WASHING & DRYING

cGMP Process Equipment for
Pharmaceutical Production and Biotechnology

PHARMA DIVISION

LAST® TECHNOLOGY

ADVANCED SOLUTIONS FOR INFECTION PREVENTION

Company

LAST Technology is the worldwide provider for cleaning, decontamination, disinfection and sterilization equipment for the life science & healthcare sectors. **LAST** takes its name from the Italian words "**LA**vaggio" (washing) and "**ST**erilizzazione" (sterilization) combined together with the concept of "**latest**" as the most innovative and newest, and "**lasting**" to describe durability and reliability of its products.

A group of experienced managers incorporated the company in Prata di Pordenone, a town near Venice (Italy). Starting with the idea of a business center of excellence, this young and innovative company is, thanks to the continuous investments in high standards and research, a leader in engineering and manufacturing, designing and developing the most innovative and effective technologies for the improvement of the quality of life of everyone.

WASHING & DRYING

cGMP Process Equipment for Pharmaceutical Production and Biotechnology

Pharma division

LAST Technology's Pharma Division provides highest quality washing, disinfection, sterilization, depyrogenation, decontamination and containment equipment for the pharmaceutical industry.

The products are developed to ensure the prevention of infections and safe processing during the development and production of pharmaceuticals. Higher performances with lower consumptions, reduced footprint dimensions and full tailor-made machines to meet exactly our customers' needs. Innovative design and process reliability, together with customer orientation for user friendly solutions is what makes the difference in LAST Technology's products.

The perfect cleaning process

WASHING & DRYING

cGMP Process Equipment for Pharmaceutical Production and Biotechnology

Comply to

- Quality Management **(ISO 9001:2015)**
- Current Good Manufacturing Practice **(cGMP)**
- International Society for Pharmaceutical Engineering **(ISPE Baseline Guides)**
- US Food and drug Administration **(FDA)**
- Medicine and Healthcare Products Regulatory Agency **(MHRA)**
- Good Automated Manufacturing Practice **(GAMP 5)**
- Code of Federal Regulation Title 21 **(FDA 21 CFR part 211 and 212)**
- Code of Federal Regulation Title 21 **(FDA 21 CFR part 11)**
- Washer-disinfectors-general requirements, terms and definition **(ISO 15883-1:2014 and ISO 15883-2:2009)**
- Sterilization, Steam Sterilizers, Large Capacities **(EN 285:2015)**
- Pressure vessels standards **(2014/68/UE** or **ASME code Sec. VIII Div. 1** or **Chinese GB 150)**
- American Society of Mechanical Engineers: Bioprocessing Equipment **(ASME-BPE)**
- Safety Requirements for Electrical Equipment **(IEC 61010-1:2010)**
- Safety Requirements for Electrical Equipment **(IEC 61010-2-040:2015)**
- EMC Directive **(IEC 61326-1:2012)**
- Governing directives for affixing the **CE** mark – machinery directive **(2006/42/EC)**
- Underwriters Laboratories **(UL)**
- Canadian Standards Association **(CSA)**
- Occupational Health and Safety management systems **(UNI ISO 45001:2018)**

