The Centre for Process Innovation
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CPI is a UK technology innovation centre and the process element of the Government’s High Value Manufacturing Catapult.

We use applied knowledge in science and engineering combined with state of the art facilities to enable our clients to develop, prove, prototype and scale-up the next generation of products and processes.
Centre for Process Innovation

- CPI has over £100m of investment in assets and technology expertise that support the process industries
- CPI has grown at almost 50% per year. It has >200 employees
- CPI works with all of the UK’s major manufacturing markets
- CPI helps clients prove, scale-up and prototype the next generation of products & processes
- CPI is impartial, confidential and trustworthy
- CPI is almost 10 years old and has completed >150 CR&D projects with a total value of >£275m with 300 partners (40% of project funds are public investment)
Services

- Product and Process Development
- Prototype, Demo and Scale-up
- Pilot Production
- Fuel Feedstock and Material Investigation
- Manufacturability and Process Assessment
- Process Modelling and Consultancy
- Commercialisation Support
- Business Incubation
Market Focus

- Healthcare
- Energy
- Consumer Goods
- Food and Drink
- Materials and Chemicals
- Built Environment
- Electronics
- Personal Care
- Transportation
## Converting Science into Wealth

<table>
<thead>
<tr>
<th>1 GBP</th>
<th>63 GBP</th>
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<tbody>
<tr>
<td>University based and curiosity driven</td>
<td>Industry based and market led</td>
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<tr>
<td>10 - 15 years</td>
<td>3 - 10 years</td>
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<tr>
<td>Academic skillset</td>
<td>Techno-commercial skillset</td>
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<td>Research</td>
<td>Innovation Assets</td>
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The National Biologics Manufacturing Centre

The Opportunity and the Challenge
What is a ‘biologic’?

- Biologics or Biopharmaceuticals are medical drugs/therapies produced using biotechnology
- This includes proteins, nucleic acids and living micro-organisms such as virus, bacteria and cells and are produced using means other than direct extraction from an existing, biological source
- Recombinant human insulin was the first biopharmaceutical to be licensed, others such as mono-clonal antibodies can treat certain cancers e.g. Herceptin (a breast cancer therapy)
The Market

- Research evidences an intervention from the public and private sector may help place the UK in a leading position globally and accumulate growth in positive GDP of £10-50 billion over 10 years.

- It has been stated the UK has the second largest R&D pipeline in the world

- In recent times UK discoveries have been all travelling offshore and exploited overseas
Barriers to getting to market

- The cost required to take a target molecule from discovery to preclinical trials is estimated to be up to £8m over a period of 1 to 3 years.
- These costs are related to clone/strain development, process development and small scale manufacture.
- Taking the molecule into cGMP manufacture for Phase 1 can cost upwards of £20m.
- The costs continue to escalate as the therapy proceeds through clinical trials typically to £150m per therapy.
Innovation is required to

- Increase the throughput of candidate drugs through the pipeline
- Develop innovative manufacturing techniques that lower costs of manufacture whilst offering equivalent or improved quality
- Stimulate innovation in the equipment supply sector
- Thus building a competitive advantage based on innovation.
- Increase the availability of the skills base that will enable the pipeline to work effectively
The Solution

• A concentration of skills and resources with the freedom to innovate develop and demonstrate new platforms, equipment and processes for the manufacture of novel biopharmaceuticals without the risk constraints imposed on companies in the sector.

• A centre designed to develop new and lower cost manufacturing to make the UK more competitive

• The National Biologics Manufacturing Centre
Industry Advisory Board agreed Themes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Description</th>
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<tbody>
<tr>
<td>Theme 1</td>
<td>New Process Technology (NPT) and new routes for manufacture of existing Biopharmaceuticals</td>
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<tr>
<td>Theme 2</td>
<td>Process Development for Next Generation Biologics</td>
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<td>Theme 3</td>
<td>Finish and Fill Technology for new and existing biopharmaceuticals</td>
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<tr>
<td>Theme 4</td>
<td>Molecule characterisation and in process testing technologies</td>
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<td>Theme 5</td>
<td>Challenging facility design and operation to reduce COGs</td>
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<td>Theme 6</td>
<td>Workforce development</td>
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Site at Darlington
The challenge

