

## QUALIFICATION OF SINGLE USE IN-LINE SENSORS FOR USE IN CONTINUOUS BIOPROCESSING

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The requirements for batch versus continuous processing will be compared along the lines of the design attributes of single use sensors for pressure, temperature, conductivity, and UV absorbance and also performance over months of continuous operation. These sensors are applicable in both upstream and downstream processing starting with pressure monitoring on single use bioreactors, sensors required for perfusion process monitoring followed by monitoring of continuous purification processes. Dissection of the materials of the sensors and their physical nature to withstand liquid exposure of up to 90 days versus (versus shorter more discrete batch processes of less than one day) will be examined on the core material basis. With single use sensors, calibration can often not be done at the time of use because of the closed nature of the bioprocess system. How the both the sensors and their corresponding monitors can meet the requirement of "no calibration required" at the point of use will be presented which is an important aspect in single use systems for continuous bioprocessing. In addition to examining impact of time and type of exposure of the sensor materials, during a continuous process of up to 90 days, the susceptibility to sensor measurement drift / change in calibration over time will be examined. Finally, during continuous processing, it is often imperative that a process can be continuously controlled and data can be logged and trended 24/7. Therefore, interface of the sensors to higher level control systems and to data historians is important and options will be examined to accomplish this for different plant architectures.