PHARMACEUTICAL

# Case Study
# Low Residue Program

## SITUATION

**Who:** A global generic drug manufacturer generating approximately $20 billion revenue annually. Their site hadn't worked with Ecolab but the Head of Microbiology had previously collaborated with the company and knew of the low residue product range available.

**What:** A cost reduction and process improvement project, focused on optimising Standard Operating Procedures (SOPs) and disinfection programmes in use across the organization.

**Background:** Previously, a chlorine solution, lacking the required efficacy, was manufactured in-house and used for disinfection. The site also used a Quat Concentrate from another supplier which caused residue issues.

**Timing:** Immediately in order to provide corrective actions and start a new protocol for cleaning and disinfection.

## PROJECT

The project objective was to test Klercide Sporicidal Low Residue Peroxide and Klercide Low Residue Quat and to evaluate the benefits of these low residue solutions. Initially for use on the new production line, with a view to rolling out to their parenteral lines if successful and proven to show excellent efficacy.

## SOLUTION

**1. Site Survey**: review existing processes with a professional consultant from the pharmaceutical industry.

**2. New low residue disinfection programme:**

- **Klercide Sporicidal Low Residue Peroxide** for use on equipment and the production line, plus daily use
- **Klercide Low Residue Quat** on large surfaces
- **Klercide 70|30 IPA** on small surfaces in all grades of cleanroom (A-D)

**3. Global guidance process for rotational disinfection:** utilizing the information from the Site Survey and experts from Ecolab.

Ecolab also recommended an external accredited laboratory undertake the validation of the disinfectants.

## RESULTS

On a daily basis, no residue removal step was needed with the Klercide Sporicidal Low Residue Peroxide disinfectant for equipment, line and large surfaces.

Savings were also made using Klercide Low Residue Quat compared to the previously used Quat Concentrate, an old formulation leaving residues.

Implementing this newly validated strategy and combining the right product with best practice, the pharmaceutical company was able to make significant savings and increase its productivity.

THIS NEW VALIDATED STRATEGY ENSURED THE TWIN GOALS OF COST REDUCTION AND PROCESS IMPROVEMENT WERE FULFILLED

THE COMPANY SELF-REPORTED THE FOLLOWING SAVINGS:

**50% REDUCTION IN ACTIONS REQUIRED** FOR DAILY DISINFECTION

**300,000** MORE VIALS PRODUCED

BATCH LEAD TIME REDUCED **BY HALF**

**VAST WATER SAVING**

**0.6 FTE SAVING** (FULL TIME EQUIVALENT)


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