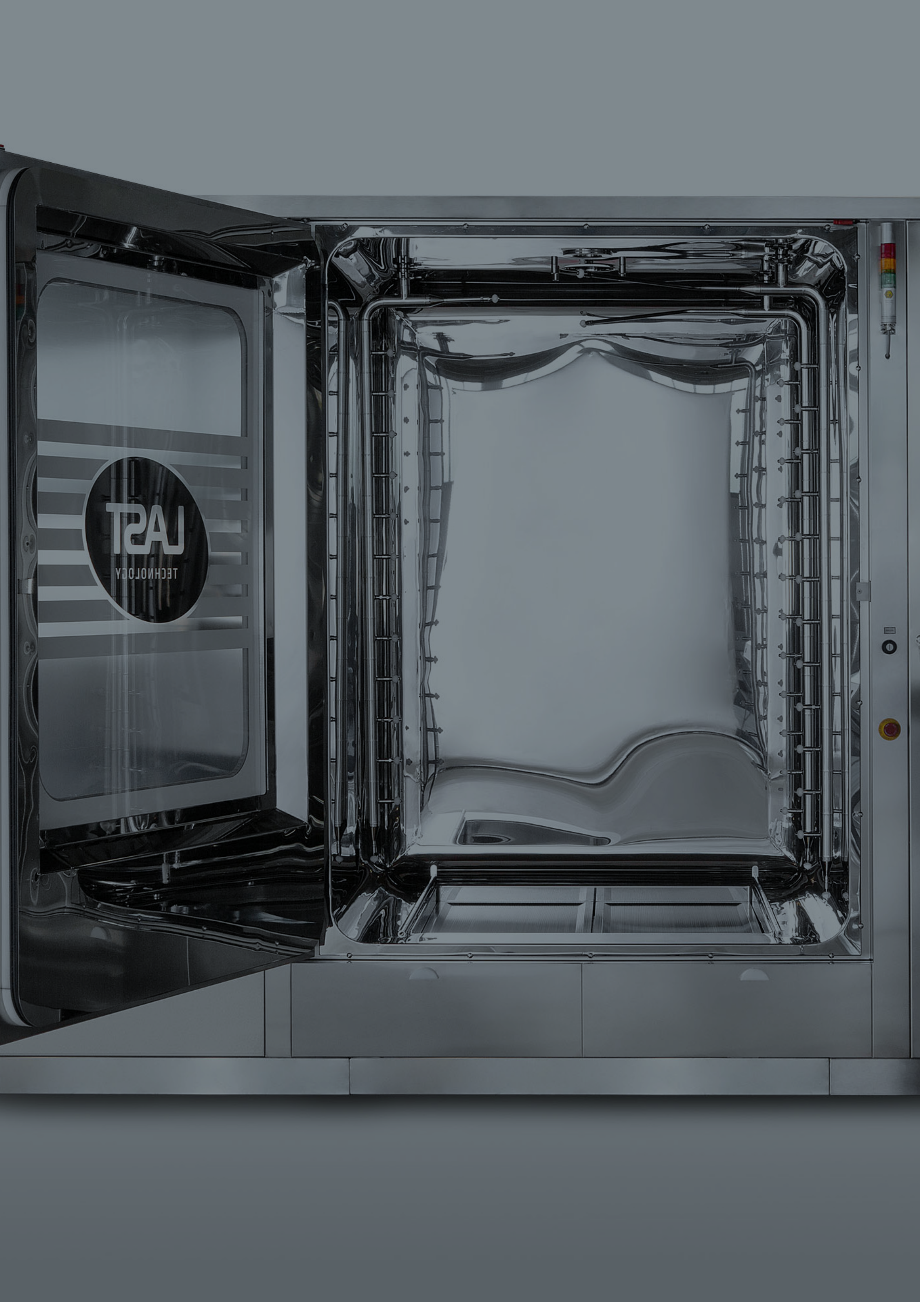
2022
case study

UCW ACE LINE

PHARMA
DIVISION

cGMP
SOLUTION

LAST TECHNOLOGY



The Customer Requirement

PROJECT INVOLVING A WASHING EQUIPMENT MODEL THAT USES SOLVENTS

LAST Technology's engineering team was entrusted to design a high-efficiency machine that could increase washing efficiency by dissolving encrustations and active pharmaceutical ingredient (API) residue from flat surfaces, such as trays and frames. More specifically, this pharmaceutical company manufacturers steroid solutions.
The LAST team received the specific request to design a washing equipment model that could simply remove surface dirt by means of a mechanically-acting liquid solution. The team identified that acetone would be the most effective solvent for this process.
Acetone is a solvent that is widely used in similar sectors, thanks to its multiple functions. In fact, it is not very toxic, is water soluble and evaporates easily; as a result, the surfaces are removed of all residue and also dry much quicker.

