



UNiTECH

SERVIZI di INGEGNERIA s.r.l.

WE DESIGN, CREATE
AND VALIDATE TECHNOLOGICAL
AND PROCESS PLANTS
AND FACILITIES

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In **May 2018**



DESIGN

CONSTRUCTION



BRANDING

ESTech
decontamination technology

COMMISSIONING AND VALIDATION





ABOUT US



Unitech has its registered office in Monteriggioni (Siena) and it has been operating since 1996 supplying engineering services to the industrial field, with a high degree of specialization in the **CHEMICAL-PHARMACEUTICAL MANUFACTURING INDUSTRY**.

Unitech's activities include **THE DESIGN, CONSTRUCTION AND VALIDATION OF TECHNOLOGICAL AND PROCESS PLANTS AND FACILITIES**, with priority to the design, construction, start-up and validation of cleanrooms, controlled-contamination areas and process equipment and systems.

Unitech's team of professionals is able to cover multiple needs in order to support its Customers in turnkey constructions: from technical and economic feasibility studies to design, from site supervision, start-up and testing to validation.

Unitech serves its Customers both as a **GENERAL CONTRACTOR** and as a **GENERAL PLANNER** of turnkey projects with the possibility of expanding its responsibility to the validation of the plant.

With the acquisition of ESTech Company, today a Unitech brand, a second sector of activity has also been consolidated: the design, construction and installation of hydrogen peroxide steam generators (VPHP generators) for the decontamination of environment and equipment. In this context, Unitech also operates for the execution of sterilizations and subsequent validations with its own equipment and personnel.

With the ESTech brand, Unitech also continues its activity of designing, manufacturing and validating equipment for the pharmaceutical sector, such as down-cross hoods and LAF systems.

Unitech is an ISO9001:2015 Certified Company.



UNITECH AS A GENERAL CONTRACTOR

Operating as a **GENERAL CONTRACTOR**, Unitech guides the Customer through the entire process leading to the accomplishment of a plant for chemical pharmaceutical production.

Great importance is given to the study of optimal solutions, the result of which are high performance systems managed by intuitive control systems with clear graphic interface and focused on the visualization of key parameters.

- Therefore, Unitech offers:
- Feasibility Studies.
- Business Plan.
- Study and development of the layout with definition of production areas, technical areas and ancillary rooms.
- Definition of personnel flows, raw materials, semi-finished and processed products, and waste.
- Definition of contamination classes and environmental parameters, such as temperature, humidity and pressure, to be guaranteed according to the works performed and the Customer's needs (URS).
- Structural and Architectural Design.
- Design of Mechanical Plants and Process Systems.
- Design of Electrical Systems.
- Design of Control and Management Systems.
- Turnkey Construction with definition of construction details and finishes.
- Start-up and Validation.



