## Developing commerciallysuccessful MedTech products

Accelerate your novel patient monitoring solution, IVD or drug device combinations to market

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







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 HealthTech markets





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

**700+** Members of staff

**500+** Scientists and engineers

Expertise in formulation, materials, design & development (including mechanical & electronic), digital & software, testing and strategy

# \$300 million

in innovation facilities

Business founded in 2004

Celebrating 20 years of innovation

Supporting Formats: Including PCR, immunoassays, lateral flow, etc

Cutting-edge equipment: including mass spec, sequencing, dPCR, etc

Enabling working with host-organisms from E.Coli, Yeast to CHO, etc

### CATAPULT High Value Manufacturing

£3 billion

investment into R&D&I

Unlocked private

Founding member of the UK's High Value Manufacturing Catapult

**1500** R&D&I projects delivered

Industry network

Senior leaders across major MedTech, Pharma and BigTech





### Fundamentals

components

Design

**Materials** 

**Fabrication** 

Digital

**Testing** 

cleanroom processes

Support with investment, early-stage regulatory guidance, life cycle analysis, carbon accounting and sustainability

Patient centric requirements and initial concept to design for manufacture, with mechanical, electronics,

Informed materials selection or development of new materials including nanomaterials and composites.

integration and process development engineers

Biomanufacturing of reagents for diagnostics

From first prototypes to upscaled processes with additive manufacturing, electronics assembly and

Data science, firmware, algorithm and software

development, including communication protocols, edge and cloud, system architecture and security

Technology pre-verification and pre-accreditation biological, mechanical and/or electrical testing of



## What value does CPI bring to MedTech?

### Locate

Trusted partners though our extensive network. Being backed by UK Government means we can connect you to the expertise, supply chains and healthcare providers needed to bring your product to market.

#### Streamline

Complex approval processes ensuring compliance with FDA (or UKCA, CE) with CPI's regulatory experts. Allowing you to focus on advancing your healthcare technology and business.

### Secure

The financing and strategic alliances needed to bring your product to market. Ether its funding, corporate investment or acquisition, CPI can help.



#### Demonstrate

The form and function of your MedTech innovation more quickly and reliably with CPI's expert team of scientists and engineers.

### **Evidence**

The manufacturability and scalability of your innovation no matter how novel, utilising our expert team and cutting-edge equipment.

### Prove

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



## **Our capabilities**

## HealthTech is a multi-disciplinary market that spans across all technical areas of CPI.



### IVD

Accelerating IVD development from technology and opportunity definition to development and scale up

- Materials formulation, characterisation, optimisation and scale up.
- Reagents- biologics, organic, inorganic and nanomaterial formulation, characterisation and scale up.
- Instrument and consumables Design, electronics, sensor platforms, microfabrication and software.
- Analytical chemistries developing and refining



### **Patient monitoring**

Developing and scaling non-invasive and minimally invasive devices that can include flexible electronic capabilities.

- Materials formulation, characterisation, optimisation and scale up.
- Sensor platforms develop, scale and embed
- Software and communications develop software and firmware and enabling wireless coms
- Design and fabrication across devices materials and reagents



### Drug-device combinations

Innovating and scaling in drug delivery and wound healing.

- Therapeutics formulation, characterisation, optimisation and scale up including novel phage / microbiome therapeutics.
- Devices- design, electronics, sensor platforms and microfabrication.
- Software and communications develop software and firmware and enabling wireless coms



### USPs

- Multimodality innovation across biologic and organic/inorganic reagents – applying synthetic biology to your application
- Flexible hybrid electronics platform enabling flexibility of form and function.
- Formulations expertise across drugs, medtech, adhesives and coatings – leverage our broad experience to improve your materials.
- Modelling and process design and development – across reagents, consumables and devices – accelerate your process scale up with confidence.



## **Case studies: Examples of our work - IVD**

#### **View Case Studies**

## Characterisation of reagents for use in diagnostic tests

We helped a client to evaluate its polyclonal antibody for the SARS in antibody-antigen binding, sensitivity and specificity using Western Blotting.

CRB were able to list the antibody product for sale on their website.

## Reagents evaluation for POC testing

We developed robust reagents for a point-of-care handheld device for Sapient Sensors, providing the stability, specificity, selectivity, and sensitivity required.

We were able to advance the development of their biosensor for COVID-19 diagnosis from saliva samples.

## Enabling point of care analysis of renal health

We produced electrochemical, highperformance sensors based on nanoinks which can simultaneously detect a range of urinary biomarkers, unlocking the way forward to clinical trials

When commercialised, they will enable high-frequency at-home testing for diabetics to measure their kidney's health for earlier interventions



## **CPI Minimally Invasive – Case Studies**

Minimally Invasive Devices

### Development of a highvolume microneedle process

High-volume production of microneedles faces challenges due to the complexity of their fabrication, materials properties and scalability.

