

Abstract

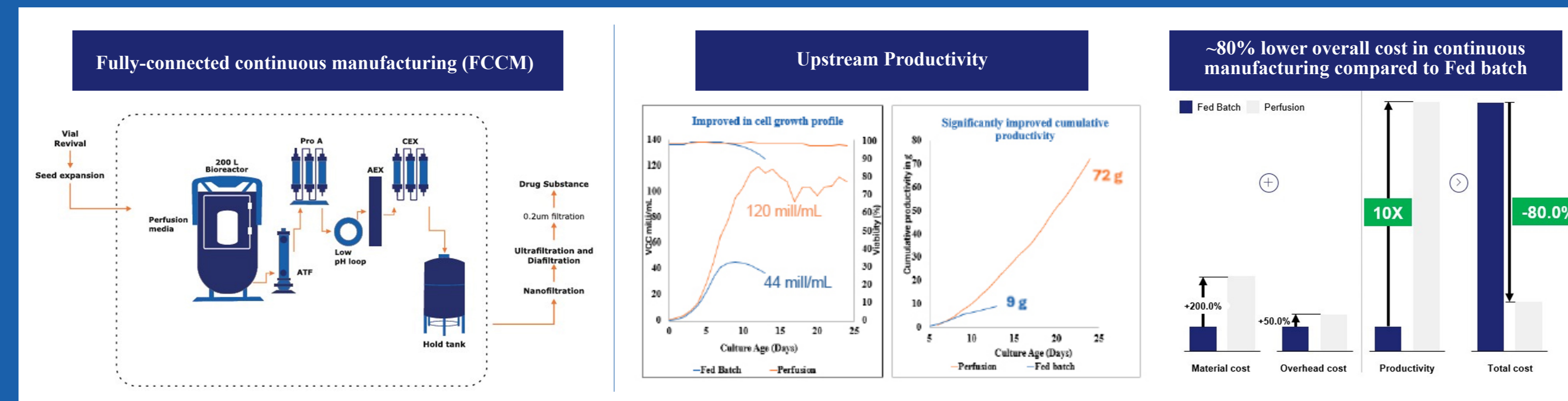
On a mission to democratize access to life-saving medicines for patients, Enzene introduces its patented fully-connected continuous manufacturing platform, EnzeneX™, revolutionizing the future of biologics manufacturing. EnzeneX™ 2.0 aims to reduce production costs to under \$40 per gram for mAbs, making life-saving medicines more affordable and accessible to patients across the world.

Fully-connected continuous manufacturing offers an innovative alternative to conventional fed-batch processes, especially for complex biologics. Traditional batch processing results in lower productivity, longer processing times, and higher operational costs. EnzeneX™ addresses these inefficiencies with a streamlined, automated continuous process from upstream to downstream. With EnzeneX™, Enzene has launched three biosimilar mAbs in India, with plans to launch one in the US and two in the EU.

Introduction

EnzeneX™ achieves 5-10 times higher productivity than traditional fed-batch processes, with high cell densities and viability. It manufactures complex biologics, including bi- and tri-specific molecules, and reduces facility footprint and costs with smaller reactors and fewer hold tanks. The upstream operation uses perfusion mode with continuous media addition and product removal via an alternative tangential flow (ATF) system. The downstream purification integrates capture, low pH viral inactivation, and two chromatography stages for seamless continuous processing.

Significant reduction in cost per gram with fully-connected continuous manufacturing

