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FujiFilm introduces novel, fully integrated continuous production system

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FUJIFILM Corporation has announced an initial $10M USD investment to establish a full scale, fully integrated continuous processing facility for non-GMP manufacture of biopharmaceuticals at its FUJIFILM Diosynth Biotechnologies, Billingham, UK location. This perfusion based facility represents the culmination of 3 years of in-house innovation by Fujifilm group companies and includes the introduction of patented, disruptive downstream bioprocessing technology to the biopharmaceutical industry.

Fujifilm's advanced upstream perfusion process utilizes a proprietary process control system with automatic feedback control for cell density and nutrient addition to maintain steady state conditions. Perfusion is a cell culture manufacturing process that involves the constant feeding of fresh media and processing of harvested media over several weeks. Fujifilm has developed an in-house, defined medium suitable for very high density perfusion culture and has adapted its Apollo X cell line for perfusion processing. This system offers a compelling, cost effective alternative to traditional fed batch cell culture processes given high efficiency and superior and consistent product quality (given reduced degradation and aggregation).

Adoption of perfusion processing by the biopharmaceutical industry has been hindered somewhat by an inability to continuously purify the culture downstream due to equipment limitations and the large buffer volumes involved. Fujifilm has dedicated significant scientific and engineering resource to re-think the existing paradigm.

Fujifilm has developed and patented a novel multi-functional system for downstream purification and is able to deliver all required unit operations including chromatography, ultra and dia-filtration (UFDF), single pass tangential flow (SP-TFF), viral inactivation and filtration and point of use in-line preparation of buffers within a common single-use flow paths. This technology can be deployed in both batch and continuous processing environments.

The new facility will include a 500L single use perfusion bioreactor and 7 patented downstream processing units that is expected to yield >15kg of antibody from a single 4 week batch at 500L scale.

The new system is available for process development services in Fall 2019.