ABOUT US

01

Masterplan

Feasibility Study / Business Plan



Preliminary Project

→ Budget ± 15%

02

Extended basic

Definitive Project



Executive Project



Tender

→ Budget ± 10%

03

Installation and Commissioning

Project Construction



Supply of Materials and Installation



Final Tests

04

Validation

Installation Qualification IQ



Operational Qualification OQ



Computer System Validation CSV



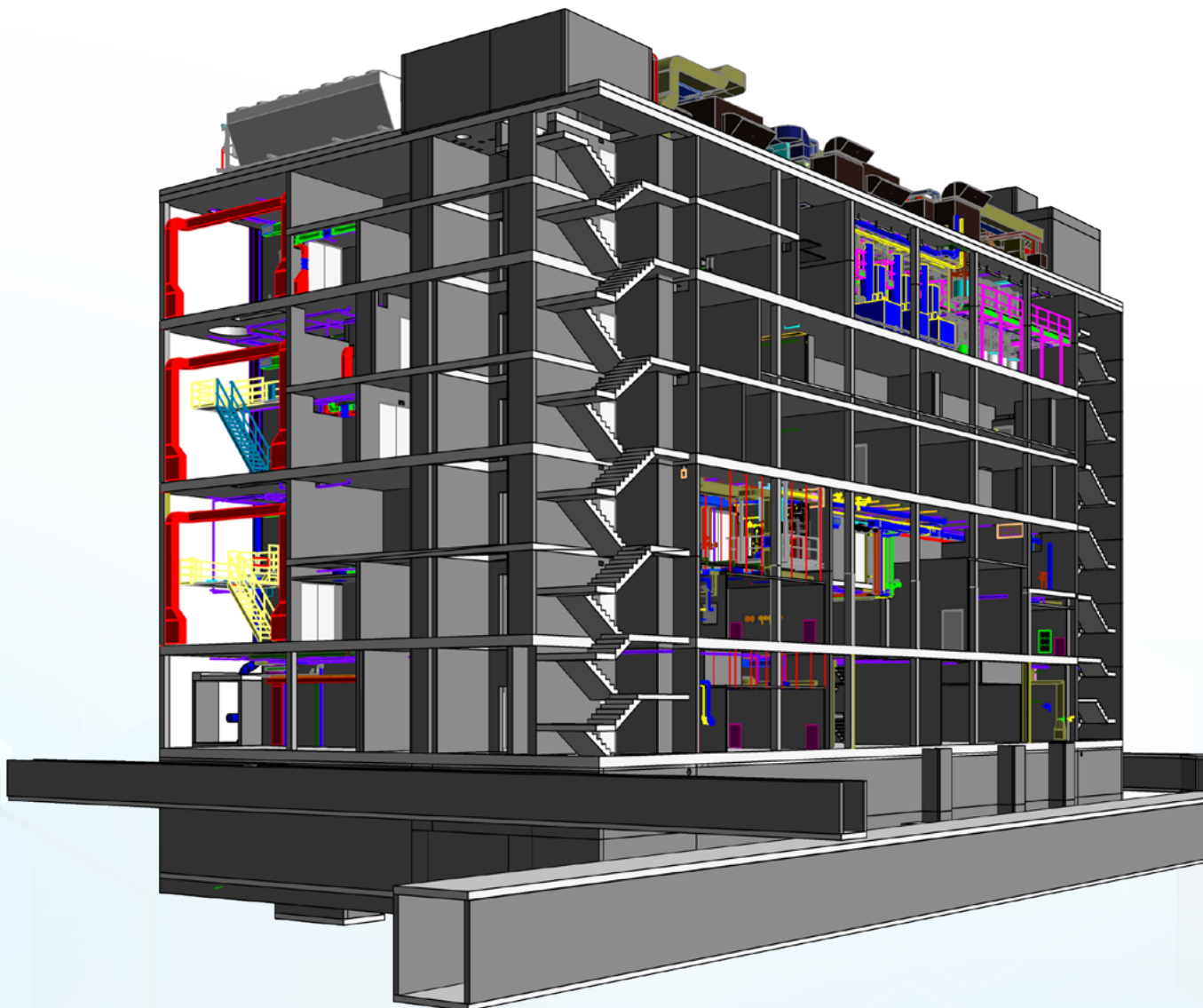
Performance Qualification PQ

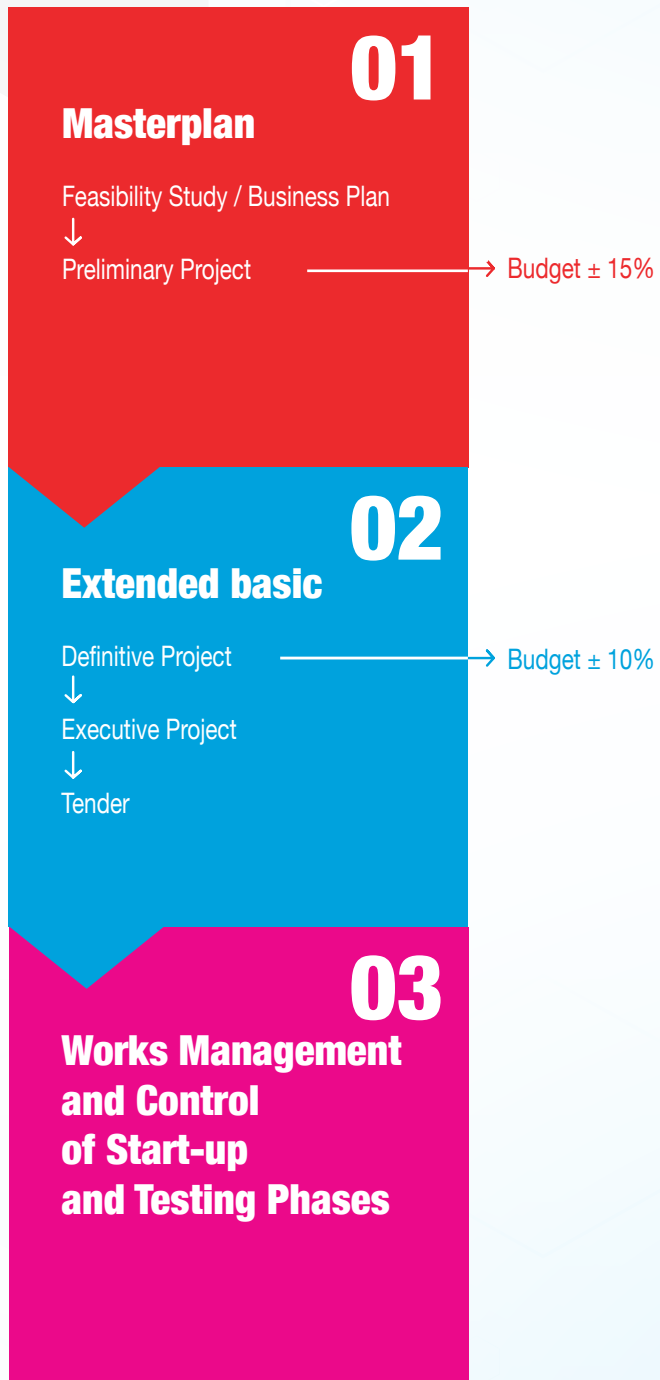
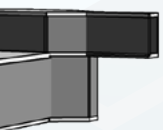


UNITECH AS A GENERAL PLANNER

Unitech is able to adapt to the needs of the Customer by limiting its activity to that of a **GENERAL PLANNER** that is getting the responsibility of the design, supervision to installations and control during start-up and commissioning carried out by the Builder selected by the Customer.

All this is aimed at ensuring that the plant is built and operates as required by the Customer before the latter takes charge.





ABOUT US

UNITECH AS A SINGLE REFERENCE FOR THE ORGANIZATION, PLANNING AND EXECUTION OF VALIDATION

Unitech offers the competence and experience acquired in the pharmaceutical sector for the validation of cleanrooms, plants and equipment.

Unitech is able to support and advise the Customer in all validation phases as defined by the **GMP** Good Manufacturing Practices, as well as to perform the associated tests in a material way.

