



PRODUCTIVE SOLUTIONS FOR EFFICIENT PROCESSES



EFFICIENT MANUFACTURING

PRODUCTIVE INSTALLATION



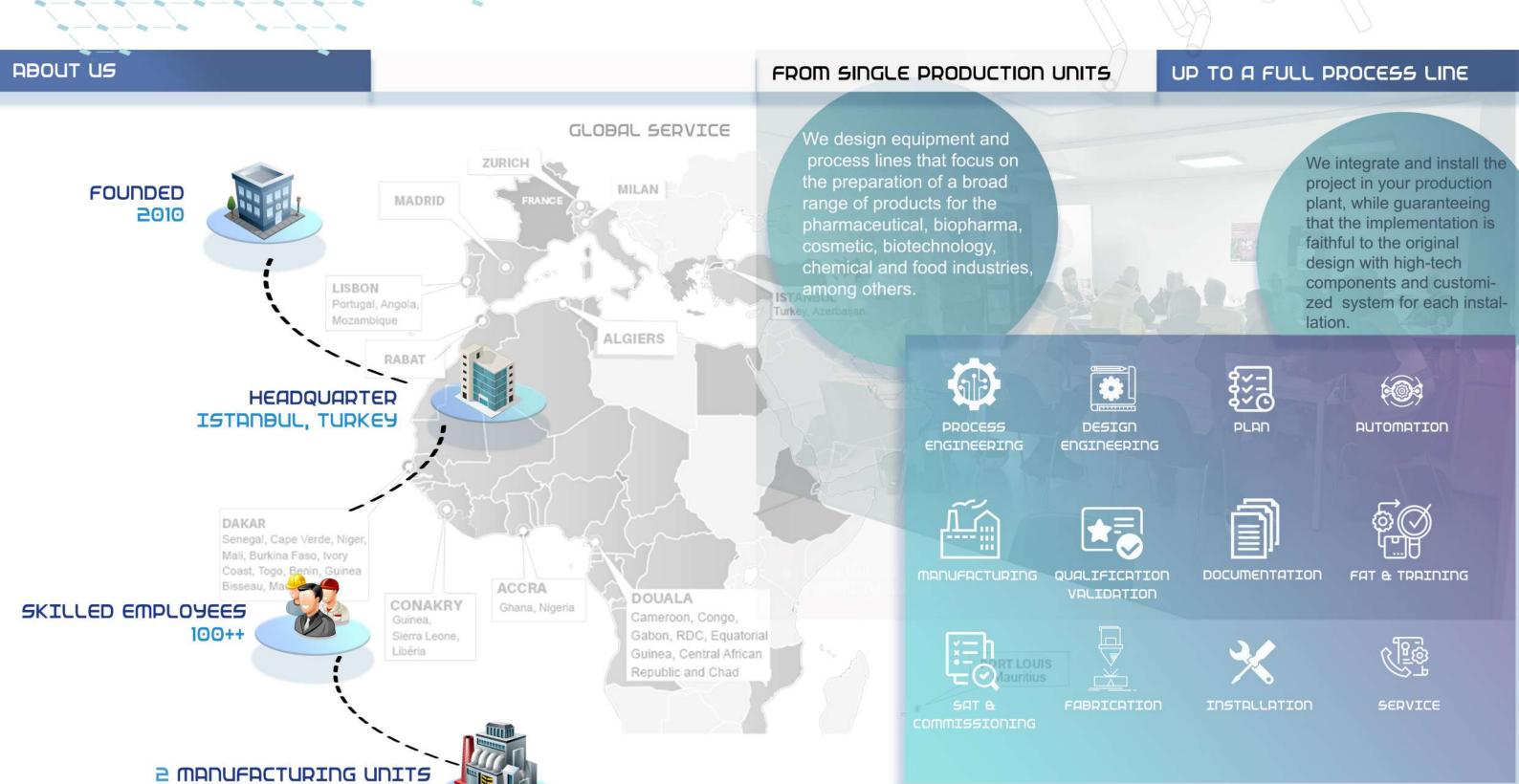
PRODUCTIVE SERVICE

TURNKEY SOLUTIONS













## VISION/MISSION

To lead the global industrial footprint with distinguished solutions and be a partner in growth for our customers. With exceptional customer focus and astute project management skills our mission is to bring inspiration and ingenuity to everything we engineer. We aim to enhance the credibility and success of our customers through our reliable path-breaking systems and equipments by being as future-oriented and diversified as the industry in which we operate.