Range of Products

The perfect cleaning & drying process

Designed for

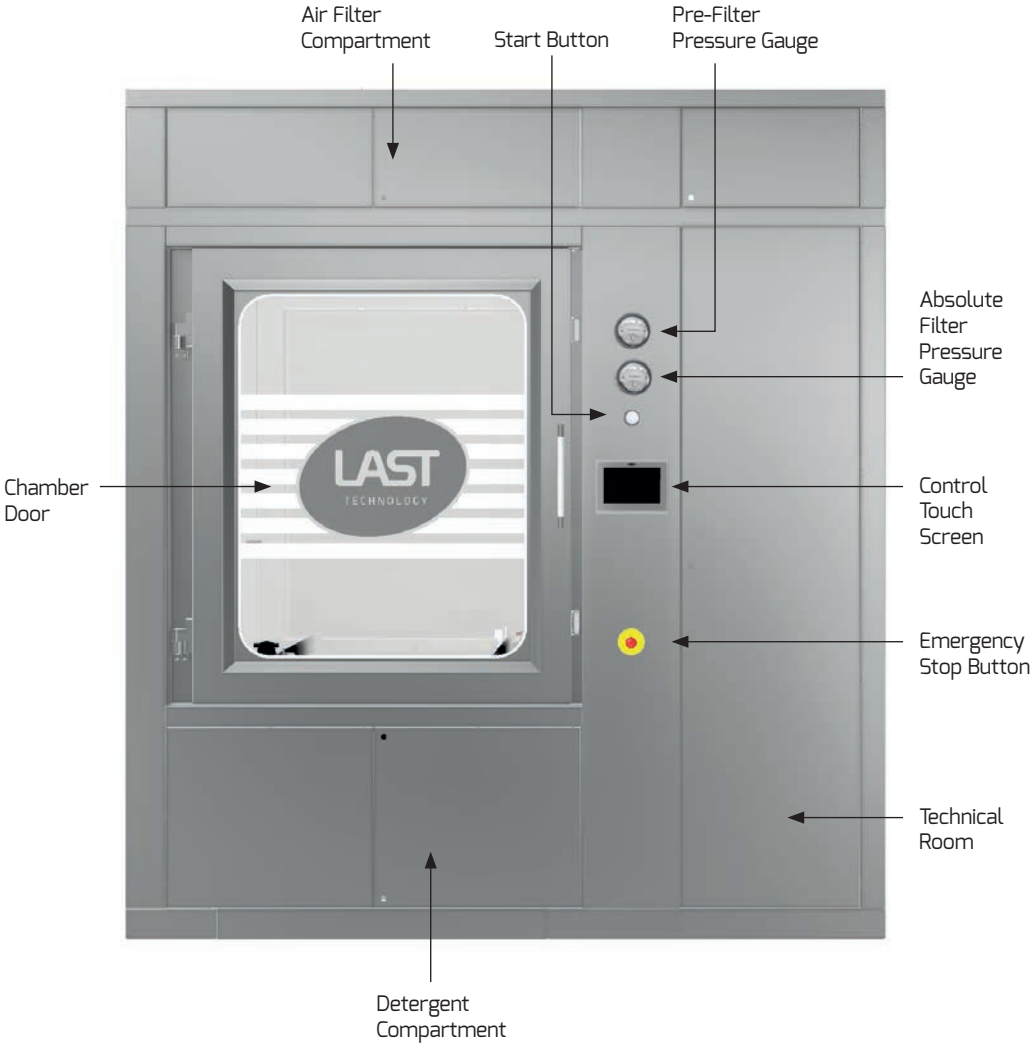
The machines type **UCW** are designed for process washing and drying of utensils, glassware, filling machines parts, IBC containers, etc.

Process features

Pre-selected and custom made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. From dirty to product ready to be sterilized; passing through a pre-washing, washing with chemicals, WFI rinsing (of once-through or recycled type) and final hot air drying (HEPA 14 filtered). Keeping under control the water T.O.C. level, the conductivity and the PH. During the phase of product washing, chemicals may be injected through an accurate and reliable system to improve the cleaning action of the machine.

Solid Construction

- Square or rectangular cross section chambers of single-wall type made of 316L or 316Ti stainless steel
- Innovative centrally located sump made of 316L or 316Ti stainless steel
- Piping and air ducts completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Respect of 3D dead legs on all piping system and 3 degree piping slopping to the floor drain
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- All internal corners of the chamber are rounded to guarantee a perfect cleaning
- Chamber doors of manual hinge or automatic vertical/side sliding type (door frame made of 316L or 316Ti stainless steel with HST tempered glass window for an internal visual inspection)
- Chamber-door sealing by unique design of silicone gasket
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, doors, piping, components and instruments are properly insulated by an advanced type material
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Brand new design of cart connection with self-ducting and self-disconnection system (100% guarantee of no leak)
- Ergonomic product loading of manual or automatic type
- Floor or above the floor loading solution


Air Filter Compartment
Start Button
Pre-Filter Pressure Gauge
Absolute Filter Pressure Gauge
Chamber Door
Control Touch Screen
Emergency Stop Button
Technical Room
Detergent Compartment
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b
e
c
a
d
f
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Type UCW Utensil and Container Washers - doors of hinged or sliding type

