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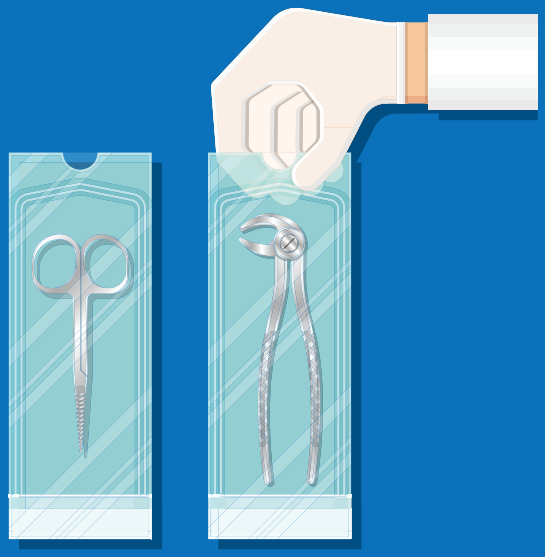
Autoclave Validation Process

Autoclave Sterilization



Testo North America
www.testo.com
800-227-0729
info@testo.com

Introduction

In the pharmaceutical and life science industry, one of most heavily used pieces of equipment is the steam sterilizer or autoclave. Autoclaves are crucial for sterilizing everything and anything that could be used in the manufacturing process to create drug products or vaccinations. One question that is always proposed is how to make sure the autoclaves are consistently sterilizing or killing all microorganisms within each autoclave load. In this white paper, we will go over the steps that need to be taken to have a successful autoclave validation process from development to implementation of validated cycles.

How to Start

When delving into autoclave validation in the pharmaceutical and life science industry, we first need to take a step back and investigate how we first validate or validated the autoclave. Each company will have different risk-based approaches to validating their autoclave(s), but most follow the International Society of Pharmaceutical Engineers (ISPE) GAMP (Good Automated Manufacturing Practice) and good practice guidance documents. These documents can give guidance on how to approach validating your autoclave and cycles.

New Autoclave?

If your autoclave is recently purchased, then it needs to be formally commissioned and validated. Off the shelf systems or non-custom systems need an equipment Installation and Operational Qualification (IOQ) with subsequent Development Qualifications (DQ) and Performance Qualifications (PQ) of programmed autoclave cycles. If you have designed and built a custom autoclave system with a reputable vendor then a Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) can be added to the list of documents and executions required. However, all these required documents depend on the risk-based approach you have laid out in your Validation Master Plan (VMP).

What to do once all FAT/SAT/IOQ Documentation is Finished

The next step in the process would be to decide what is going to be sterilized within your autoclave. Companies validate programmed cycle loads, which means each load needs to be validated or checked for performance, lethality, and sterility.

What is a Programmed Cycle?

A “programmed cycle” is the autoclave cycle that was programmed by users based on different parameters within the autoclave software program. Many different manufacturers of autoclaves have similar names for pre-programmed cycles within the autoclave software application. Each pre-programmed cycle has a specific function like performing a leak test to make sure the vacuum is sealed, or a Bowie Dick test to make sure sterilization is occurring before the autoclave is used that day. In the case of program cycle validation, companies and users can customize their own sterilization cycle parameters like time of exposure, cool down, and so on. This custom program will be tested in validation and quality control studies to meet the expectations of sterility within the load.

Testing Developmental Qualifications (DQ)

Once you have validated your autoclave with an IOQ, you need to decide what "load" will be sterilized and validated. A load is what will be put into the autoclave and sterilized for use within the facility. Loads can be anything that you think needs to be sterilized before it is used in manufacturing or quality control processes. Loads could be one hundred (100) pieces of material, or five (5) digital bioreactors probes. Each load will be different, and each load will need to be validated with a specific custom program cycle to reach lethality and sterility. The developmental phase is testing the custom programmed cycle for lethality values that are acceptable according to Standard Operating Procedures within your site. The developmental qualification should be performed three (3) times with successful lethality in all three cycle runs for a maximum load. To encompass the entire mass range within the autoclave, one minimum run should be added and performed. The total of four runs need to pass expected lethality in succession. This is the time where you can play around with the sterilization parameters to optimize your sterilization cycle. If changes are made to load size or any cycle parameter, then the whole developmental process needs to be repeated. Once lethality has been achieved in four successful developmental runs, users can move to the Performance Qualification of the custom programmed cycle.

Testing Performance Qualification (PQ)

After all the developmental runs have been proven to reach the required lethality for sterility, it is then time to move to a Performance Qualification. In this qualification, the parameters that were tested in the Developmental Qualification are now retested with biological indicators. Biological indicators (BI's), which are small single strips that are made of filter paper inoculated with single species of bacterial spores, are placed within autoclavable housings or bags. If the autoclave cycle works correctly, the high heat and steam will kill or sterilize all microorganisms within the autoclave including the bacterial spores in the biological indicators. After the autoclave program cycle has completed, the BI's are then tested for growth (not sterile) or no growth (sterility) within a quality control lab. If tests come back as no growth within all BI's, then your programmed autoclave cycle has the required lethality to sterilize the entire load. A growth reading within the BI's means your programmed autoclave cycle did not have the required lethality to sterilize the load. This test will need to be performed four times with three maximum and one minimum load to assure lethality can obtained for each cycle load.

