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SMALL-SCALE PLATFORM FOR RAPID ON-DEMAND MANUFACTURING OF RECOMBINANT PROTEINS

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The current timeline for manufacturing high-quality recombinant proteins used for therapeutics and vaccines, and delivering them to patients, typically requires many months. There are many circumstances, however, where the rapid production, release, and delivery of these biologics could address unmet medical needs, including shortages, emergency situations, and pandemics. This talk will present a new platform developed to produce biologic medicines on demand called Integrated and Scalable Cyto-Technology (InSCyT). This platform comprises an integrated, subliter-scale portable system for the (semi)continuous operation of fermentation, filtration of cell debris from secreted product, innovative affinity-based purification, polishing, and finishing. This program also emphasizes integrated on-line PAT and process control for QbD production and product qualification for release. Examples of the underlying technologies enabling this platform will be presented, along with examples of its integrated operation to produce multiple high-quality recombinant proteins on the same platform, each in less than 48 hours from initial seed to dose.

Beyond the applications for rapid manufacturing of biologics at point-of-care, the speed of production enabled by automation and integration highlights other opportunities for vaccine development and conventional manufacturing. These include modeling complete manufacturing processes during process development, rapidly creating materials for preclinical and early-stage clinical testing, and manufacturing therapies for orphan diseases, among others.