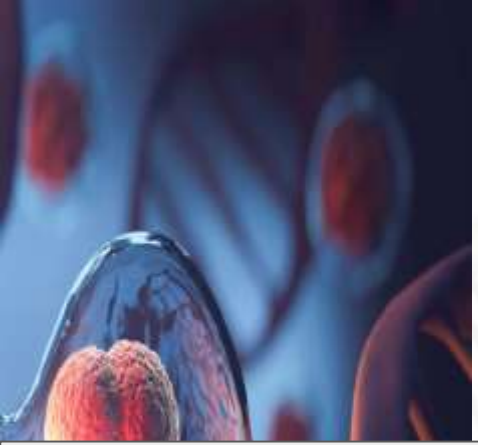

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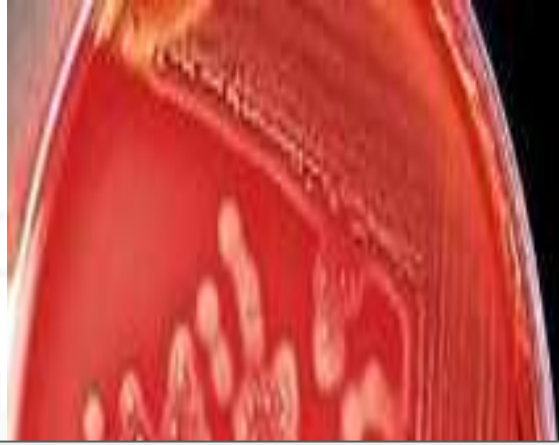


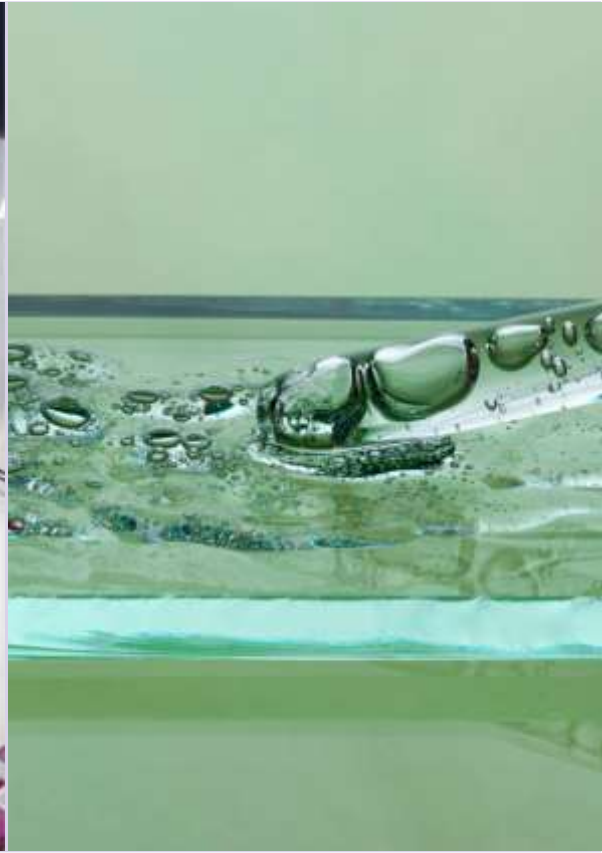
Pharmaceutical Water Purification Solutions: In Biotechnology

Why Ultrapure Water Is Critical for Cell Culture Success in Biopharmaceutical Manufacturing?

Understanding the Vital Role of Water in Cell Culture

In the world of biopharmaceutical manufacturing, cell culture is the foundation for producing vaccines, monoclonal antibodies, recombinant proteins, and gene therapies. However, the success of these sensitive biological processes hinges on one crucial element — ultrapure water.

We understand how high-purity water treatment systems directly impact cell viability, product safety, and regulatory compliance.



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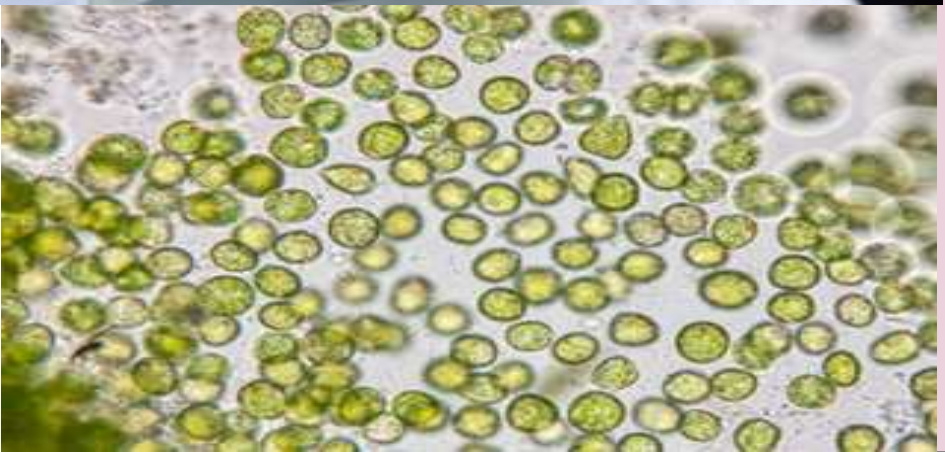
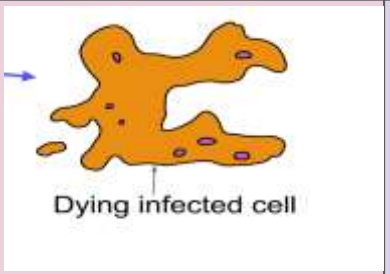
Water is not just a component — it is the **primary ingredient** in