How do you record and evaluate the whole autoclave temperature profile?

Autoclaves are designed to introduce high pressure and extreme heated steam into a vacuum to sterilize. The extreme pressure and temperature conditions within autoclave cycles will destroy or degrade equipment that needs to record temperature and pressure conditions. The validation of your autoclaves and programmed cycles requires crucial durable and reusable validation equipment capable of withstanding extreme pressure and temperature. There are many different options for autoclave validation equipment, but you need look at a couple of crucial pieces of information first to decide.

Testing Performance Qualification (PQ)

A wired validation system mostly uses thermocouples to record temperature that is connected to a sensor input module. The sensor input module then reads and records the temperature data connected to a recording device like a laptop or a PC. A data logger system compromises of different models of single data loggers that can record temperature or pressure. The loggers are not wired or connected to a PC or laptop to record temperature and pressure values; however, the loggers are connected to a PC or laptop to configure parameters and export data to software.

Wired systems are subject to more wear and tear within the thermocouples, as holes need to be cut in each thermocouple to allow condensation to escape before reaching the electronic sensor input module. This cut hole allows for more wear and tear within the thermocouples, which in turn means replacement every year or so to protect the electronics, but also to consistently record accurate temperatures. Wired systems require more setup and break down time within the autoclave validation port. A validation port on autoclaves is used to wire or place thermocouples throughout the autoclave. This opening of the validation port causes many problems for validation representatives as the vacuum tight seal is now broken or unsealed. Thermocouples need to be spread evenly within the port and leak tested with a leak test program. This can add many hours to the validation process trying to achieve a tight seal after thermocouples are placed within the validation port. The introduction of thermocouples now creates two areas where air can leak from the validation port or cut thermocouples' holes allowing for air to escape.

On the other hand, data logger systems require less setup and break down time within autoclave systems. There is no need to fidget with the validation port which would create a loose seal. Loggers can be programmed and placed within an autoclave in considerably less time allowing for less mistakes. The electronics within each data logger are protected by 316L stainless steel which will withstand high pressure and extreme temperatures, while being able to be reused repeatedly. Lastly, there is no wear and tear within each data logger as the recording device is not manipulated in anyway.

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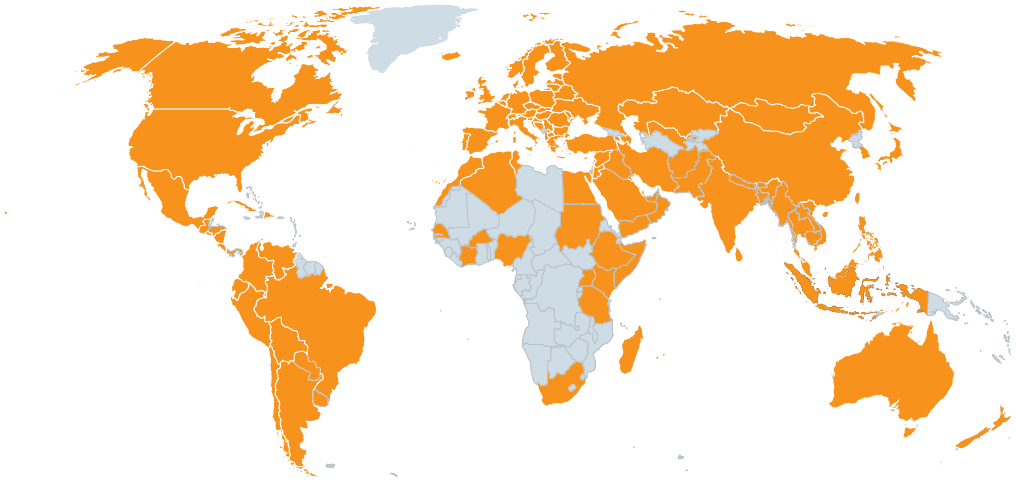
Testo is a world leader in the design, development, and manufacture of innovative products and services for environmental and industrial measurement. For more than 60 years, leading companies in the life sciences industries have relied on Testo to help protect their products.

Testo's first product was a simple electronic thermometer. Today, the product line has expanded to include a large variety of critical measuring instruments, such as data loggers, air velocity meters, humidity and dew point meters, sound, pressure, and light meters.

With over 2,700 employees in 33 offices worldwide, Testo understands local requirements and culture. Testo currently has hundreds of thousands of data loggers in the market, storing over 17 billion data sets.



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info@testo.com