PLASMA FRACTIONATION
GLOBAL SOLUTIONS
Boccard, the global process solutions

An industrial integrator and major player in the design and construction of equipment and process lines for 100 years, Boccard has become a preferred partner for world leaders in the pharmaceutical and biotech industries. From modular process skids to full scale plants, our team integrate turnkey solutions utilizing our worldwide network.

We fully understand the needs of our industrial partners, as well as the issues regarding consumer and patient health and safety. Whether building complete blood fractionation units, tailor-made equipment, or specific reactors, our Health & Care Excellence Center will design your projects with strict adherence to safety and hygiene. Our multidisciplinary teams ensure that the manufacturing processes are of the highest quality and in compliance with Good Manufacturing Practices as well as the User Requirement Specifications of our clients (cGMP and URS). We guarantee performance, productivity, and optimum maintenance requirements of all installations.

Product viability, guaranteed time-to-market, efficiency, and flexibility... Our principles ensure the best possible service and project experience. This is why Boccard Health & Care has been relied upon by the most prestigious biotechnology laboratories in the world for over 20 years.

Design & Build
for shared satisfaction
Boccard has extensive experience in the industry of blood plasma fractionation. Prestigious biotechnology laboratories trust us to design, build and maintain their blood fractionation units worldwide:

- **LFB**, France
- **Green Cross Biotherapeutics**, Canada
- **Hemoderivados**, Argentina
- **Chengdu Ronsen Pharmaceutical**, China
- **CAF-DCF**, Belgium
- **Quimbiotec**, Venezuela
- **Kazpharm**, Kazakhstan
- **Greenfield**, Latin America
BLOOD FRACTIONATION PROCESSES

Certified and compliant with

Our certified company delivers global process solutions compliant with high quality standards worldwide.
The thawing vessels, for a successful fractionation process

If there is a crucial stage in the blood plasma fractionation process, it’s thawing the product. There is very little time to melt the frozen blocks of plasma before the quality of the proteins start to deteriorate; the performance of the melting tanks is, therefore, essential.

Boccard innovation

To ensure that the fractionation process is successful, our R&D teams have developed annular tanks, an innovative design that is specific to blood plasma fractionation. This type of tank takes into account many particularly restrictive parameters. Our innovating thawing vessel design helps resolve the equation of short stay + maximum thermal exchange surface area + extremely precise temperature regulations + protected quality of the proteins. This method also produces a measurable productivity gain.

Our thermal control units guarantee outstanding precision heat control systems: + or − 0.5°C

Maximum flow rises 930 L/H at 0.5°C

Yield is increased thanks to our innovating design

“We were convinced that thawing vessels design could be improved. Our experts worked on it. They proposed an innovative design which enables to double the heat transfer surface while keeping the same tank volume. The thawing flow has been therefore highly increased.”

Stephanie Severac, Boccard Health & Care Senior Project Manager
PRODUCING ALBUMIN

“Thanks to their technical skills and sound experience, our teams provide tailor-made solutions that meet our clients’ varied requirements. Expertise in blood plasma fractionalation, management of complex projects, knowledge of local standards, in-house premium stainless steel working, specialised profiles in engineering, processes, automation, electrics, assembly, quality assurance, qualification… all benefits appreciated by our clients who seek customised, intelligent and long-term solutions.”

Juliette Kopp, Boccard Process Solutions Manager
Albumin

Blood plasma is fragile and precious. Plasma fractionation is a process that extracts proteins to produce medications that treat a number of serious, and often rare, diseases.

Albumin makes up 60% of plasma proteins. It is responsible for maintaining optimum arterial pressure by enabling the vessels to be filled and by transporting molecules (fatty acid, hormones, ions, calcium). Widely used in emergency medicine, it can be used for a serious haemorrhage, serious burns victims, septic shock, pregnant women (in neonatal medicine), as well as for cirrhosis of the liver in children and adults… and in all situations that produce significant protein leakage.

During the fractionation process, the albumin production workshop is an important facility. Unique know-how and proven industrial experience: Boccard Health & Care is highly skilled in all ultra-filtration processes and the complex thermal processing required to obtain albumin. We design and make precipitation reactors in-house: our specialist metalworkers produce stainless steel equipment in our own workshops, ensuring that the product undergoes careful agitation and homogenisation. Materials and processing are of highest quality and designed to facilitate cleaning in place (CIP).

Our global solution excels in the design for process optimisation, heat regulation, automation, optimized ergonomics and qualification for the pre-fabricated equipment and systems. Skids and modular process systems arrive at the customer facility optimized for assembly and commissioning. Our strategy minimizes the down time required for installation and setup.