## LIQUID PROCESS

PRODUCTION TANKS
STORAGE TANKS
PRODUCT TRANSFER SYSTEMS
TEMPERATURE CONTROL SKID
CIP/WIP/SIP CLEANING SYSTEMS
CONTROL UNITS
AUTOMATION

#### SEMI SOLID PROCESS

PRODUCTION VESSELS
SYSTEM INSTRLLATION
UTILITY CONNECTIONS
CIP-SIP SYSTEMS
PIGGING SYSTEMS



## SOLID PROCESS

SYSTEM INSTALLATION PLATFORM INSTALLATION CIP SYSTEMS VACUUM SYSTEMS

## WATER PROCESS

PRE-TREATMENT SYSTEMS
PW PRODUCTION
PW STORAGE & DISTRIBUTION SYSTEMS
WFI STORAGE & DISTRIBUTION SYSTEMS
PS DISTRIBUTION SYSTEMS
PASSIVATION PROCESS
COMMISSIONING & DOCUMENTATION
AUTOMATION



## BIO-PHARMA

BIO-PHARMA
VACCINES
STERILE FORMULATIONS
MDI (METERED DOSAGE INHALER)







# PRODUCTION TYPE

**Hygiene safety**: Sanitary - design stirrers meeting ASME BPE standards that maintain seal tightness and vacuum conditions. CIP/SIP cleaning process can be easily integrated in the vessel.

Easy loading of raw materials via vacuum or other systems: Complete emptying of vesselguaranteed, in accordance with ASME BPE standards.

Customizable capacity according to the client's requirements: Vessels equipped with magnetic mixers allow working from 10-15 % up to 100% of its usable.

**Control system:** With the customized software by VENTUS PROCESS you can automate recipes, record process variables, adjust dosing and manage the heating/cooling with temperature control.

#### CUSTOMIZED VERSATILITY

**Integrated solutions:** Turnkey production plants for the cosmetic, pharmaceutical and food industries, including production vessels, accessories, such as melting and auxiliary tanks, as well as cleanrooms, utilities and air treatment system.

**Consulting:** Through dynamic and continuous dialog with the client, our team of experts in chemical engineering and mechanical and electrical processes develop the perfect solution for each project.

**Conceptual design for optimal performance:** We study personnel and product flows, as well as storage requirements to design the most versatile and cost - effective plant.

**Optional Supervision System:** Integration of eqipment control in a SCADA system for remote control and maintenance support.

Control system: With the customized software designed by VENTUS PROCESS you can automate recipes, record process variables, adjust dosing and manage the heating/cooling process with temperature contrai. Delivery with CE or UL markings and optional complance with Title 21 CFR Part 11 Regulations.









#### GRANULATION PROCESS LINES

#### **Full installation solutions:**

Ranging from the key eqipment, such as high - shear mixer - granulators and fluid bed dryers, up to ail accessories, including safeo/ systems, binder solution tanks, wet and dry mills, vacuum air systems for producttransfer and CIP/WIP cleaning sy stems.

We advise, conceptualize, design, manufacture, install and put granulation lines into operation to cover the requirements of the life science and chernical industry.

Hygienic design: In accordance European Machinery Directive (2006/42/EC) to prevent cross contamination.

Control system: With the customized software designed by VENTUS PROCESS you can automate recipes, record process variables, adjust dosing and manage the heating/cooling process with temperature contrai. Delivery with CE or UL markings and optional complance with Title 21 CFR Part 11 Regulations.

## EFFICIENT SANIT ARY AND INDUS TRIAL CLEAN

## - IN - PLACE (CIP) SYSTEMS

From design and fabrication to installation and start up by Ventus Process. CIP/SIP/WIP skids are designed to clean and/or sterilize egipment in pharmaceutical, biotechnological, cosmetic and food & beverage industry production, guaranteeing compliance with the strict cleanliness re@irements of these sectors. We help our clients comply with current regulations and manufacture their products without any cross contamination, a key element in guaranteeing the quality of the final product.