Therefore, Unitech supports the Customer in conducting the Risk Analysis **RA** and in drafting the Validation Master Plan **VMP**.

Unitech also offers to draw up the User Requirements Specification **URS** in full compliance with the Customer's internal procedures and to prepare the essential elements of the Traceability Matrix **TRM** based on these.

Unitech performs all the validation phases of equipment, plants, fluids and systems as defined by the **GMP** and the Code of Federal Regulation **CFR**:

- Design Qualification **DQ**
- For equipment: Factory Acceptance Test **FAT**
- For equipment: Site Acceptance Test **SAT**
- Installation Qualification **IQ**
- Operational Qualification **OQ**
- For control systems: Computer System Validation **CSV**
- Performance Qualification **PQ**

Both from a documentary point of view and from the execution of assessments.

Unitech also supports the Customer in the management of Change Requests **CRs** and in the drafting of Standard Operating Procedures **SOPs**.

All the documents drawn up by Unitech respect the Good Documentation Practices **GDP**, conforming to the Customer's standards, in full compliance with the Quality System of the latter and, in particular, of its **VMP**.



ABOUT US

01

Organization and Planning of Validation Activities

Risk Analysis RA



Validation Master Plan VMP

04

Validation

User Requirements Specification URS



Design Qualification DQ



Factory Acceptance Test FAT



Site Acceptance Test SAT



Installation Qualification IQ



Operational Qualification OQ



Computer System Validation CSV



Performance Qualification PQ

MECHANICAL PLANTS

The control of environmental parameters is one of the basic requirements for chemical pharmaceutical environments. For this reason, one of Unitech's main sectors of activity is the design, installation, start-up and validation of the following:

- Air Conditioning Systems - HVAC
- Systems for the production, storage and distribution of service fluids - black utilities:
 - Industrial Steam
 - Chilled Water
 - Hot Water





ACTIVITY SECTORS

ELECTRICAL AND CONTROL SYSTEMS

Unitech completes its activities in the plant-engineering sector with the design and construction of electrical systems, both high and low voltage, and BMS management systems.

BMS includes the following:

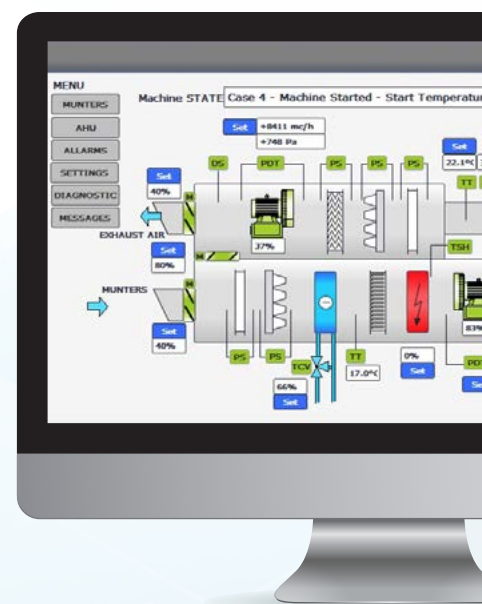
- Field: controlled instrumentation and components installed in the system.
- Direct Control: hardware for the acquisition and management of signals coming from the field and for command sending.
- Supervision: SCADA and HMI.

