturing

USPs

- **Freedom to operate** - CPI's flexible approach to IP ensures clients retain full ownership and freedom to use their innovations without restrictions.
- **Multimodality expertise –** biologics, oligonucleotides, mRNA therapeutics, microbiome and phage
- **Process excellence –** digitalisation, continuous manufacturing, and sustainability
- **Formulation leadership –** across complex and advanced pharmaceutical formulations

Case studies: Biologics

View Case Studies

Improving glycoprotein analysis for biopharmaceuticals

We supported the development and optimisation of a novel glycoprotein analysis tool to improve speed, specificity and cost-effectiveness in biotherapeutic production.

This enabled a more efficient and scalable analysis process, supporting reduced manufacturing costs and faster turnaround.

Scaling nanomedicine production for advanced therapies

We developed a scalable microfluidics-based process to enable the clinical translation and commercialisation of nanomedicines.

This work established advanced capability for nanomedicine manufacturing, helping accelerate novel therapeutics development.

Developing oral delivery of antibody therapies

We supported the development of a scalable manufacturing process for the first oral formulation of a monoclonal antibody therapy for Inflammatory Bowel Disease (IBD).

This enabled a stable, clinically ready oral antibody product, helping to advance a new treatment option that improves patient convenience and reduces the need for hospital-based infusions.

Case studies: Biologics

View Case Studies

Advancing continuous biomanufacturing

We automated process control within a continuous biomanufacturing system to enhance robustness, intensify production, and improve efficiency and scalability.

This work enabled more consistent and scalable production of biologics through advanced process automation.
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Boosting infant health with breast milk-derived probiotics

We optimised and scaled a co-culture bacterial fermentation process for a next-generation infant gut supplement containing probiotic microbes isolated from breast milk.

This enabled robust, multi-strain production at scale, accelerating manufacture of a product that supports early immune and gut development in newborns.

Scaling up DNA manufacturing for vaccines

We supported the scale-up and optimisation of an advanced DNA manufacturing process for vaccines and genetic medicines.

This accelerated process readiness for GMP production and helped attract significant private investment in advanced therapy manufacturing.

Case studies: Oligonucleotides and mRNA

View Case Studies

Enabling sustainable manufacturing of oligonucleotide therapeutics

We are developing scalable, liquid-phase and enzyme-driven production methods to support the sustainable, cost-effective manufacture of oligonucleotide medicines.

This work is reducing solvent use and waste, cutting costs, and helping to accelerate patient access to advanced oligonucleotide therapies.

Developing ambient-stable RNA vaccine formulations

We supported the development of a thermostable formulation using deep eutectic solvents (DES) to enable storage and transport of RNA vaccines encapsulated in LNPs without freezing.

This innovation allows manufacturers to store RNA vaccines at ambient temperature, dramatically reducing cold-chain costs and improving global vaccine access.

Intensifying mRNA manufacturing

We evaluated novel advanced chromatography resins to intensify in-vitro transcription reactions, enabling cost-effective and sustainable manufacturing of mRNA vaccines and therapeutics.

This supported greater process efficiency and improved the scalability of mRNA production.

Case studies: Formulation and Process Optimisation

View Case Studies

Accelerating nano-pharmaceutical manufacturing

We supported the development of an open-access pilot manufacturing line and end-to-end supply chain to enable faster, more sustainable production of nano-pharmaceuticals.

This helped advance regulatory readiness, reduced manufacturing costs, and enabled clinical progression of novel therapies for cancer and other unmet medical needs..

Advancing targeted drug delivery for cancer treatment

We developed a continuous microfluidics-based manufacturing process to produce monodisperse Paclitaxel-loaded PLGA microparticles with high encapsulation efficiency.

This enabled improved drug delivery, reducing side effects and allowing lower dosage in ovarian cancer treatments.

Accelerating continuous manufacturing of oral medicines

We developed an integrated multi-step continuous process platform aligned with portable, modular and digital manufacturing principles for oral solid dose production.

This enabled faster optimisation of oral solid drug formulations, supporting more efficient and flexible pharmaceutical manufacturing.

Thank you

For more information visit **www.uk-cpi.com**

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CASE STUDY

Cell Free Expression

Cell free expression has the potential to revolutionise the supply chain for specific biopharmaceuticals. As personalised medicines become a reality, the necessity for small batch sizes makes traditional manufacturing approaches prohibitively expensive; the use of CFE offers a cost-effective solution.

This project focused on exploring the potential to exploit CFE to manufacture biopharmaceuticals. A fully scalable CFE platform was developed to facilitate rapid and flexible manufacture of the next generation of biologics, bringing better treatment options for patients one step closer.

