

27 August 2020

Siemens, Perceptive Engineering and PSE become partners in the Medicines Manufacturing Innovation Centre to advance continuous manufacturing

CPI has today announced the signing of partnership agreements with Siemens plc, Perceptive Engineering LTD and Process Systems Enterprise LTD (PSE), making them a part of the Medicines Manufacturing Innovation Centre collaboration. The partnership agreements will help strengthen the UK's position as a global leader in pharmaceutical manufacturing through the development of continuous manufacturing innovations. Each partner will contribute to the development of a digital manufacturing solution, which will help the pharmaceutical industry as it moves towards smaller batches of more personalised medicines that require faster and more efficient manufacture.

Siemens is a global leader in process automation and will provide both hardware and software to enhance the control of pharmaceutical manufacturing processes. The application of Siemens' leading-edge digitalisation technologies will connect the physical and digital worlds and provide the real-time information necessary for rapid decision making in a secure manner.

Innovation partner Perceptive Engineering will utilise its fully integrated software platform, PharmaMV, to enable the generation of Advanced Process Control models for optimised continuous manufacturing. Rather than simply reacting to a set of data points for in-process control, the PharmaMV platform adapts manufacturing process parameters in response to predictions, ensuring tighter manufacturing specifications can be achieved and quality information is generated in real-time. These approaches also enable the future application of technologies such as Machine Learning and Artificial Intelligence to pharmaceutical processing.

PSE is the leading supplier of Advanced Process Modelling (APM) software and will utilise predictive process modelling to increase R&D efficiency, reduce tech transfer risk, and develop more robust control strategies. Through use of mechanistic models for continuous drug manufacture in PSE's gPROMS FormulatedProducts platform, the industry is able to move away from a design-make-test cycle and toward a 'predict first' model (i.e. design, test, make). By reordering the R&D paradigm, more design activities can be undertaken before committing material, which will result in fast, sustainable and cost-effective manufacturing process development.

By connecting real-time information, data modelling and Advanced Process Control, we will be able to forge a clear pathway to faster, cheaper and more sustainable continuous medicines manufacturing.

The Medicines Manufacturing Innovation Centre is a collaboration between CPI, the University of Strathclyde and founding industry partners, GSK and AstraZeneca with funding provided by Scottish Enterprise and UK Research and Innovation. The partnership agreements will help the Medicines Manufacturing Innovation Centre achieve its flagship Grand Challenge projects. Bringing together three technologies for advancing continuous manufacturing will help fulfil Grand Challenge 1 and its aim to explore how oral solid dosage medicines can be produced more robustly and efficiently. The contribution by Siemens will also support Grand Challenge 2 and its focus on the faster delivery of medicines to patients through adaptive clinical trial supply.

Mark Higham, General Manager, Process Automation, Siemens Digital Industries GB & Ireland, said: "We are delighted to be part of such a forward-thinking, innovative collaboration with Perceptive Engineering, PSE and the Medicines Manufacturing Innovation Centre. We look forward to unlocking the power of digitalisation to achieve continuous improvement and efficiency in pharmaceutical manufacturing in the UK."

Dave Lovett, Managing Director of Perceptive Engineering, said: "We are honoured to have been asked to play a part in this ground-breaking initiative. Building on our experience with research organisations and industry leaders worldwide, we are excited to be working collaboratively with CPI at the new Centre. We look forward to helping design and build the next generation of innovative manufacturing technologies for the production of pharmaceutical therapeutics."

Sean Bermingham, Head of Formulated Products at PSE, said: "We are excited to be part of this initiative aimed at publicly demonstrating the benefits that digital design and digital operation approaches bring to the development and operation of continuous drug manufacture processes. The Medicines Manufacturing Innovation Centre ecosystem is uniquely positioned to successfully achieve this, facilitate knowledge transfer to industry and ultimately bring the associated benefits to patients."

Dave Tudor, Managing Director of the Medicines Manufacturing Innovation Centre, Biologics & Quality at CPI, said: "I am delighted that Siemens, Perceptive Engineering and PSE will be joining the Medicines Manufacturing Innovation Centre. Combining the specialised skills, expertise and experience of all three companies will be critical for developing disruptive technologies that will accelerate the delivery of a more agile and responsive pharmaceutical supply chain."

Notes to the Editor

About the Medicines Manufacturing Innovation Centre



The Medicines Manufacturing Innovation Centre is a collaboration between CPI, the University of Strathclyde, UK Research and Innovation, Scottish Enterprise and founding industry partners, AstraZeneca and GSK.

The consortium aims to develop the medicines manufacturing processes of the future, enabling a more agile, responsive medicines supply chain through improved manufacturing processes. It will enable new and disruptive technologies to be proven at scale in a GMP environment. This will allow the rapid adoption of next-generation processes that reduce risk, cut costs and save time, enabling a healthier society and a robust UK economy.

With a collaborative innovation culture and state-of-the-art facilities, the centre will enable industry, academia, healthcare providers and regulators to work collaboratively in order to address challenges and maximise technology opportunities within the medicines supply chain.