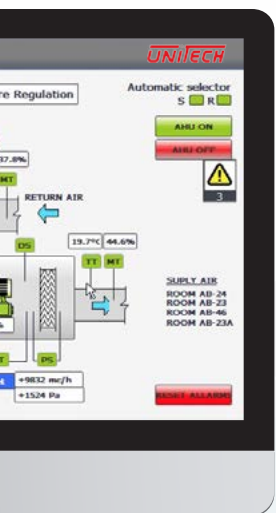
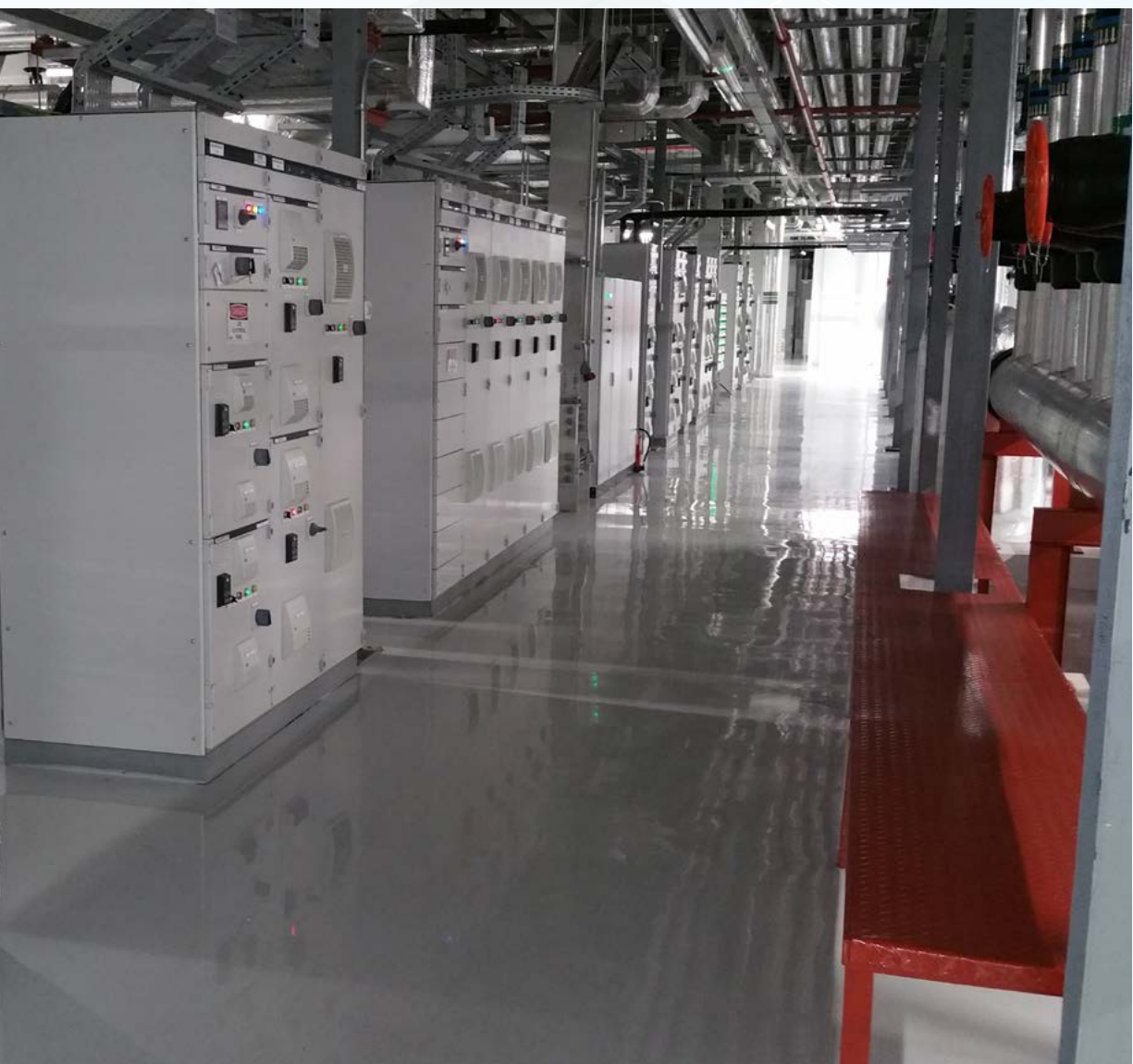
Unitech programs and realizes **with its own competences** SCADA systems adapted to the specific needs of the Customer, compliant with CFR21 as well.

Unitech is therefore able to develop both software and interface graphics.

Unitech guarantees the BMS provided by carrying out FAT and SAT checks on the control panels and on the SCADA.

In the case of CFR21 compliant systems, Unitech is also able to perform the CSV validation according to the Customer's standards.





ACTIVITY SECTORS

PROCESS

As part of the pharmaceutical process, Unitech is able to be the sole referent for the design, installation, start-up and validation of equipment and systems such as:

- Reactors and dissolvers
- Transfer lines
- Filling and bottling machines
- Production, storage and distribution of pure fluids - clean utilities

Osmotized water – RO (Reverse Osmosis)

Pure steam – PS

Purified Water – PW

Water for Injectables – WFI

- Washing systems (CIP, Clean-in-Place)

Unitech is also able to carry out a service of development of pharmaceutical processes thanks to the presence of **personnel trained in the chemical-biological field** within its staff.

Therefore, its Customers can find in Unitech all the **technical-scientific skills** necessary to conceive and implement an entire production process, from a purely engineering definition to that relating to the raw materials to be used and to the product itself.

Unitech also offers qualified personnel able to support the Customer and transfer the necessary knowledge in the early stages of plant production.





ACTIVITY SECTORS

FACILITIES



CLEANROOMS

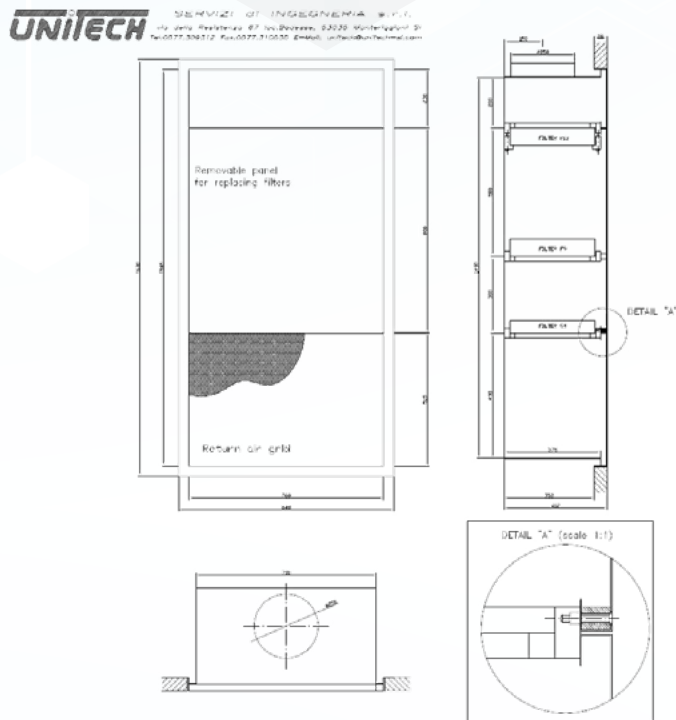


ACTIVITY SECTORS

CLEANROOMS

The “all-inclusive” approach used by Unitech in the management of its works raises the level of attention to details.

