User Requirement Specifications of GMP autoclave for clean materials (1 unit)

1. System requirements
    a. Autoclave should be especially suitable for GMP regulated pharmaceutical companies. Designed for general purpose, sterile room supply, media preparation, or terminal sterilization applications performed in biopharmaceutical and pharmaceutical facilities
    b. The design and construction of the unit should be in compliance with Current Good Manufacturing Practice (cGMP) and Good Automated Manufacturing Practices (GAMPP.
    c. Temperature distribution within the chamber, including drain temperature, should be guaranteed to be within ±0.5°C (±0.9°F) of the process sterilization temperature (exposure setpoint).
    d. The sterilizer should be fully tested and prevalidated during factory qualification. Prequalification reports of the installation, operational, and performance qualifications should be provided, along with complete documentation on machine design, construction and control software.
    e. Sterilizer should be manufactured in an ISO 9001, ASME Section VIII Division 1, PED Module H/H1 and EN729-2 certified facility and should meet applicable requirements of the following listings and standards.
        i. GMP
        ii. GAMP 5
        iii. EN285
        iv. EN ISO 17665-1
        v. Underwriters Laboratory (UL) Standard 508
        vi. Canadian Standards Association (CSA) Standard C22.2 No. 125
        vii. ASME Code, Section VIII, Division 1 for unfired pressure vessels.
        viii. FDA 21 CFR Part 11 Compliant/EU Annex 11. STERIS Finn-Aqua develops, documents, and enforces policies and procedures that ensure security of electronic records and signatures according to 21 CFR Part 11. Together with our Customers, Finn-Aqua will help implement and enforce Part 11-compliant solutions involving validation, audit trails, and security of our computer systems.
    f. Control System should be configured with Allen-Bradley® PLC or Siemens® PLC control. Control system should monitor and control all sterilizer operations and functions. PLC control should allow up to 20 sterilizing cycles to be configured to meet specific processing requirements. All control system components should be mounted in an integral cabinet.
    g. Operator Interface should consist of either a 7" (Allen-Bradley) or a 9" (Siemens) color touch-sensitive screen and panel printer located on non-sterile (operating) end of sterilizer. All sterilizer functions, including cycle initiation and cycle configuration, should be performed using touch screen. Displayed messages should be complete phrases with no codes that need to be cross-referenced. Screen should display any abnormal (alarm) conditions that may exist in or out of a cycle.
    h. A 42-column impact printer should provide real-time process data and alarms in a comprehensive batch report.
    i. Chamber and Jacket Pressure Gauges should be mounted on non-sterile end. Pressure should be displayed in bar/psig and inHg (vacuum).

j. Horizontal or Vertical Sliding Door(s) should be pneumatically operated by buttons on control panel. Each door should be equipped with a steam-activated, non-lubricated gasket. When cycle completes, gasket should retract under vacuum into machined groove in sterilizer end frame.
k. Equipment Documentation Package should include three copies of user manual and one copy each of manufacturing, control system, and qualification documentation. Package should contain information required to assist in development of validation procedures and final validation of the equipment.
l. Calibration should be provided through the control panel to all system temperature and pressure channels. Calibration should be performed in Calibration Mode, accessible through touch-screen display, and accomplished using external temperature and pressure sources. Control system should provide a printed record of all calibration data for verification of current readings.
m. Interface Port should be provided for downloading cycle information to Customer-furnished data acquisition system.
n. Depending on cycle options selected, sterilizer should be factory-programmed with following process cycles:
    i. Cycle B should be a standard high vacuum cycle provided for sterilization of all dry goods and porous loads at 110-135°C (230-275°F). Preconditioning should include air-removal phase using vacuum and steam pulses. Alternatively, preconditioning could consist of a forced air removal. Forced air removal should remove air from chamber by introducing steam to force the air out through drain line system. Vacuum pump should be simultaneously operated to assist in evacuating air. Forced air removal should be designed for liquid loads in vented containers. Drying should be accomplished by fast exhaust, deep vacuum or vacuum pulsing. Pre-vacuum and post-vacuum pulses should be programmable. Vented Liquid cycles should be also possible using slower rated exhaust. Cycle B should be primarily used for production, clean room supply and production support.
    ii. Cycle C should be an optional cycle designed to efficiently process liquid products such as Small and Large Volume Parenteral (SVP and LVP) solutions packaged in vented and non-vented containers that require fast cooling during post-conditioning phase. Cooling phase should be designed to cool chamber by flowing cooling water through jacket with simultaneous air over-pressurization in chamber. This process should cool the load and should prevent the product from boiling. Cycle C sterilization process should include Process B cycle. Cycle C should include compressed air back-up for door gasket(s).
    iii. Process CX (Ejector-enhanced indirect water cooling) should be designed to replace conventional fan assembly in sterilizer chamber. An air ejector cooling process should provide air circulation equal to, or more effective than, that which can be provided by a conventional fan. Ejector process should be designed to speed up cooling process by generating symmetrical air flow pattern for transferring heat from load to water-cooled chamber walls. Chamber pressure should be controlled automatically by bleeding excess air

out. There should be no moving parts or penetration seals through the chamber to wear.

