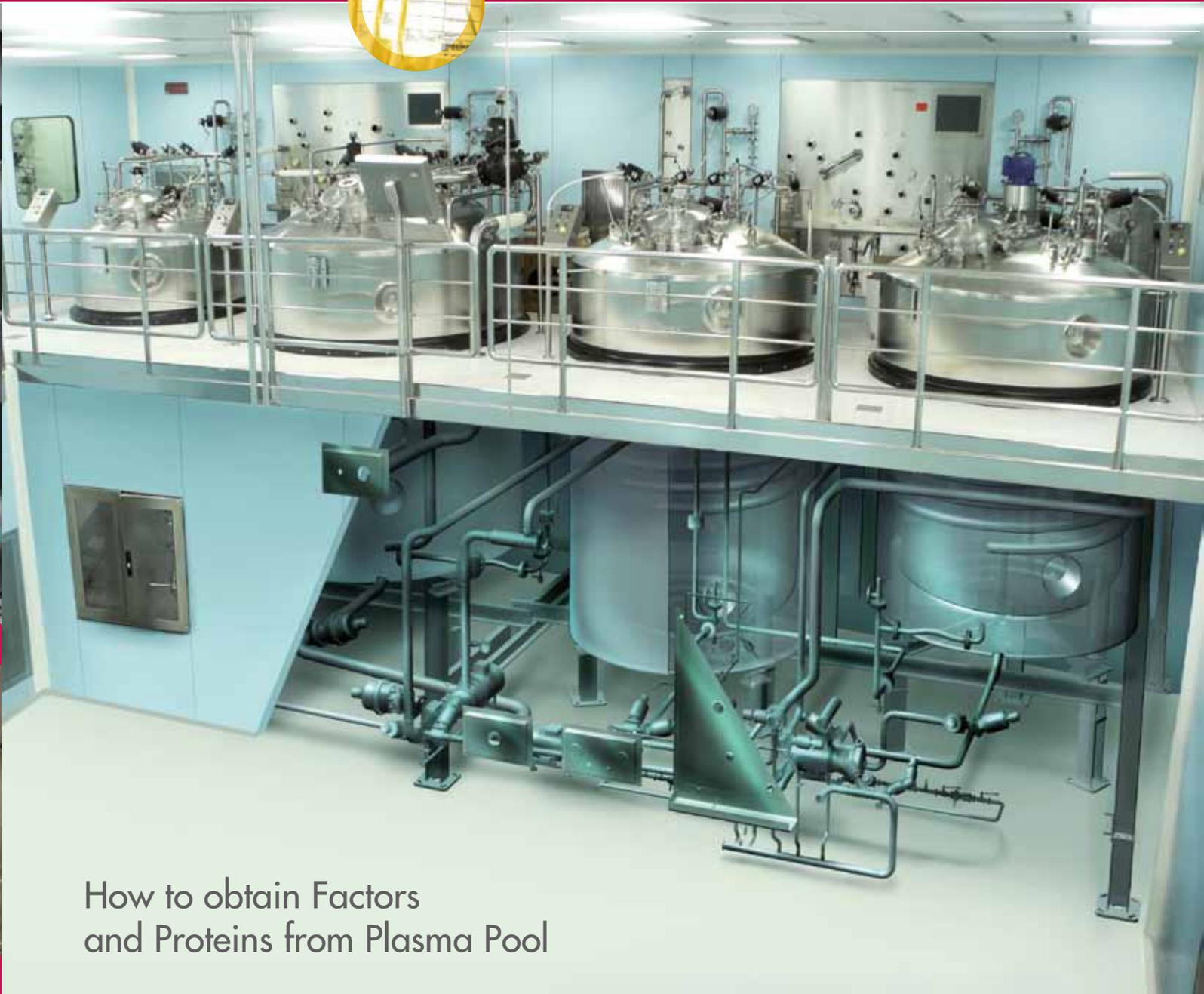


Blood Plasma / Fractionation



How to obtain Factors
and Proteins from Plasma Pool

TECNinox UltraFiltration and PastORIZATION skids.



The fractionation process is based on the different solubility of the plasma proteins in relation to different conditions of some parameters, both chemical and physical, like ethanol concentration, temperature, pH, ionic strength.

To get homogeneity in batches of plasma from thousands of donations and reduce the risk of viral transmission, before the definitive release for packaging, plasma products always undergo several virus inactivation steps depending on the final product, such as:

- Pasteurization
- Heating of freeze dried products
- Detergent/solvent treatment
- Nanofiltration
- Low pH
- Chromatography
- Sterile filtration.





Thawing System.



The process starts with thawing of FFP (Fresh Frozen Plasma) that arrives in pharmaceutical companies from thousands of donations.

Factor IX
Factor VII



Separation vessel: Ion exchange resin with PTC absorbed from Blood.



