Clean Steam Energy Conservation Process Design

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Abstract — The objective of this article is to design the sterilization methodology and processes needed in a product or equipment that requires the injection of clean steam to create a sterile environment. Clean steam is preferred over plant steam which is created by the boilers carrying undesirable contaminants and additives that may be in contact with the product or equipment. The use of clean steam in pharmaceutical manufacturing is determine by Good Manufacturing Practices (GMP) and ruled by the Code of Federal Regulations CFR Title 21, Part 211[1]. These general rules will not provide any specific recommendation regarding the steam, but focusing on facility, operations, equipment, and systems requirements. The clean steam purity is defined by the purity of the condensate that is often referenced with water purity standards. Steam sterilization is injected to a piping to create a sterile environment or into an autoclave were components are exposed to it.

BACKGROUND INFORMATION

One of the main concerns in Pharmaceutical Companies for the manufacture of parenteral solution, biopharmaceutical manufacturing, and manufacture of sterile solution is cleaning, disinfecting and sterilizing facilities, product or equipment that can be in contact with the product or healthcare environment. These three terms of cleaning, disinfecting and sterilizing can be misled or brought to confusion to many people as synonymous but the process is different in each one. The most basic definition for cleaning is the removal of debris. A basic example of cleaning is using water and soap. Debris contributes to the propagation of bacteria and diseases in all areas. Adequate debris removal at the cleaning stage will benefit the disinfectant stage. Antibacterial soaps are not disinfectants so it should not be confused for using it in place of a proper disinfectant. Disinfectants cannot work with big portions of debris stock on.

Disinfecting means that it removes most of the microorganisms presented on surfaces which can cause infection or some kind of disease. Disinfecting is useful against a number of bacterial and viral microorganisms. The Code of Federal Regulations CFR Title 21, Part 211.113 will not provide any specific recommendation regarding Control of microbiological contamination but Appropriate written procedures that shall include validation of all aseptic and sterilization processes are expected[2]. There exist many disinfection and sterilization products on the market as; alcohol, bleach, chlorine, ammonia, hydrogen peroxide and other solutions. Some of the same product can be used to disinfect and to sterilize; the difference is in the strength of the solution and/or the amount of time the solution is left in contact with the surface. After applying the solution it is necessary to rinse out thoroughly to eliminate any toxic residual at sterilized area. Disinfection, will only remove organisms that can cause disease. High temperature sterilization it is another process. These processes began more than 400 B.C. when sterilization process by fire was first used and then the use of boiling water for cleaning. Greeks and Romans used steam in public baths for hygiene purpose. Some microorganism agents such as spores, bacteria and viruses can be eliminated through sterilization.

Some of the methods used to achieve sterilization are: Autoclaves Hot air ovens, Ethylene oxide, Low-temperature steam and formaldehyde, Sporicidal chemicals, Irradiation,

and Gas plasma. In industries and hospitals, the more common method used is with autoclaves using heat principle for sterilization. From laboratory testing, using saturated steam or moist heat, bacterial spores that are resistant to harsh environment are killed when temperature is at 121°C for an amount of time. Simple boiling at 100 °C, however, is not completely effective for sterilization because many spores can survive this temperature.

When boiling point of water raise when exposed to increased pressures as in a pressure cooker where the pressure is 15 pounds/sq inch, water boils at 121 °C. The first steam pressure cooker, that is the precursor of the autoclave, was invented in 1681 by a physicist Denis Papin [3].

An autoclave operates by using steam under pressure as the sterilizing agent. High pressures enable steam to reach high temperatures, thus increasing its heat content and killing power. Most of the heating power of steam comes from its latent heat of vaporization. This is the amount of heat required to convert boiling water to steam. The ability of air to carry heat is directly related to the amount of moisture present in the air. The more moisture present, the more heat can be carried, so steam is one of the most effective carriers of heat. Steam therefore also results in the efficient killing of cells, and the coagulation of proteins.

