Process Solution for Pharmaceutical and Biotech industries

tecninox group

Company profile

THE GROUP

01 > **TECNinox**
Headquarter

02 > **Ilinox**
Manufacturing facility

03 > **Ilinox Kft.**
Manufacturing facility

04 > **ERsistemi**
Software automation facility

Team Synergy

In the central head office the management group has its seat: design process, innovative approach, business activities and marketing, management, purchasing, training and quality control.
A team of Project Managers, engineers, software, experts, analyzes the vendor jobs in detail evaluating accurately the technical aspects, in continuous partnership with the final customer.

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From 1983 Ilinox is leader in stainless steel electrical control cabinet and process vessels production unit. In all these years Ilinox create a very specialized production and marketing team, thanks to a qualified staff and advanced technology to guarantee quality and reliability to its customers.
All vessels are made out of stainless steel and can be supplied as stand-alone equipment or as automated process units integrated in fully functional module.

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Established in 1995, Ilinox Hungary is a few kilometers far from Budapest. A compact and reliable team of specialized technicians supports an extreme flexible structure for the production of stainless steel electrical control cabinet.

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ER Sistemi is an hardware and software integration company. Became part of TECNinox group in 1995 is specialized in the design and realization of automation systems for process control by PLC, PC and DCS. ER Sistemi 's staff is able to use PLC, SCADA and BATCH products, manufactured by the world 's leading suppliers, of which we are also partners: this enables us to offer the best solution to customers.

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tECNinox quality by design

HISTORY

1978 > TECNinox a history of passion and success.

In 1978 Giovanni Miglioli and Vito Bocchi, after twenty years' experience in the realization of food/pharmaceutical plants, decided to make their business dream true. Thanks to their enthusiasm and competence they specialize more and more in the design and realization of process system for the production of liquid dose technology becoming the reference for the most important world-wide industries.
Passion for work!

A winning choice!

tiTECNinox group

Innovation for over 40 years

Head office

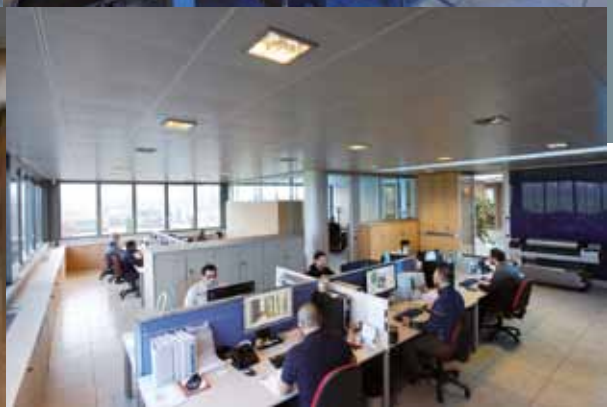
In the central head quarter the group has its strategy,
Our corporate vision is based on passion, commitments, spirit of sacrifice.
We focus our knowledge and competences on the engineering and development of high-tech equipment for Pharma and Biotech industry.

Team

A team of Project Managers, engineers, software experts, analyze the specification in detail, evaluating accurately the technical aspects in continuous partnership with the final customer.
More than 250 motivated and highly educated employees follow the company's vision always with passion.





To be responsible for the entire manufacturing process and to control the technology

Every project is different... Every solution is unique.

