

Process Solution
for Pharmaceutical
and Biotech industries



Company profile

THE GROUP



01 > **TECNinox**
Headquarter



02 > **Ilinox**
Manufacturing division



03 > **Ilinox Kft.**
Manufacturing division



04 > **ERsistemi**
Software automation division



Team Synergy



From 1979 TECNinox Headquarter is the place where process ideas are realized. A team of Project Managers, mechanical engineers, software engineers and process experts develop and customize projects together with clients. A team of Plant Managers, certified welders, skilled technicians and documentation experts build up and test equipment.

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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 and 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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HISTORY



1978 > TECNinox a history of passion and success.

In 1978 Giovanni Miglioli and Vito Bocchi, after twenty years of 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.

A winning choice!





Over 40 years of innovation

> 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.



WE LISTEN, WE DESIGN, WE CREATE. WITH PASSION.



Our mission

The endless development of idea and new solutions has always been the mission of our company. From design to installation till plant validation: we can offer turn-key process plants for pharma, biotech and cosmetic world.

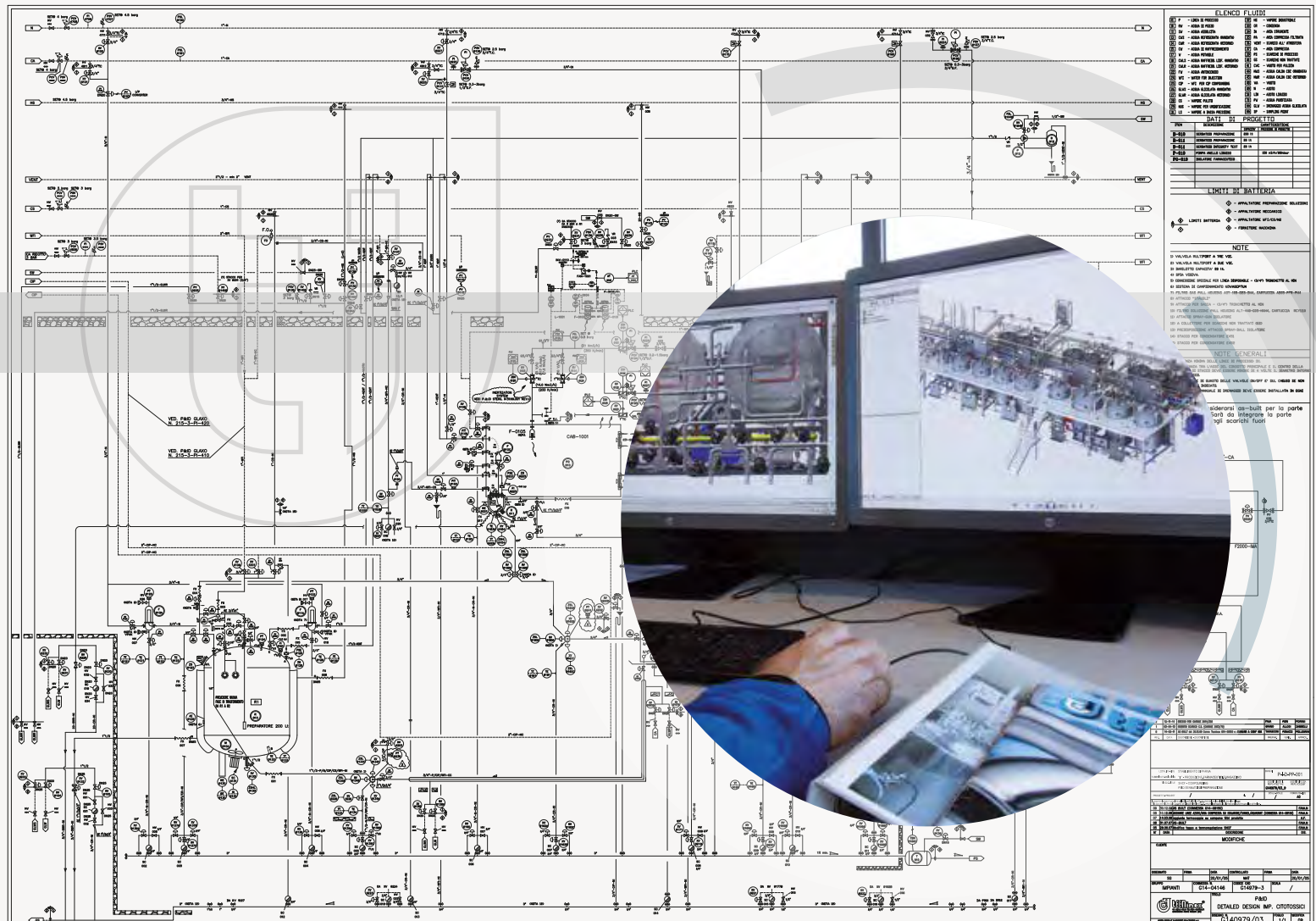
> A tailor-made solution

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

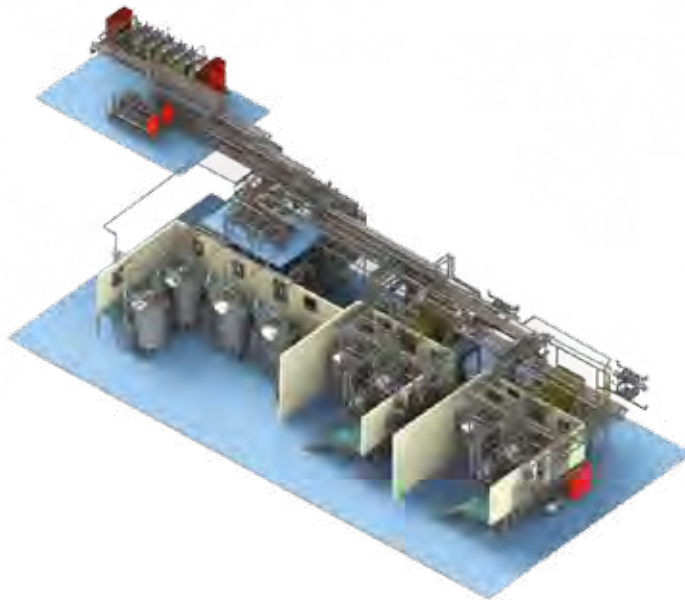


Engineering

TECNinox has a team of engineers ready to develop new innovative process solutions and in step with the latest technologies.

From virtualization to reality. Design development goes hand in hand with 3D system modeling. These models are used to fully articulate the development of the project and allow to prevent critical issues and develop alternative solutions.

From design to realization



Be responsible for the entire manufacturing process and 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.



PROCESS SOLUTIONS

➤ 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 turn-key solutions, from process engineering, through commissioning and qualification.

