Water Conservation at Lifecore Biomedical, LLC

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University of Minnesota

Driven to DiscoverSM



Company Background

Biopharmaceutical Sector

- Two facilities in Chaska, MN
- Around 350 employees
- Operating 24/7 based on 3 shifts
- Manufactures sodium hyaluronate
- Manufactures injectable drugs
- Clinical injectable development





Sodium Hyaluronate Products (lifecore.com)



Project Motivation



Vapor Compression Still (meco.com)

Water is Key Component

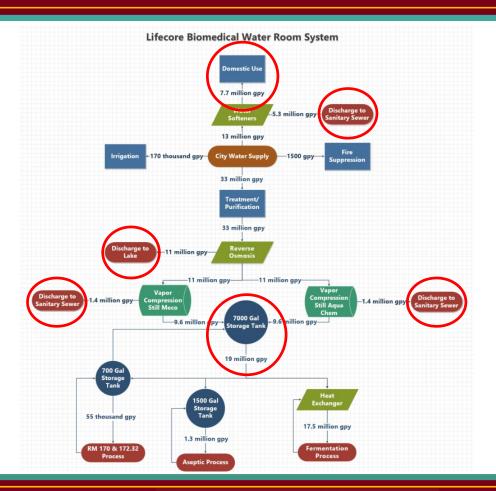
- Need for consistent Water for Injection (WFI)
- Cost and equipment of WFI
- Possibility of expansion



Project Overview

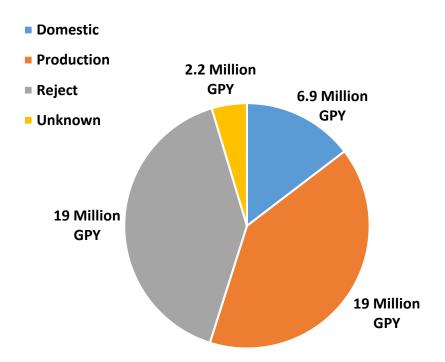
Water Conservation

- Map water use in facility
- Quantify water intensive procedures
- Identify areas of water conservation





Water Overview



| Not Included:IrrigationFire Suppression System | Amount (MGPY) 0.17 0.0015 |
|------------------------------------------------------------------------------------|---------------------------------|
| | 0.0013 |
| • Domestic: | |
| Condensate coolers | 5.3 |
| Toilets and sinks | 1.5 |
| Boilers, chillers, cooling | 0.12 |
| • Production: | |
| Fermentation | 17.5 |
| • Aseptic | 1.5 |
| • Reject: | |
| Reverse osmosis system | 11.0 |
| Water softeners | 5.3 |
| Vapor compression stills | 2.8 |



Approach

Gather Information

- Analyze records
- Use ultrasonic flow meter
- Observe and meet with technicians

Apply Information

- Collect more data
- Research
- Create documentation





Primary Recommendation

Adjustment to SOP – Remove "Trickle"

| Trickle (✓) | | | | |
|-------------|--|--|--|--|
| □ Yes □ No | | | | |
| □ Yes □ No | | | | |
| □ Yes □ No | | | | |

Background

- Heat exchangers and pipes needs to be sanitized before use
- Constant low flow left on
- Benefits of trickle not previously tested



Primary Recommendation

Adjustment to SOP – Remove "Trickle"

Methods

- Collected water samples from sink ports without trickle
- Selected sinks with shortest and longest pipe distance

Results

- Both sinks had 0 CFU/100mL bioburden and < 0.0050 EU/mL endotoxin after 24 hours
- Change practice to leave sinks off and sanitize once every 24 hours

| Recommendation | Annual reduction | Total cost | Annual savings | Payback period | Status |
|-------------------------------------|------------------|---------------------|----------------------|-------------------|--------------|
| Remove practice of leaving sinks on | 43,000 – 77,000 | \$10,000 - \$20,000 | \$90,000 - \$160,000 | 0.5 - 1 months | Implementing |



Solutions

| Recommendation | Annual reduction (gallons) | Total cost | Annual savings | Payback period | Status |
|--------------------------------------|----------------------------|-----------------------|-----------------------|----------------------|--------------|
| Create water use training | 25,000 - 570,000 | \$5,000 - \$10,000 | \$55,000 -\$1,200,000 | 5 days - 2 months | Implemented |
| Remove practice of leaving sinks on | 43,000 - 77,000 | \$10,000 - \$20,000 | \$90,000 - \$160,000 | 0.5 - 1.5 months | Implementing |
| Repair and adjust condensate coolers | 2,500,000 - 3,000,000 | \$5,000 - \$10,000 | \$17,000 - \$21,000 | 1 - 1.5 months | Implementing |
| Install process water meters | 42,000 - 68,000 | \$12,000 - \$26,000 | \$90,000 - \$140,000 | 1 - 3.5 months | Recommended |
| Change filter press cloth type | 45,000 - 90,000 | \$45,000 - \$70,000 | \$96,000 - \$190,000 | 4 - 6 months | Recommended |
| Replace reverse osmosis system | 11,000,000 - 11,500,000 | \$250,000 - \$320,000 | \$71,000 - \$77,000 | 3 - 4 years | Recommended |



Anecdote



Cleanroom Gowning

- Learned about cleanrooms and controlled environments
- Became yellow and blue gowning certified (ISO 7 & 8 cleanrooms)

•Discovered scrubs are comfy!