However, the use of acetone as a chemical cleaning agent introduces the risk of an explosive atmosphere, due to its high flammability.
According to UNI EN 1127-1, an explosion results from a sudden increase in pressure and temperature caused by an oxidation or exothermic reaction.
An explosion can be triggered when, in time and space, a fuel (acetone), a comburent (oxygen inside the washing chamber) and a trigger with sufficient energy coexist. A spark produced from the electrical control devices or other instrumentation could be enough to pull the trigger, or even an electric arc generated by different-potential charged surfaces or the high temperature inside the chamber, provided that it is sufficient to start the oxidation reaction.
The solvent itself has its own autoignition temperature, i.e. when a particular temperature is reached, it spontaneously starts to burn.
Another design-related risk factor that was taken into consideration was the environment in which the entire process would take place... one in which the formation of an explosive mixture was highly possible.

The request, therefore, was to design a washing equipment model able to not only dissolve the very specific dirt produced by the aforementioned pharmaceutical company but also control and eliminate one of the factors that leads to combustion.
By eliminating the possibility of effective ignition sources being generated, the explosion is prevented.

Preliminary points to consider before designing the right machine solution

Before performing the in-depth analysis of the possible solutions to satisfy the customer's request, the engineering team focused on the key points which were essential for correctly designing the washing equipment model in question:

- The machine would have to be designed for use in the pharmaceutical sectors.
- It had to comply with the EC, EudraLex, FDA, cGMP and GAMP 5 directives.
- It had to take loads of different nature, size and shape (especially hollow ones) into account.
- It had to be equipped with technical compartments designed to make maintenance operations easier.
- The machine had to guarantee energy savings that allowed for minimal solvent consumption during the washing phases.
- It had to be equipped with safety systems that prevent the doors from being opened during washing operations.
- Furthermore, it had to be fitted with safety valves designed to protect both the machine and the operator from high pressures in the pressurised circuits.

- **Respects CE regulation**
- **Atex Execution**
- **Flexibility by load type**
- **Minimum consumption of solvent**
- **Advanced security systems**
- **Easy maintenance**

Analyses

The use of acetone as a washing fluid - rather than standard pressurised water - poses a series of risks:

- **An explosive mixture could form inside the chamber.**
- **The action of the electromechanical and electronic devices could ignite the mixture.**
- **The mixture could be ignited, should the acetone's autoignition temperature be exceeded.**

Based on the above-listed risks, the formation of an explosive mixture could not be ruled out. In this regard, the current ATEX legislation would consider the area inside the chamber as zone 1, i.e. "an area in which explosive atmospheres may be present, both periodically and occasionally, during normal operations".
Classifying this area would have therefore involved a thorough certification process and the purchase of zone-classified electromechanical devices.
As the customer agreed that they would prefer not to go down this road and given the fact that many of the devices required for normal operation are not marketed for the aforementioned classification, the engineering team decided to put forward another option.

The UNI EN 12921 standard concerning "machines for surface cleaning and pre-treatment of industrial items using liquids or vapours" offered an alternative route.

CHOOSING NITROGEN

Part 3 of the aforementioned standard contains the safety requirements for machines that use flammable solvents.

After a painstaking analysis, the LAST team proposed using nitrogen during the washing phases, which being an inert gas, would have downgraded the machine with all the necessary bureaucratic and design benefits.

Furthermore, risk management would have become more streamlined for the purchaser installing the machine at their production site.