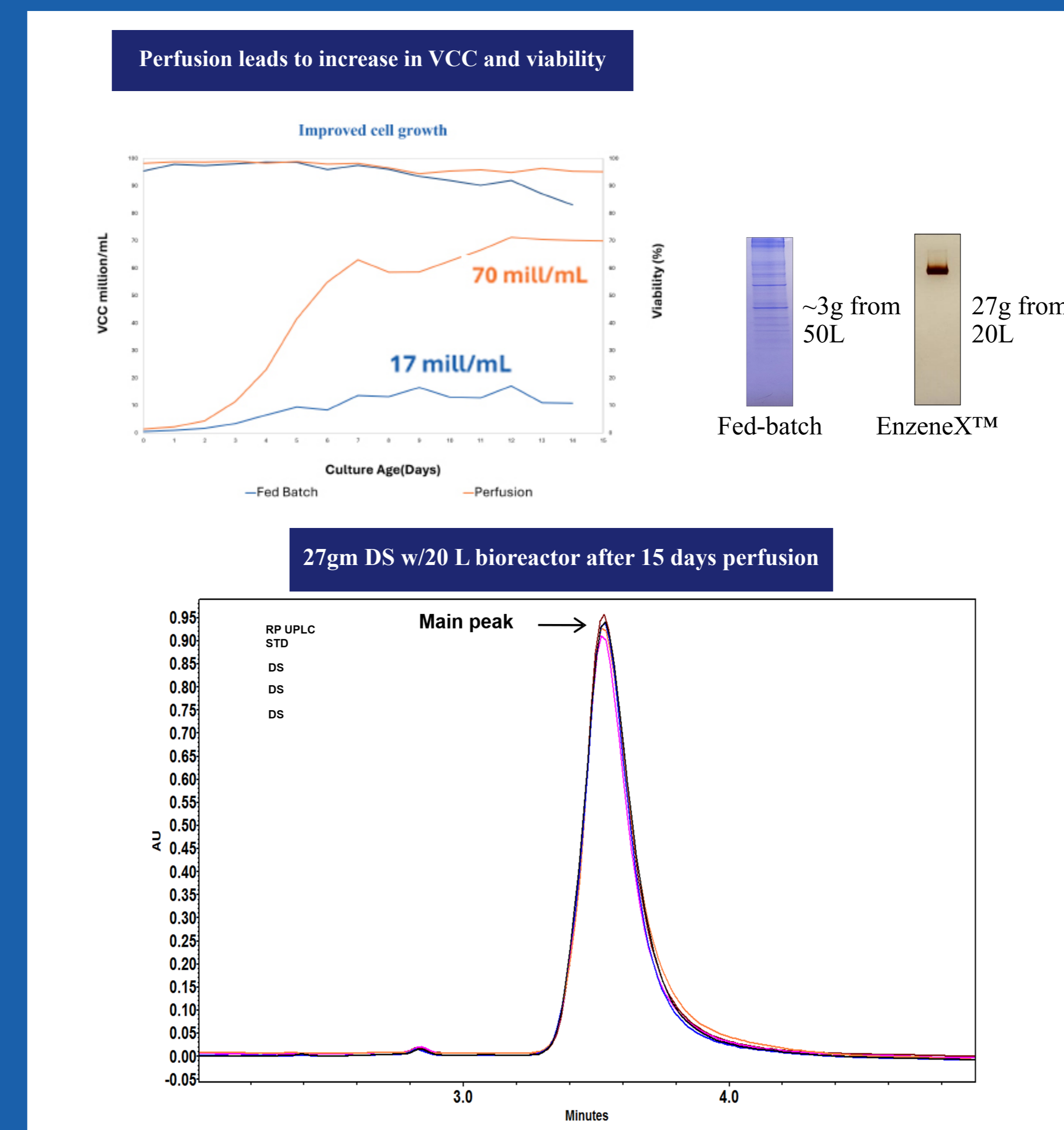


Challenges with fed batch process

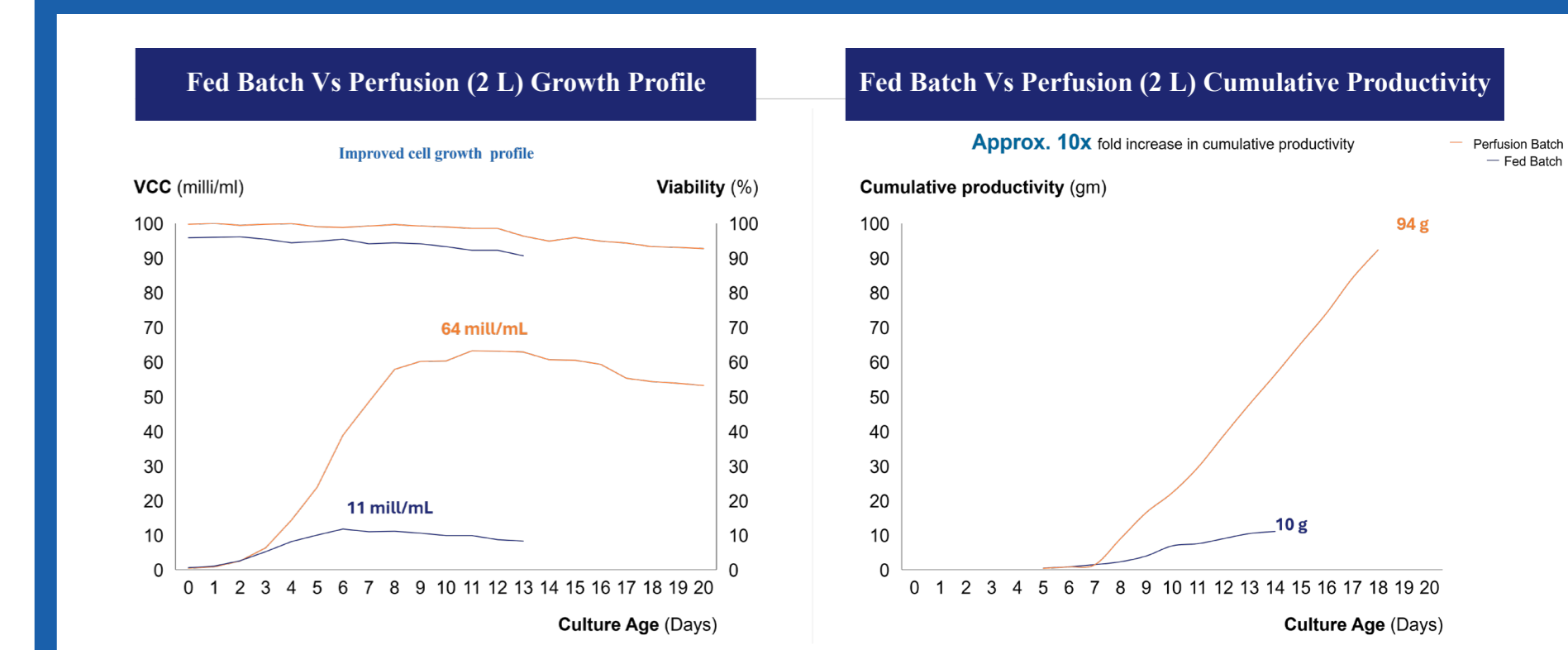
- Poor viability in Fed batch after day 10
- Proteolytic clipping of the molecule during manufacturing (upstream and downstream)
- Limited operational pH range
- Absence of a true capture step for the molecule
- Heparin affinity: low recovery and leachability, expensive reagent

Key impact of EnzeneX™

- 27 grams high quality, purified protein via 20L perfusion process
- Commercially viable manufacturing process development and cGMP technology transfer within **6 months**
- Batch to batch **consistency and scalability** from bench to commercial
- Yield > **500,000 doses** of Drug Product via 20L perfusion process



EnzeneX™ 2.0 targets a cost efficiency of \$40 per gram for protein-based therapeutics



40 kg per batch

Conclusion

We are at a pivotal moment in biologics drug manufacturing, needing to enhance processes, reduce footprints, ensure PAT compliance, improve quality, and accelerate development timelines, all while lowering costs to improve global access. EnzeneX™ 2.0 aims to deliver cost efficiency at \$40 per gram for mAbs through fully-connected continuous bioprocessing. High capital investment has been a barrier to continuous biologics production, but EnzeneX™ offers a proven setup from development to commercial production. Through extensive trials, we developed a reliable workflow, establishing Enzene as a leader in fully-connected continuous manufacturing with a commercially validated end-to-end platform.