Healthcare

Electronics

Materials and Biology
Source and top image: Thin Film Electronics ASA
The future – Personalised Medicines

• Manufacture will need to be aligned with the demand for multiple batches of small volume products.
• The response between manufacturing and demand will need to become more immediate.
• Costs of manufacture and in particular product changeover will need to decrease.
• Final formulation of active ingredients may become a localised activity that is based on patient characteristics and may ultimately be located closer to the patient.
The opportunity –

• Can we develop a range of small disposable sensors as diagnostic tools?

• The challenge of process control in factories of the future which are distributed and local (table-top?) may require miniaturised sensors for each individual batch?

• Product changeover will need to avoid and measure for contamination as individual lots are prepared?

• Final formulation of active ingredients may need careful measurement?

• May we formulate/print biologics onto an edible chip?
The opportunity –

• There is a live challenge of measurements in disposable technology eg measurements in plastic bag single use fermenters

• Could we grow individual doses using individual ‘cell factories’ on an ‘edible’ chip?
Sensors arrays (optical, IR, x-ray) or force sensors

- OTFT backplanes can be integrated with optical sensing elements (photo-diodes) or strain gauges
- Array is similar architecture to display backplane

Artificial “e-skin” Someya et al.
Sensors arrays (optical, IR, x-ray) or force sensors

CPI’s new high resolution processing line is ideal for the development of sensor arrays on plastic.

Lithography resist process sputter etch inspection
Ion sensitive gate field effect transistors (ISFET)

- Similar principle of operation to silicon based devices but with plastic integration capability (low cost, flexible, disposable, bio-compatible)

Requires integration of microfluidics – the North East has some notable capability in this area Teesside University (Prof Zulf Ali) and Epigem Ltd.
Sensor arrays (chemical or biological)

**Organic TFT sensors**
(solvent concentration sensing)

Digital printing of specific OSC materials can create arrays of sensors with differing sensitivities to a range of polar solvents

**Organic bio-sensors**
(incorporation of protein receptors in lipid bilayer membranes on TFTs)

Potentially very large scope for sensitive bio-sensors based on these principals but as yet the technology is immature

http://spie.org/x37019.xml?pf=true&ArticleID=x37019
**Possible Chem/Bio sensor configurations**

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- Sensing mechanism is chemical interaction with organic semiconductor in FET
- Non-specific interaction with analytes requires several OSC material types in an array to give a matrix response (that has to be learned through calibration)
- Repeats of same material allows greater accuracy in sensor

- Sensing mechanism is specific absorption of analyte to receptor - “lock and key”
- Receptor functionalised molecules can be printed in specific locations
- Ability to detect for many analytes with a high degree of specificity

- Requires substantial alteration of OSC material to incorporate bioreceptor molecules in their functioning state or functionalisation of gate surface to make “biomimetic”
# Digital fabrication methods for sensors

<table>
<thead>
<tr>
<th>Ink jet</th>
<th>Aerosol jet</th>
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| ![Ink jet image](image1.png)  
Deposition of aqueous and solvent based materials with 15 micron precision | ![Aerosol jet image](image2.png)  
- Ability to write 10 micron width lines with a wide range of soluble materials  
- Registration to underlying patterns possible to within +/-1 micron (stage repeatability) |

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<th>Digital R2R lithography</th>
<th>Digital laser assisted printing</th>
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| ![Digital R2R lithography image](image3.png)  
4 micron minimum feature, 1 micron positional accuracy | ![Digital laser assisted printing image](image4.png)  
OLAE+ project started May13 with OLAE+ project started March13 with [HEIDELBERG instruments](https://www.heidelberg.com)  
[SENSOTARS](https://www.sensotar.com)  
[CATAPULT](https://www.catapult-corr.org)  
[cpi](https://www.cpi.co.uk) |

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