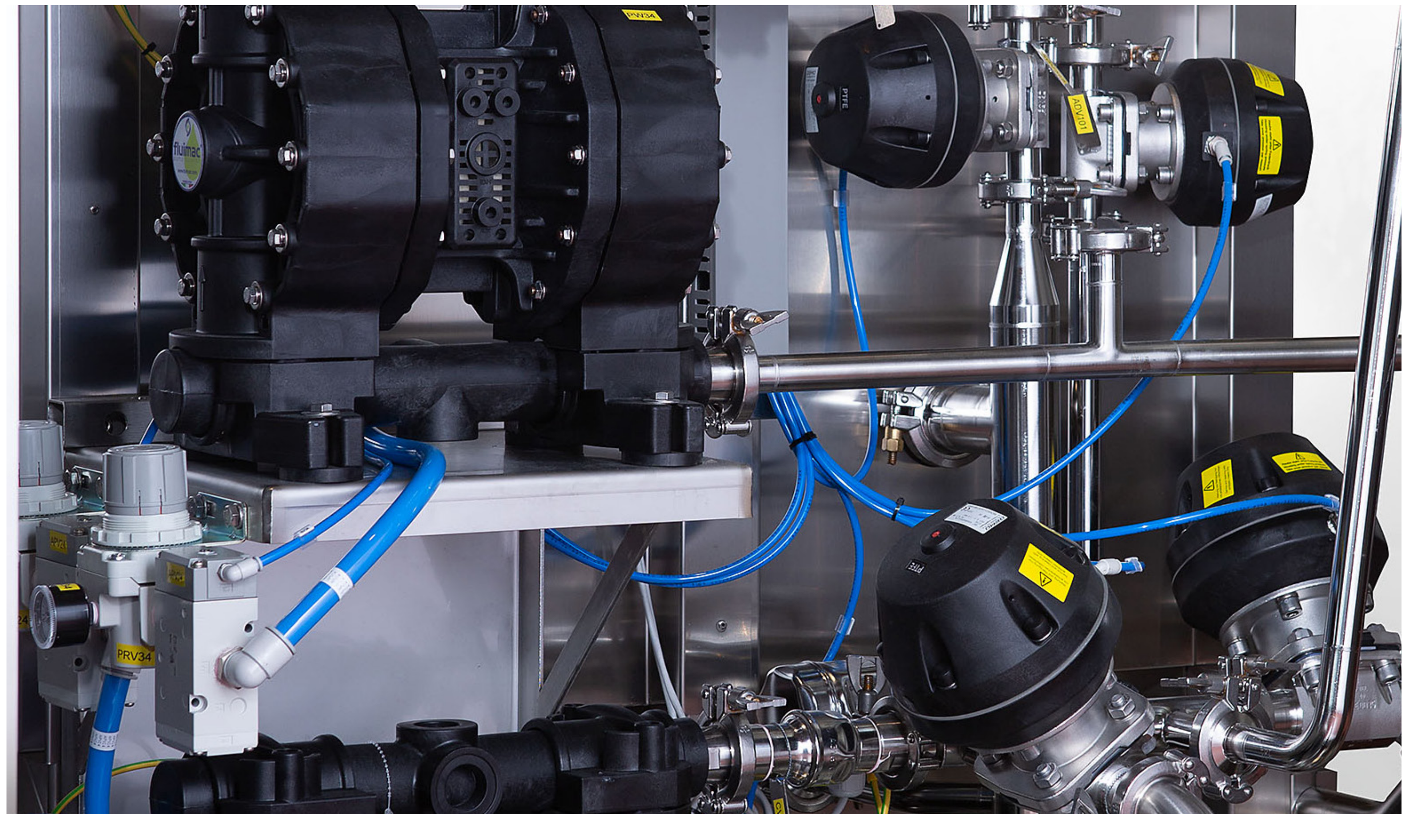
The process phases

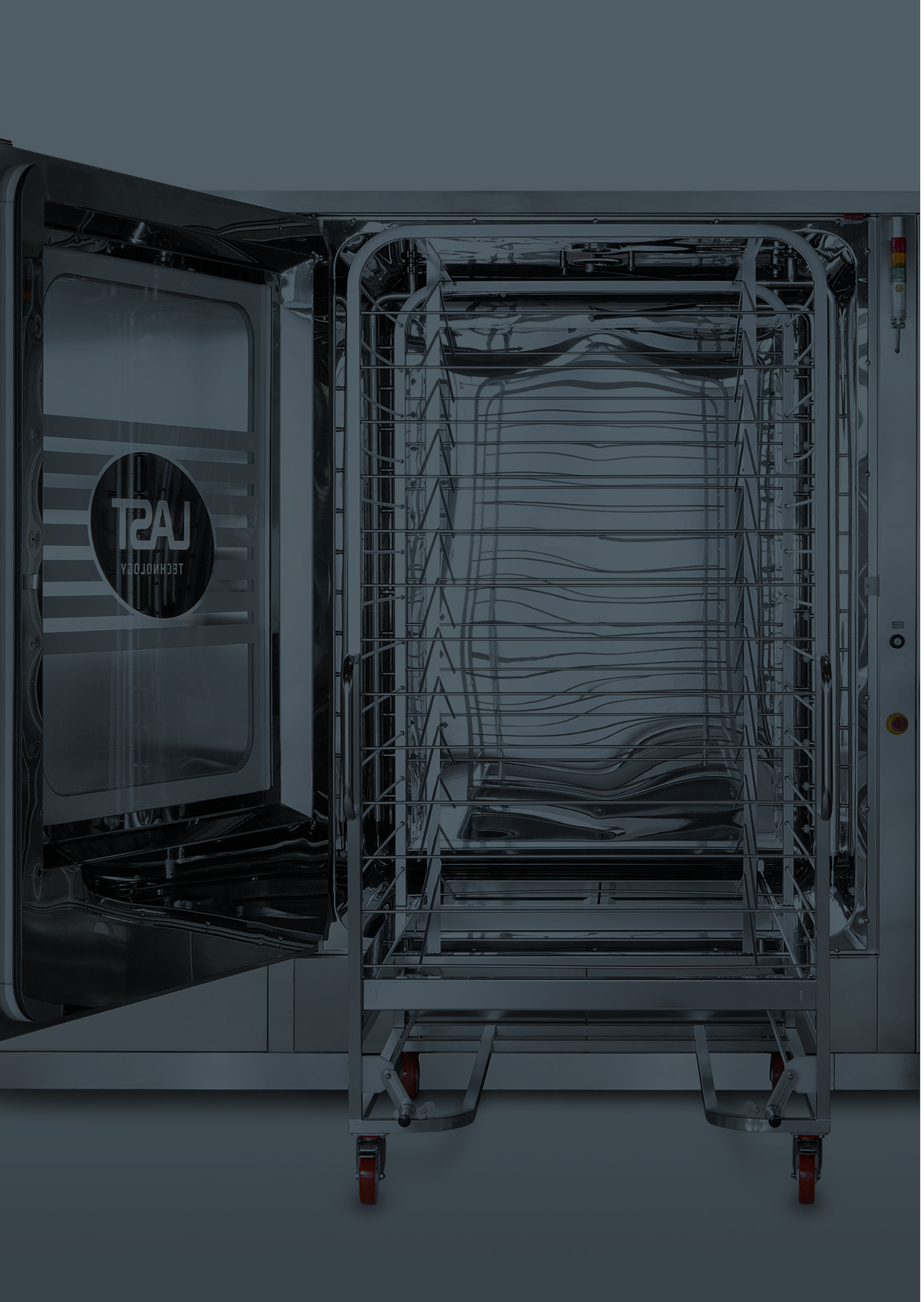
In pharmaceutical practice as standard, the washing phases consist of pre-washing, washing, rinsing, drying with hot air and cooling.

By deciding to use nitrogen, we opted to integrate a new process phase, called INERTISATION.
In this phase, the percentage of oxygen inside the chamber is reduced to such a level that the combination of acetone + oxygen is no longer an explosive mixture.
The oxygen level would therefore be monitored throughout the wash cycle.
By means of a heat exchanger - designed specifically for this eventuality - the solvent would be continuously cooled in order to always keep its temperature below 45°C, as anything higher would trigger its autoignition.

Therefore, during the drying phase, the properly filtered air will not be heated and as a consequence, there will no longer be a cooling phase.

According to legislation, as there is only an Inertisation phase, the machine can be downgraded in a non-classified area with all the appropriate benefits during normal use.
It was therefore decided to classify the machine as zone 2. This classification involved choosing zone-suitable components and the appropriate design measures required by the ATEX directive.





The project

The resulting machine is characterised by the following process phases:

- **Inertisation**
- **Pre-washing**
- **Washing**
- **Rinsing**
- **Drying**

Several constructive considerations were taken into account whilst designing each process phase and sub-phase, with the focus on the goal of maximising the efficiency of the washing action.
After the last rinsing phase, the drying phase is carried out; the latter is obtained by introducing large quantities of filtered ambient-temperature air into the chamber.
It will take a maximum of 20 minutes for the load to be fully dried and returned to a low level of relative humidity, as required by pharmaceutical practices.

During the entire process, the chamber's internal environment maintains a slight overpressure (up to a maximum of relative 250 Pa), in order to eliminate and dispel any possibility of contamination from the waste products and/or external environment.

UCW 4000 ACE line

The inside of the chamber as well as all the elements that come into contact with the process fluids are made of AISI 316L, while the external structures are made of AISI 304.