Inputs

Access to CPI's state of the art bioprocessing facilities

Shared expert technical and industry knowledge

Project scoping, consortia building and proposal development

Outputs

Generation of a robust and scalable manufacturing process

Establishment of high throughput screening tools

Development of an optimised and scalable protocol for cell free expression

Improved production process for novel product

Outcomes

A new manufacturing route for biopharmaceuticals

Benefits to the supply chain as biopharmaceuticals and vaccines can be manufactured faster with increased flexibility

Benefits to patients as the supply of biological medicines can be improved

"As well as developing a new manufacturing route for Ipsen's biopharmaceuticals, the Ipsen team have benefitted significantly though the collaborative nature of this research project. Technical discussions and site visits have introduced new equipment and broadened the experience of the scientists working on this project."

David Gruber, Head of BioProcess Development – Ipsen

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CASE STUDY

Supporting Touchlight Genetics to revolutionise DNA manufacturing for treatments and vaccines

The genetic medicines market has grown dramatically in recent years, with advanced therapies driving transformational improvements in the treatment of devastating diseases. However current manufacturing processes are slow and inflexible, and its bacterial sequences include unwanted antibiotic resistant genes.

Touchlight Genetics have worked with CPI over a number of years to support the development of their proprietary DNA production platform termed DbDNA™. Their disruptive technology has the potential to revolutionise DNA manufacturing, allowing breakthrough vaccines and cancer treatments to move closer to market.

By working collaboratively with CPI, Touchlight Genetics has produced a scaled up, commercially viable process to bring genetic medicines to market, secured £147m of private investment and created new high value jobs within their organisation.

TOUCHLIGHT GENETICS

"CPI has skill sets and equipment that are not readily available anywhere else.

By using CPI Darlington's skills, we have saved many months of process development"

Dr Jill Makin – CTO (Touchlight Genetics)

Inputs

CR&D Funding

Technical expertise

Access to CPIs Biologics, Formulation and Electronics facilities

Agnostic consultancy

Outputs

Further CR&D funding secured

Scaled up and improved process capable of GMP manufacture

Upskilled workforce

Cost reduction of current process

Detailed consultancy outputs identifying further development pathways inc. mRNA applications

Outcomes

New high value jobs created

Investment in R&D assets

£147m private investment secured

Commercially viable process to bring genetic medicines to market faster

Won OBN award for Best Established Biotech Company

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CASE STUDY

Supporting GlycoSeLect to Accelerate the Delivery of Biotherapeutics to Market

Robust, rapid and reliable analysis and purification of glycoproteins is vital to the biopharmaceutical industry. Working with CPI led to significant cost savings in the development and manufacturing of their novel analysis tool.

GlycoSelect's product now offers faster, cheaper and more specific outputs, therefore contributing to the cost effectiveness of end-products. This is critical to the biopharmaceutical industry where high costs can result in patients being unable to access treatments.

GlycoSeLect

"The expertise and support of our CPI colleagues was crucial in the successful completion of this technically challenging project."

Robert Dunne, CEO – GlycoSeLect

Inputs

Technical knowledge and expertise

Access to state-of-the-art equipment

Signposting

Consultancy

Outputs

TRL progression (3 – 9)

Proven proof of concept

Enhanced product and process

Upskilled workforce

Further R&D projects

Outcomes

Job creation in the UK & Ireland

Improved product to market

Demonstrable >80% cost reduction

Increase speed of analysis >90%

Enhanced service offering

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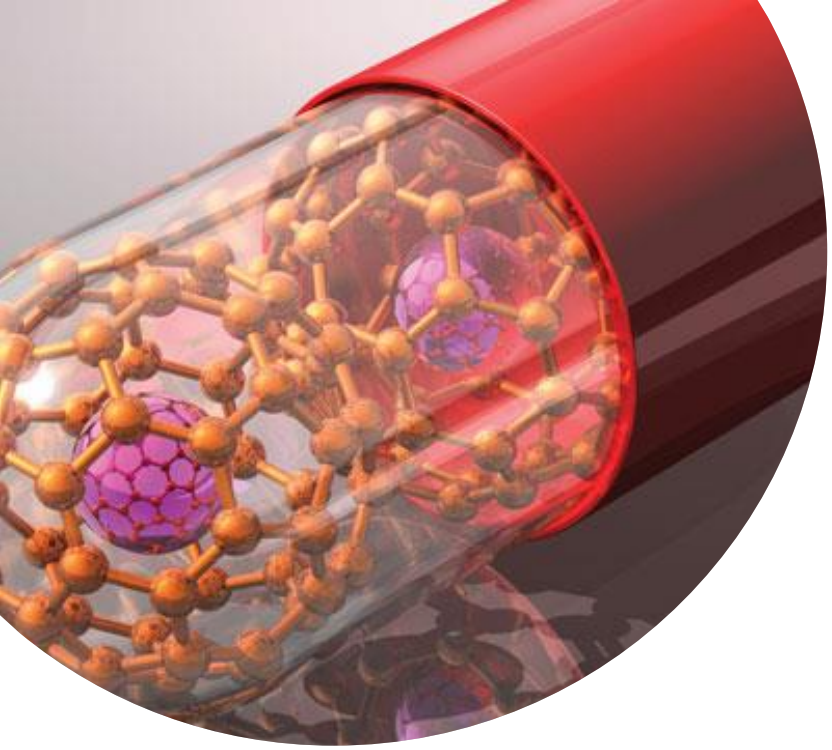