Clean Steam Generation Process Description

The Clean steam operational conditions are 60 psi @ 145 °C with a requirement of feed water purity of >1 Mohm*cm [5] and Condenser Cooler conductivity > 0.8 Mohm*cm [6]. The actual high temperature shortens generator life and damages gaskets due to continuous thermal change. Also add maintenance cost due to continuous system interventions, increase in spare parts consumption and increase system downtime due to continuous system interventions.

Autoclaves steam is feed via structural piping that comes from the Clean Steam Generators. Clean Steam Generators are designed to provide Clean or Pure Steam at a specific point of use or equipment as the autoclave for a steam sterilizer process. Clean Steam Generators are fed with Water-for-Injection, USP Purified Water or Deionized Water. The main purposes for these requirements are to produce pyrogen-free quality pure steam. Clean Steam Generators can be heated by plant steam or combined with an integrated electrically-heated boiler when plant steam is not available.

The concept as part of the methodology is a Kaizen approach. Kaizen was created in Japan after World War II. Kaizen means "continuous improvement"[4]. Kaizen is composed from the Japanese words 改 ("kai") that means "change" or "to correct" and 善 ("zen") that means "good". Kaizen is concept is based on making small changes on a usual basis: to improve productivity, safety and effectiveness and at the same time reducing waste. Kaizen is based on making changes anywhere that improvements can be made. Some of the Kaizen system components of Japanese businesses that have been seen are; Quality Circles, Just-in-Time, Quick Changeover, Total Production Maintenance, Failure Mode Effective Analysis, Lean Manufacturing, Kanban and 5S. Kaizen involves setting standards and continuous improving it.

Objectives

The main objective for this project is to decrease the operation temperature of the Clean Steam Generator at building utilities from 145 °C to 140 °C and pressure from 60 psi to 30 psi. The main focus is to lengthen generator life, lowering impact on equipment flexibility and availability, lowering spare parts consumption and finally reducing on Plant Steam and Deionized Water (DI) consumption.

The energy consumption of these systems can be subject of evaluation. Operating temperature set point of 145 °C exceeds the requirements temperature of 121 °C at users' point of use and autoclaves generating an opportunity of energy saving which favorable impact plant operations.

This project aligns with the Company's goal of operational excellence and Operational Equipment

Efficiency (OEE). The Clean Steam Generator works 7 days a week 24/hours a day. Due to the fact that at Quality Control laboratory all equipment and system are validated, special considerations must be taken. A clean steam generator system operating over 121 °C maintains system sterilization. Clean steam equipment by its self sterilize because it has a continuous blow down to assure system integrity.

The system will be operated at 140 °C instead of 160 °C during its normal daily operation; also, the system will be operated at 130 °C during night and weekend depending on the client requirements. Minimum thermal change maintains business continuity and does not affect equipment qualification so it does not need system sampling and results evaluation due to system requalification.

METHODOLOGY

Over the past years, steam leaks issues are seen more often due to worn gaskets. Excessive pressure and high temperature are the key factors that shorten life to the gaskets and lower equipment up time by maintenances interventions. Leaks in the system will drop pressure and temperature becoming a safety hazard and greater energy consumption trying to maintaining thermal and pressure set points. This brings an area of opportunity for improvement approach to the equipment.

The research methodology strategy to determine the possibility of process continuous improvement is a Kaizen approach.

Change Control Implementation- It does not required a change control because it does not compromise quality of intermediate end product [7].

Validation- It does not required an equipment revalidation due to Quality Assurance system "Release" that depends on sampling results will not be required because temperature will be over 121 °C at all point of use, maintaining integrity and business continuity. As per Qualification equipment shouldn't be shutdown more that 3 hrs [8].

Cleaning utilities sampling will continue for specification testing/inspection criteria as per standard operational procedures [9].

Equipment Changes- No equipment change is needed but it will bring benefits of; lowering in equipments operational time interventions and lowering in man hours and spare parts due to less required maintenances.

