

PROBING FOR SOLUTIONS: EVALUATING NEW PH SENSORS FOR UPSTREAM SINGLE-USE APPLICATIONS

Nick Rummel, Genentech, Inc.
Rummel.nicholas@gene.com
Arthi Narayanan, Genentech, Inc.

Key Words: pH probe, Sensors, Single-Use Technology.

The growing field of single-use manufacturing has created a desire for single-use pH sensors that are comparable in performance and operational ease of use to traditional multi-use pH sensors. Some of the current challenges with single-use pH technology include narrower pH ranges, lot-to-lot variability, limited sensor lifecycles, and complicated calibration procedures. Additionally, although sterile connectors allow traditional glass pH probes to be utilized, they have complex assembly procedures that lead to contamination concerns. A wave of new single-use pH sensors are being developed to address and improve upon the aforementioned challenges. Prototype sensors from three different vendors were evaluated to determine their ability to replicate the robustness and reliability of multi-use sensors.

This presentation/poster discusses the evaluation of three new pH sensor technologies with the goal of providing a recommended path forward for pH sensors in upstream single-use processes. One of the sensors evaluated was a solid state “glass-free and calibration-free” pH sensor. The other two sensors were glass probes enclosed in an adapter and built into the SUB. The glass elements remained wetted with a storage solution in the adapter, thus enabling prolonged shelf life of the sensors. A series of experiments were conducted to compare the performance of these sensors against the performance of a traditional glass multi-use pH probe. The experiments included pH buffer range tests (pH 2 – pH 11), drift tests, experiments in non-cell media under normal process parameters (agitation, temperature control, pH control, and sparging), and traditional cell culture runs (including implementation in SUBs). The data from these experiments provide a basis for assessing the performance of each sensor (such as pH measurement range, drift, resolution, scan rate, effect of agitation, effect of sparging, response to changes in pH, and performance in cell culture), and determining whether the sensor is viable for implementation in upstream single-use applications for both development and GMP Manufacturing.