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# Robust, fast and accurate pH sensing platform solution targeting Single Use application

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# Robust, fast and accurate pH sensing platform solution targeting Single Use Application

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**Abstract:**
QbD in biotech and life-sciences necessitates good process metrics in drug discovery, development and manufacturing. Accurate knowledge of pH measurements remains fundamentally important. There is much to be desired with use of conventional glass potentiometric probes for monitoring pH. Challenges being measurement accuracy, system drift, and need for frequent calibration. Additionally glass being fragile compounds the situation further in manufacturing.

Glass probes for pH measurement are really unattractive for single use system applications (SUS). Optical based solutions while easy to integrate lack range, need calibration and are a problem in storage (application timing).

We demonstrate a robust Platform Solution tested for a variety of applications that includes environs demanding repeated use and SUS. The innovative solution deploys electrochemical based redox chemistry engineered to deliver a scalable (semiconductor technologies) non-glass, calibration-free, drift-free, robust sensing platform. The System Solution is flexible and simply packaged as a 2D 'sticker' easily molded into a bag or a 3D probe for insertion in typical 12mm ports in-place for glass probes.

Technical performance data will be presented indicating wide performance range (pH 3.0 – 12.0), accuracy (+/- 0.1), covering $5^{o}$ C – $50^{o}$ C, calibration-free (factory set, and stable), drift-free (over process duration greater than 35 days), ability to withstand Clean-In-Place (CIP), Steam-In-Place, and gamma irradiation expected of SUS as well as up-stream and down-stream applications.

The author will share experience driving six sigma methodologies in successful development of a pH sensing platform.