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## KTP between Sterling Pharma Solutions and Northumbria University builds new commercial opportunities

A Knowledge Transfer Partnership (KTP) project with partners Sterling Pharma Solutions and Northumbria University has been awarded the top grade of 'Outstanding' by Innovate UK's independent assessors. The KTP provided an ideal approach for the application of Northumbria's knowledge in biocatalysis research to create new commercial opportunities, building on Sterling's existing expertise in development chemistry.

With over 850 employees based across the UK and the US, <u>Sterling Pharma Solutions</u> is a Partnership Development and Manufacturing Organisation producing Active Pharmaceutical Ingredients (APIs) in a business model which develops customer-driven solutions, integrated into customers' supply chains. The KTP is directly aligned to the company's distinctive approach which sets a new standard of transparency and collaboration with scientific partnership at the core.

KTP Associate Greg Holgate was recruited to join the KTP shortly after graduating with a first-class MChem degree in Chemistry with Medicinal Chemistry. KTP Associates have a hybrid role, working at the company, with regular visits from academic staff to supervise the project and discuss with the company team.

Greg joined the Research and Development (R&D) team at Sterling Pharma Solutions and quickly got to grips with delivering the project plan, undertaking experimental work in the lab and desk-based research to investigate and select new manufacturing routes using biocatalysis.

Greg participated in Northumbria's pilot of a bespoke Action Learning programme for the university's cohort of Associates. This powerful problemsolving activity was vital to support Northumbria Associates during the pandemic, which was showcased in the 2021 KTP Awards.

## The Challenge

The use of biocatalysts in the pharmaceutical industry is rapidly expanding, as it offers compelling advantages like improved efficiency, reduced costs, customisation capabilities, and enhanced sustainability.

In order to win business on customer development projects, Sterling Pharma Solutions' aim was to further its knowledge, particularly at an industrial scale and demonstrate credibility in deploying the relevant technology.

Partnering with Northumbria University on the KTP provided an ideal mechanism to address this challenge for biocatalysis. The KTP created new knowledge and expertise in biocatalysis to enable the company to identify and apply natural and engineered enzymes to accelerate customers' syntheses, enabling them to realise enhanced efficiency in a sustainable and

## The project

To meet this challenge, the KTP created a new commercially driven enzyme discovery workflow developed through practical application of biocatalytic methodology in lab experiments and analyses, directed by research insights from the Academic team.

Throughout, the lab work was closely aligned to the market potential and the company's production processes. Decisions on candidate compounds and routes to manufacture considered the needs of customers, regulatory requirements, alongside the scientific parameters of improved yield, efficacy, and recycling of raw materials.

Dr Mark Muldowney is Head of Technology and Innovation explains the KTP's impact:

"The KTP with Northumbria was envisaged initially to address a specific business opportunity but our experience of the KTP and what has been possible through it has led to a broader appreciation of how the technology can be deployed and developed to innovate further and create value in the business. The close collaboration with the Academic Team has led to other collaborations and an ongoing relationship where ideas are regularly shared and issues discussed."

During the KTP, new modules have been developed at Northumbria University for the teaching of 'Industrial Biochemistry and Biocatalysis'. Dr Graeme Turnbull, Senior Lecturer at Northumbria University, who is a synthetic chemist with a focus on the application of biocatalysis to improve routes to synthesis, designed this module directly informed by his work on the KTP, with research-rich examples at the core.

Students will receive case study lectures from guest speakers from industry including Mark who will explain the KTP process. Several undergraduate research projects were carried out during the KTP as a result of the collaboration.

Dr Turnbull comments:

"This KTP has given me the opportunity to explore the processes and practices of the pharmaceutical industry while contributing to my own research group. As an Early Career Researcher, being able to work with a talented team of academics and industrialists to train our Associate and transfer knowledge into the company has been a rewarding experience."

Dr Turnbull was joined on the KTP by Professor Justin Perry, who has over 15 years' experience of working closely with the polymer, biotechnology and formulation sectors through industry-funded collaborative research including PhD projects and KTPs across the coatings, inks and additives industries, and Professor Gary Black, who has over 20 years' experience of using a multi-omics approach to enzyme discovery and characterisation for industrial biocatalysis applications. Justin and Gary jointly lead a cross-disciplinary research group in biocatalysis and biotransformation which has worked on developing the methodology from enzyme discovery to technology transfer of litre-scale reactions for process biochemists.

The broader than anticipated benefits of Sterling Pharma Solutions' new knowledge in biocatalysis resulted in new business being won during the KTP, and several new contracts and projects are in development and ongoing. These include new customers who have not previously partnered with Sterling Pharma Solutions and a healthy pipeline of enquiries.

Sterling Pharma Solutions can now quote customers for an 'end-to-end' service, from the initial development of appropriate biocatalytic technology through to scaled-up manufacture as they have the knowledge, processes, and facilities to confidently deliver. This is being expanded to incorporate in silico design in a second KTP with Northumbria, to develop new capabilities in biotechnology and computational biology.

John Clayton, Innovate UK KTN's Knowledge Transfer Adviser, to the project, summed up the value to the partners as being:

"Outstanding across the three agendas delivering a new, market- and sector-leading, capability in biocatalysis for the business, a blue-chip relationship with a global business for the University which has developed into a recently awarded second KTP, and a prestige career opportunity for the Associate."

Greg now has a new role as Biocatalysis Chemist at Sterling Pharma Solutions, and continues to work on a range of projects, including the

continuation from the KTP project.

Knowledge Transfer Partnerships (KTPs) are an Innovate UK programme, designed to enable collaboration between academia and industry, facilitating the transfer of knowledge and technology to increase competitivity and to promote an innovation culture.

KTPs are funded by UKRI through Innovate UK with the support of cofunders, including the Scottish Funding Council, Welsh Government, Invest Northern Ireland, Defra and BEIS. Innovate UK manages the KTP programme and facilitates its delivery through a range of partners including <u>Innovate</u> <u>KTN</u>, Knowledge Bases and Businesses. Each partner plays a specific role in the support and delivery of the programme.

Northumbria has a long track record of successfully collaborating with small and large businesses on KTPs, read more of our <u>KTP case studies</u>.

Find out more about KTPs at https://www.ktp-uk.org/

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