

SAMPLE-FREE OPERATION IN CELL-CULTURE SIMULATIONS USING SINGLE-USE PH SENSOR WITH BUILT-IN SELF-CALIBRATION CAPABILITY

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Key Words: pH sensor, sample-free, single-use, cell culture, self-calibration

Single-Use Technology has evolved into a major manufacturing platform in the biopharmaceutical industry. However, pH, one of the most important parameters in the cell culture process is still monitored using the same operations as with the traditional protocol. This requires extensive time, personnel, and resources to perform autoclaving, sample extraction, off-line pH measurement, and control system standardization. The key principles of Single-Use technology are flexibility, simplicity, and the shifting of equipment preparation responsibilities from the end-users to the vendor. Broadley-James' SU800 pH sensor has been developed with full observation of these principles. The SU800 pH sensor, manufactured with a patented coplanar design, allows the sensor to be installed in a BPC then shipped while stored in its calibration position (Fig. 1 a). When the BPC is filled and ready, the sensing element can be extended to the process media (Fig. 1 b) right after its internal calibration *without the need of sampling and offline pH measurement systems*. During the process run, the sensing element can always be pulled back for recheck of its calibration while maintaining the sterility of the system.

This paper reports the sensor operation and performance in a 30-day simulated cell culture process. The process was carried out in a 5 L bioreactor with a simulated cell culture media at 37 °C. A quantity of 5 SU800 pH sensors were installed on the bioreactor and CO₂ was used for the media pH adjustment at 7.3. Fig. 2 shows the sensor pH reading deviations during the simulated cell culture process, which is the sensor drift without using the internal self-calibration. Fig. 3 shows sensor pH reading deviations when the sensor is pulled back for self-calibration every 7 days during the simulated cell culture process.

