DM² collaboration demonstrates how Industrial Digital Technologies makes the development and manufacturing of medicine faster, more efficient and sustainable

A collaborative centre involving academia, industry and public engagement has developed innovative digital approaches to accelerate the development, production and supply of pharmaceuticals using novel data-driven technologies.

> *"This collaborative, systems-based approach not only accelerates drug development but also reduces costs and waste, while the SkillsFactory initiative helps build a skilled workforce to support these advancements."*

Led by the Continuous Manufacturing and Advanced Crystallisation (CMAC) centre of excellence for advanced pharmaceutical manufacturing research and training, the aim of this research centre is to develop and accelerate the adoption of industrial digital technologies (IDTs) in the pharmaceutical sector to improve data generation and communication across pharmaceutical supply chains.

Based at the University of Strathclyde, CMAC collaborates with over 30 partners including Cambridge and Loughborough universities, pharmaceutical companies including AstraZeneca, GSK and UCB, along with SMEs, technology companies, Made Smarter Innovation, and public sector organisations. CMAC is responsible for the Digital Medicines Manufacturing (DM²) collaboration with MSI and is itself a world leading centre for pharmaceutical manufacturing research.

DM2, along with its partners, has produced a suite of innovations involving collaborative robotics, AI and digital twins that can enable on-demand, autonomous, low quantity pharmaceutical manufacturing that can adapt quickly to the needs of emerging clinical trial supply demands or the personalisation of specialist locally-produced medicines.

Their table-sized Tableting DataFactory rapidly generates large, structured data, turning it into actionable insights for pharmaceutical manufacturing that allows rapid tablet development, reducing manufacturing times from months to less than a day - up to a 90% improvement - using minimal materials, reducing waste by 60% and costs by 50%.

To accelerate Industry's adoption and use this new manufacturing approach, DM² has developed an online learning resource known as the Skills-Factory, to offer training in existing and emerging industrial digital technologies (IDTs).

Prof Alastair Florence, CMAC Director and PI on DM2 said: *"The pharmaceutical industry faces the global challenge to enhance the development and manufacture of medicines to be faster, more cost effective and productive, to embed sustainability and to deliver improved security of supply whilst still assuring the quality and safety of medicines to patients.*

"DM² has shown how technology can transform medicines manufacturing, by making it faster, more efficient, and sustainable. It has been a remarkable example of the level of innovation that can be achieved through collaboration."

The Inspiration
Medicines manufacturing is a key sector for the UK investing over £4Bn on R&D, and generating exports of over £25Bn generating the highest gross value added (GVA) of any sector (£8.5Bn).

While drug discovery continues to accelerate as an industry, developing the processes to convert molecules into formulated medicines for patient-use still typically takes 10-12 years, and costs an exorbitant amount of money.

Increasingly the bottleneck sits with the development of chemistry, manufacturing, and controls (CMC) processes. The nub of the challenge is that the data, which fuels IDTs such as artificial intelligence (AI) and automation to drive understanding and accelerate R&D, is siloed, unstructured and spread across organisations.

Integrating and standardising data and IDTs offers the opportunity to create agile, resource-efficient development and manufacturing platforms, together with integrated supply chains that can accelerate the development of new products, reducing waste, and improving productivity.

Similarly, IDTs can transform quality control, an essential component of assuring medicines compliance with regulatory and safety standards. Traditional approaches are inefficient, fragmented, time consuming and can amount to over 20% of total production cost. Digital approaches offer reliable means to streamline quality assurance whilst maintaining patient safety.

Prof Daniel Markl, Associate Director at CMAC and Lead for DM2 Platform Two, said: *"By better leveraging what already exists and applying innovative solutions, medicines development and manufacturing can be quicker, cheaper, more efficient, less wasteful and more sustainable. It can also simplify and make more resilient current complex and fragile medicine supply chains."*

The Innovation
Over the last three years, DM² has developed five integrated platforms working to deliver innovative IDTs that will benefit the medicines manufacturing supply chain.

Platform one created a foundation to build trusted and structured data sets that are findable, accessible, interoperable and reusable (FAIR).

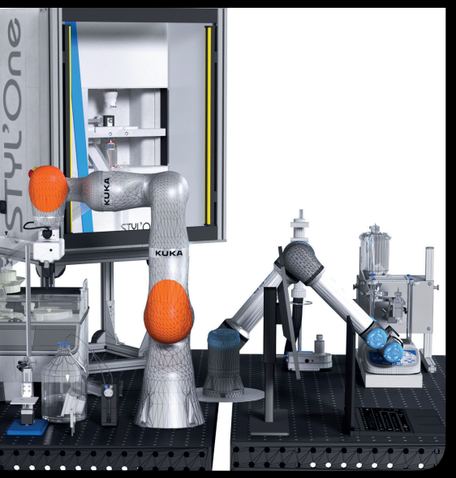
The team developed an 'extract, transform and load' (ETL) tool to simplify automatic data acquisition from multiple instruments, such as the static imaging system for particle size/shape analysis, and gas pycnometry for true density measurements.

The ETL tool has been future-proofed to allow new data from other instruments and processes

to be easily integrated. An interface has been designed so that non-expert users can easily upload files on the server from instruments in a few clicks, while dashboards help users explore and analyse the data in intuitive and interactive ways.

