

Downstream Purification: A Toolbox Approach for Adaptive Multi-Serotype AAV Solutions



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PHARMARON

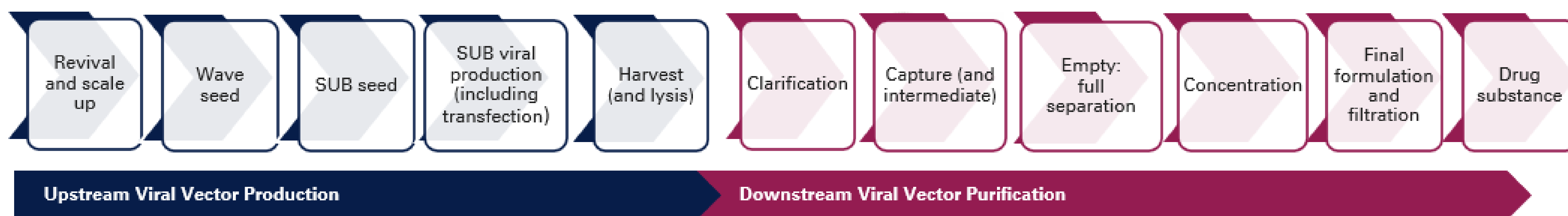
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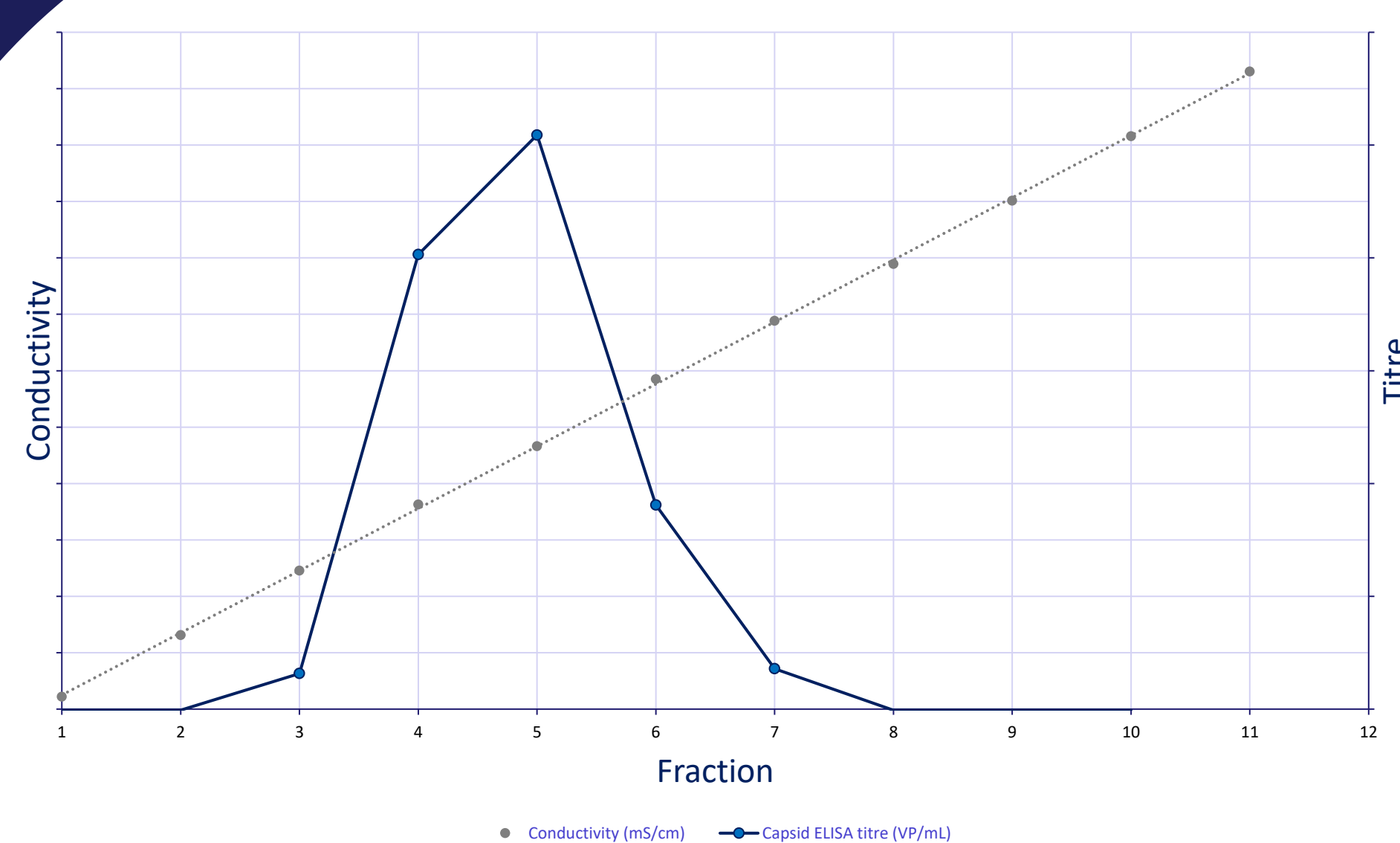
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Pharmaron's AAV Platform Process