Unitech is in fact responsible for the entire installation and, for this reason, it pays particular attention to the choice of plant components, creating custom-made assemblies in order to obtain their perfect integration into the premises.



BOOTHS



ACTIVITY SECTORS

INTERLOCK SYSTEM

The control of door opening in rooms, pass-boxes and equipment is generally a fundamental component of contamination control.

Avoiding the simultaneous opening of doors that connect areas for which a pressure drop is required, such as SAS areas of passage between rooms with different cleaning classes, we guarantee the preservation of the so-called “**pressure cascade**” and, therefore, of the correct direction in the air flow.

Unitech designs, builds and installs interlocking systems.

Unitech creates autonomous systems, systems managed by dedicated local control units, and systems that can be integrated into the SCADA system for plant supervision.

In any case, Unitech integrates the system integrally, thus also dealing with programming and interface graphics.





ACTIVITY SECTORS

MANUFACTURING

Unitech designs, manufactures, installs and validates **equipment for protection against environmental contamination and for the guarantee of sterility such as in hoods and decontamination systems.**

The department of Unitech that manufactures equipment operates under the **ESTech** brand.

ESTech was born as a separate Company aimed at developing and applying a new idea of the use of H₂O₂ hydrogen peroxide steam generators for decontamination of environments.

The innovation lies in the fact that the **VPHP** (Vapour-Phase Hydrogen Peroxide) generator developed by ESTech does not require any auxiliary equipment for the distribution of hydrogen peroxide vapour in decontaminating both large and small volumes.

The VPHP is a system that can be integrated into new or existing air conditioning systems to service the areas to be decontaminated.

From this it is easy to understand how there has always been a close connection and collaboration between ESTech with its new VPHP and Unitech with its ability to design and build plants and control systems.

This connection is so strong that Unitech made the decision to incorporate ESTech inside its company, thus eliminating the formal aspect that divided them into two different companies.

Unitech has assessed the importance acquired by ESTech in the field of hydrogen peroxide vapour decontamination and it has kept its name as a trademark for this reason.

The ESTECH VPHP range includes generators with peroxide steam production capacity ranging from 0.8 to 44 Kg / h.

The standard configuration is for the sterilization of controlled contamination environments equipped with HVAC conditioning systems:

the VPHP is inserted inside the HVAC and interfaced with its control system. Therefore, it will be the same HVAC system carrying the peroxide vapour during decontamination. In the same way, once the peroxide intake by the VPHP has been completed, the same plant will introduce the washing air into the rooms subject to decontamination to eliminate the peroxide.



THE ESTECH BRAND

TECHNICAL DATA

Model	Max H ₂ O ₂ vapour production (kg/h)	Application field	Air flow (mc/h)	Air static pressure (Pa)	Electric power input (kW)	Electric power input with de-humidifier (kW)	Size Width x Height x Depth (mm)	Weight (kg)
LGH 0.8	0.8	Biohazard hoods Materials decontamination box Isolators	30	400	1,6	/	380 x 240 x 260	12
CMP 1.6	1.6	Materials decontamination box Isolators	100	800	3,1	/	420 x 400 x 260	44
CMP 3.6	3.6	Filling machines	200	2100	/	7,8	500 x 760 x 500	82
CMP 7.2 *	7.2	Clean rooms HVAC for clean rooms	500	800	12,5	/	950 x 1260 x 600	118
CMP 16	16	HVAC for clean rooms	160	2200	18,8	21,6	1000 x 1950 x 550	240
CMP 22	22	HVAC for clean rooms	200	2100	24,5	28,2	1000 x 1950 x 550	240
CMP 44	44	HVAC for clean rooms	320	2200	48,4	52,8	1000 x 1950 x 550	345

* Wheeled

Data reported in this paper might be changed without notice. Please do not hesitate to contact ESTech for further information before ordering the generators.

MANUFACTURING

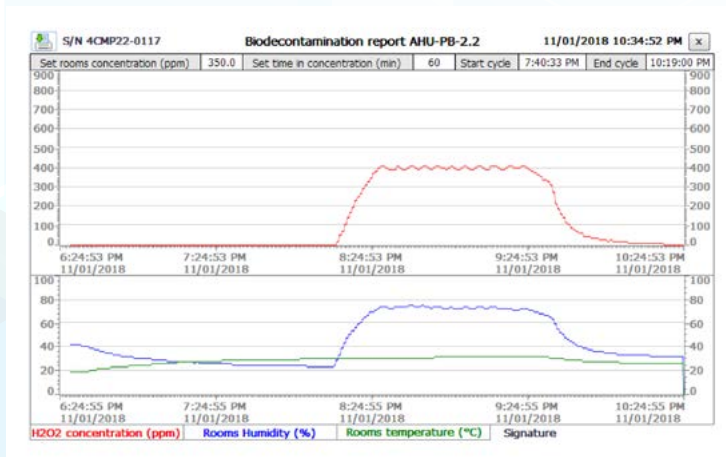
There are then more compact generators, up to becoming portable, for the treatment of environments not equipped with HVAC systems. The most common use is for the decontamination of the following:

- - Biohazard or Laminar Flow Hoods
- - HEPA Filters
- - Areas surrounding the aseptic filling or packaging areas for sterile or easily perishable products



Unitech also continues the service activity already provided by ESTech by performing decontaminations with its own equipment and personnel at Customers who have not yet purchased the VPHP system.

The effectiveness of decontamination is verified both with chemical and microbiological tests.