Albumin



Fr V Resuspension Vessels and Albumin Production Room.

Afterwards many different separation steps could follow one another:

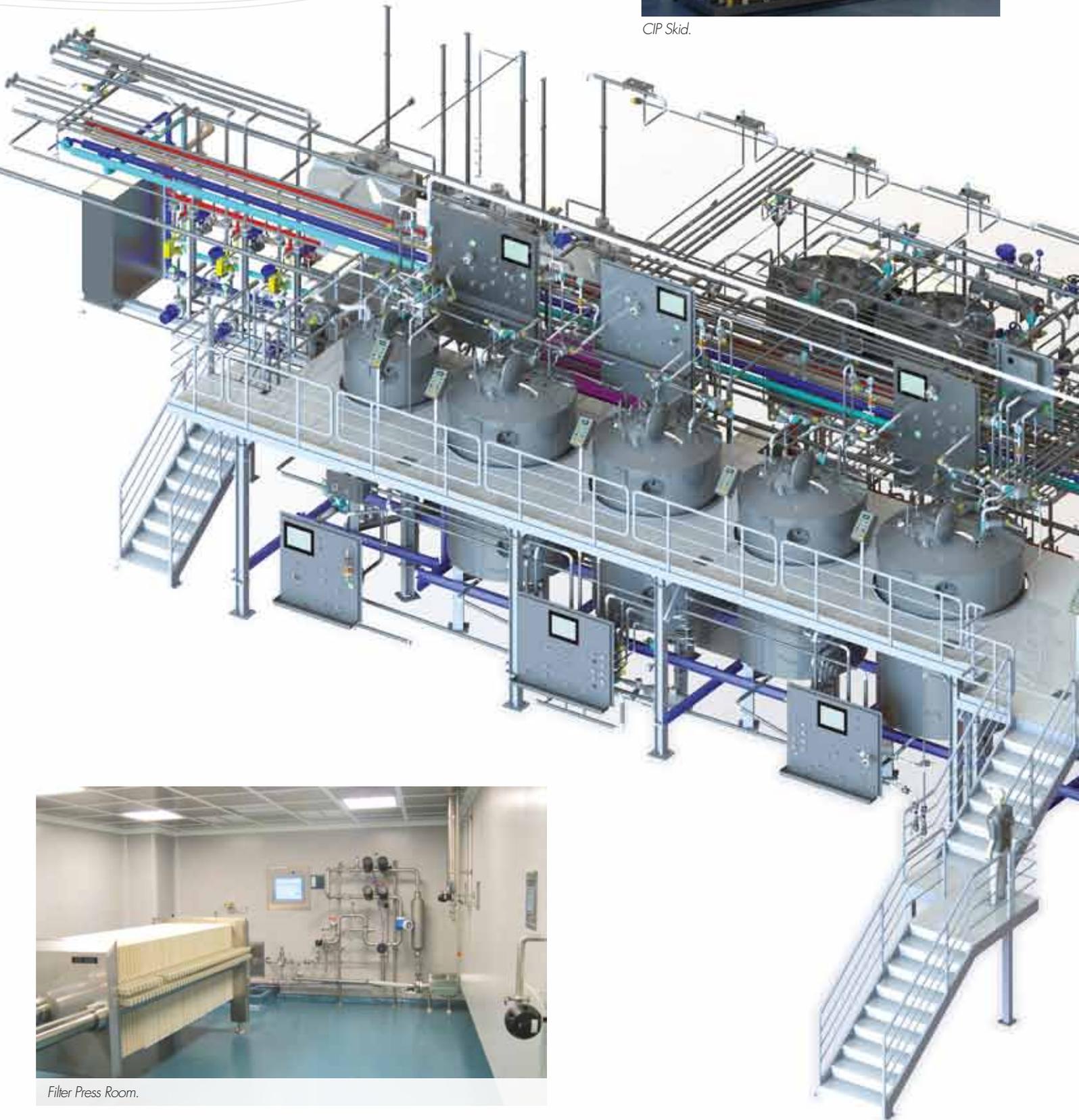
- ✓ Cryo-precipitation
 - ✓ Ion exchange chromatography
 - ✓ Affinity chromatography
 - ✓ Alcohol precipitation
 - ✓ Salt precipitation
 - ✓ PEG precipitation
 - ✓ Centrifugation
 - ✓ Ultrafiltration
 - ✓ Partitioning through filter press
- Physical methods
- pH precipitation
- Mechanics methods



Temperature Control Module.



CIP Skid.



Filter Press Room.