CASE STUDY

Microsun

Nanomedicines have the potential for protection against and treatment of serious diseases, including those that were previously untreatable by drug therapies. However, robust manufacture and scale-up of nanomedicines is challenging, often presenting technical challenges which can prevent new products from making the transition from the lab into clinical trials and ultimately to the patient.

In collaboration with a range of industry partners and leading academic experts, CPI has created a microfluidics-based open-access facility which supports the clinical development and commercialisation of emerging nanotherapeutic drug products such as RNA vaccines, which have become critical as part of the COVID-19 response.

Inputs

Funding via the National Formulation Centre grant and co-investment from industry partners

Technical knowledge and expertise

Access to state-of-the-art facilities

Collaboration with leading academic experts

Outputs

Development of a new nanoparticle manufacturing pilot line

Demonstration of tech transfer from bench scale to pilot scale

Upskilled workforce

3 peer-reviewed publications

Outcomes

Unique UK capability supporting the translation of emerging nanotherapeutics into the clinic

Onshoring UK capability in the field of nanomedicine

Stimulating the UK ecosystem by promoting the retention of UK SMEs

Enabling the development of therapies e.g. vaccines and cancer treatments

" This work has enabled us to consider and develop production processes that map from bench to GMP production, which supports the rapid development of nanomedicines. "

Yvonne Perrie, Professor in Drug Delivery – University of Strathclyde

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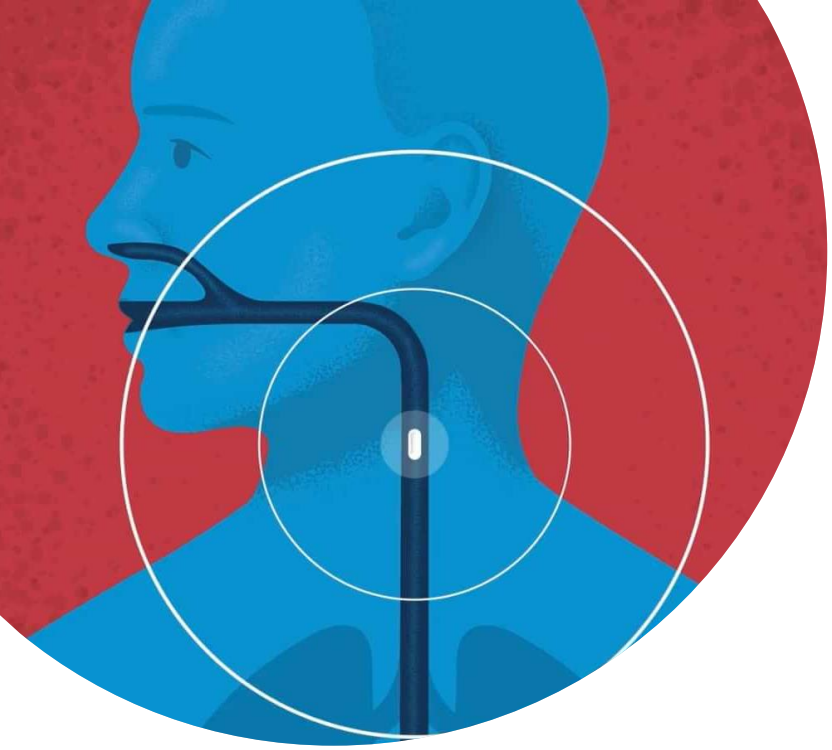


CASE STUDY

Revolutionising treatment of Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a chronic inflammatory disorder of the gastrointestinal (GI) tract. Crohn's disease and ulcerative colitis are two of the main IBDs, in which the immune system attacks the body, causing severe flare-ups. Although there is no cure for IBD, it can be managed with monoclonal antibody (mAb) therapies, such as Infliximab, which can help keep the immune system at bay.

These treatments need to be delivered to patients in hospital via intravenous infusions which are invasive, time consuming and inconvenient for patients. Development of treatments that can be taken orally remains a challenge for pharmaceutical companies, due to the harsh conditions within the GI tract that break down mAb therapies, reducing their efficacy.