Unitech uses the ESTech brand to continue its activity of designing, manufacturing, installing and validating systems to protect against contamination and cross contamination risks.



THE ESTECH BRAND

NETWORKING

Over the years, UNITECH has developed experience and expertise in the service of the pharmaceutical industry, always keeping in mind the regulatory updates and new technical solutions that the market offers every day.

For this reason, Unitech is registered in sector associations of international importance.



Associazione per lo Studio e il Controllo della Contaminazione Ambientale



Unitech proves to be innovative with publications in magazines of international importance.



Unitech expands its network of contacts thanks to the participation in major trade fairs and international exhibitions and conferences all over the world.



Unitech is a TLS incubated company

THE TLS FOUNDATION: Toscana Life Sciences is a non-profit organization active in the regional Tuscan territory to support research activities and encourage the emergence of innovative companies in the field of Life Sciences. Born on the impetus of the main institutional subjects of university, clinical, industrial and financial worlds in Tuscany, the Foundation is based in Siena, in the historic area of "Torre Fiorentina", where in 1904, Achille Sclavo founded the homonymous Tuscan Therapy and Vaccinogenic Institute and where today important vaccine multinationals strategically choose to locate their main research and development activities.

<http://www.toscanalifesciences.org/it/bioincubatore/imprese-incubate/>



Year	Client - Country	Activity by Unitech	
		P - Design and Site management M - Start-up and Commissioning	C - Construction V - Validation
2018	Siegfried Ltd - M	AS BUILT HVAC systems for the addition of dehumidifiers	P
	Propharmal - DZ	Walls and HVAC and control systems for 4 weighing stations	P
	Kedrion - IT	Siena plant - Equipment and hoods. Including instrument calibration	V
	Philogen -IT	Montarioso plant (SI) - PW loop revamping	P
2017	New FaDem - IT	Turnkey for cream department revamping class D	P - C - M - V
	Kedrion - IT	Siena plant - Equipment and hoods. Including instrument calibration	V
	Synthesis - IT	HVAC systems for class B - C - D areas and process machines	V
	Galenica Sen. - IT	HVAC systems for class A - B - C - D areas	V
	Pfizer Wyeth Lederle - IT	Catania Plant - Modification to PW, WFI, PS clean utilities' and IS, TOWER WATER, CONDENSATION black utilities' systems for the installation of new steam generators and distiller. Including changes to SCADA. STEP 2	P
	Celonic - CH	HVAC revamping and walls for new reactor	P - C - M - V
2016	Tabuk Ph. - UAE	VPHP generators (on behalf of La.ser company)	P - C - M - V
	New FaDem - IT	LAF for sampling department	P - C - V
	New FaDem - IT	Turnkey for the realization of new sampling departments and class D dispensing	P - C - M - V
	Siegfried AG - CH	BAU 425 - HVAC systems, electrical, control and industrial fluids for new API department of about 200 sq. m	P - C - M - V
	Propharmal - DZ	Modifications to load-bearing structures, walls, finishes and new HVAC, electrical, control and fluid systems for modification and expansion of the existing plant for the construction of new granulation and production departments. Total area about 1400 sq. m	P

