ULTRAPURE WATER COMPLIANT WITH FDA STANDARDS

CASE STUDY I Healthcare

| The client's needs

In the medical sector, regulations mandate manufacturers to ensure the market placement of medical or surgical devices manufactured in accordance with the U.S. Food and Drug Administration's (FDA's) good manufacturing practices. This requirement compels our client to align their ophthalmic devices with current standards and implement a quality management system for them. Their initiative aims to enhance the efficiency of existing procedures within the company and the quality of their end products.

Consequently, this industrial entity is actively seeking a customized solution that meets the new FDA requirements, while ensuring a reliable and efficient supply of purified water and ultrapure water for its operations.

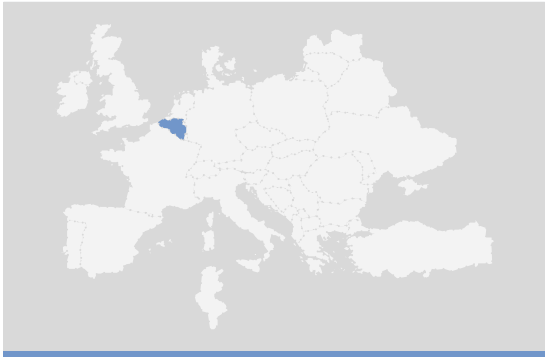
| The solution

Purified water: we have implemented the **Medica™ Pro** EDI system, utilizing electrodionization (EDI) to deliver four liters per minute of water compliant with the CLSI® standard (Clinical and Laboratory Standards Institute). Its autonomous and compact design, tailored for laboratories, incorporates all water purification components, along with a storage tank to ensure a very quick and cost-effective installation.

Ultrapure water: production is ensured by our new technology, the **PureLab® Pharma Compliance**. This solution guarantees compliance with Good Manufacturing Practices (GMP), adheres to FDA and EU requirements for digital records, and meets USP (United States Pharmacopeia) 643 and 645 standards for water purity.

| Key Figures

- Resistivity: 18.2 MΩ-cm
- Flow-rate: up to 2 L/min
- TOC: 1 – 3 ppb
- Bacterial Endotoxin: <0.001 EU/ml
- Bacterial Spec: <0.001 Cfu/ml



Belgium

| The client

A manufacturer of ophthalmic devices based in Belgium has sought our expertise to establish a new production and distribution station for purified water and ultrapure water, in compliance with FDA standards.

> ***We are aware of the crucial role of quality control in the pharmaceutical industry, as well as the importance of water compliance in laboratory settings. Our ambition is to establish Purelab Pharma Compliance as the top-of-the-line solution for water in pharmaceutical quality control laboratories worldwide.***
>
> ***Brieux Sailly**, Technical Sales Engineer*

| Process description

The Medica Pro station is paired with a 60 litres per hour duplex recirculation system on an external 500 litres polypropylene tank. It is distributed through a polyperinaphtalene loop with welds qualified to meet FDA standards. The system includes pumps, a ultraviolet lamp, a 0.22 micrometers endotoxin filter, and 316 litres stainless steel measuring instruments with 3.1 material certificates. This centralized distribution supplies multiple laboratories with an autoclave, a washing machine, sinks, and two ultrapure water producers.

The PureLab Pharma Compliance delivers 18.2MΩ ultrapure water from a reliable, intuitive & simple to use system designed to meet GMP requirements.

| Results

The client benefits from compliant digital data storage, meeting both FDA and EU standards, thanks to the secure software integrated into the system. This feature provides robust evidence during regulatory audits, streamlining the entire compliance process.

Furthermore, the Purelab Pharma Compliance has been designed with space efficiency in mind, making it compact, modular, and available for multiple points of use. This optimization enhances quality control efficiency and allows companies or laboratories to use their space effectively.

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