2022
case study

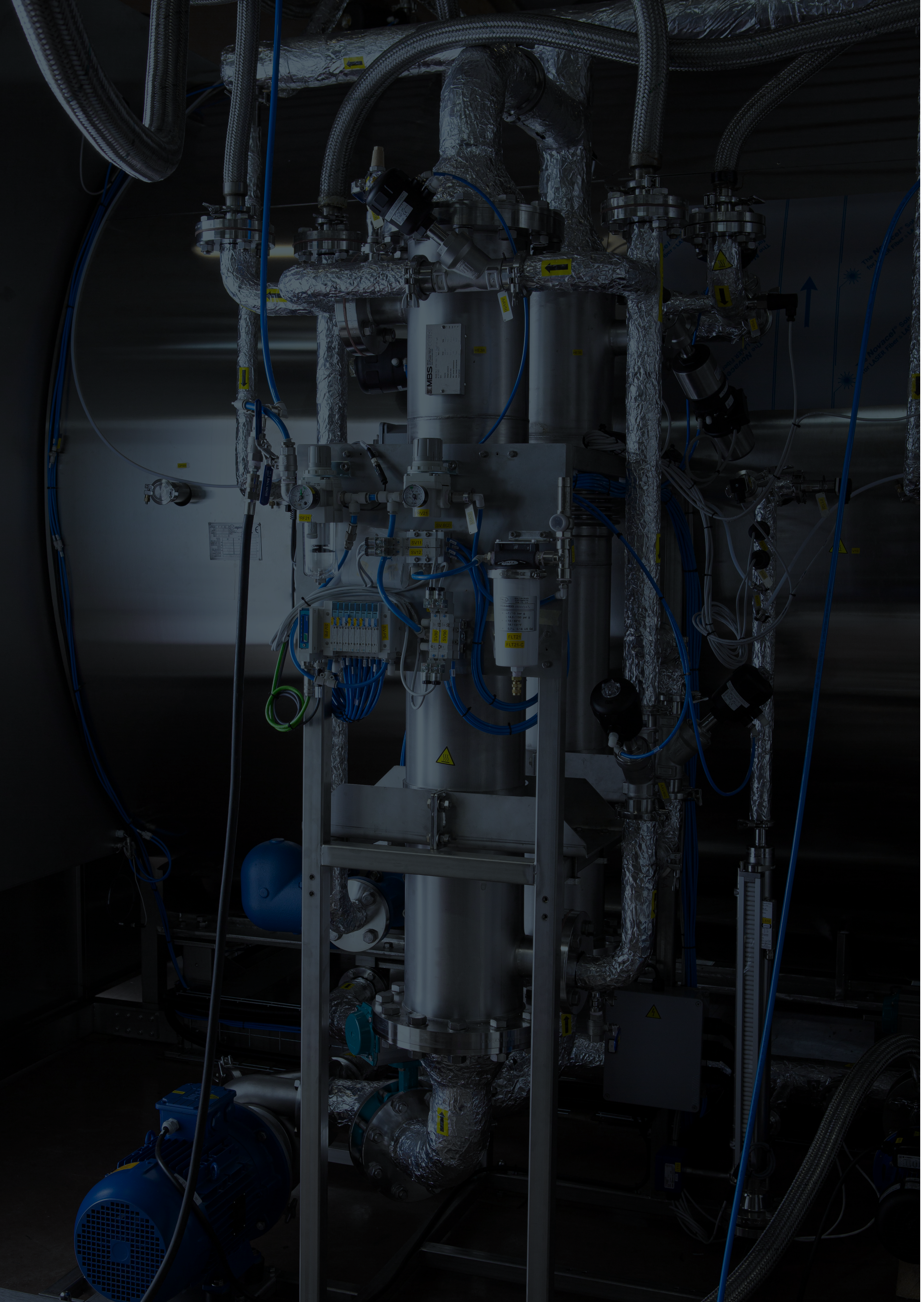
TS ROTO

PHARMA
DIVISION

cGMP
SOLUTION

Project for a terminal sterilizer with load rotating system

LAST TECHNOLOGY



Customer request

A major multinational pharmaceutical company asked us to produce several terminal sterilization autoclaves.
In light of the product to be sterilized, the engineering team realised from the start that the sterilization process, in this case, would be complex.

The product to be treated needed to be kept moving throughout the cycle because the fluid inside it, if allowed to remain static and heated, would have undoubtedly separated.

These were vials and bottles containing lipid injectable solutions with a tendency to coagulate easily.
The physical condition of the load and container could not, therefore, have withstood a typical sterilization cycle as with porous solids or textiles. Moreover, the fluid inside the receptacles had to be constantly stirred all the time.

Creating a vacuum inside the chamber would have caused a imbalance between the pressure inside the product and the exterior, most likely leading to rupture of receptacle and loss of the product.
Avoiding separation of the solution inside the receptacle was critical to achieving a suitable sterilization cycle.

Removing the air from the chamber thus became impossible. This was, however, necessary in order to establish a direct relationship between pressure and temperature during the processing stages.

THE GOAL

The goal, therefore, was to sterilise the product, compliance with the relevant regulations, without the fluid inside being separated. The ultimate goal was to subject it to a constant, uniform temperature for a fixed time maintaining continual motion.