Around 300 clinical studies using AAV viral vectors are currently in progress, with global demand for gene therapy development and manufacture rapidly increasing. At Pharmaron, we have successfully developed a platform process for the creation of such therapies but with a highly adaptive toolbox to manage varying AAV products and serotypes. We offer a triple transfection suspension-based platform with chromatography-based purification at scales of 15mL to 500L.



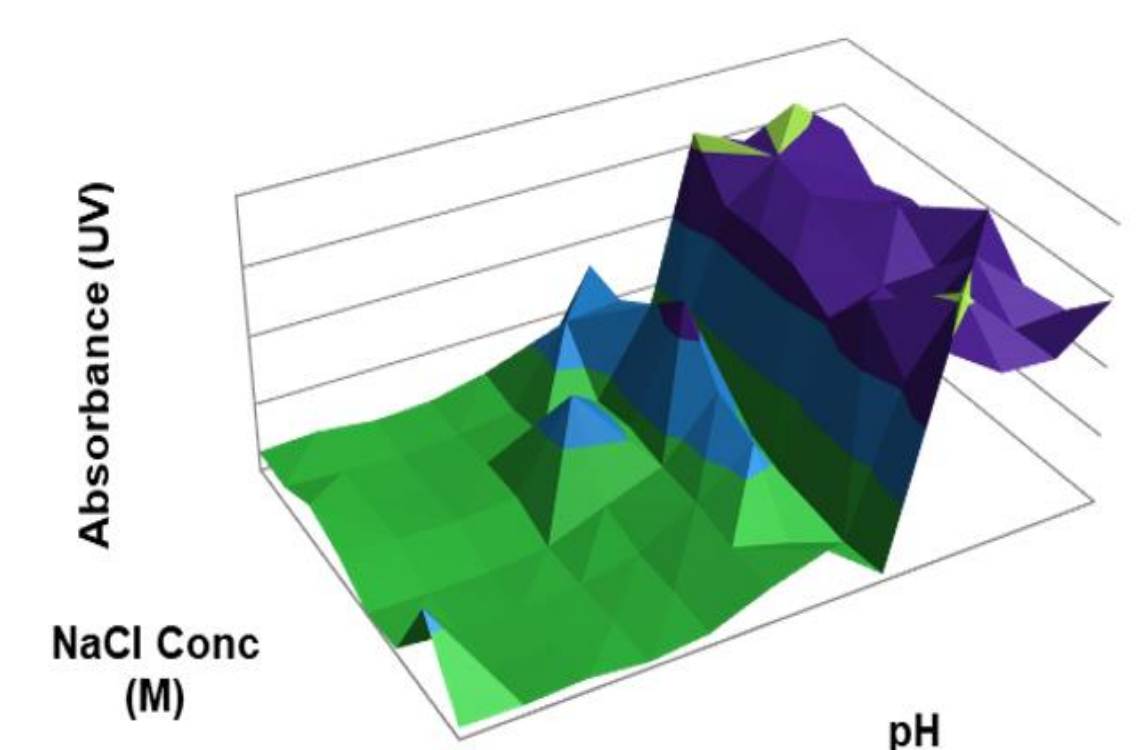
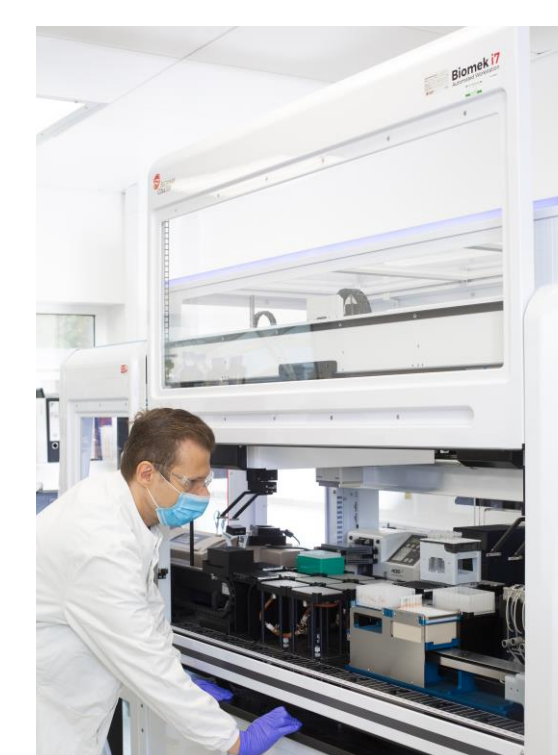
High Throughput Process Development