Implementation- This is a suggested project plan with the most relevant milestones, with estimated due dates for each activity. See Figure 1.

Steps	Description	Due Date
1	Verify possible validation impact for QC Lab system.	2/1/2011
2	Mueller Assessment for generator impact.	2/28/2011
3	Generate W/O's for systems data collection.	3/15/2011
4	QC Lab System operational data collection.	3/30/2011
5	QC Labs data evaluation.	3/30/2011
6	Obtain current system DI/Purified Water and Plant steam consumption.	4/30/2011
7	Implementation	5/15/2011
8	Compare before/after utilities consumption to obtain profits.	5/30/2011
9	QC impact document revision	6/15/2011

Figure 1
Implementation Time Frame

RESULTS & SOLUTION

All the data for this evaluation was collected from validated platforms' from PCS (Process Control System) and BMS Building Management System from the current working values and values after set point changes.

The presented working parameters of the clean steam generator are 60 psi @ 145 C. The Figure 2 demonstrates the base parameters values of the working clean steam generator.

Working Temperature @ 160 °C

#	Parameter	Value
1	Generator Working Temperature	160 °C
2	Generator Working Pressure	58 psi
3	Generator Condensate Temperature	38.0 °C
4	Generator Purity	.021 µS*cm
5	Condenser Cooler Conductivity	.84 MoΩm
6	Condenser Cooler Temperature	100.9 °C

Figure 2
System Working Temperature Parameters at 160°C

The first step was to change from 60 psi @ 145 C to 140 C and observe pressure drop at working conditions. The five key operating parameters for monitoring are; generator working temperature, generator working pressure, generator condensate temperature, condenser cooler conductivity and condenser cooler temperature. The generator purity is used for reference only. See Figure 3 working at 140 °C.

Working Temperature @ 140 °C

#	Parameter	Value
1	Generator Working Temperature	140 °C
2	Generator Working Pressure	44 psi
3	Generator Condensate Temperature	37.0 °C
4	Generator Purity	.022 µS*cm
5	Condenser Cooler Conductivity	.85 MoΩm
6	Condenser Cooler Temperature	100.2 °C

Figure 3
System Working Temperature Parameters at 140°C

The pressure drop from 60 to 44 psi and quality and purity parameters were not affected.

Steam Generator parameters were changed to 130 °C to simulate working setting in weekends and nights and monitored the same critical parameters. See Figure 4.

Working Temperature @ 130 °C

#	Parameter	Value
1	Generator Working Temperature	130 °C
2	Generator Working Pressure	31 psi
3	Generator Condensate Temperature	36.0 °C
4	Generator Purity	.029 µS*cm
5	Condenser Cooler Conductivity	.86 MoΩm
6	Condenser Cooler Temperature	100.2 °C

Figure 4
System Working Temperature Parameters at 130°C

The pressure drop from 44 to 31 psi and quality and purity parameters were not affected.

Quality and purity criteria were unaffected. The generator purity value was monitored but only used for reference only and to help troubleshooting and does not reject or close point of use [6]. The condenser cooler conductivity quality is a key operating parameter that will input out of specification will reject and close point of use. The condenser cooler conductivity quality complies with the specifications of > 0.8 Mohm*cm. Resistivity values with system working temperature parameters at 140°C was 0.85 Mohm*cm and with system working temperature parameters at 130°C was 0.86 Mohm*cm.

The utilities water and steam consumption was measure before and after parameters changes. The results were taken from the flow transmitter instrument to consider plant steam consumption with transmitter xxx-FIT-002, considering that our only variable affecting the current system it's the temperature change due to this test. See Figure 5.