CPI has developed a process to enable high volume production to enable a flexible platform that can be used within sensing or drug delivery.

### Technical roadmap development for bioelectronic materials

Innovation in minimally invasive bioelectronic devices needs improvements in materials.

CPI worked with partners and over 60 researcher, innovators, funders and policy makers to map out a (UK) country wide materials strategy up to 2040 and identify innovation gaps and precompetitive challenges.

### Materials characterisation for dissolvable stents

**View Case Studies** 

A conventional penile stent requires two invasive surgical procedures, one to insert and the other to remove the device. CPI worked with a client who had developed a materials set that enabled dissolvable stents to prove that their production process was reproducible and that the stent materials would dissolve under standard conditions.

When deployed, the device could minimise invasive surgery and improve the lives of men suffering from ED.

Let's innovate together



## **CPI Non-Invasive – Case Studies**

Non-Invasive Devices

### Development of a wearable temperature monitor for neonatal care

Many premature babies are born in difficult situations outside of hospitals where environmental temperatures can vary significantly. Accurate continual monitoring of the body temperature of these babies is essential for their survival and difficult to achieve.

From defining user needs, through to development of a non-invasive wearable device. We helped the client to fulfil an unmet need in neonatal care. Stroke can be a significantly debilitating medical condition that can leave patients with severe limitations in movement. Our client had a concept to develop a wearable garment that would support rehabilitation for those impacted by stroke.

Non-invasive treatment

device for stroke

rehabilitation

We worked in partnership with the client to realise functional prototypes which included electronics, auditory stimulus and mechanical actuation. Helping to rehabilitate those who need it most.

### Next generation photonic based patient monitoring devices

**View Case Studies** 

The measurement of multiple physiological parameters (e.g. blood pressure, temperature, heart rate, respiratory rate) is a common tool in triage and individual health assessments, however measurements are often taken incorrectly and inaccurately, placing patients at risk.

From technology and, IP, value prop and commercialisation remapping through to design and feasibility study we accelerated the client's concept towards the market.





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## Scaling up of glycopeptides for in-vitro diagnostics tests



### Dramatically improving fermentation processes for reagents

Increased productivity of biological process for the manufacturing of a critical reagent for an IVD test enabling the client to own their process, reduce reliance on external manufacturers whilst increasing yield by 5 times

Improved process

Reduced costs

#### PROBLEM

The reliance on a single supplier for a high-cost and critical component of an IVD test posed significant business risks. The partners successfully synthesized the correct glycoprotein using a novel synthetic biology approach. However, process development was necessary to achieve a low-cost, high-efficiency, and commercially sustainable reagent.

#### **VALUE REALISED**

- Increased fermentation productivity of glycoprotein expression through developing upstream and downstream fermentation processes
- Reduced cost for the client by removing the need for a high-cost inducer.
- Enabled the client to have their own IP and control their own manufacturing process – reducing reliance on a single external supplier.

Our partnership with CPI yielded promising results in upscaling and commercialisation of a key reagent of ours. The team was highly motivated, proactive and insightful, readily sharing updates, suggesting strategic guidance, and ultimately helping Hart take steps to reducing the risk of a single-supplier dependency."



## **Advancing** *In-vitro* **Diagnostics**



European Union European Regional Development Fund

## **Characterisation of reagents for use** in diagnostic tests

Cambridge Research Biochemicals is a producer of custom-made peptide and antibody tools, supplying the pharmaceutical, life science and academic sectors worldwide. In this project CPI helped CRB with the evaluation of one of their reagents, a polyclonal antibody against SARS-Cov2 S1 spike protein. The main aim of the project was to determine antibody-antigen binding, antibody binding sensitivity and specificity using Western Blotting.

#### **OUTCOMES AND IMPACT**

- CRB were able to list the antibody product for sale on their website.
- Target market: researchers and developers of salivary diagnostic immunoassays for SARS-CoV-2.



ERDF 1 month



## **Advancing** *In-vitro* **Diagnostics**

## Characterisation of an anti-SARS-CoV-2 spike antibody using Western Blotting

The Western blotting technique relies on two key properties of antibodies: specificity, an antibody's ability to recognize and bind to its target antigen; and selectivity, an antibody's preference to bind its target antigen in the presence of a heterogeneous mixture of competing sample proteins. In this project, Western Blotting was used to examine the specificity and selectivity binding of antibody to target antigens separated by denaturing polyacrylamide electrophoresis (SDS-PAGE). This enabled better understanding of the binding of test antibody to the antigen and non-specific binding to related antigens and salivary proteins.

### How we helped:

- Demonstrated target binding of one of CRB's novel polyclonal antibodies raised against a unique peptide from SARS-CoV-2 the infective agent for COVID-19.
- Demonstrated that the new antibody binds specifically to its target with no crossreaction to related SARS Viruses SARS-CoV and MERS spike proteins
- Showed that the antibody did not cross-react with human salivary proteins.

