Innovation Launchpad Network+

CASE STUDY

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CPI (High Value Manufacturing Catapult) & Medicines Discovery Catapult

The Challenge

This project explores the growing global threat of antibiotic resistance — a major healthcare challenge. Between 2025 and 2050, antimicrobial resistance is projected to cause an estimated 39 million deaths (UK data source pending confirmation). One promising alternative to antibiotics is phage therapy, which uses viruses (phages) to target and destroy antibiotic-resistant bacteria. However, in the UK, significant barriers remain around phage manufacturing.

Our core research question was:

How can we manufacture high-quality, safe, and effective phages for therapeutic use in the UK — and what would that look like from a regulatory perspective?

We set out to identify the most effective purification methods for a range of phages and develop analytical techniques to measure host cell residuals — a critical safety requirement. From there, we focused on analysing the integrity and bioactivity of the final phage product to ensure it remained effective. This work lays the foundation for developing a scalable manufacturing process, with the ultimate goal of adapting it into a GMP-compliant system capable of producing phage products for clinical use.

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This project aimed to address the manufacturing barriers within the UK through exchange of knowledge and expertise between the CPI, the Medicines Discovery Catapult and UoL to enable the manufacture and scale-up of high-quality novel phages.
An objective was to produce safe phages by developing a method so purify the phage product, we established which phage purification process would result in the most impurities being removed and the phages still being bioactive. This is significant as the process would be key in the production process of clean, safe and active phages.
Another objective was to measure the integrity and therefore the efficacy of the phages throughout the process, we developed a ddPCR method that can be used to measure a variety of critical quality characteristics of the phage product phage DNA integrity, phage titre and host cell DNA. Significant because monitoring of these will be key in proving that the products safe and effective
With Medicines Discovery Catapult we developed of a novel way of imaging phages using high-resolution microscopy. This was innovative as it's a new method that could be used to establish the integrity of phages with further optimisation.

Result

This project set out to overcome key manufacturing barriers in the UK by fostering collaboration and knowledge exchange between the CPI, the Medicines Discovery Catapult, and the University of Liverpool. The aim was to support the production and scaleup of high-quality, novel phages for therapeutic use. One of the main objectives was to produce safe phages by developing an effective purification method. We identified which purification processes removed the highest levels of impurities while keeping the phages bioactive. This is a critical breakthrough, as purification is essential to ensuring phage products are clean, safe, and therapeutically effective. Another objective focused on monitoring phage integrity — and therefore efficacy — throughout the process. To do this, we developed a digital droplet PCR (ddPCR) method capable of assessing key quality indicators: phage DNA integrity, phage titre, and host cell DNA content. This is significant, as being able to track these attributes is vital for demonstrating that the final product is both safe and effective. Working with the Medicines Discovery Catapult, we also developed a novel high-resolution microscopy technique for visualising phages. This innovative method provides a new way to assess phage integrity and, with further optimisation, could become a valuable quality control tool.

Impact

One of the project's most significant achievements was moving phage production from a small-scale academic lab into a manufacturing setting at the CPI — a facility capable of Good Manufacturing Practice (GMP). This is a major step forward, as there are currently no GMP-grade phages being produced in the UK, yet this is the minimum standard required for clinical use in humans. CPI now has the capability to develop processes that could be scaled to meet GMP standards, and they are actively promoting this expertise — a move that will benefit and help drive the UK phage therapy field forward. There is growing interest in phage therapy not only for human healthcare, but also in veterinary medicine and agriculture. If CPI can take this process all the way to GMP, it has the potential to unlock and significantly expand the UK phage market. While commercial-scale phage production is still some way off, the small-scale manufacture of GMP-grade phages for compassionate use is now within reach — and demand is already high. This project has been the catalyst for a broader shift towards GMP-compliant phage manufacturing in the UK, with the potential to save lives in the near future.

CPI - HVM Catapult

"CPI's participation in the RinR scheme has greatly improved our capability and knowledge in the phage production, purification and analytical development space. Phage process development has been highlighted as a key part of CPI Biologics microbiome strategy and the knowledge gained from Dr Duignan in the RinR scheme has allowed CPI to increase the number of interactions with future customers and collaborators. An example of a recent successful collaboration is the CF-Trailfinder project funded by LifeArc and CF Trust which brings together leading CF academics and clinicians, where CPI will be aiming to develop phage production methods which are suitable for GMP manufacturing."

Libby Duignan

"The RinR has been an amazing opportunity, allowing me to finally see phage breaking out of the research cage and taking it there myself, after studying phage and their use as therapeutics for the last 9 years. The field has come on so far in that time and CPI and MDC were fantastic collaborators with so much experience taking quite primitive product ideas and processes into large scale. This has been by far the best opportunity I have taken in my academic career, this exposure to industry has been eye opening and has made me realised the sector where CPI sits between research and commercialisation is exciting, innovative and carries more impact, which is why I have left academia and taken a role at CPI."

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