

CHALLENGES OF THE WORKFLOW FOR INTEGRATION OF SENSORS INTO SINGLE USE SYSTEMS

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Over the last decade single use systems have become a crucial part of biopharmaceutical production setups. The usage of single use systems creates a lot of challenges when it comes to the mechanical setup and mechanical stability. Especially for the increased scale; up to 2000 l for fermentation and 3000 l for mixing. Extra focus is towards the ports and connections for sampling, feeding and sensors.

Particularly in the case of sensors a lot of topics come up. Compared to stainless steel systems with similar sensors a comparable resolution and accuracy is requested also for the single use. The major difference is the working life span, from a few hours in mixing up to weeks during fermentation in single use. The separation of a single use part for the sensing element and a reusable amplifier / transmitter has become a principal standard. The sensing element must be active over the whole shelf life and is pre-calibrated or any type of calibration could be done. This also means that the sensing element is part of the single use validation, including sterilization/autoclaving, aging, extractables etc. The integration of the sensing element has also to withstand the mechanical stress, including static and dynamic pressure.

In this presentation it will be shown how the general process is established. It will be shown some challenges during the mechanical integration, qualification runs and the automation connection, including calibration. As an example, the integration of pH and conductivity sensors in mixing bags was selected.