Led by Intract Pharma, we collaborated with SGS Quay Pharma and Pharmidex, to develop the first oral formulation of infliximab. Intract Pharma's innovative oral delivery technology has the potential to transform IBD treatment by offering safer and more effective oral biologic therapeutics that patients can easily take at home.

"Thanks to the expertise in drug development and manufacture brought by the colleagues from Quay, CPI and Pharmidex, we successfully developed a scalable manufacturing process for oral antibody products."

Silvia Matiz, Formulation Scientist – Intract Pharma

Inputs

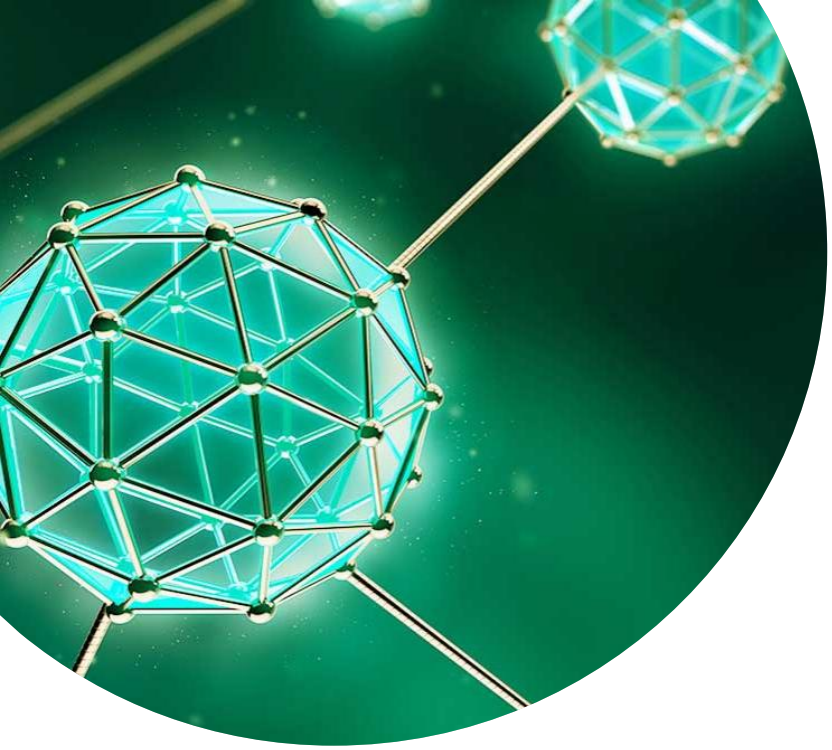
- CR&D Funding
- Technical expertise
- Access to CPIs Biologics and Formulation capabilities
- Analytical Development expertise

Outputs

- Development of a scalable and optimised process capable of GMP manufacture
- Proof of Concept achieved in preparation for clinical trials
- Shelf life of product determined via stability testing

Outcomes

- Licencing agreement for application of Intract Pharma's drug delivery technology
- Revolutionary IBD treatment ready for next stage clinical trials



CASE STUDY

Collaborating to accelerate the development of Nano-pharmaceuticals bringing more effective therapies to market quicker

Despite significant progress being made in pharmaceutical therapies, there are still many conditions with unmet clinical needs. Innovations such as nano-pharmaceuticals are transforming treatment for rare cancers, autoimmune diseases and viral infections.

CPI worked as part of the pan-European 'Nanofacturing' consortium to develop new manufacturing methods and improve supply chain co-ordination for Nano-pharmaceuticals. All of which resulted in an open access pilot manufacturing line, increased regulatory understanding, lead partner securing £13.4m Private Investment and clinical trial acceleration.

Inputs

Bid Writing and Consortia Building

Facilities and equipment

Technical knowledge and expertise

Research and development

Process development

Outputs

Creation of an End-to-End Supply Chain

TRL Progression 4-7

Scaled Up process created

Creation of a Pilot Manufacturing Line & Large-Scale sterile production facility

Reduced Manufacturing Costs & More Environmentally Friendly Process

Outcomes

Open Access Pilot Manufacturing Line Created

Increased regulatory understanding allowing products to be commercialised quicker

Nano-pharmaceuticals for Brain & Liver Cancer now progressing through clinical trials

£13.4m private funding raised by Lead Partner

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Targeted drug delivery for treatment of ovarian cancer

CASE STUDY

PARTNERS

Bio Moti

pharmidex

UKRI Innovate UK

CPI ROLE

- Developing a continuous manufacturing process based on microfluidics to produce monodisperse Paclitaxel loaded PLGA microparticles with superior encapsulation efficiency.