Type	Chamber Dimensions (mm - inches)			Capacity (litres / cu. ft.)	Overall Dimensions (mm - inches)		
	Width (a)	Height (b)	Lenght (c)		Width (d)	Height (e)	Lenght (f)
UCW 350	735 / 29	700 / 27.5	815/ 32	400 / 14	1450 / 57	2200 / 86.5	980 / 38.5
UCW 500	710 / 28	710 / 28	1000 / 39.5	500 / 17.5	2200 / 86.5	2200 / 86.5	1215 / 48
UCW 1000	992 / 39	992 / 39	1000 / 39.5	1000 / 35.5	2500 / 98.5	2550 / 100	1215 / 48
UCW 1250	992 / 39	1242 / 49	1000 / 39.5	1250 / 44.5	2500 / 98.5	2800 / 110	1215 / 48
UCW 1500	1242 / 49	992 / 39	1250 / 49	1500 / 53	2750 / 108	2550 / 100	1465 / 57.5
UCW 4000	1392 / 55	1852 / 73	1554 / 61	4000 / 142	3000 / 118	2800 / 110	1691 / 66.5

The perfect cleaning & sterilization process for caps and stoppers

Designed for

The machine type **CPE** are particularly designed for the complete process (from dirty to ready to be sterilized or ready to be used) of pharmaceutical closures such as rubber stoppers, rubber pistons, rubber seals, plastic parts, aluminum caps, combi-seals, etc.