#### Ventus Process Systems provides multiple CIP design options:

- Single pass
- Single use
- Multi tank reuse systems
- Educator assisted CIP return designs
- Dual and simultaneous solution supply

Our CIP design criteria is based on present 3 A, USDA, cGMP, ASME (U&R), BPE, FDA and API standards. Process contrai can be achieved through existing PLCs, self supporting contrai systems or manual operations.

### Our Clean-in-Place (CIP) techonology offers significant advantages to manufactueing facilities including:

- Improved operational hygiene and cleaning efficiency due to reproducible cleaning processes
- Improved product Q.Ualiry, recovery and puriry due to enhanced plant hygiene
- Reduced expenditure of time and personnel for manual!Y performing the cleaning tasks
- · Reduced pollution and production costs through the effective use and reuse of water, cleaning chemicals and boiler condensate
- A safer, more consistent method of plant sanitation



Time-Time saving: Fast "in place" cleaning process.

Safety: Prevents cross - contamination

Automatic and repeatable: Fui!}' automated process via certifiable software with consistent re-

sults from each cleaning cycle.

Cost reduction: Low energy, water and detergent consumption.

Mobile or fix:ed versions: VP Clean units can be designed to be static or mobile, according to the client's needs. They are always designed to be as compact as possible to gain space and reduce weight.







## PURIFIED WATER (PW) AND WATER FOR INJECTION

## STORAGE AND DISTRIBUTION SYSTEMS (WFI)

Purified Water and Water for Injection Storage and Distribution Systems

Function and use: Distribution loops for water of different qualities necessary for production Advantages;

**Comprehensive engineering:** We guarantee an optimum integration with the rest of the plant installations and a rapid assembly.

VENTUS PROCESS designs storage and distribution systems in compliance with the standards requested by International Pharmacopoeias.

#### Validation

VENTUS PROCESS cGMP Compliance & Validation area organizes and develops validation activities User reQuirements specification preparation (URS).

Functional & design specification preparation (FOS).

Design Qualification (DQ).

Installation Qualification (IQ);

Operational Qualification (OQ);

Computerized control system validation as per GAMP and 2 1 cfr part. 1 1 requirements.

## WATER, A BASIC ELEMENT FOR PRODUCTION

#### Purified Water and Water for Injection Production

VENTUS PROCESS design that Reverse Osmosis + Electro Deionization (RO + EDI) plants constitute a reliable alternative to the traditional double stage Reverse Osmosis for the production purified water. VENTUS PROCESS design RO+EDI plants in compliance with the standards requested by International Pharmacopoeias.

#### Distillation (WFI) Unit Design

Total energy saving is 75% as less heating energy and less cooling water are required.

Pyrogens are removed by centrifugai force developed & specially designed spiral baffle.

All contact parts are SS316 quality.

All pipes and tubes are seamless, and PTFE gaskets.

Distillate Temperature is quite high; 90 C - 95C

Distilled water as per IP/BP

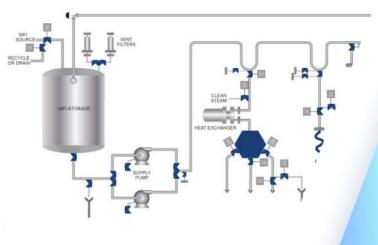
standards and conductivity less than 1 micromhos/cm.

Online temperature monitoring of WFI

Conductivity monitoring and control for feed water & WFI

Automatic feed water control to prevent column flooding





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Sterile formulations manufacturers are looking for strong and effective solutions to compound a wide variety of formulations, which include

products administered by injection (IV, IM, IP, SC-SQ, ID, intrathecal, epidural) or via otic, intranasal or

ophthalmic routes.

We have decades of experience in developing innovative technologies and smarter solutions for challenging pyrogen free and sterile formulations.

#### **Efficient Systems:**

- Manufacturing/ Compounding vessels.
- · Holding/ Filtration vessels
- · Filtration skids with Integrity testing
- · Buffer vessels for all filling lines
- CIP systems
- SIP systems
- · Neutralisation systems/ Inactivation systems
- Integrated suites
- WFI coolers

Bio-pharma and vaccine industries require large investment in time and capital to effectively translate scientific discovery into novel and affordable therapies.

With years of experience, VENTUS PROCESS has become a strategic driver in providing scalable and flexible bioprocess solutions of high quality.