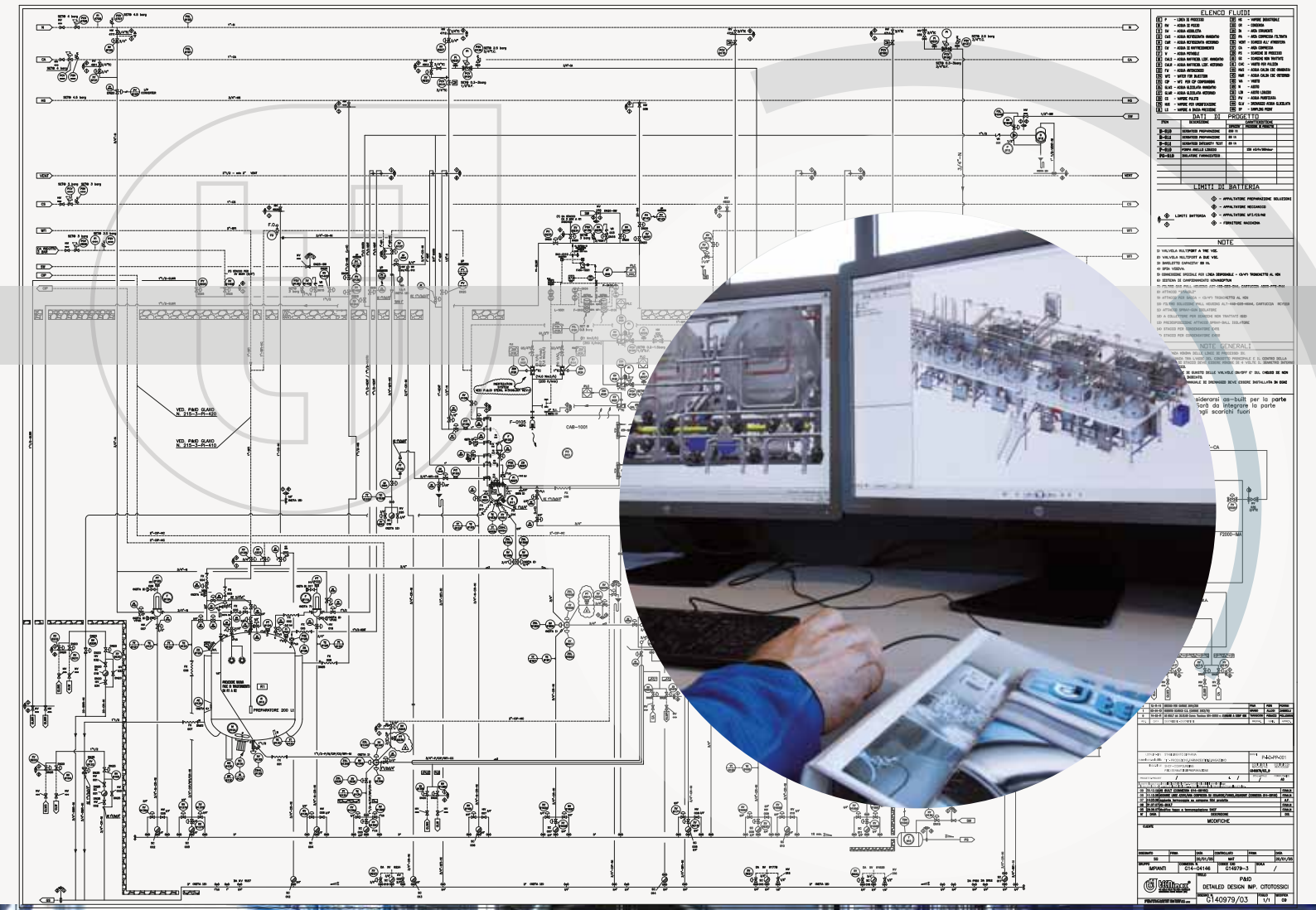
TECNinox is a leading international supplier of integrated process systems for the production of liquid products for the pharmaceutical and biotech industries.

Core Competencies

Working closely with our customers TECNinox's scope of supply ranges from planning, development and installation of completely integrated production lines. Our experienced engineers will collaborate with your project team to supply innovative and efficient process solutions for your applications.

The extensive product portfolio, technologies and services includes complete system and components for the production of:

- insulin
- cytotoxic
- vaccines
- clean utilities
- blood-derived products
- monoclonal antibodies
- syrup and suspension
- large volume parenteral



Engineering

The company's engineering expertise in Pharmaceutical equipment, clean utilities, electrical, mechanical erection utility piping; pharmaceutical capacity simulation system, integrated automation - IT processes, and 3D modeling

To deliver the complete design solution, TECNinox's engineering team draw on the disciplines of Vessel Design, Process, Mechanical, Electrical and Automation and are continually challenged to develop innovative process solutions for our clients. The development of the design goes hand-in-hand with 3D Modelling of the systems. These models are used to fully articulate the design development, allowing the client to fully critique the "virtual" model of the systems. From virtualization to reality.

