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Enabling technologies for integrated / continuous downstream processing of biologics

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Pfizer Bioprocessing R&D is focused on developing enabling technologies that will reduce capital and operational expenses, decrease equipment scale, increase automation and utilize fewer FTEs.
To realize this vision, Purification Process Development has piloted new technologies and operational strategies that have enabled a fully integrated downstream process. Our current work has demonstrated a continuous process that includes tangential flow filtration harvest from a perfusion bioreactor, Protein A capture, inline viral inactivation/conditioning and AEX polishing. This process was fully automated and demonstrated at the 100 L scale. We have also shown feasibility of multi-day virus reduction filter operation and a continuous ultrafiltration/diafiltration using counter-current single-pass tangential flow filtration. These technologies and strategies are critical elements of our long term goal of establishing a fully integrated process from bioreactor to drug substance. With this process, we hope to remove product supply as a critical path activity for both toxicology and clinical needs.