#### **Efficient Systems:**

- In-Situ Fermenters/ Bioreactors
- Upstream bioprocess vessels for Media /Buffer preparation, Feed hold, Serum Vessels
- Transfer sterile filtration skids with Integrity testing
- Downstream processing Harvest Vessels, Pooling Vessels, Buffer preparation, Purification Vessels
- TFF/ Cross flow concentration Skids
- · Blending/ Formulations vessels
- Product feed vessels for filling machine
- Integrated suites
- Virus inactivation systems
- Bio-kill/ Decontamination systems Continuous & Batch
- CIP systems Mobile/ Centralized
- SIP systems Integrated/ Standalone
- Temperature control units (TCUs)



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There has been a significant rise in the prevalence of the diseases that are related to the respiratory system such as chronic obstructive pulmonary diseases, asthma, chronic respiratory diseases and others.

The demand for the metered dose inhalers, Dry powder inhalation and nebulizers has increased.

We have vast years of experience in designing and executing standalone and integrated process systems from Pilot to production scale with VibroMixers, Top mounted Agitators and Bottom mounted Magnetic Mixers.

#### **Efficient Systems:**

- Mixing/ Compounding Vessel
- Homogenizing Vessel
- API charging ball/ Drug addition vessel
- Integrated suite
- Inbuilt or Standalone CIP system

#### **Process Tanks**

VENTUS Process Systems designs and fabricates stainless steel process vessels to 3-A, USDA, cGMP, ASME (U&R), BPE, FDA, and API standards. Fabrication is completed in a 100% stainless steel hygienic and controlled environment to prevent cross contamination of materials. Process vessels are designed for optimal clean-in place capabilities.

Various heat transfer options available. Custom agitation systems available.



## Filter Housing Production

VENTUS PROCESS produces sterile filter housing and integrated into our process equipment.

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#### **Engineering and Design Resources**

The process design engineers at VENTUS PROCESS offer several services including industrial process design, hygienic process design, Clean-In Place (CIP) system design and circuitry, and piping design.

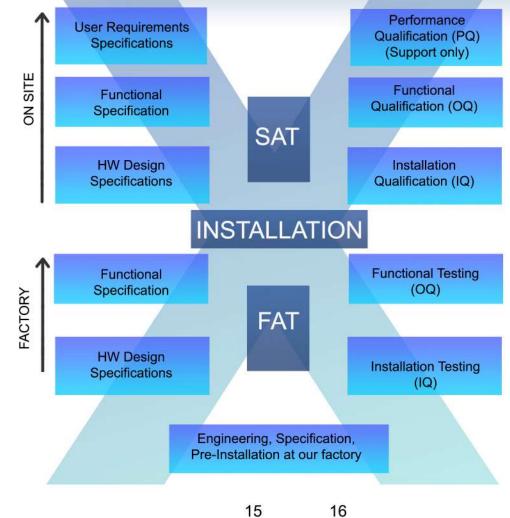
Process design engineers at VENTUS PROCESS work with you to evaluate your unique needs and assume responsibility for the complex details of multi-phase projects, including assessment of existing process systems or eQUipment, system design, automation, documentation to support validation and one-on one start up training.

#### **Skilled Team**

VENTUS PROCESS' certified welder, skillied pipe fitters and experienced supervisors have been trained for site works especially with the equipment below

- · Orbital welding,
- · Orbital cutting,
- · Borescope,
- · Pipe installation according to pharma requirement,
- · HSE,



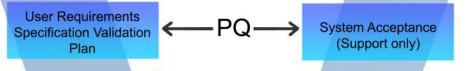












Quality Plan

Functional
Specification
Sequences/Recipes

HW Integration Test
SW Integration Test
(OQ Protocol and Report)

HW Design Specifications
SW (Module Design Specifications)
PLC/OPC/PCS/Feldbus/SCADA/LAN

TOP DOWN

 $\leftarrow$ IQ $\rightarrow$ 

**HW Construction** 

HW Purchase SW Implementation HW Component Acceptance SW Module Testing (IQ Protocol and Report)

Validation Report

**BOTTOM DOWN** 



#### Codes, Guidelines and Standards

- ASME BPE
- · ASME/PED
- GAMP
- CGMF
- FDA, MHRA, WHO
- ASME U-Stam
- 21CFR Part 11 compliance
- UL
- EHEDG
- CE
- ATEX/ IECEx/ EXd/ EXi/ Exe/ FLP



































EXDERTISE



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