➤ We manage the project, coordinating all activities and taking full responsibility to minimize cost overruns, time delays and technical difficulties typical of conventional construction, ensuring the delivery on time.



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





PROCESS SOLUTIONS

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

➤ 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 team will develop project documentation according to your individual needs and deliver the project on time, according to the agreed budget and quality level.



CLEAN UTILITIES



Water is the most widely ingredient in drug manufacturing; therefore, systems for the production, storage and distribution of pharmaceutical water and steam constitute essential elements in most manufacturing facilities. Thanks to the experience gained, TECNinox offers itself as the ideal partner for complete water purification systems, from design to execution.

PW / WFI / PS / Storage & distribution

➤ PW generator unit: ROTEC

Purified Water? TECNinox ROTEC is the solution. Reverse osmosis is a separation technique that quantitatively eliminates ions, bacteria, particles, pyrogens and organic matter. Reverse Osmosis systems, following the modular criteria, are extremely compact while still guaranteeing the maximum operating space for scheduled and special maintenance operations.



➤ WFI generator unit: DITEC

A group of distillation columns in series designed to evaporate the purified water and condense pure steam. This system ensures a reliable and automatic production of pyrogen-free and high-quality Water For Injection. Our computer-aided design with 3D modelling are constantly updated according to the latest heat transfer technology.

➤ PS generator unit: GVP

The TECNinox Pure Steam Generator is designed for the production of sterile, pyrogens-free pure steam. This high purity steam is suitable for sterilization (S.I.P.) of equipment components like tanks, preparation vessels, piping systems, filling machines, filters as well as for humidifying of clean and cleanest rooms where is requested Compendial steam quality.