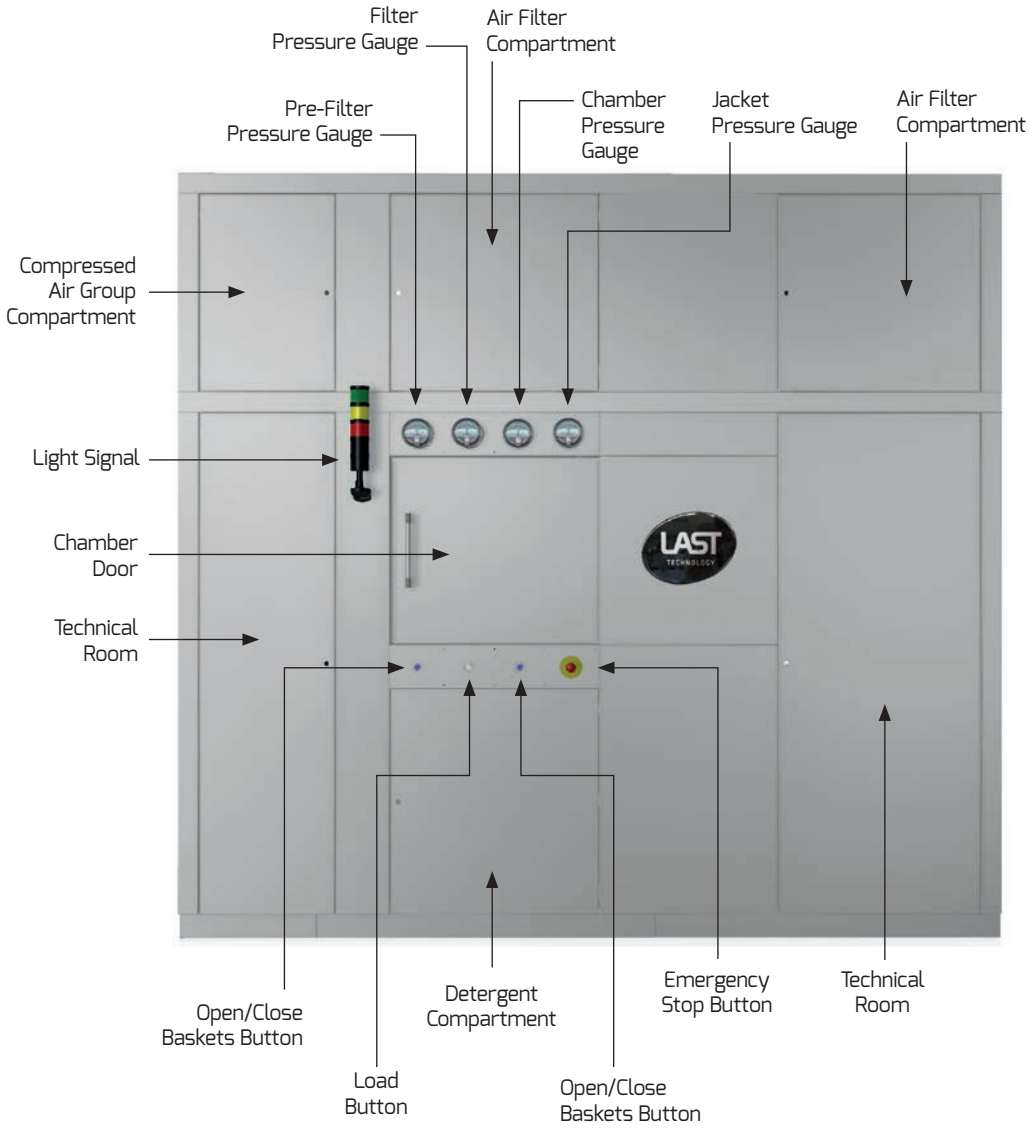
Process features

Pre-Pre-selected and custom made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. The process consist on the following events: fluid bed pre-washing, fluid bed de-latching, fluid bed washing with or without chemicals, fluid bed WFI pulsed rinsing, fluid bed siliconization, steam sterilization at 121 °C, hot air drying (HEPA 14 filtered).
During product cleaning (pre-washing, washing and rinsing) a water fluid bed and air bobbles are created by the action of a sanitary recycling pump. This combination of events captures the particles contained in the product and move them in suspension on the water. Than the same pump built up an over flow for skimming out all those particles. At the end each phase the water of the fluid bed is completely drained out and an automatic machine cleaning in place (CIP) is run. During the phase of product washing, chemicals may be injected through an accurate and reliable system to improve the cleaning action of the machine.

The de-latching is normally processed between the pre-washing and washing phases basically to "exhaust" all chemical residuals contained in the product. This phase consist on loading the water into the chamber and a further injection of clean steam though a PID controlled valve. The consequence of such combination of events made possible to built up overheated water which "purify" the product.
Product siliconization by means of a combination of water fluid bed and injection of silicone. The silicone is dosed upstream the water recycling pump through an accurate and reliable system which allow the perfect distribution and avoid any stratification. At the end of the process the water of the fluid bed mixed with the silicone is completely drained out and an automatic machine cleaning in place (CIP) is run.
Product sterilization by means of Fractioned Vacuum process (removal of air through alternative pulses of vacuum and injection of clean steam). After the removal of all air, the steam is injected into the chamber through a PID controlled valve at the desired set point value and the condensate is continuously evacuated through the drain for guaranteeing an excellent distribution of the heat during all exposure phase (temperature deviation below ± 0.4 °C). At the end of the exposure, the steam is evacuated by means of a vacuum brake filter and vacuum pulses.
Drying of product by means of blowing into the chamber large quantity of hot clean air. Cleaning of air by HEPA 14 or Cartridges 0.2 µm filtering unit. Air heating by electrical elements or heat exchanger of multi-tube double head type. At the end of the process, fresh air in injected to cool down the product.

Solid Construction

- Round cross section chambers of double-wall type made of 316L or 316Ti stainless steel
- Jacket of round-flat type made of 304 or 316L/316Ti stainless steel
- Piping and air ducts completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Respect of 3D dead legs on all piping system and 3 degree piping slopping to the floor drain
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of manual hinged or side sliding type
- Chamber-door sealing by pneumatically pressurized gasket (by process air)
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, doors, piping, components and instruments are properly insulated by an advanced type material
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Bio-seal flange for ducting to a VHP isolator
- Ergonomic product loading/unloading of manual or complete automatic type


Filter
Pressure Gauge
Air Filter
Compartment
Pre-Filter
Pressure Gauge
Chamber
Pressure
Gauge
Jacket
Pressure Gauge
Air Filter
Compartment
Compressed
Air Group
Compartment
Light Signal
Chamber
Door
Technical
Room
Open/Close
Baskets Button
Load
Button
Detergent
Compartment
Open/Close
Baskets Button
Emergency
Stop Button
Technical
Room