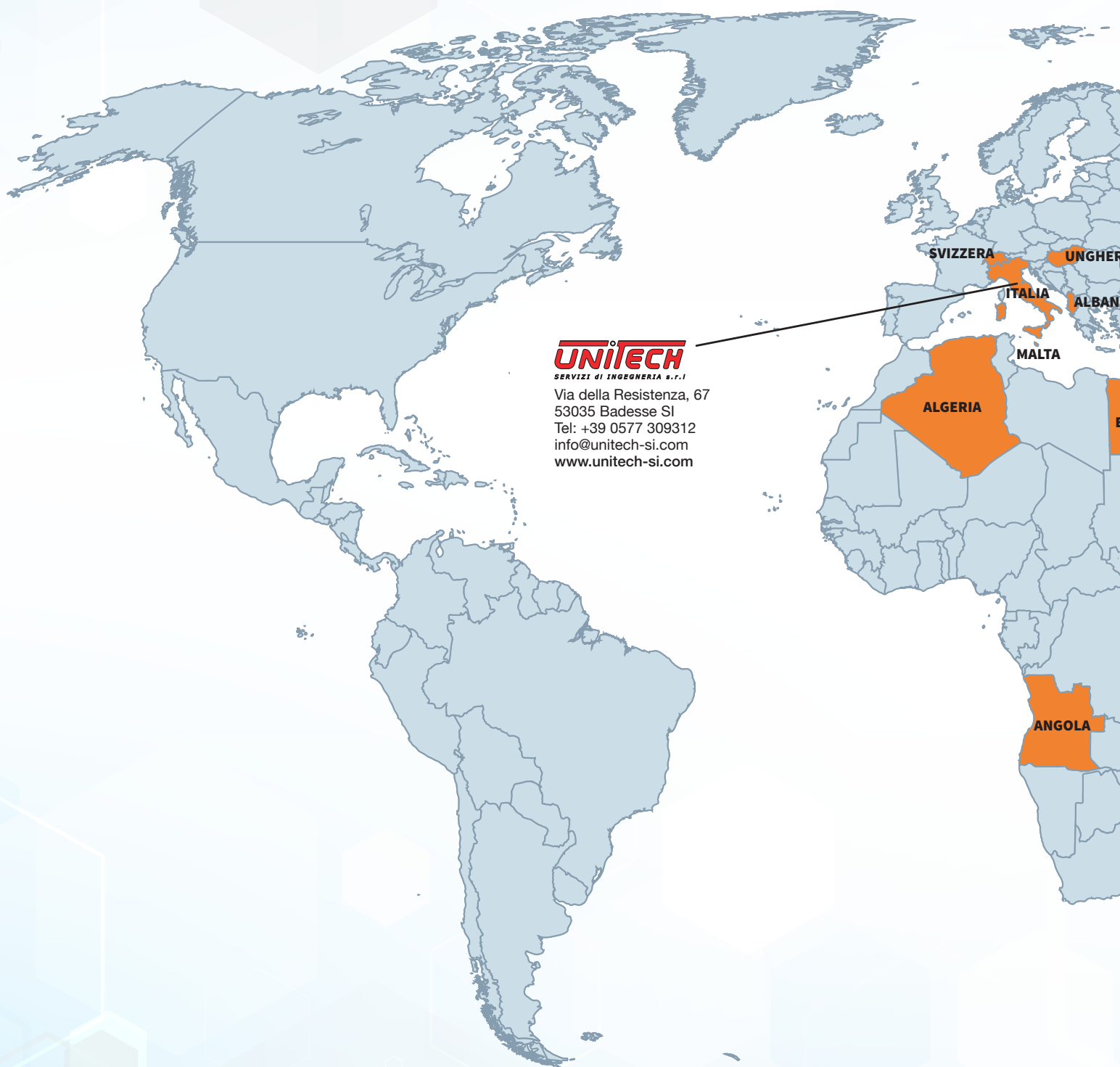
Year	Client - Country	Activity by Unitech	
		P - Design and Site management M - Start-up and Commissioning	C - Construction V - Validation
2016	Synthesis - IT	HVAC systems for class B - C - D areas and process machines	V
	Pfizer Wyeth Lederle - IT	Catania Plant - Modification to PW, WFI, and PS clean utilities' and IS, TOWER WATER, CONDENSE black utilities' plants for the installation of new steam generators and distiller. Including changes to SCADA	P
	Galenica Sen. - IT	HVAC systems for class A - B - C - D areas	V
2015	Tabuk Ph. - UAE	HVAC and control systems for class D rooms with a total surface area of 4200 sq. m (on behalf of La.ser)	P - C - M - V
	Liofilchem - IT	Reactors for product preparation of capacity 500 and 360 l	P - C - V
	Propharmal - DZ	Turnkey for 3 down cross hoods and warehouse HVAC system	P - C - V
	Marcyrl Ph. - ET	HVAC and control systems (on behalf of La.ser company)	P
2014	Galenica Sen. - IT	HVAC system for class B - C - D rooms	P - C - V
	Siegfried AG - CH	BAU 425 - HVAC systems, electrical, control and industrial fluids for new production plant. Total area 9800 sq. m	C - M - V
	Bial Aristegui - IT	HVAC systems for class B - C - D areas and process machines	V
2014	Galenica Sen. - IT	HVAC systems for class A - B - C - D areas	V
	Tabuk Ph. - UAE	HVAC and control systems (on behalf of La.ser company)	P - C - M - V
	SEDICO - ET	HVAC, electrical, control systems (on behalf of La.ser company)	P - C - M - V
	Siegfried AG - CH	BAU313 - HVAC system and related instrumentation for production booth composed of sas personnel, sas materials and class D production area	P - C - M - V

REFERENCES

Year	Client - Country	Activity by Unitech	
		P - Design and Site management M - Start-up and Commissioning	C - Construction V - Validation
2014	Bial Aristegui - IT	HVAC systems for class B - C - D areas and process machines	V
	Galenica Sen. - IT	HVAC systems for class A - B - C - D areas	V
	Propharma - DZ	HVAC system, pharmaceutical walls and furnishings for new SAS personnel	P - C - M - V
2013	StarPharma - M	HVAC system for 3 class C and D rooms	P - C - M - V
	Siegfried Ltd - M	HVAC system for new class C "blending" department	P - C - M - V
	Bial Aristegui - IT	HVAC systems for class B - C - D areas and process machines	V
	Galenica Sen. - IT	HVAC systems for class A - B - C - D areas	V
	Biomeest - DZ	"Turnkey" for new production plant. Surface of controlled contamination area: 850 sq. m	P - C - M - V
	Siegfried AG - CH	BAU 425 - HVAC systems, electrical, control and industrial fluids and fire protection for a new production site. Total area 9800 sq. m	P
	Siegfried Ltd - M	HVAC, electrical and control systems for new class D rooms (Phase4)	P - C - M - V
	Siegfried AG - CH	BAU530 – Stainless steel cabins for pharmaceutical chemical production	P - C - M - V
	Siegfried AG - CH	BAU228- Revamping of HVAC systems and building service control with class D areas and technical zones subjected to temperature and pressure control	P - C - M - V
2012	Siegfried Ltd - M	"Turnkey" of 2 stability rooms of 15 square meters each: walls, HVAC, electrical and control systems	P - C - M - V
	Diversey - IT	HVAC systems	V
	Siegfried Ltd - M	"Turnkey" of dust containment cabin and air shower: walls, HVAC, electrical and control systems	P - C - M - V
2011	Siegfried AG - CH	HVAC and control systems for class C laboratories	P - C - M - V