The large volume of the chamber, over 7,000 litres, meant the company was forced to choose a different media than steam alone due to the high costs and the desire to optimise processes where possible.

Moreover, during the cooling stage, the fluid load would not have been cooled at the same rate as the chamber after the thermal exposure of the sterilization tray.
The chamber would have cooled with an inevitable loss of pressure while the load remained hot. Consequently, the internal pressure, which would have been greater than the external pressure, would have led to the receptacle being deformed or broken.

Preliminary points for correct production of the machine

Before creating the ideal sterilization solution without deforming the receptacle and preventing fluid separation, the engineering team set out:

- to produce a machine for use in research laboratories and/or pharmaceutical production in compliance with EC, EudraLex, FDA and cGMP good manufacturing practice regulations
- to make the machine flexible allowing different types and size of loads to be treated
- to make internal and external surfaces accessible for easy cleaning and dirt removal and technical compartments for easy machine maintenance
- to create an automated loading/unloading system for the palletized trays on which the different products are placed
- to produce a rotating loading system that would allow the sterilization of multiple products whilst keeping the product moving throughout the sterilization process to avoid thickening and/or separation
- to implement an automation and control system that could be managed from a user panel (HMI) to limit operator intervention
- to introduce energy-saving solutions to recover the heat produced and minimise dispersion
- to implement safety systems to prevent the machine doors from opening under pressure
- to use safety valves to protect the machine and operator from high pressure that could be generated in the steam and pneumatic circuits
- to use manufacturing solutions to minimise machine noise

Complies with CE regulation

Flexibility by load type

Easy cleaning and maintenance

High quality safety standards

System of software sampling

Reporting systems

User automation

Noise propagation limitations

The project

The definitive solution was the design of a rotating structure that ensured the movement of the product inside the chamber but avoided damage to the various receptacles within it.

Firstly, regulations and legislation dealing with the definition of sterile load were researched. In this case, UNI EN 17665-1 on moist heat sterilization was referenced. In particular, the processing solutions involving sterilization by spraying superheated water on the load.

Steam is an excellent heat transfer fluid capable of exchanging large amounts of thermal energy with the load during the condensation phase, but has high operating costs and is, therefore, not very cost-effective.

Superheated water sprayed inside the chamber was, therefore, the most suitable solution.
Using shell and tube heat exchangers fed with industrial steam, the purified water is superheated, recirculated and sprayed inside the chamber by means of centrifugal pumps.
As mentioned initially, it was not possible to remove the air from inside the chamber. Due to the presence of air during all cycle stages, the machine was fitted with nozzles that distribute the superheated water spray throughout the chamber to ensure internal temperature uniformity.

Due to the above-mentioned reasons, the air, during the cooling stages, therefore, enters the chamber in back pressure regulated according to the internal pressure of the receptacles. Cooling in this way is also quicker and thus saves energy.

Back pressure air is also appropriately regulated in the early stages of heating.

TS ROTO

Starting from a static TS-OW, the possibility of inserting a rotating structure inside the chamber was investigated without changing the nozzle system and hydraulic layout.

Having already developed the most suitable solution for managing the processing parameters in the past with excellent results, the team did not want to make significant changes to the machine to avoid compromising the sterilization stage.

The internal rack is driven by an electromechanical system controlled by an encoder-motor-gearbox installed above the chamber to which a drive shaft with a pinion is connected.

The pinion, inserted in the chamber, drives the rack which then rotates the load structure.
The rack and all the parts involved in moving the pallets are made of AISI 316L stainless steel as required by the GMP regulation. The pinion is made on AISI 630 steel since the material is more resistant to mechanical and heat stress.

An automatic loading and unloading module complete the machine. The platform on the loading side is designed to load the pallets sequentially, while the unloading side is equipped with a platform that allows all the pallets to be unloaded at once. This shortens the process time by enabling the new pallets to be loaded into the autoclave in the meantime.
Both platforms are automated and controlled by an HMI installed in the field.

All the valves, instrumentation, centrifugal pumps, heat exchangers and process pipes are made of AISI316L stainless steel. The valves are driven by the process logic and controlled by the central control system consisting mainly of a PLC that detects the physical values in the field (temperatures, pressure, levels, etc.) and, where required, electrically controls the solenoid valves that provide the interface between the controller (PLC) and the pneumatic system.

To safeguard the pressurised parts, pressure relief valves were used, sized to relieve any overpressure that might be generated inside the receptacles and in the pneumatic line.

A safety system (electrical and pneumatic) was designed to prevent the doors from opening simultaneously and under conditions exceeding safe pressure and temperature in the chamber (ambient pressure and temperature below 50°C).

The rotation speed and direction of the load structure is set by the manufacturer and cannot be changed by the end user.
The software code, however, includes a procedure to change the direction of rotation and/or speed at each change of cycle. This ensures that the gears do not suffer excessive wear and tear, compromising their correct operation.

Lastly, hardware was implemented to ensure safety during loading/unloading: laser photocells were inserted to verify the correct positioning of the rotating structure before loading/unloading pallets and load boxes.

The modular hydraulic, pneumatic and electrical assemblies are confined in a special technical compartment, accessible by key only to authorised personnel.

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