iv. Steam-Air-Mix (SAMX) Cycle should be designed for moist heat sterilization of various types of non-vented liquid products such as ampoules, vials, bottles, bags, etc. The SAMX process should use one or multiple air ejectors to provide required differential pressure in chamber and to circulate steam and air mix within chamber. Air ejector(s) occupy only 4 inches (102 mm) of space in top of chamber. There should be no moving parts or penetration seals through the chamber to wear.

v. Leak Test Cycle should be a standard cycle provided for verification of chamber integrity. Cycle parameters should be user-configurable. Default values for the leak rate test may be used, or specific leak rate test parameters may be configured in accordance with Customer's Standard Operating Procedure (SOP).

o. Emergency Stop Button should be located on operating end (and non-operating end if double door unit) of sterilizer. The Emergency Stop Button should return valves to safe condition and halt cycle processing when pressed. Once pressed, operator should be able to choose to either abort or continue cycle operation.

p. Security Access Codes should provide restricted access of unauthorized users to critical operational modes. Five access levels should be available:

i. Operator level password (level 1) permits the user to select a cycle, start a cycle, acknowledge alarms, view cycle parameters and manually print reports;

ii. Supervisor level password (level 2), in addition to level 1, permits the user to edit cycle parameters, edit the Proportional Integral Derivative (PID) parameters, skip the current step of the running cycle and stop the Programmable Logic Controller (PLC) from accumulating exposure time;

iii. Calibrator level password (level 3), in addition to level 2, permits the user to calibrate instruments;

iv. Service level password (level 4), in addition to level 3, permits the user to view inputs, view system diagnosis, activate/deactivate outputs, edit common settings and change date/time;

v. Administrator level password (level 5), in addition to level 4, permits the user to configure user names and edit passwords.

q. Compressed Air Back-up for door gasket(s) should be provided on all double door sterilizers and with C cycle, decontamination cycle, and bioseal installations.

r. Door Sensing Device should automatically stop if an obstruction is detected while the door is closing.

s. Pressure Relief Devices on chamber and jacket should limit the amount of pressure buildup so rated pressure of vessel should not be exceeded.

t. Steam Valve Interlock should prevent steam valve from opening when door is open.

u. Pressure Interlock should prevent user from opening door when unit is above/below atmospheric pressure.

v. Pressure Vessel: The standard chamber pressure vessel should be a fully jacketed-type vessel that meets ASME and PED pressure vessel codes. Pressure vessel inner shell (chamber) and outer shell (jacket) should be designed to withstand operating pressures

from full vacuum to 3.1 bar (45 psig). Chamber and jacket should be constructed of stainless steel. All process contact surfaces should be mechanically polished to a finish of Ra < 0.6 µm (< 25 micro-inch). Jacket should be insulated with 13 mm (1") black foam insulation with aluminum backing. Steam-supply openings, inside chamber, should be shielded by a full-length baffle to evenly distribute clean steam as it enters chamber. A 63 mm (2-1/2") chamber penetration with TRI-CLAMP® 1 connections should be provided for validation purposes.

w. Chamber Door: Door should be constructed of AISI 316L stainless steel and insulated with mineral wool to reduce surface temperature of stainless-steel door cover. Door should be equipped with a one-piece, silicone sealing gasket. Gasket should be activated by pure steam or compressed air pressure, and retracted by pulling a vacuum.
x. Fascia Panel(s): Sterilizer framework should be enclosed by a front fascia panel, located on operating end. If sterilizer is equipped with double doors, a back fascia panel should enclose the sterile end. Fascia panels should be constructed of stainless steel with No. 3 brush finish.
y. Vacuum System: Two-stage, water ring seal-type pump should be used for evacuating sterilizer chamber. Pump should be sized to create a 7.0 kPa (1.0 psia) vacuum in five minutes utilizing 20°C (68°F) sealing water.
z. Air filter, used for chamber pressure equalization, should be 0.2 µm hydrophobic bacteria-retentive filter. Filter should be steam-sterilized up to fifty times.
aa. Process piping for clean steam and sterile air to chamber, and drain piping up to first valve should be constructed of AISI 316L stainless steel. All piping connections should terminate within confines of sterilizer and be accessible from right side of sterilizer, when facing non-sterile (operating) end. All sanitary stainless-steel piping should utilize sanitary TRI-CLAMP fittings. Other piping connections should be screwed or compression fittings.
bb. Sterilizer should be designed for freestanding or recessed mounting through one or two walls. All sterilizer components should be integrally mounted within sterilizer confines of footprints. Each sterilizer should be equipped with adjustable leveling legs.
cc. Air Filter Test Ports: valves and ports should be added to perform integrity test in-place.
dd. Automatic Air Filter Sterilization cycle should be used for sterilization of the 0.2 mm sterile air filter, filter housing and piping (from filter housing to chamber air shut-off valve) either prior to or after cycle processing.

