Efficient Design for Utilities in a GMP Facility

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1. Background & Motivation

Pretreatment

Filters impurities out of incoming city water before entering WFI section of process.

Sterility and Patient Safety

Water for Injection

Water is sanitized in a high pressure and temperature process. WFI is the mechanism for drug delivery in patients.

Clean Steam

Used to sterilize equipment in plant. This steam is WFI quality to ensure proper sanitation.

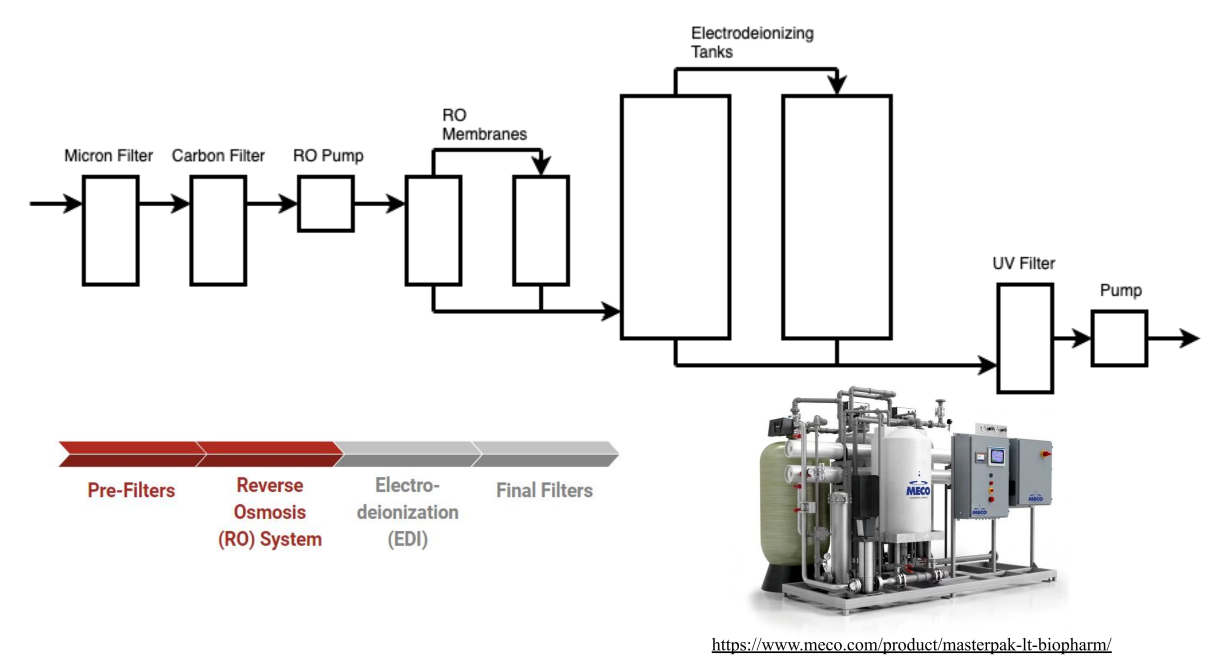
2. Project Goals

1. Model an Efficient Clean Utilities System
2. Conduct Safety & Environmental Analysis
3. Develop an Overall Material and Energy Balance
4. Perform a Financial Analysis to Ensure Feasibility

3. Equipment Selection

	Method	Advantages	Disadvantages
Pretreatment	Stick Built	- No limitations on purified water generation - More customization for the system	- Higher capital cost - Longer implementation time with building and CQV
Pretreatment	Skid Built	- Lower capital cost - Quicker implementation time	- Limitations on purified water generation
Water for Injection	Membrane Distillation	- More sustainable and cost effective - Lower utility and energy costs	- Highest risk to WFI purity; operation at ambient temperatures
Water for Injection	Vapor Compression Distillation	- Good for medium to large processes - Low risk to WFI purity - Lower maintenance	- Difficult to scale - Higher upfront costs - Produces WFI at ambient temperatures
Water for Injection	Multiple Effect Distillation	- Easy to scale - Operates at high temperatures	- Higher utilities necessary
Clean Steam	Electric Heating	- Good for small processes - High temperatures for vaporization	- High energy use - Too small for this process
Clean Steam	Steam Heating	- Reduced energy consumption - Larger scale capacities	- Higher utility requirement