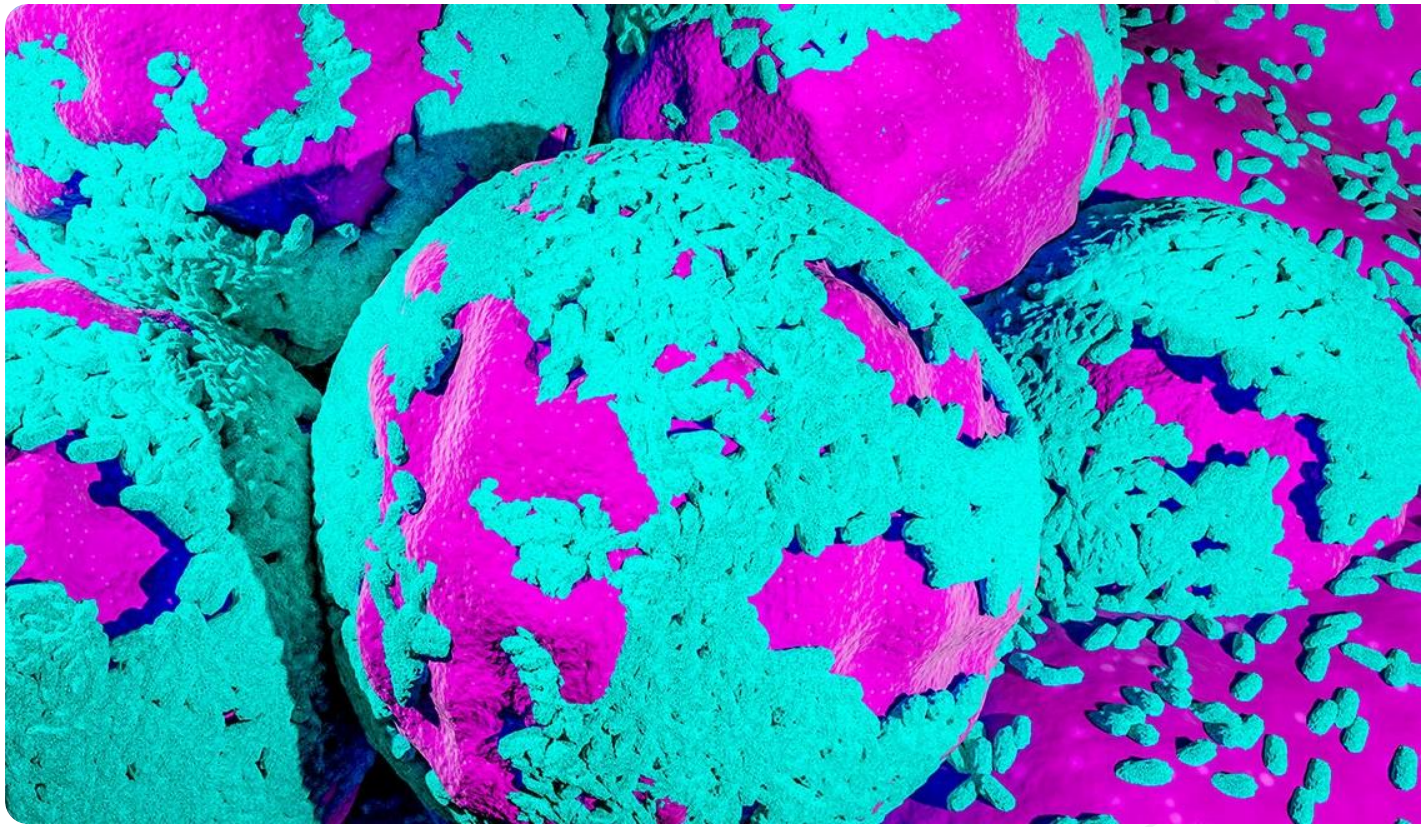
OUTCOMES AND IMPACT

- Enabling increased encapsulation efficiency of the Paclitaxel drug resulting in reduced side-effects and lower dosage during its use in cancer treatments.

PROJECT TYPE Collaborative R&D

PROJECT DURATION 1 year

PROJECT VALUE £100,000



Combinatorial genome editing for enhanced biomanufacturing platforms

CASE STUDY

PARTNERS

horizon INSPIRED CELL SOLUTIONS

MANCHESTER 1824 The University of Manchester

UKRI Innovate UK

UKRI Biotechnology and Biological Sciences Research Council

CPI ROLE

- Creating a pipeline of engineered Chinese Hamster Ovary (CHO) cells with characteristics and performance that enable improved manufacture of novel biologic products.

OUTCOMES AND IMPACT

- Enabling new development routes for difficult to manufacture biologics products.