e
d
f

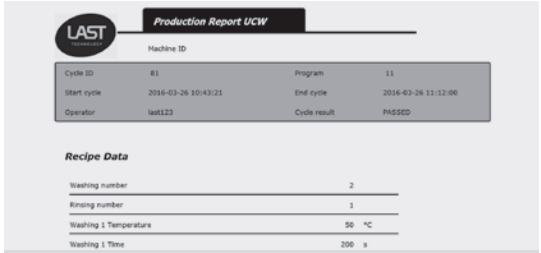
Type CPE Closure Processing Equipment

Type	Chamber Volume (litres / cu. ft.)	Number of hoppers	Useful hoppers volume (litres / cu. ft.)	Total hoppers volume (litres / cu. ft.)	Overall Dimensions (mm - inches)		
					Width (d)	Height (e)	Lenght (f)
CPE 50	700 / 24.7	4	50 / 1.8	150 / 5.3	2800 / 110	2800 / 110	1300 / 51
CPE 100	1000 / 35.3	8	100 / 3.5	300 / 10.6	2800 / 110	2800 / 110	1500 / 59
CPE 150	1600 / 56.5	12	150 / 5.3	450 / 15.9	3200 / 126	3000 / 118	1700 / 67
CPE 220	2000 / 70.6	18	220 / 7.8	660 / 23.3	3200 / 126	3000 / 118	1900 / 75
CPE 250	3000 / 106	20	250 / 8.8	750 / 26.5	3600 / 142	3200 / 126	2100 / 82.5
CPE 300	3600 / 127	24	300 / 10.6	900 / 31.8	3600 / 142	3200 / 126	2300 / 90.5

Type CPE Loading capacity (closure / quantity)

Type	Regular stopper 13 mm	Regular stopper 20 mm	Regular stopper 32 mm	Lyo stopper 13 mm	Lyo stopper 20 mm	Lyo stopper 32 mm	Alu caps 8 mm	Alu caps 13 mm	Alu caps 20 mm	Alu caps 32 mm
CPE 50	65000	19000	3000	45000	13000	1850	140000	75000	25000	5000
CPE 100	130000	38000	6000	90000	26000	3700	280000	150000	50000	10000
CPE 150	195000	57000	9000	135000	39000	5550	420000	225000	75000	15000
CPE 220	286000	83600	13200	198000	57200	8140	616000	330000	110000	22000
CPE 250	325000	95000	15000	225000	65000	9250	700000	375000	125000	25000
CPE 300	390000	114000	18000	270000	78000	11100	840000	450000	150000	30000

Interactive technology



Report example

CPE Typical Cycle

- T-Chamber (°C)
- T-Jacket (°C)
- P-Chamber (bar)

Supervision, Traceability and Control System

Machines automated by a Programmable Logic Controllers (PLC) which guarantee high level reliability. The Human Machine Interface (HMI) is guaranteed by a touch screen Operating panel (OP). A PID based control manage all machine parameters, recipes, settings, sequence of operations, and their storage. The brand commonly used for hardware and software are Siemens, Allen Bradley and Asem.

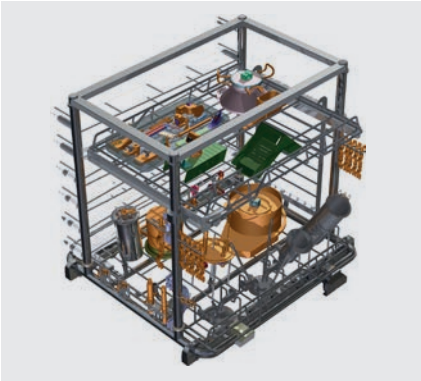
Remote Control

All machines are equipped with a software for a remote control. The application can be installed in any iOS and Android devices. The system allows the remote control of the machines via wireless connection. Operators do not need any longer to be in the same room of the machine to control the progress of the cycle, they will get a notification for any problem with the machine. Multiple number of machines can be controlled through this simple APP from a single source (device).