The initial focus of the centre will be to deliver two 'Grand Challenges', with the first exploring how oral solid dosage medicines can be produced more robustly and efficiently utilising continuous direct compression. The second focuses on how these medicines can then be delivered to patients with minimal waste and maximum speed, using Just in Time manufacture and supply capabilities.

www.uk-cpi.com/mmic

About CPI

CPI works with partners to translate inventions into products and processes that enhance health and wellbeing, protect and improve our environment and increase productivity across industries.

With a deep understanding of technology fore-sighting, innovation processes and funding, outstanding technical expertise and industry-relevant assets, we enable the accelerated development of transformational products and processes that have the potential to disrupt and revolutionise markets. We also engage in incremental technological innovation that allows established products and processes to be optimised for better performance and efficient manufacture.

Through the breadth of our technology platforms, we support our partners across many diverse markets, including pharmaceuticals, speciality chemicals, food and drink, electronics and transportation.

www.uk-cpi.com

About Perceptive Engineering

Perceptive's award-winning software – PharmaMV – is designed to meet the rigorous needs of 21CFRPart11 manufacturing. Combined with a wealth of experience from lab-scale to pilot plant to full-scale production, Perceptive's team provides consultancy and practical knowledge on all aspects of process development and



manufacturing optimisation. PharmaMV includes chemometric methods, univariate and multivariate analytical tools, advanced control systems, and real time optimisation engines to operate with a sophisticated User Access controlled platform. The platform is constantly evolving to meet rapidly-changing user needs, providing fully configurable dashboarding, Machine Learning tools, cloud connectivity and is already the standard choice for many companies making the transition to AI enabled manufacturing.

About Process Systems Enterprise

Process Systems Enterprise, A Siemens Business, is the world's foremost provider of Advanced Process Modelling software, services and solutions to the process industries for digital R&D, design and operations.

PSE provides the gPROMS FormulatedProducts modelling suite for optimising the formulation and manufacture of drug substances and drug products using mechanistic process and material models of unit operations – such as crystallization, spray drying and granulation – combined with in-vitro/vivo product performance models.

Use of PSE's technology and services results in faster innovation, more rapid formulation screening, improved process and product designs, enhanced operations, reduced risk, more effective R&D and experimental campaigns and better capture and transfer of corporate knowledge across the organisation.

Since 2013, the company has been pioneering the emerging science of Systems-based Pharmaceuticals with Bayer, Eli Lilly, GSK, Pfizer, Roche and Sanofi. PSE was also the leader of the £20.4m AMSCI funded digital design ADDoPT project.

www.psenterprise.com

About Siemens

Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 170 years.

The company is active around the globe, focusing on the areas of power generation and distribution, intelligent infrastructure for buildings and distributed energy systems, and automation and digitalization in the process and manufacturing industries.

Through the separately managed company Siemens Mobility, a leading supplier of smart mobility solutions for rail and road transport, Siemens is shaping the world market for passenger and freight services.

Due to its majority stakes in the publicly listed companies Siemens Healthineers AG and Siemens Gamesa Renewable Energy, Siemens is also a world-leading supplier of medical technology and digital healthcare services as well as environmentally friendly solutions for onshore and offshore wind power generation.

In fiscal 2019, which ended on September 30, 2019, Siemens generated revenue of €86.8 billion and net income of €5.6 billion.

At the end of September 2019, the company had around 385,000 employees worldwide.



About the University of Strathclyde

For more than 200 years, the University of Strathclyde has been meeting the needs of students, employers, industry and wider society through world-class research, teaching, innovation and enterprise. Today, as a leading international technological University, Strathclyde works side-by-side with business, industry, government and the public sector, to improve health, safeguard the future of energy supplies, set new standards in manufacturing, and pioneer technologies. Its entrepreneurial environment makes Strathclyde the partner of choice for growing numbers of organisations across the world, and has been recognised through the award of Times Higher Education UK Business School of the Year, Entrepreneurial University of the Year, and University of the Year.

About Scottish Enterprise

[Scottish Enterprise](#) is Scotland's national economic development agency. We're committed to growing the Scottish economy for the benefit of all, helping create more quality jobs and a brighter future for every region.

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About UK Research and Innovation

This project has been funded by the Industrial Strategy Challenge Fund, part of the government's modern Industrial Strategy. The fund is delivered by UK Research and Innovation.

The **Industrial Strategy Challenge Fund** brings together the UK's world-leading research with business to meet the major industrial and societal challenges of our time. It provides funding and support to UK businesses and researchers, part of the government's £4.7 billion increase in research and development over the next 4 years. It plays a central role in the Government's modern Industrial Strategy.

UK Research and Innovation is a new organisation that brings together the UK Research Councils, Innovate UK and Research England into a single organisation to create the best environment for research and innovation to flourish. The vision is to ensure the UK maintains its world-leading position in research and innovation.

www.ukri.org

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