PROJECT TYPE Collaborative R&D

PROJECT DURATION 3 years

PROJECT VALUE £2.5 million

Developing a scalable viral vector manufacturing solution

CASE STUDY

PARTNERS

COBRA BIOLOGICS

UKRI Innovate UK

CPI ROLE

- Development of an industrial manufacturing platform for adeno-associated virus (AAV) production to support gene therapy products.

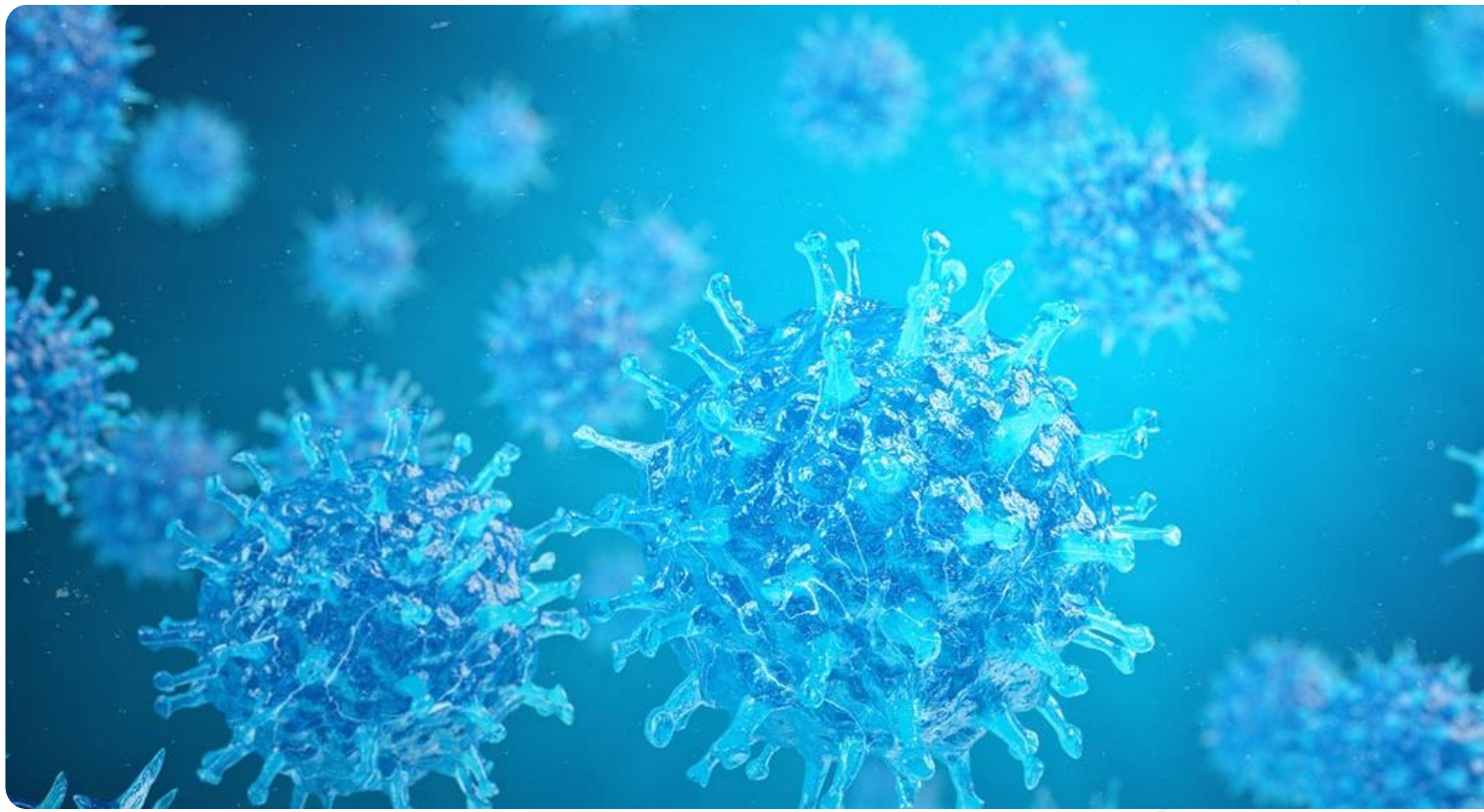
OUTCOMES AND IMPACT

- Enabling the advancement of treatments using viral vectors into the clinic.

PROJECT TYPE Collaborative R&D

PROJECT DURATION 3 years

PROJECT VALUE £1.8 million



Advancing protein characterisation

CASE STUDY

PARTNERS

Applied Photophysics

University of Exeter

AstraZeneca

UKRI Innovate UK

CPI ROLE

- New platform for hydrogen / deuterium-exchange (HDX) mass spectrometry to deliver more sensitive analysis of proteins and peptides against current standards.