➤ Storage, distribution & management Unit: Looptec

Once water for pharmaceutical use has been obtained, it must be stored and distributed to the points of use; this step is crucial to minimize possible contamination and the proliferation of micro-organisms. Appropriate design and operation of the storage and distribution system is critical to the success of a pharmaceutical water system: our LoopTec unit is the correct choice!

UTILITIES



CIP/SIP/DIP/TCM - UTILITIES PANEL

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

CIP/SIP/DIP:

Automated CIP, SIP and DIP Systems are currently the best method for cleaning, sterilization and drying of process Skids. They ensure safety and efficiency, residual removal and toxic contamination prevention and are repeatable over time.



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".

Utilities Panel:

Utilities Panel is a skid to supply WFI, PS, N2 and CA to mobile vessels in order to perform CIP/SIP and DIP. Its layout, with valves and instrumentation installed in the technical side, allows to have the clean side as clear as possible.



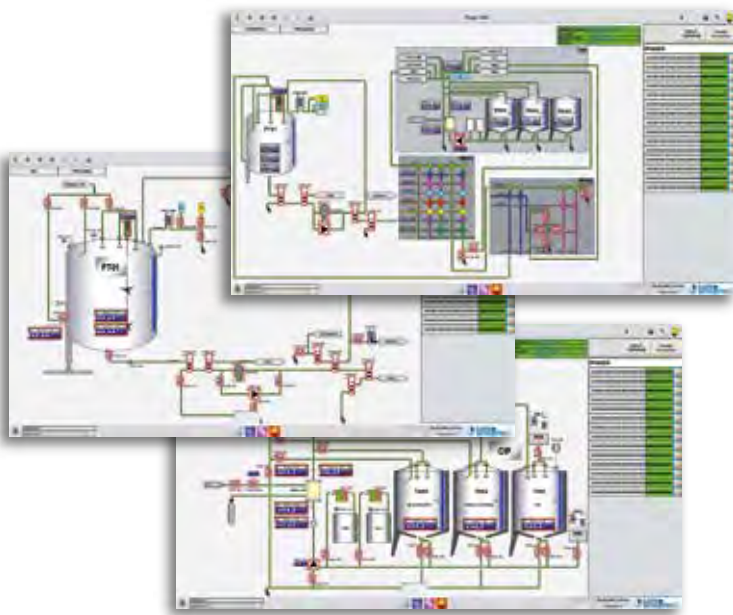


AUTOMATION

> 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.



> Engineering:

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 & Data Integrity guidelines.

> Design play:

Our software for process control are always designed according to the standard ANSI/ISA S88. Both recipes and batch control functionalities are available. Process phases can be run automatically in a recipe-driven mode or manually by the operator. A very challenging testing phase is performed in factory before the system release. Advanced technologies of plant's simulation - the so-called digital twin - and virtual commissioning are used to reduce commissioning time which also results in a significantly shortened time-to-market.





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), FDA regulations (CFR 21 Part 11 for control systems), Good Automated Manufacturing Practices (GAMP), while meeting the requirements of European, American or applicable national standards.



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

Our goal is the customer satisfaction: to achieve it we involve and guide the client, step by step, all along the whole life of the project. The entire workflow is monitored by the Project Manager, who represents a reference point for the customer.

01 > Conceptual & basic design

The Technical Office, starting from the URS, develops the P&ID and preliminary layout: our experience allows us to define the feasibility and concretize the needs of our customers.

02 > Detailed design

The Technical Department, in cooperation with the process specialists, defines all aspects related to the industrialization and develops detailed specifications as well as shop and installation drawings.

03 > Construction

In this phase all the components are assembled to obtain the final configuration, following the so-called Skid Modular Approach.

04 > FAT

More than 20 P.O.U.s (with PW, IS, CS, Power and CA) allocated in our workshop, enable us to test the equipment in the same conditions of customer site.



Our supports during the whole life of the project



05 > Assembly on site

The plant is assembled at final location: rigging and hook-up are performed, modules are positioned and connected.



06 > Commissioning & Start-up

Validation of the equipment on site is done, the plant takes its first steps...



07 > Documentation & Certification

The documentation, which comes to life from the earliest stages, is collected and delivered as per customer URS.



08 > Service & support

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





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