- Cell culture media preparation
- Buffer solutions
- Instrument and vessel rinsing
- Bioreactor feed systems
- Sterile washing processes

Even a trace amount of contamination can alter pH, introduce endotoxins, or disrupt osmotic balance — all of which can compromise cell growth and productivity.

What Happens If Water Quality Is Poor?
If your cell culture water is not ultrapure:

✕ **Cell death** due to microbial or endotoxin contamination	✕ **Reduced protein yield** from stressed or non-viable cells	✕ **Inaccurate research results** and failed clinical trials	✕ **Regulatory non-compliance** (FDA, GMP, USP, EP standards)	✕ **Batch failures** and costly downtime in manufacturing
				

Industrial Water Treatment System Used in Cell Culture

SWJAL PURE PROCESS provides **advanced water purification systems** engineered for cell culture and biopharmaceutical use. The ideal system configuration includes:

✓ 1. Pre-Treatment Unit

Removes sediments, chlorine, and hardness to protect downstream RO membranes.
Includes:

- Pressure sand filter
- Activated carbon filter
- Softener or antiscalant dosing
- Cartridge filtration

✓ 2. Reverse Osmosis (RO) (RO – EDI System)

Eliminates up to 99% of dissolved salts, microbes, and organic impurities.
Ensures low conductivity and reduced bio-burden in initial feedwater.

✓ 3. Electrodeionization (EDI)

Polishes RO output to reach **Type II or near-Type I quality** with resistivity >15 MΩ·cm.
Removes residual ions and maintains consistent water purity.

✓ 3. High-Purity Purified Water Storage & Distribution System

While ultrapure water is generated using systems like RO + EDI + UV + UF, it must be stored and distributed in a way that maintains purity all the way to the point of use (POU) — especially in cell culture applications.

Prevents microbial regrowth, TOC increase, and biofilm formation.
Ensures consistency in water quality for media and buffer preparation.

✓ 4. Ultrafiltration (UF) System

Final step to remove endotoxins, viruses, and pyrogens — key threats to cell viability.

Especially important for monoclonal antibody and vaccine production.

→ **Purpose**: Final protection against contaminants harmful to cells.

Cell Types & Categories Using Ultrapure Water

1. Mammalian Cells

- CHO (Chinese Hamster Ovary) cells
- HEK293, Vero, BHK
- Used in: Monoclonal antibodies, therapeutic proteins, viral vaccines

2. Insect Cells

- Sf9, Sf21 (baculovirus expression systems)
- Used in: Recombinant proteins and gene therapy vectors

3. Bacterial and Yeast Cells

- E. coli, Pichia pastoris
- Used in: Enzyme production, insulin, recombinant proteins

4. Stem Cells

- iPSC, hESC
- Used in: Regenerative medicine, cell therapy

All these cells require water that is free from endotoxins, heavy metals, and bacteria — achievable only with ultrapure water systems.

✓ Regulatory Requirements

Organizations like **USP, EP, JP, FDA, and GMP** mandate strict water quality guidelines for cell culture.

API (Active Pharmaceutical Ingredient) compliance

SWJAL PURE PROCESS systems are designed to meet:

- TOC < 500 ppb (for Purified Water)
  Endotoxins < 0.25 EU/mL (for WFI)
  Resistivity >18.2 MΩ·cm (for Ultrapure Water)

✓ Why Choose SWJAL PURE PROCESS?

SWJAL is a trusted and best Purified Water Generation System in Pharmaceutical Industry manufacturer in india that give ultrapure water systems tailored for the biotech and pharmaceutical industries. We provide:

- End-to-end solutions (RO, EDI, UF, UV, SCADA)
- cGMP-compliant skid systems
- Validated performance and service support

The importance of ultrapure water in cell culture cannot be overstated. Whether you're cultivating CHO cells for antibody production or stem cells for regenerative therapy, water quality directly impacts your product, process, and patient safety.

- Trust SWJAL PURE PROCESS to deliver ultrapure, reliable, and compliant water treatment systems that ensure success at every stage of your cell culture workflow.

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: https://www.swjal.com/

: +917602713555

: sales@swjal.com

: swjalprocess

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Thank you