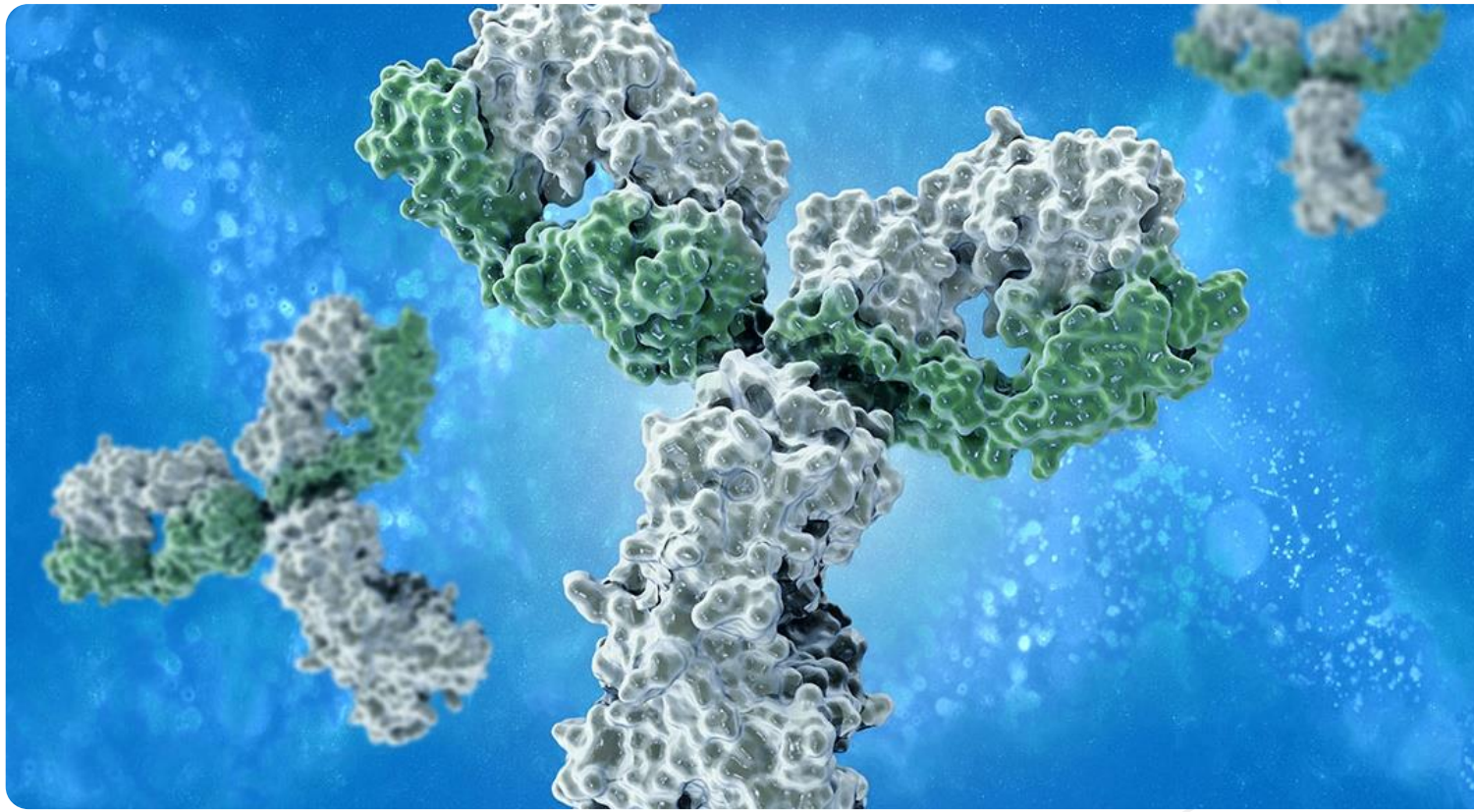
OUTCOMES AND IMPACT

- Enabling accurate peptide characterisation.

PROJECT TYPE Collaborative R&D

PROJECT DURATION 2.5 years

PROJECT VALUE £900,000



Enabling continuous direct compression

CASE STUDY

PARTNERS

CPI ROLE

- Developing an integrated, multi-step continuous process demonstrator platform that is aligned to the principles of portable, continuous, modular and digital manufacturing.

OUTCOMES AND IMPACT

- Enabling quicker optimisation of oral solid drug formulations.

PROJECT TYPE

Collaborative R&D

Developing automated just-in-time supply chains

CASE STUDY

PARTNERS

AstraZeneca, gsk, University of Strathclyde Glasgow, CMAC Future Manufacturing Research Hub, Scottish Enterprise, Applied Materials, Siemens, CME, UKRI Innovate UK

CPI ROLE

- Enabling a clinical supply chain that can rapidly and responsively process material based on an ‘actual’ or ‘short-term’ demand-driven basis that reduces material waste.