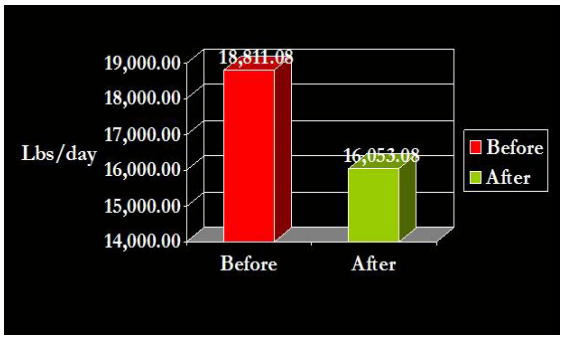

Figure 5
Plant Steam consumption

Equipment to consider DI Water consumption was the valve xxx-XV-008, considering the system design water supply toward the valve opening time per number of times that it opens. See Figure 6.

Figure 6
Deionized Water consumption

For the cost saving analysis for Plant Steam and DI water consumption were assigned in units/costs. For plant steam Lbs/day = $0.032 dollars and DI water gal/day = $0.60 dollars. See Figure 7 for calculated savings of each utility.

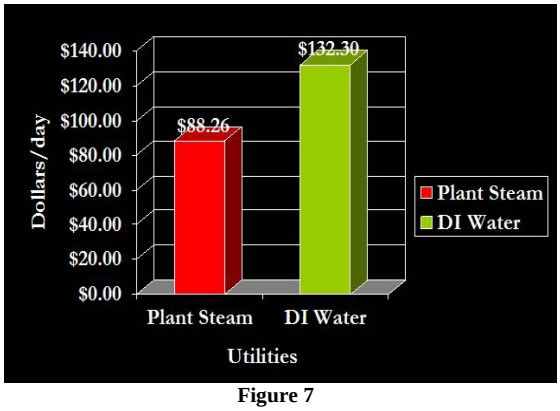

Figure 7
Cost Savings

Figure below 8 will show a time frame cost and expected forecast savings daily and annually.

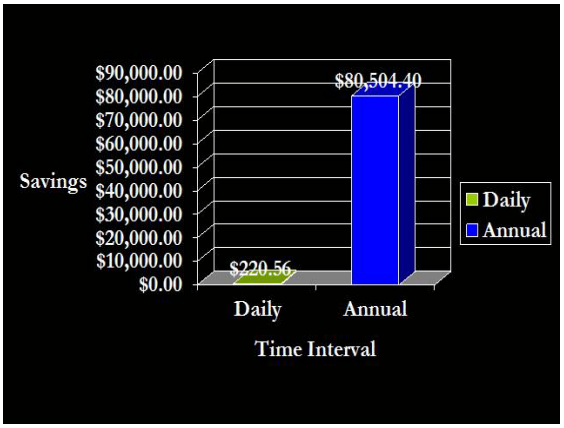

Figure 8
Daily & Annual Cost Savings

Alternate cost reduction findings are to close Autoclaves Chamber doors once cycle ends or not in use.

Improvements to the system were that the main steam controlling valve actuates less and maintains temperature set point in less time. Also the system will be more up time working because gasket damages leaks due to continuous thermal change and high pressure reduced.

Benefits of Autoclaves Chamber doors once cycle ends or not in use are:

- Reduce in clean steam consumption
- Reduce in time in cycle start up. Chamber temperature will be maintained at operational parameter.
- Avoid cycle abortion during the first day cycle run.
- Reduce the jacket over condensation.

CONCLUSION

For the past years, the Clean Steam Generator has worked as efficient equipment in the utility area but with opportunities to work on. The obtained reduction in plant steam consumption was 2758lbs/day of energy cost savings $88.26 dollars/day a 14.66% of reduction. The obtained reduction in DI water consumption was 220.5

gal/day and cost savings $132.30 dollars/day a 21.65% of reduction. These daily benefits of energy cost savings in only at one building that was tested and can be implemented in other 4 more buildings that have the same unit. The project shows that it's viable, does not affect business continuity, easy implementation, longevity to the equipment and cost reduce. Now day's pharmaceutical industry is confronting huge challenges, maintaining low cost on operations will keep competitiveness. Steam sterialization creates a sterile environment that is important and vital in operations and clients/patients when a contaminate medium can take a huge impact between live and death.

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