Integrated and continuous manufacturing strategies take evolving forms, but are driven by similar needs: the ability to meet the market demand, cost reduction, and speed to patient. For example, Amgen’s next-generation Manufacturing is reported to achieve a smaller facility footprint with intensification of processes and the use of certain disposable systems. Sanofi, Shire, Jansen publically report applying various extents of continuous and integrated processes. Novartis is currently commercializing its Advanced Integrated Biomanufacturing platform as an end-to-end manufacturing aimed at capacity, speed, cost, and patient access.

While CHO-derived products represent a major component of the current industry portfolio, there are opportunities to utilize integrated and/or continuous techniques to drive benefits beyond productivity. In the case of microbial processes, continuous fermentation approaches may be able to drive quality attributes that are elusive in batch systems. Other emerging aspects of the industry, such as cell or gene therapy, are in the phase where meeting demand is the priority and driver. For these emerging therapeutic areas, integrated processing will likely be necessary to break through to the “cost effective” and/or “fast” stage. While we should not expect to see a direct carry-over of the end-to-end integrated process, that are developed for large proteins, key technology features will certainly be leveraged. We will advance the discussion around the current focus areas and future possibilities.