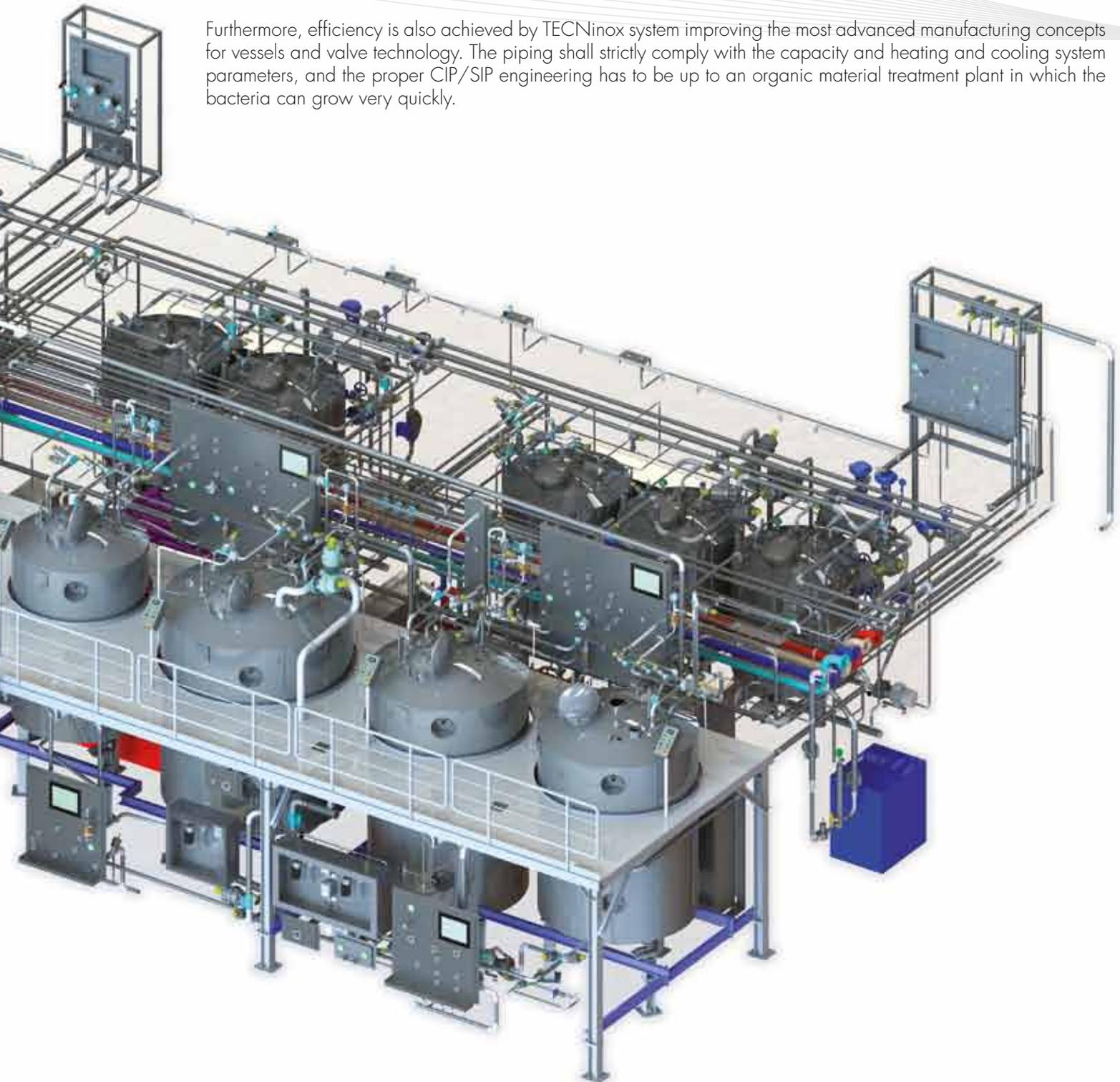
Plasma Fractionation

*Human Plasma is not only a life element of our body;
it's the key element in immunodeficiencies and other diseases treatments.*

