Process Analytical Technology for upstream process

pH sensor CPS171D, focus on fermentation

Biotech Training Facility is a production center where pharmaceutical training is given in an actual, real-life environment. Biotech Training Facility is completely equipped with cleanrooms, laboratories and a technical area full of state-of-the-art, easily accessible utilities. Endress+Hauser has a close collaboration with biotech Training Facility to train biotech engineers.

More information you find on their website:
www.biotechtrainingfacility.com

A crucial activity during fermentation is the control of the acidity of the culture medium which is measured by the indispensable pH sensor.

Fermentation and Process Analytical Technologie Several cell lines are used for the production of lifesaving biologicals or biosimilars. Those cell lines are of mammalian, yeast, bacterial, plant or insect origin. Cells are selected based on the quality of the product and productivity.

The best performing clone is selected after extensive tests that take place in the bench scale reactors of the development lab. After selection the clone is passed on to the clinical/commercial manufacturing production. Tight control is key as well as the reliability of the process analytical technologies used both in development and production.

Temperature, pH, oxygen and cell growth are the most commonly measured parameters in the fermentation.

Endress+Hauser your partner in Life Science Endress+Hauser has developed and produced a line of Process Analytical Technologies (PAT) for the Upstream and Downstream bioprocessing. Important key feature of the offered PATs is the usability across the process life cycle in development phase as well in the production phase. An example: a pH sensor can be used for the 3L batch reactor but also for the 2000L single-use bag or the stainless steel biofermenter. Without any doubts a real advantage when it comes to scale-up, process validation and risk assessment. The Memosens CPS171D pH sensor is one of the available PAT.

Endress+Hauser
People for Process Automation

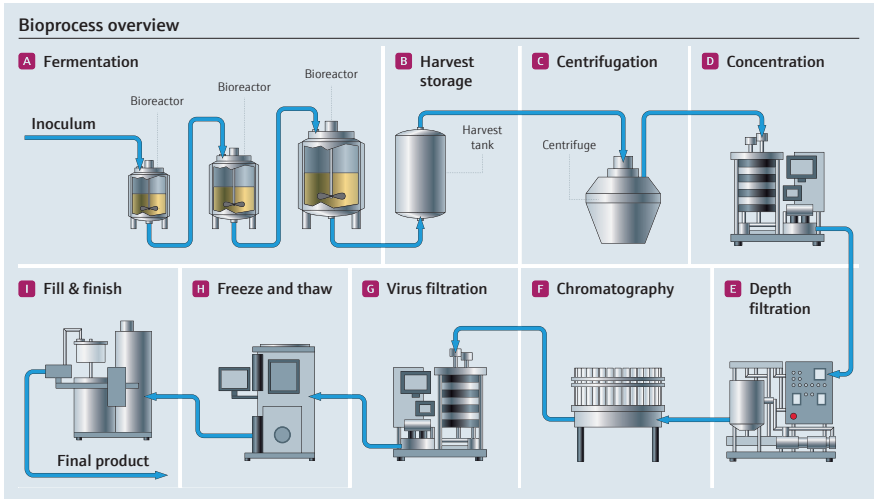
Memosens CPS171D pH sensor

The pH sensor is specifically developed for use in biofermeter applications where - batch after batch - the accuracy, linearity and reproducibility has to be guaranteed. The CPS171D is much less affected than other pH sensor to the heavy process conditions during Cleaning In Place (CIP), Sterilization In Place (SIP) or autoclave sterilization. This improvement could be reached thanks to the use of a new glass bulb combined with a specialized gel reference which by the way does not discolor and a new ceramic diaphragm with small pores overcoming the microorganism intrusion. The combination of those elements makes the sensor more resistant to the chemical and thermal process conditions.

There is no galvanic contact between the sensor and the cable (Memosens connector technology) therefore the problematic of electromagnetic interferences, moisture and cable defect is solved.

Calibration at GxP surrounding

Furthermore the Memosens technology allow to easy calibrate the sensor in the lab or workshop by using the Memobase Plus CYZ71D software. The software is FDA21 CFR part 11 compliant and supports the complete life cycle of each sensor very advantageous in a GLP and GMP work environment.



The software supports the complete lifecycle of each sensor, obvious advantages in a GLP and GMP work environment. Thanks to the “As Found-As Left” calibration conform FDA21CFR it is possible for every production batch calibrate, document and manage each sensor.

The Endress+Hauser instrumentation are comply with the stringent industry regulation.

We insure our instrumentations do not contaminate, alter or have any reaction with your lifesaving therapeutics. Food and Drug Administration (FDA) certification and biocompatibility according to United States Pharmacopeia (USP) provided with each instrument are there to prove and ensure your validation process.

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