From design to realization

To be responsible for the entire manufacturing process and to control technology. This is the only way to blend experience and technology together in a constantly new alchemy, ensuring a continuous evolution that always starts with field experience.

LIQUID FORMS

Based on the TECNinox concept, we are in the unique position of being able to offer our clients absolute, industry-specific solutions at every stage of development. We offer total solutions, from process engineering, through commissioning and qualification.

We manage the project, coordinating all activities and taking full responsibility to ensure your plant is in production on schedule. Cost overruns, time delays and technical difficulties typical of conventional construction are thus minimized, making the whole process more effective and, more importantly for you, far more economical.

TECNinox has become one of the leading vendors in the field of designing, manufacturing and commissioning so-called “skids module approach”.

Our product portfolio includes process plant for the manufacture of liquid products for the pharmaceutical and biotechnology industries.

LIQUID FORMS

The modular approach is an ideal application to defer the fabrication of complex piping and instrumentation to a shop environment where there is close proximity to tools, materials and expert resources.

Based on established standards, our project teams will devise project documentation that's specific to your individual requirements and competently deliver the project on time, on budget and to the agreed level of quality.

Offering a comprehensive range of services and project management, we guarantee successful outcomes and a tailor-made solution for your application.

CLEAN UTILITIES

Water is the most widely used product in the pharmaceutical industry. It is present in a vast amount of products as a raw material, and is often the main component. Furthermore, "pharmaceutical water" is one of the few raw materials that is normally prepared on site, by further purification of drinking water or purified water.

RO/WFI/GVP/Storage & distribution

RO generator unit

Reverse osmosis is often used as a preparation for secondary demineralization, either by means of a second reverse osmosis stage or a continuous electro-deionization stage.
Reverse osmosis is a separation technique of great value as it can eliminate up to 98% of dissolved ions, in addition to bacteria, particles, pyrogens and organic matter.

WFI generator unit

A group of distillation columns in series designed to evaporate the purified water and condense pure steam. Their design allows the steam water drops, containing impurities, particles and pyrogens to be separated by the effect of gravity.

GVP generator unit

Steam generators are units capable of separating drops carrying impurities (particles, pyrogens, etc.) and therefore produce constantly high quality pure steam.

Storage & distribution

Once water for pharmaceutical use has been obtained, it must be stored and distributed to the points of use; there is no point in producing quality water unless it is correctly stored and distributed. This stage is of vital importance to minimize possible contamination of the water and the proliferation of micro-organisms.
Systems must be sealed with continuous recirculation and must have a sanitization system.
Our LoopTec unit is the correct choice!

UTILITIES

CIP/SIP/DIP/TCM

CIP (Clean-in-Place), SIP (Sterilization-in-Place), DIP (Dry-in-Place), TCM (Temperature-control-Module)

CIP/SIP

Automated CIP and SIP are currently the best methods for cleaning/sterilizing processing systems.
They ensure safety and efficiency, remove residues, prevent toxic contamination of products and minimize recontamination of the process.

DIP

Through an exclusive cleaning device the unit system will send air (hot air) to eliminate the liquid still residing in the equipment.

