



ADVANCED DIGITAL DESIGN OF PHARMACEUTICAL THERAPEUTICS

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FOR IMMEDIATE RELEASE 9.00AM, GMT  
January 28, 2016

## New £20.4m project set to transform UK pharmaceutical development and manufacturing

CAMBRIDGE January 28, 2016 --- The Department of Materials Science and Metallurgy (DMSM) in the University of Cambridge is a partner in a newly launched major collaborative project that is set to transform the UK pharmaceutical industry by enabling the manufacturing processes of the innovative medicines of the future to be designed digitally.

The ADDoPT (Advanced Digital Design of Pharmaceutical Therapeutics) project addresses a key challenge for the pharmaceutical industry; getting new innovative medicines to market in the quickest and most cost-effective way possible to ensure access for patients. The collaboration will pursue this goal by developing and implementing advanced digital design techniques that eliminate non-viable drug candidate formulations as early as possible, streamlining design, development and manufacturing processes.

'Digital design' combines research insight and mechanistic modelling to provide links between raw materials, formulation, manufacturing processes and drug product quality. It spans all operations, processes and procedures during the development and manufacture of medicines, and their in vivo application.

ADDoPT draws on the expertise of UK technology and academic leaders in the field of digital design concepts including the Macromolecular Materials Laboratory in DMSM, led by Dr James Elliott, which has specific expertise in multiscale modelling of pharmaceutical materials. This will be applied to industrial case studies provided by the four major pharmaceutical companies (Pfizer, GSK, AstraZeneca and Bristol-Myers Squibb) within the consortium. A key objective is to achieve better design and scale-up for robust products and processes through more targeted future experimentation and better understanding of risk.

ADDoPT builds on UK excellence in big data, mechanistic modelling, process optimisation and control to establish a highly competitive UK knowledge value supply chain for the pharmaceutical sector that will seek to:

- protect UK drug manufacturing and support future growth

- encourage reshoring of existing pharmaceutical production
- contribute to job creation and safeguarding in the pharmaceutical supply chain
- enhance UK skills and capabilities through the training of operators and scientists in new design and control tools and methodologies
- get new innovative medicines to market as efficiently as possible to ensure access for patients.

Project Lead Sean Bermingham of Process Systems Enterprise Limited said,

*“By building on UK excellence in process modelling, optimisation and control, we can give UK pharmaceutical development and manufacturing a genuine competitive advantage in this globally significant sector.*



*The ADDoPT consortium partners met for a project kick-off meeting at PSE’s Hammersmith offices on 15<sup>th</sup> January 2016*

[ENDS]

[INFORMATION FOR EDITORS]

1. The ADDoPT project is a £20.4m UK Government-Industry-Academia collaboration, part funded under the Advanced Manufacturing Supply Chain Initiative (AMSCI – see Note 2) running until March 2019. The full list of project partners includes:
  - Leading businesses in the pharmaceutical value supply chain – Pfizer Ltd, GlaxoSmithKline Plc, AstraZeneca UK Limited, and Bristol-Myers Squibb Pharmaceuticals Limited
  - Knowledge-driven small to medium sized enterprises (SMEs) – Process Systems Enterprise Ltd, Perceptive Engineering Ltd, and Britest Ltd

- Specialist knowledge-based partners from UK universities and research centres – Cambridge Crystallographic Data Centre (CCDC), University of Leeds, University of Cambridge, STFC Hartree Centre, and the EPSRC’s Centre for Innovative Manufacturing in Continuous Manufacturing and Crystallisation (CMAC) at the University of Strathclyde.

ADDoPT partners will be working across the pharmaceutical value chain to define a system for the top-down, knowledge-driven Digital Design and Control of drug products and their manufacturing processes. This will bring together a wide range of predictive models and insight from industrial case studies at the four major pharmaceutical companies, allowing more targeted future experimentation, a better understanding of risk, and hence better design and scale-up for robust drug products and processes.

The project is coordinated by Process Systems Enterprise Ltd (PSE), Project Manager Sean Bermingham, [s.bermingham@psenterprise.com](mailto:s.bermingham@psenterprise.com). The project was initiated by the Medicines Manufacturing Industry Partnership (MMIP - see Note 3).

2. AMSCI supported manufacturing supply chains in England to reshore in the UK and improve global competitiveness by encouraging innovative, collaborative projects which established strong, sustainable and balanced growth. Complementing the Regional Growth Fund, AMSCI offered flexible funding support for R&D, skills, training, capital finance and leveraging private sector investment. AMSCI is administered by Finance Birmingham Limited.

<https://www.financebirmingham.com/amsci/>

The ADDoPT project received a conditional offer of support under the Advanced Manufacturing Supply Chain Initiative (AMSCI) on 5 March 2015. An unconditional offer of support was ratified by the AMSCI Board on 27 November 2015. Formal project kick-off was 15 January 2016.

3. The Medicines Manufacturing Industry Partnership (MMIP) was jointly established in September 2014 by the Association of the British Pharmaceutical Industry (ABPI) and the BioIndustry Association (BIA). The Partnership brings the biopharmaceutical industry together to work towards a common goal of creating an attractive and innovation-driven environment to ensure UK competitiveness in medicines manufacturing.

<http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/230914b.aspx>

The Knowledge Transfer Network (KTN) also played a key role in securing funding for the ADDoPT project and has worked closely with the MMIP since its establishment.

4. A project website will be established shortly at [www.addopt.org](http://www.addopt.org).