INTENSIFIED BIOPROCESSING – DATA, DATA, EVERYWHERE…

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> *Water, water, everywhere,*
> *Nor any drop to drink…*
>
> *From: "The Rime of the Ancient Mariner" (Samuel Taylor Coleridge, 1798)*

Intensified and/or continuous bioprocessing typically involves multiple unit operations running in harmony. Consequently, the amount of data and the speed at which it is generated is typically an order of magnitude higher than in traditional non-intensified bioprocessing platforms. This presents opportunities for enhanced process control, including process analytical technology (PAT) solutions, along the entire biomanufacturing platform. With these enhanced control capabilities, intensified bioprocessing beholds the promise of more consistent process conditions and hence more consistent product quality.

The key to such enhanced control of intensified bioprocessing platforms, however, is the ability to translate the data into information to allow meaningful decisions in a useful timeframe. This may include the use of enhanced statistical approaches such as multivariate data analysis (MVDA), to visualize and confirm process consistency, and/or detect any process trends on critical process parameters before they cause a deviation outside the design space.

The use of enhanced statistical approaches to review the raw data also provides opportunities to minimize the burden of data review and shorten release times on the batch report. Opportunities such as review by exception may become a reality even with the amount of data generated in a single batch. Review by exception involves automatically highlighting records that are not within specification, rather than manually scrutinizing every individual data entry in the batch report. As such, enhanced data management aligns with the regulatory needs for an intensified process.

In this presentation, we will show various approaches to data generated in integrated continuous downstream processing platforms for monoclonal antibodies. The use of enhanced statistical data review allows, among others, identification of the biggest source of process variability. With this it provides opportunities for demonstrating process consistency and early detection of process drift.