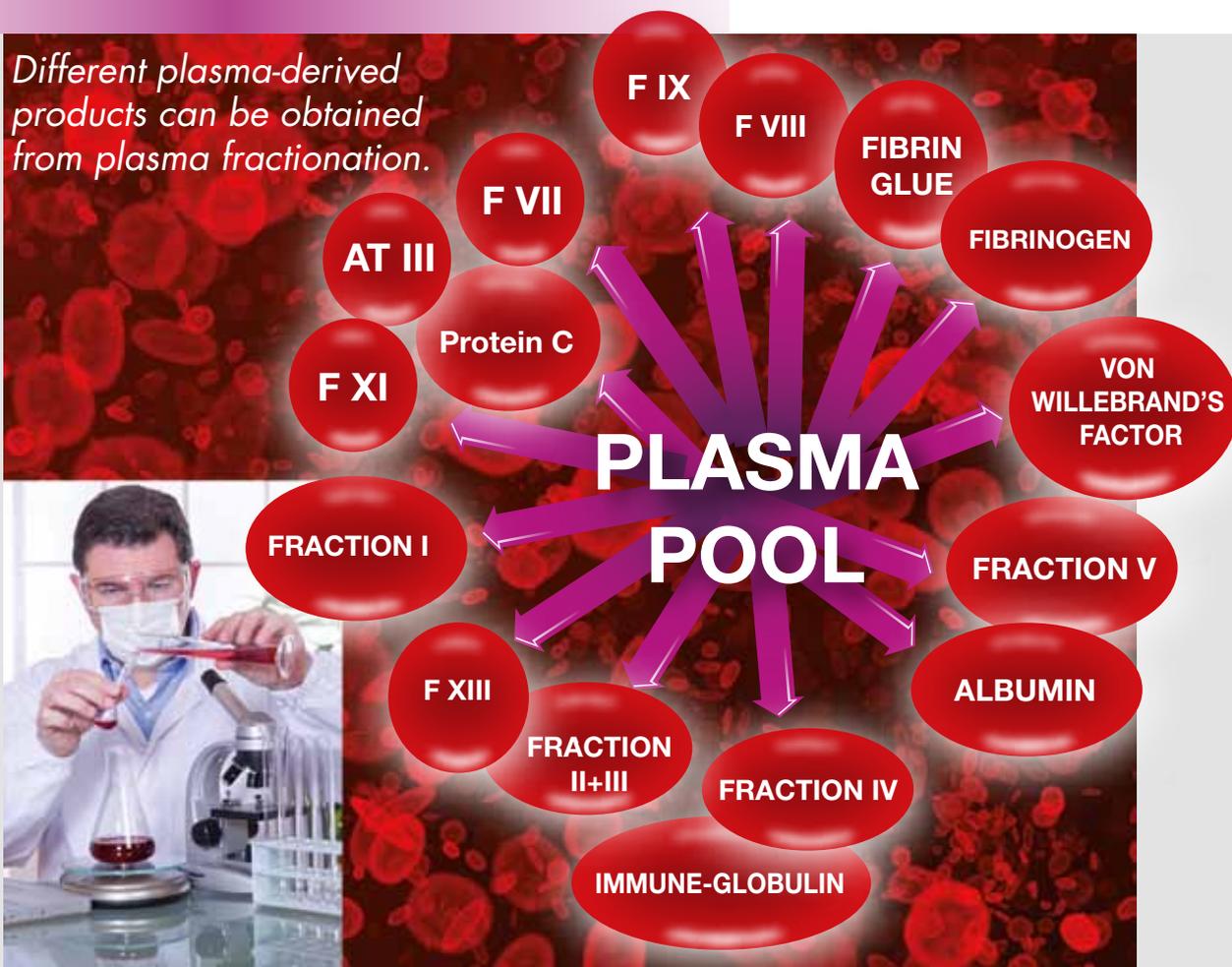
The large part of plasma-derived products can only be treated from plasma, and plasma can only be extracted from human donors. Consequently, plasma is a finite resource that cannot be replicated or mass produced in large industrial process.

TECNinox has realized many plants for leading companies in plasma fractionation. Today, modern fractionation plants are large and complex, capable of fractionating millions of litres of plasma into a variety of therapeutic products. Thus, the plasma must be used efficiently by producing as many products as possible from each liter collected. The conditions under which all plasma fractionation steps take place are very important; for example the temperature of buffer addition in precipitation tanks, the pH of suspension before each filtration or centrifugation, the optical density of permeate during the Albumin Ultrafiltration...

Furthermore, efficiency is also achieved by TECNinox system improving the most advanced manufacturing concepts for vessels and valve technology. The piping shall strictly comply with the capacity and heating and cooling system parameters, and the proper CIP/SIP engineering has to be up to an organic material treatment plant in which the bacteria can grow very quickly.



Different plasma-derived products can be obtained from plasma fractionation.



The whole Plasma Fractionation Plant that TECNinox can provide is the result of an engineered study based on a deep knowledge of the productive process acquired over the years working in close contact with customer, talking to production operators, understanding their needs and always sharing advantages and potential problems.



An automatic or semi-automatic control system supervises each process recipe or maintenance phase; the system allows the customer to monitor and record all process parameters, both critical and not critical, it can guide the operator in each process operation and become a batch record visualised on the Operator Panel: **user friendly and mistake-proof** are our key words.

Our strength is the competence and reliability largely felt by anyone who entrusts to us, right from the stage of basic design and process engineering.



There are few companies in the world that can meet these demands, TECNinox is one of them!



Generation
Storage and
Distribution
System for
Purified Media



Blood Plasma



Syrup and
Suspension



Cream
Gel
Suppository



Vaccines



Cytotoxic
Anticancer



Parenteral
Formulation
Compounding



Biotech
Modules
Superskid



Insuline



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