

In progress

General notes

Key buzz word: PAT-Process Analytical Technology

Key technology: Miniaturization of bioreactors and incorporation of optical-chemical sensing technology to create a more efficient, reliable and cost-effective model for scaling up cell cultivation. More disposable bioreactors are being used.

Very difficult applications: chemical synthesis process e.g. vitamin or hormone production. (InPro 4800)

AMGEN uses disposable Optical pH and DO sensors.

A) Water Purification-Also called Water Preparation

Potable water, purified water, sterile purified water, water for injection, bacteriostatic water for injection, sterile water for irrigation, sterile water for inhalation. Purification process: water softener, ion exchanger, various fine filters, Reverse Osmosis, ultrafiltration and membrane degasification.

Conductivity: Very important, before water softener and after stage 2 RO

pH before the RO stage one

Resistivity: ???

Water Injection/Sterile Steam

None

Water Distribution Loop

Includes multiple user points. When water is not needed, it circulates to the main loop.

Products: conductivity

Buffer Tanks/Storage

None

CIP/SIP: (Clean in Place/Sterilize in Place)

Conductivity (Ingold InPro 7108 VP) in return flow. In Acid tank, in Caustic tank. Provide VL retractables.

Media Preparation

The media products, vats, tanks, plumbing etc..., are sterilized. Product quality is utmost important.

Products: pH measurement on the tank. VL can add the auto calibrator to this.

B) Fermentation & Cell Culture Process

The biological process so microorganism can thrive and yield. These use a bioreactor.

Products: pH (memosense), dissolved oxygen (E+H COS22D memosense), turbidity (NIR absorption sensor OUSBT66)

Synthesis Reactor:

?

C) Separation & Filtration & Crystallization & Drying – Also called Downstream processes

Industrial centrifuges are used to separate the product from the bulk liquid. Other methodologies include different steps of filtration via microporous materials. Sometimes reverse osmosis is utilized.

Products: pH

Chromatography

Products: pH, verify the quality of the buffers on the column, control the quality of the gradient, detect the separation of phases, assure a perfect cleaning and rinsing cycle of the column. E+H product: memosense.

Optical Density Measurements: To follow up the outlet of the proteins, UV for optimal sensitivity, used for acceptance of the product, to analyze the contamination. E+H product OUSAF44

D) Effluent Treatment:

pH, DO, Conductivity, Turbidity

Laboratory Applications:

pH: TRIS buffers, proteins, enzymes.

Benefits

Available in several lengths to accommodate any fermenter and bioreactor.

PG 13.5 thread

Sensors are 316L, sterilizable and autoclaveable, CIP/SIP resistant