OUTCOMES AND IMPACT

- Enabling delivery of just-in-time clinical supply material through late-stage-customisable produce, label and pack processes.

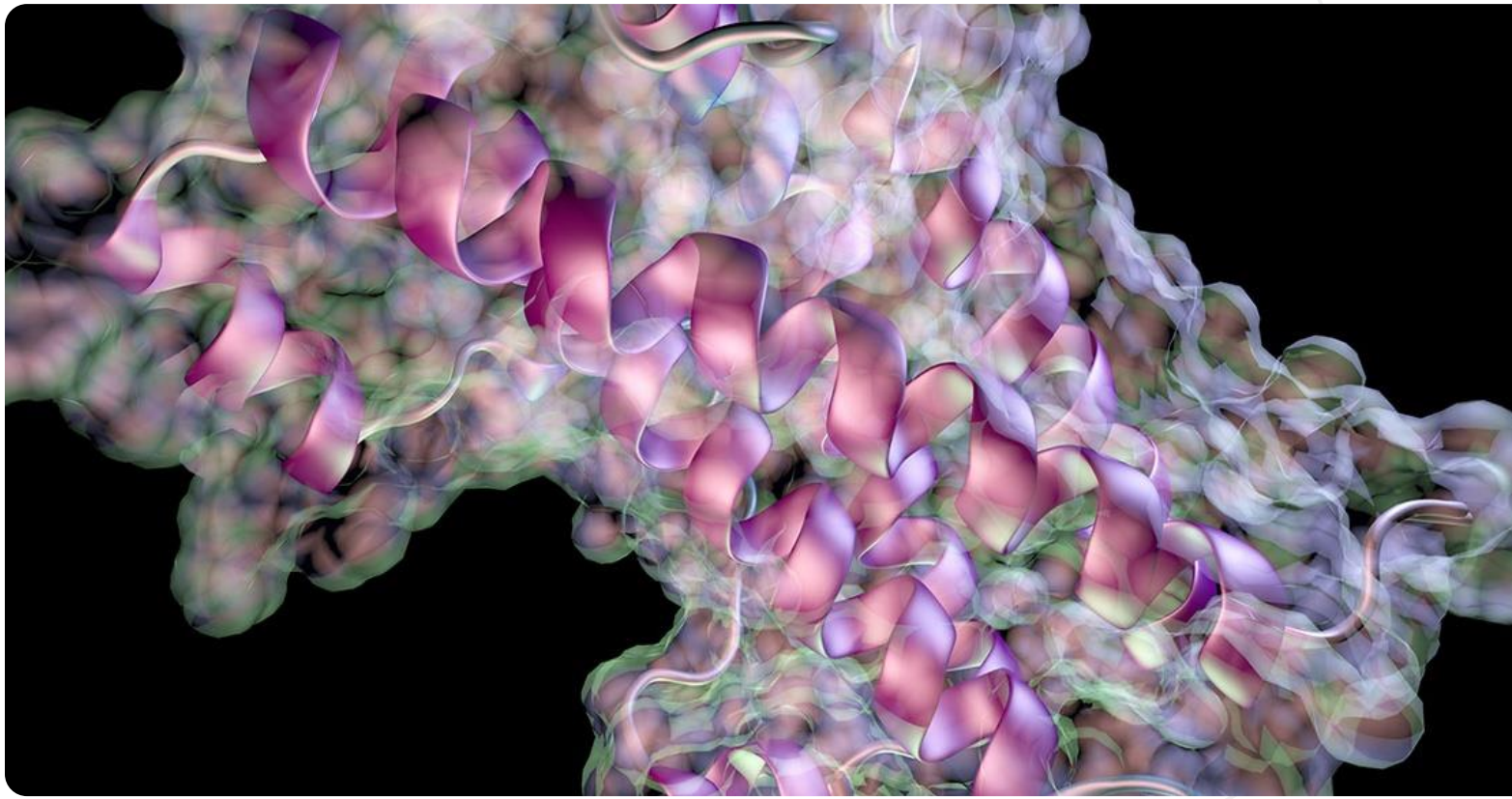
PROJECT TYPE

Collaborative R&D

Analytical characterisation

AppliedPhotophysics

Enabling quantification of structural changes during bioprocess development



Quantitative analysis of biotherapeutic structures using a circular dichroism (CD) spectroscopy model-based approach.

OUTCOMES AND IMPACT

- Enabling better understanding of the effects of manufacturing, formulation, and storage conditions on protein conformation and stability

Collaborative R&D | 1 year | £300,000

Upstream | Downstream | Formulation and stability | Clinical trials | High throughput experimentation | Digital | **Analytics**