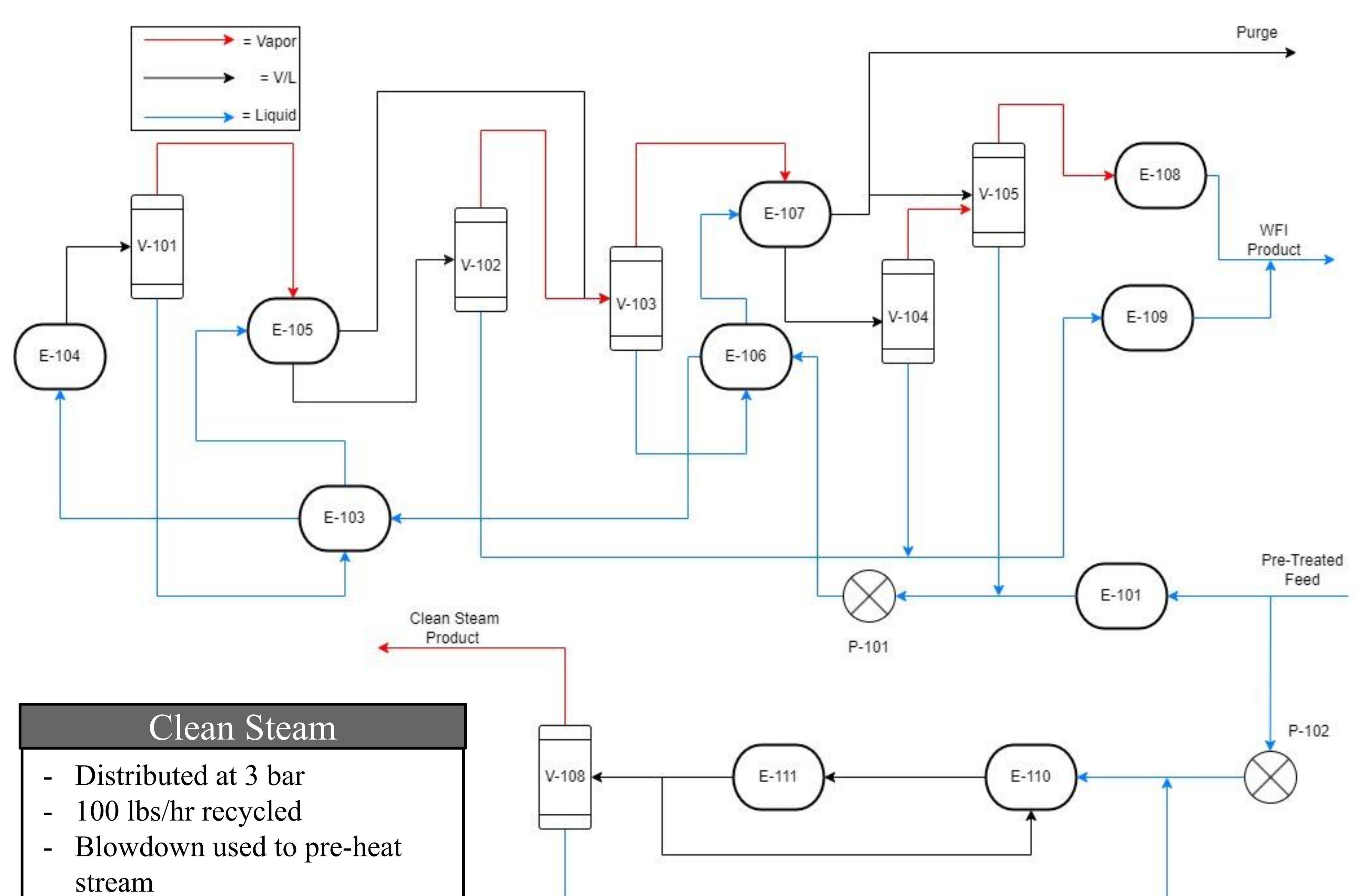
4. Pretreatment Design



- First stage of treating city water
- Minimize risk of fouling during WFI production
- Facilitates removal of organic matter, microorganisms, endotoxins, inorganic ions (heavy metals and salts), and particulate matter

5. Water for Injection & Clean Steam Design

Stage 1	Stages 2 & 3	Stage 4
- Saturation point at at 7.908 bar and 170°C - Vapor fraction of 0.4 through the use of high pressure steam	- Latent heat of pure steam vaporizes water - Pressure drop of 30 psig per stage to achieve transfer of heat	- Pure WFI collected and routed for storage and distribution - Remaining pure steam condensed - Maintained at 80°C for purity



Clean Steam

- Distributed at 3 bar
- 100 lbs/hr recycled
- Blowdown used to pre-heat stream

Pre-Treated Water	WFI	Clean Steam
16,000 gallons/day	4,000 gallons/day	16,000 pounds/hour

6. Cost Analysis

Cost Type	Value
Capital Cost	\$615,701
Cost of Operating Labor	\$1,996,012 / year
Cost of Utilities	\$240,229 / year
Cost of Raw Materials	\$21,450 / year

$COM_d = 0.180FCI + 2.73C_{OL} + 1.23(C_{UT} + C_{RM}) =$ \$5,881,804

7. Material and Energy Balance

	In	Out	Error
Material	2902.54 kg/hr	2901.39 kg/hr	0.039%
Energy	-193149.35 kW	-193143.4171 kW	0.003%

8. Recommendation

- The most important consideration when designing a clean utilities process for pharmaceutical manufacturing is that of the health and safety of the patients affected.
- The most efficient design for utilities production, minimizing risk of contaminants, includes water pretreatment, a multiple effect distillation system, and a clean steam generator.
- Next steps include creation of a PFD that combines each stage of WFI production into one distillation still, for further analysis of system cost and efficiency.

9. Acknowledgements

We would like to extend a huge thank you to the Merck mentor team for partnering with us this year, and for their guidance on this project. We also would like to thank Dr. Lisa Bullard and Aaron Frye for their continued support throughout the year!