TCM

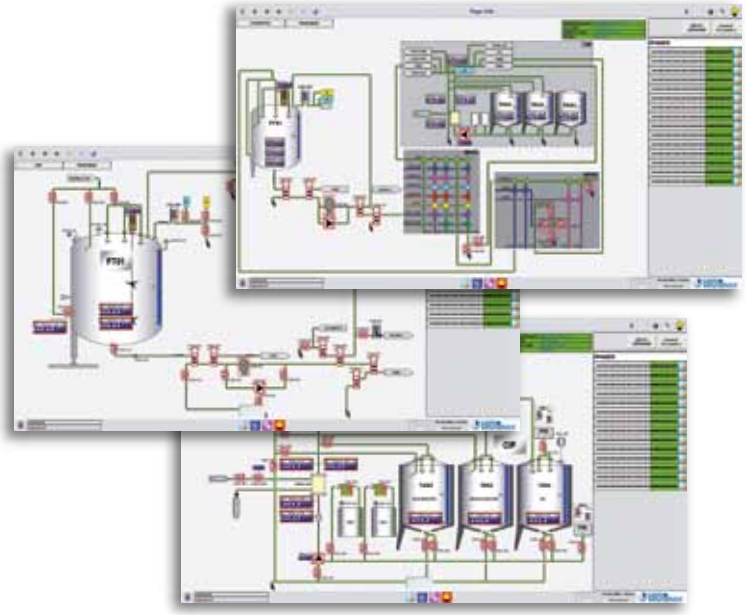
The temperature control module is an intelligent I/O module that can accommodate heat/cool PID loops for barrel temperature control or other injection molding temperature control applications.
The module is completely pre-assembled and connected to the jacket tank/ exchanger in order to have a system "ready to go".


Getac

AUTOMATION

Integrated solution that generate value added.

Pursuing and carrying out high quality products has obviously become part of TECNinox business policy.
Not only. In fact quality standards go beyond, because realization and fulfilment of specific procedures guarantee product reliability and quality.



Engeeeniring

In order to meet the most demanding pharmaceutical requirements, great care has been taken in designing our software: from the conception phase to components selection and definition of system architecture and project management, through the project phase and the definition of product management procedures (change control, configuration management, support, repair, maintenance, etc.) according to the GAMP guidelines.

Design play

Our software assures the commercial availability of standards components, the integration levels required in modern pharmaceutical plants together with functions and performances to meet quality and safety standards of those production processes for which the application is intended.

TECNinox's quality policy with respect to designing and manufacturing equipment has always been to follow the most stringent guidelines and quality standards of the industry.

QUALITY ASSURANCE

Equipment for use in the Pharmaceutical Industry is designed for operation according to Good Manufacturing Practices (GEP and GMP), FDAregulations (CFR 21 Part 11 for control systems), Good Automated Manufacturing Practices (GAMP), while meeting the requirements of European, American or applicable national standards.

Test and Controls

Synergy

Every technical and business department is involved during each step of the project. The Customer-User has an important role in the preliminary design phases writing out construction and functional specifications that are the guide for the manufacturer to realize the right product for the particular problem. In addition TECNinox is vertically integrated and has its own welding shop for fabrication of stainless steel vessels certificated as pressure equipment to PED – ASME (U-stamp) – SELO (China).

Productivity and competition

Productivity and competition are the bounds between which the company pursues its objectives introducing not only preventive tests, but also intermediate and final ones before the delivery to the User.

Process reliability

It consists of a periodic monitoring of test and inspection instruments carrying out a customized and specific test and maintenance schedule.
Instrument calibration ensures result reliability and reduces failure tolerance.
All TECNinox companies are ISO 9001 certified for design, production, sales and after-sales activities.
Design (DQ), Installation (IQ) and Operational (OQ) qualifications. Exhaustive testing and documentation are common practice at TECNinox. The aim is to provide customers with an end product that complies with the strictest regulations, which can be installed and used anywhere in the world.

WORKFLOW

Marketing is the first step to cooperate with the customer:
TECNinox supports him during the whole life of a plant.

01 Conceptual & basic design

Based on your URS, the project is formulated to meet your requirements.

02 Detailed design

Detailed specifications, as well as shop and installation drawings are developed.

03 Fabrication

Fabrication is carried out in our workshops under controlled conditions.

04 Installation of equipment

Equipment is installed and integrated, the plant is tested and prepared for shipping.

Our supports during the whole life of the project

05 > Assembly on site

The plant is assembled at final location.
Modules are set and internal hook-up performed.

06 > Commissioning & qualification

Site commissioning and qualification IQ and OQ
are performed leveraging the work in the workshop.

07 > Client validation activities

The client performs PQ and start-up activities and
manufacturing commences.

08 > Service & support

Start-up/technical assistance, upgrades and after
sales services.

www.visual-ink.it C.P. ED.09-2016

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