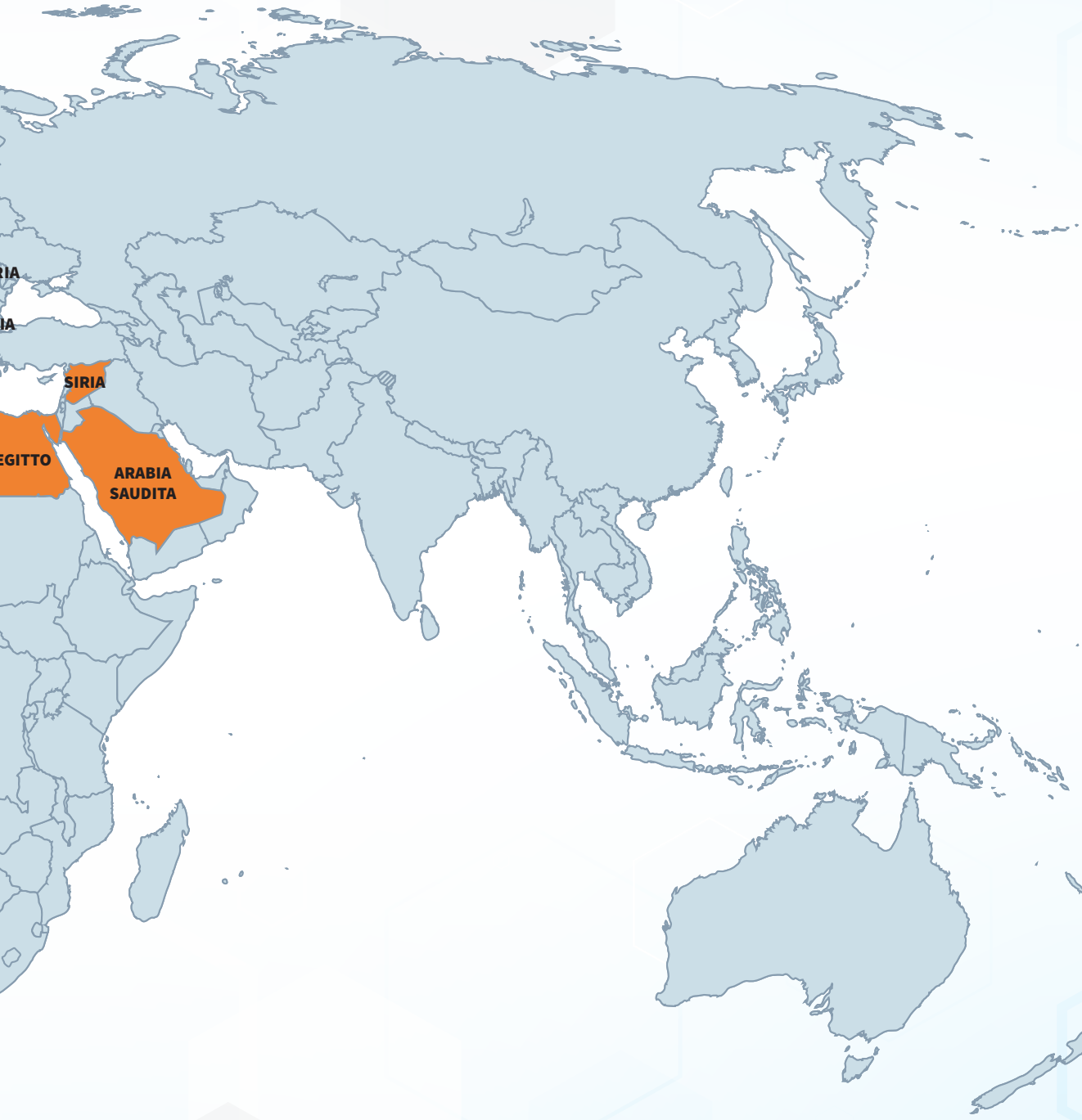
REFERENCES

Year	Client - Country	Activity by Unitech	
		P - Design and Site management M - Start-up and Commissioning	C - Construction V - Validation
2011	Siegfried Ltd - M	Revamping of composters and blistering departments, class C production areas	P - C - M - V
	Novartis - IT	Bellaria factory, Rosia (SI) - Industrial steam production plant with capacity 16.000 Kg / h (On behalf of Jacobs Company)	P
	Sanamed - DZ	HVAC systems for granulates production plant	M - V
	Gedeon Richter in Debrecen - H	HVAC and process systems (on behalf of Jacobs Company)	M - V
2010	Saidal Constantine - DZ	Validation of autoclaves and process machines	V
	NCPI Aleppo - SYR	HVAC and control systems for the production and filling of sterile liquids, granules and powders, and oral liquids. 2400 sq. m total	P - M - V
	Novartis - IT	Validation of autoclaves and process machines	V
	SARM Allergeni - IT	Validation of HVAC and process machines	V
	Novartis - IT	Bellaria factory, Rosia (SI) - HVAC and electrical systems for laboratories, auditoriums and offices	P
2009	Galenica Senese - IT	HVAC system and contamination control (LAF) for production and filling department	V
	Toscana Life sciences - IT	"Turnkey" of thermostatic cell: walls, HVAC, electrical and control systems	P - C - M - V
2008	Siena Biotech - IT	HVAC, technology and gas systems	P - C - V
	Wyeth Catania - IT	PW, WFI and PS systems	P - C - M - V
	Sanofi Aventis - IT	PW plant	P - M - V



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azienda con il sistema di gestione per la qualità certificato

ISO 9001:2015