Molecular weight markers
 SARS-Cov-2 spike
 SARS-Cov-Spike
 MERS-Cov-Spike



A. Coomassie stained spike proteins after SDS PAGE; B. Western blot of same probed with anti-SARS Cov 2 spike protein antibody from CRB-Discovery.



## Advancing novel technologies for Point-of-care testing

## SapientSensors® Construction European Union European Regional Development Fund

## **Reagents evaluation for POC testing**

Sapient sensors are developing a hand held device to measure target molecules at the point-of-care (POC). POC testing needs to be accurate in multiple environments and the reagents used provide the stability, specificity, selectivity, and sensitivity required. As such, the development of robust reagents is an important consideration when developing these types of tests.

#### **OUTCOMES AND IMPACT**

- Demonstrated effective binding of immobilised aptamers to SARS-CoV-2 spike protein.
- Sapient sensors were able to advance their development of a point of care biosensor for COVID-19 diagnosis from saliva samples.







## Advancing novel technologies for Point-of-care testing

## ELISA assay demonstrated binding of aptamers to target spike antigen

The enzyme-linked immunosorbent assay (ELISA) is an immunological assay commonly used to measure molecules such as antibodies and antigens in biological samples. In this project, ELISA was used to evaluate the binding of two aptamers raised against SARS-CoV-2 spike protein – the infective agent for COVID-19. Experiments enabled better understanding of the test antibody-antigen interaction and evidence of non-specific binding to related antigens and salivary proteins.

### How we helped:

- Demonstrated binding of two aptamers raised against SARS-CoV-2 spike protein the infective agent for COVID-19.
- Showed that one of the aptamers had better binding characteristics when immobilised in an assay well plate.
- Demonstrated that the binding activity was slightly inhibited in saliva but the assay was still viable.



Results for detection of SARS-CoV-2 spike protein on ELISA using aptamers as primary capture molecules. Zero control had no spike protein. Others were spike protein at 1 ug/mL in either buffer or saliva with added magnesium chloride. Each bar represents the average of three wells. Y-axis,  $A_{405}$ .



## Identifying the early signs of sports injury in women



## Cost effective sports analysis tools

The project team aimed to address this gap in the Healthy Ageing space by developing a new movement analytics service designed specifically for women of advanced age. It provided evidencebased information on bespoke exercise regimes and injury prevention to support continued safe participation in physical activity.

# Improved process Faster time to market Innovative solution

#### PROBLEM

The project partners identified that older adults often have to cease their participation in sport permanently due to sport related injury. There is no easily accessible movement analysis tools available to identify early signs of sports injury which would enable proactive preventive measures to be applied.

#### **VALUE REALISED**

- Enabled a low cost pressure sensitive shoe insole: Via scalable screen-printing processes and embedded electronics with flexibility and thin networks to be use in a sport shoe.
- Enabled real time communication software with a phone app: Developed an application to communicate wirelessly with the shoe insole to provide real time movement data
- Produced a mature prototype system which is currently in early trials at the University of Exeter. This prototype will inform the next stage of product development.





## **Printed biosensors for urine analysis**



## Enabling point of care analysis of renal health

Innovations in scalable nano-ink formulations and printing processes, enabling multiplexed electrochemical IVD devices with high sensitivity, selectivity and reproducibility to be developed.

#### **OUTCOMES AND IMPACT**

- Produced sensors simultaneously detect a range of urinary biomarkers including creatine, unlocking way forward to clinical trials
- When commercialised, will enable high-frequency at-home testing for diabetics to measure their kidney's health for earlier interventions and reduced healthcare service provider costs







## **Printed biosensors for urine analysis**

### Enabling improved sensitivity and reliability in multiplexed printed biosensors

Diabetics are at risk of developing diabetic nephropathy. Currently kidney function is assessed by healthcare practitioners through a urine sample sent to a centralised lab. Home testing enables more frequent and easier testing for patients and can potentially detect the disease earlier, enabling intervention and reducing kidney transplants and other health implications. A high sensitivity, reproducible and mass producible test is required, and CPI enabled this through our cross functional expertise in formulation, printing and electronics

### How we helped:

- Characterised and screened commercially available detector species including metal oxide nanoparticles
- Developed a stable ink formulation and the compatible, industrially scalable printing processes (screen printing and micro jetting)
- Developed and tested sensors (single channel and multiplexed)
- Demonstrated a significant improvement in current/voltage response for single channel devices



Improvement of measurement response displayed via cyclic voltammetry. Larger current is measured as the voltage is swept for the CPI formulation, yielding a more sensitive electrochemical diagnostic device, with clear distinction between clinically relevant concentrations