The AISI 316L stainless steel washing chamber boasts a 4 m3 volume, in addition to mirror-polished interiors with no edges, that make the routine cleaning operations easier for the operators.
It slopes by 2 degrees in order to prevent any liquid stagnation and thus, the formation of microorganisms and bacterial colonies.

The chamber and entire machine have been designed specifically for use in the same temperature conditions from 0 to 200°C (the minimum and maximum admissible temperature) and in pressure conditions from 0 to 250 pascals (the minimum and maximum admissible pressure, respectively).
To reduce the consumption of the solvent used - i.e. nitrogen - the bottom of the chamber is fitted with a collection tank which creates a buffer for the centrifugal recirculation pump. An additional 550 L external tank (with a capacity equal to three washing phases) is installed to store the washing fluid used for the last rinse, and then reused in the next cycle's pre-wash phase.

The load is washed with acetone, supplied by the user, and suitably cooled by means of a heat exchanger placed at the centrifugal recirculation pump's outlet.
The fluid is sprayed at high pressure onto the load by means of "rotating heads", installed on the walls of the washing chamber and suitably positioned to ensure that the internal volume is fully covered.

The chamber inertisation is performed at the beginning of the cycle and maintained throughout the entire washing process. The user-supplied nitrogen is introduced into the chamber by means of a properly controlled valve.
The centralised automation system will close this valve once an environment with an oxygen percentage below 7% has been established (a percentage at which the environment is no longer considered combustive and as such, does not permit the formation of an explosive atmosphere). This percentage will be continuously monitored by the oxygen sensor. Nitrogen will be constantly injected into the chamber during the subsequent washing phases by means of a calibrated needle valve.

The chamber is equipped with a pneumatically-closing door upon which an inflatable gasket is installed to guarantee a hermetic seal. The pneumatic safety system prevents the risk of the door accidentally opening. The control system monitors the door's status and will not let it open until the environment inside the chamber has an oxygen level that will not asphyxiate the operators.

The machine is classified according to the ATEX directive
- IIA
- T6! 40°C

SOLIDS AND SEMI-SOLIDS

20°C - 120°C

WATER + DETERGENT + AIR

All the components used, such as the sensors, pumps, valves, etc., have been appropriately chosen in accordance with the aforementioned ATEX classification for zone 2 or higher.
The air handling unit is composed of a fan - which draws the air from the external environment through a duct - and a HEPA H13 filter, able to retain all particles ≥ 0.3 µm with a ≥ 99.97% efficiency.

At the chamber's outlet duct, the air is filtered once more by a HEPA H13 filter, sucked in by another fan and expelled outside through two distinct chimneys, separated by two opposing butterfly valves that have been specifically channelled through the installation site (NO and NC-controlled by the same solenoid valve). The first chimney directly expels and discharges the air inside the chamber during the inertisation phases. The second, on the other hand, conveys the waste air - saturated with evaporated solvent - which must be treated by the client by means of abatement systems, such as burners or activated carbon filters, before expelling the air into the environment.

Once an inert environment has been established, the system will control the solenoid valve, by permitting exchanges between the two ducts. This exchange will then be carried out once more during the drying phase.
There is a Bag In/Bag Out-type filtration system for the two HEPA filters. This method guarantees maximum operator safety during the operations that involve removing and replacing filters potentially steeped in solvent, because they are prevented from coming into direct contact with the inside of the housing. Pharmaceutical regulation-compliant AISI 316L stainless steel was used for the piping. The entire hydraulic circuit has been designed with slopes to avoid the formation of stagnated fluid.
The hydraulic-pneumatic assembly is housed in the technical compartment - specifically designed to be easily accessible and make maintenance operations easier for authorised personnel only - whilst the remote electrical cabinet is located in the service room (non-classified zone).

By adopting the requirements of ISO 14118 in terms of LO/TO solutions, the machine has been designed in such a way to allow residual energies to be discharged before proceeding with any maintenance work.

The cycle is controlled by means of probes placed in the machine's key points. The automated control system detects the temperature and/or pressure data and carries out appropriate corrective operations.
The system's use can be optimised from the panel by modifying the washing parameters and drying cycles according to the quantity, characteristics of the materials and the morphology of the product being treated, thus reducing power consumption.

The control system can also be used to print cycle reports via a printer or transmit all the available data to a remote PC for data storage and recording purposes. Furthermore, the system has been designed for implementation in Industry 4.0 projects; it shares files, databases, archives and instant data by communicating with the premises' central MES.

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