Fractionation at increasing conductivity simulates IEX elution gradient using robocolumns®.

Our High Throughput Process Development (HTPD) team have established methods for scale-down experiments to assess a product's platform fit, allowing buffer and resin screening, along with process optimisation for affinity and IEX chromatography via utilisation of robocolumns®.

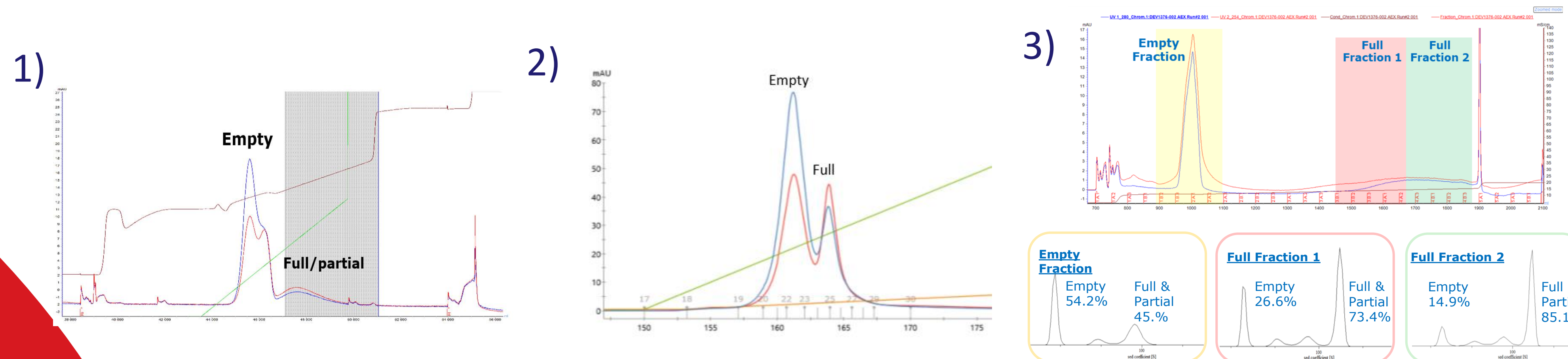
Our multi-platform approach, coupled with our HTPD, allows selection of the best purification process from multiple methodologies, ensuring the optimal process conditions for any AAV serotype.



HTPD allows rapid screening of optimal process conditions via DoE.

Multi-Platform Approach

Working alongside global biotechnology companies, we have continued to optimise our platform through evaluation and implementation of new technologies to ensure we have solutions to purify all AAV serotypes. A key part of our toolbox is our highly sensitive in-process analytics, that in combination with our manufacturing process, ensure delivery of the product to the right titre and the right quality.



Process data from Pharmaron's 1) resin-based, 2) monolith-based & 3) The importance of highly sensitive analytics for product quality.

Delivering Solutions

Our facilities enable provision of rapid process optimization and production tools over several scales and platforms. This offers significant improvement on the one-platform fits-all approach, ensuring delivery of technical solutions for a vast range of gene therapy products.