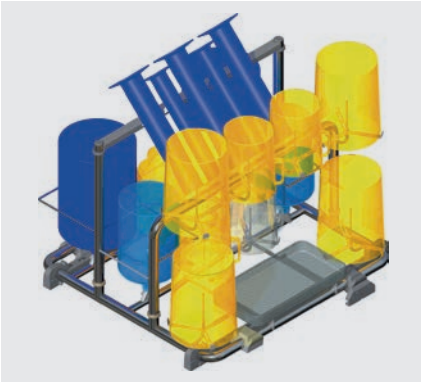
FDA 21 CFR Part 11 compliant

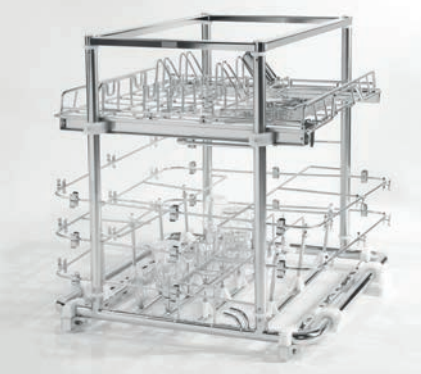
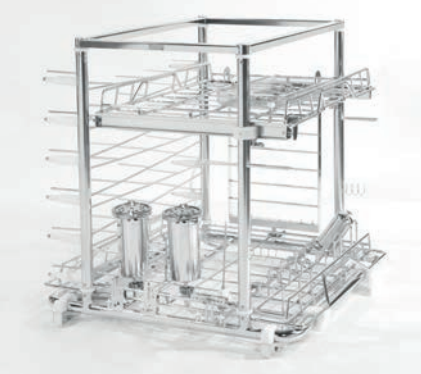
LAST provides the right answer to the issue of compliance to the 21 CFR Part 11 by the installation of a Supervisory Control and Data Acquisition (SCADA) system. The software is developed and engineered following the Good Automated Manufacturing Practices (GAMP 5). The hardware can be installed "integrated" in the fascia panel of the machine or in a standalone version (remote solution).

Fully integrated solutions






Product Handling System

- Possibility to choose between manual or full automatic product loading systems, both developed in order to ensure the highest ergonomic standards considering the height and weight of the loads.
- The cart system is of multi-level type according to products that need to be processed (for UCW only).
- Transport trolleys for the movement of the carts can be of fixed or variable height (for UCW only).
- Dedicated conveyor for loading IBC containers/bins (for UCW only).
- Full automatic stoppers/caps loading system by vacuum and full automatic unloading into containers of various sizes or into clean bags with thermo-sealing unit technology (for CPE only).
- Full automatic product unloading into bags or containers with RT port and/or thought an VHP isolator (for CPE only).

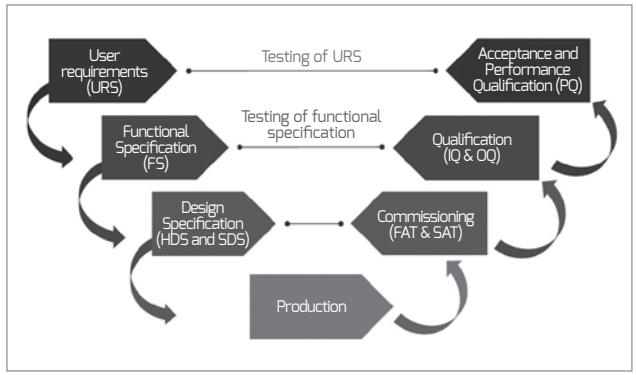
Be green. Be Smart

Sustainability

Concentrating on environmental sustainability as a differentiation feature of the company is an informed decision of LAST, which is in fact convinced and conscious that the attention towards environmental issues can lead to substantial economic benefits in the medium-long term.
The company's decision to invest in human capital highly qualified in the technical-engineering field, and in research projects to develop new equipment and improve their performance in energy and water consumption terms, embodies LAST's idea of being green and considering the environment as an opportunity to grow.

GAMP 5 / V-Model

Sequential approach for system validation.



Activities, Services and Documentation

From the User Requirement Specification (URS) to the machine Qualification, LAST provides extensive documentation and services for supporting all steps of the project as per the internal operating procedures and flow diagram:

- Analysis of URS and reexamination of feasibility
- Project Plan (Gantt)
- Quality Plan (QP)
- Document Qualification (DQ) including P&ID, lay out drawing (GAD), Utility Interface Agreement (UIA), Software Interface Agreement (SIA), Electrical Diagram (ED), Pneumatic Diagram (PD), Bill of materials/ components (BOM), Functional Design Specification (FDS), Software Design Specification (SDS), Hardware Design Specification (HDS), Installation, User and Maintenance Manual (IUMM), Welding Validation Manual (WVM), Machine and software Validation Manual (MSVM).
- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Machine positioning, Installation and Start up
- Installation, operation and performance qualification (IQ, OQ & PQ)
- Training courses
- Program of preventive maintenance
- Spare parts and consumable products

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