Optimizing pH Control in Biomanufacturing with Pulsafeeder NextStep Pump

Executive Summary

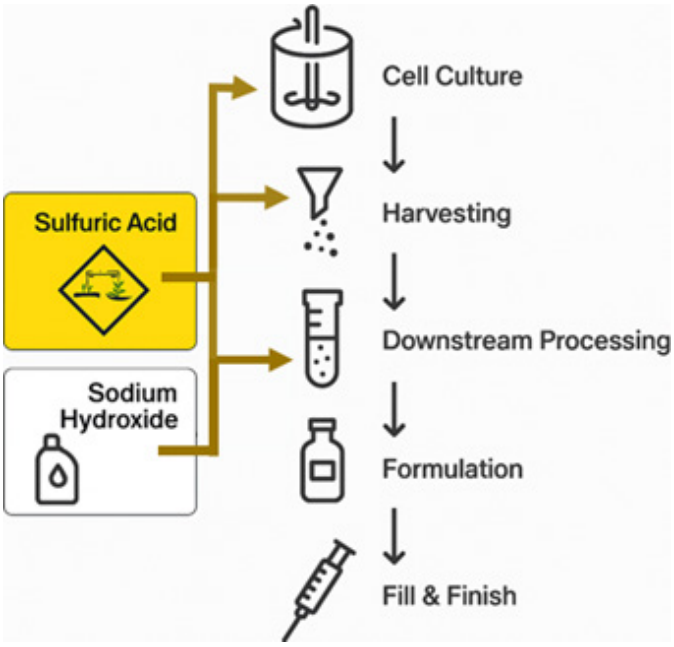
Precise pH control is critical in biomanufacturing processes to ensure product quality, consistency, and safety. This white paper explores the challenges of pH management across bioprocessing stages and introduces Pulsafeeder's NextStep pump as a reliable solution for accurate chemical dosing and process stability.

Introduction

Biomanufacturing leverages engineered microorganisms or cells to produce complex products such as medicines, vaccines, biofuels, enzymes, and sustainable materials. These processes rely on living systems, using fermentation and cell cultures as micro-factories to create substances that traditional chemical methods cannot easily replicate.

Biomanufacturing Process Overview

Throughout biomanufacturing, pH must be maintained within narrow ranges to optimize cell growth and product stability. The following stages highlight where pH control is essential and how chemicals like sodium hydroxide (NaOH) and sulfuric acid (H2SO4) are used.



- **Cell Culture:** Maintain pH for optimal cell growth using NaOH to neutralize acids released by organic processes.
- **Harvesting**: pH adjustments prepare material for downstream steps.
- **Clarification & Filtration:** Prevent undesirable protein formation through pH control.
- **Chromatography:** Ion-exchange requires precise pH; buffers adjusted with NaOH or H2SO4.
- **Viral Inactivation:** Acidic conditions deactivate viruses; neutralized with NaOH.
- **Polishing & Formulation:** Ensure stability and compliance with product specifications.
- **Fill & Finish:** Final pH check for product integrity and packaging.

Challenges of pH Control

Failure to maintain pH can lead to protein degradation, aggregation, and loss of efficacy, resulting in inconsistent and unsafe products. Reliable pH control is essential for process integrity and product quality.

Solution: Pulsafeeder NextStep Pump

- PVDF construction resists chemical attack from strong acids and bases.
- Stepper motor technology ensures precise and accurate chemical dosing.
- Near-laminar flow prevents concentration spikes that could cause batch failure.
- Modbus communications and multiple control modes simplify integration into customer control and monitoring systems.
- 5-year warranty, including diaphragm, demonstrates proven reliability.

Conclusion

Biomanufacturing demands precise pH control at every stage. Pulsafeeder's NextStep pump delivers the accuracy, reliability, and chemical resistance required to meet these challenges, ensuring consistent, high-quality products for the biopharma industry.

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