2. Dimensions
    a. Chamber dimensions: WxHxD = 26”x37”x49”

3. System feature

FEATURES	BENEFIT
Temperature Distribution within the chamber	± 0.5 °C
Chamber and jacket key design parameters	Design temperature of both chamber and jacket is +145 °C [293 °F]. Design pressure for both chamber and jacket is 3.1 bar [45 psig].
Chamber Material and Finish	Chamber is manufactured from AISI 316L stainless steel with a Ra of 0.6 µm
Jacket	Full 304 stainless steel jacket for superior temperature distribution.
Chamber Steam Inlet and a chamber baffle	The design of steam inlet port to chamber provides uniform steam distribution to chamber.
Chamber Validation Ports	One dedicated port is provided for validation purposes.
PID Control Loop	PID control loop modulates the on-off valve ensuring accurate chamber temperature control.
Temperature Monitoring	Temperature probe located in the drain for control and monitoring. An independent reference probe for temperature monitoring is also connected either to independent temperature display or optional recorder.
Drain Line	Equipped with a check valve, non-clogging type plug valves and atmospheric air break to prevent back-flow of contaminates to the chamber.
Sterile Air Filter	Air entering the chamber is filtered through a 0.2µm hydrophobic autoclavable air filter.
Two-stage Vacuum Pump	Provides quiet and efficient operation and longer expected life. A separate steam condenser is not required.
Standard Safety Systems	Redundant door interlock systems are provided to ensure operator safety. An Emergency Stop is also provided.
Effluent Cooling Tank	Effluent discharge is cooled to 60°C or below through water saving controlled mixing chamber. Closed loop systems are also available for enhanced water savings
PLC Control	Standard, commercially available PLC control system platform.
Operator Interface	Color touch screen with cycle trends, maintenance and diagnostic screens.
Secure Access	Five users access levels with up to 30 alphanumeric users' names.
Printer	Panel printer to print cycle parameters, real-time process data and alarms in a comprehensive batch report.
Fo Based Exposure	Available as an option for liquid loads

Factory Acceptance Test	Fully tested at factory according to FAT procedures.
Noise Level	Noise levels have been tested and fulfill the OSHA requirements for ear-protection-free operation.

4. Utilities requirements

UTILITY	CODE	CONNECTION	PRESSURE	REMARKS
Steam	042	Tri-Clamp	2.8 bar ±0.3 bar (40 psig ±4 psi)	Saturated pure or clean steam
Domestic water[1]	010	NPT or G-thread	1 – 3 bar (15 – 44 psig)	Hardness <125 ppm as $CaCO_3$
Compressed Air	051	NPT or G-thread	5.3 – 8.3 bar (77 – 120 psig)	Dry and oil free instrument air
Drain[2]	060	Open (Atmospheric break)	Gravity discharge	-
Safety relief device for chamber	071A	Tri-Clamp	3.1 bar (45 psig max) Release to open air, no back pressure	-
Safety relief device for jacket	071B	NPT or G-thread	3.1 bar (45 psig max) Release to open air, no back pressure	-
Electricity[3] (Main unit)	090	Terminal blocks	-	3 Ph /50 - 60 Hz / 208 - 600 V
Optional Closed Loop Cooling Water[4]	024/ 025	NPT or G-thread	3 – 6 bar Supply (44-87 psig) 2 – 5 bar Return (29-73 psig)	-

5. Items should be included in quotations
    a. Pressure Vessel Finish - Polished Ra < 0.6 - Epoxy Coated Carbon Steel Frame (installed on unit)
    b. PALL Novasip -0.2 Micron Filter and Disposable Housing Loading cart
    c. Control System Allen-Bradley-Compact Logix CPU, PanelView Plus 700 Color Touch Panel
    d. Integrated Control System
    e. Panel printer 83 characters per row
    f. Loading Cart (Incl. One Wire Shelf)
    g. Transfer Trolley
    h. Wire Shelf For Loading Cart (Brackets Included)
    i. Enclosure Side Panel (Left Side)
    j. Enclosure Side Panel (Right Side)
    k. Chamber Tracks
    l. Automatic Sterilization Of Air Filter
    m. Air Filter Test Ports option
    n. Start-Up - Finn-Aqua GMP Sterilizer

    i. Execute the STERIS Installation/Start-up Checklist for the equipment
    ii. Verify that building utilities are to the design specification of the equipment
    iii. Verify that the installation is adequately performed and documented
    iv. Verify that the operational requirements are met
o. Utility Supervision And Monitoring
p. Utility Shut Off Valves
q. Chamber Passivation
r. Extended Control System Validation Documentation
s. Extended Pressure Vessel And Piping Documentation
t. FAT Procedures And Results
u. Manufacturing Procedures Documentation
v. SCADA Data Exchange Table (Allen-Bradley)
w. Component Data Sheets
x. Supervision Of Installation
y. 1st Year PM - GMP Steam Sterilizer
z. IQ/OQ - F/A BPS Sterilizer documentation
aa. IQ/OQ - F/A BPS Sterilizer execution