Platform two, developed the Tableting DataFactory, an autonomous microscale development, manufacturing and testing facility to make and test individual pharmaceutical tablets. This AI-driven robotic platform uses predictive models and adapts to real time feedback to select and optimise tablet formulations and processes for small-scale manufacture or rapid scale-up.

The large data sets which are generated are used to develop hybrid computational models using mathematical techniques and artificial intelligence.



Platform three developed a set of digital tools for quality control. These tools allow the assessment of the information content the data received from the DataFactory and enable maintenance of the digital twins and self-optimisation of quality control requirements.

The ESTAN toolbox is a world first, allowing assessment of the data information content and enhancing the prediction capabilities of digital twins. Built and validated using several exemplars, ESTAN can treat any kind of parametric models or simulation tools to identify model characteristics, guaranteeing effective prediction capabilities.

A new method was developed to evaluate which process parameters and material properties are most important to pharmaceutical product quality. Using digital twins for both individual and combined processes, this approach helped identify the key parameters and materials that need to be controlled. It also established a "robust design space", a safe range of settings that ensure quality while supporting real-time quality testing of pharmaceutical products.

Another area focuses on capsule filling, where advanced computer models simulate how particles move and interact during the process. These simulations help define important process parameters and material properties, along with optimal operating ranges, which are then used to design a control strategy. This approach demonstrates how digital quality control methods can enhance process consistency and quality.

Platform four explored the application of IDTs in selected real-world healthcare manufacturing supply chain settings. Research focused on aggregated patient demand data from customers – nursing homes, hospitals, and clinics – with supply-side production capabilities.

Supply chain mapping, modelling and analytical tools were developed to evaluate alternative manufacturing supply chain configuration scenarios, based on the adoption of smart factory IDTs.

The team then evaluated digital interventions in three use cases, enabling more adaptive manufacturing supply networks, better able to respond to changing patient demand and healthcare provider needs.

1. The first model is a digital platform that connects patient demand to pharmaceutical and medical device manufacturing operations, including upstream procurement.

2. The second focuses on unlicensed specialty medicines and combines real world customer demand data analysis with a smart manufacturing environment to support more synchronised planning and control.

3. The third aims to improve clinical trial resilience by preventing stockout events which can have a hugely detrimental impact on a clinical trial. This involved extensive supply chain data analytics, insights from which are informing clinical trial operating model planning design rules.

Their approach has led to the development of a clinical supply chain analysis dashboard prototype tool to improve supply chain resilience.

Platform five is establishing a SkillsFactory, which is a new online platform accessible to students, industry professionals and individuals seeking reskilling and upskilling in digital medicines manufacturing.

CMAC, in collaboration with Glasgow School of Art, has also developed an Augmented Reality (AR) application, which visualises multi-modal data to support data-driven decision making for operators, and a Mixed Reality (MR) application to enable real-time, remote monitoring in a structured, user-friendly way.

THE IMPACT

DM² has been a groundbreaking example of collaboration with project partners collectively supporting the creation of 13 first generation and 23 second generation demonstrators.

DM² has laid the foundations for a systems approach which registers supply chain demand signals, triggering a rapid manufacturing response drawing on a unique CMC data platform, and utilising the digital Quality Control tools to release the medicines safely and efficiently to meet that demand.
Central to its success has been the development of the Tableting DataFactory which enables the rapid generation of large, structured data, turning it into actionable insights for data-driven decisions. As a result, tablet development has been accelerated to under 24 hours using only a fraction of previously required materials (only few grams, compared to months/100s of grams via traditional).

As CMAC amplifies its commitment to industry leadership and enhances its research and innovation portfolio, we continue to deliver value grounded in exceptional research and innovation. Our focus on growing CMAC's research portfolio, and in accelerating the implementation of our Translation to Industry strategic initiatives, which DM2 is a key component of, aligns seamlessly with our vision to revolutionise medicines development and manufacturing on a global scale through digital transformation of CMC and Quality by Digital Design (QbDD).

The SkillsFactory, to be launched in Spring 2025, will offer personalised, flexible learning in IDTs to boost employability by filling the gap in existing educational platforms. The use of immersive technologies is forecasted to enhance training, safety, virtual collaboration, and process understanding, and boost productivity.

Education and engagement around the capabilities of DM² has been widespread through over 20 published articles, over 300 research presentations, and six public/patient engagement activities. These activities, as well as workshops and webinars have upskilled around 600 people in the capabilities of IDTs

in the pharmaceutical sector. The programme has further developed a critical mass of medicines manufacturing expertise and capability in the West of Scotland, alongside the National Manufacturing Institute Scotland (NMIS).

Prof Florence added: *"By integrating data acquisition, automating tablet production, and enhancing quality control, the DM² creates a more adaptive and resilient supply chain. This collaborative, systems-based approach not only accelerates drug development but also reduces costs and waste, while the SkillsFactory initiative helps build a skilled workforce to support these advancements.*

"DM² also exemplifies a forward-thinking model for UK medicines manufacturing, by paving the way for rapid, data-driven responses to healthcare needs. Beyond the current achievements, future efforts could focus on advancing these technologies and applying the acquired insights to additional dosage forms, such as inhaled and liquid medicines, for targeted therapeutic modalities."

DM² Digital Medicines Manufacturing