Associated technologies

- Inactivation
- Centrifugation
- Dissolution
- Precipitation
- Separation/Clarification
- Filtration
- Ultra-filtration/Nano-filtration
- Chromatography
The design and setup of blood plasma fractionation workshops are complex subjects. As an industrial integrator, we support our clients throughout the world, offering them a global solution to ensure their projects are successfully completed. Our teams comprise a wide range of specialists in process engineering, management of large projects, stainless steel work, construction, electrics, automation, quality control, qualification. We have a high level of expertise in various separation technologies and our wide range of blood fractionation projects are additional bonuses that are especially appreciated by our clients.”

Eric Marcellin, Boccard Health & Care Director
Immunoglobulins

Blood plasma is fragile and precious. Fractionation allows proteins, such as immunoglobulins, to be extracted from the plasma. The low content of immunoglobulins in plasma makes the production processes very sensitive.

Polyvalent and specific immunoglobulins (IgIV) (antibodies) make up 20% of blood plasma. These proteins play an essential role in the body’s defence system and protect it by neutralising bacteria, viruses and various toxins that may be found in the bloodstream. They are also used in the event of immune deficiency (haematological diseases, autoimmune diseases).

From deep or sterilising filtration skids that are both compact and mobile, to ultra-filtration and chromatography skids, including mobile tanks that are suited to your space, we design and build to facilitate your immunoglobulins production.

Working with your team, we will design and make effective skids that are ergonomic, compact and easy to maintain. Special attention is given to limit product losses and to ensure the therapeutic quality of the extracted proteins.

Associated technologies

- ✓ Inactivation
- ✓ Centrifugation
- ✓ Dissolution
- ✓ Precipitation
- ✓ Separation/Clarification
- ✓ Filtration
- ✓ Ultra-filtration/Nano-filtration
- ✓ Chromatography

We have a high level of expertise in separation techniques. We also know and respect local standards. We can easily incorporate 3rd party equipment.
PRODUCING CLOTTING FACTORS

“Safety for products and users is one of our main concerns. We believe the risk of contamination is the greatest hazard associated with plasma derived products. That is why our teams are very cautious when designing and building process solutions. Being demanding is a prerequisite when dealing with human health.”

Olivier Boutur, Boccard Health and Care Quality Manager
Clotting factors

The blood plasma fractionating process also produce other substances such as clotting factors. These substances are used for hemostatis treatment.

Coagulation factors that are present in blood plasma in small quantities play an essential role. A deficit in a single one of these factors can impede the normal coagulation process and cause haemorrhaging. Coagulant fractions can be used to treat haemophiliacs, preventing complications that can lead to incapacity. They also help the organism to fight off certain orphan diseases.

When fractionating blood plasma, every drop counts. Our teams design and make equipment to limit the loss of product and to ensure its therapeutic quality. Thanks to our proven know-how in all these processes, our deep filtration or sterilisation, compact and mobile skids, ultra-filtration skids, and chromatography skids from our workshops meet the highest safety and hygiene standards.

Our blood plasma fractionation technical know-how has been improved considerably by our broad experience and by listening to the needs and requirements of our clients. Consequently, it ensures Effectiveness, Quality, Ergonomy and Easy Maintenance of your facilities.

Associated technologies

- Inactivation
- Centrifugation
- Dissolution
- Precipitation
- Separation/Clarification
- Filtration
- Ultra-filtration/Nano-filtration
- Chromatography

FVIIFVII
FIBRINOGEN
PPC
FVIII
FVII
FV
XI
FV

Fully compliant with ASME BPE.

Stand alone modules can be qualified independently.

Your products are precious. We consequently pay special attention during the whole fractionation process.
**CLEAN UTILITIES**

**Auxiliary fluids** *(WFI, PW, PS, CIP & SIP)*

Our teams have been installing pharmaceutical fluid facilities over 20 years. Our water loops and sub-loops are designed to reduce energy consumption while meeting Good Manufacturing Practice (GMP), turbulence rates, temperature regulation needs...

Cleaning in Place (CIP) and Sterilization in Place (SIP) systems are key factors in the quality production and the productivity of your plant. We proudly hold 100 years of expertise in piping and welding. Consequently highly experienced in clean utilities, including CIP & SIP, we design and build efficient systems adapted to your specific needs.

**Buffers preparation**

How to improve laminar air flow? Reduce the surface area and cost of your clean rooms? Boccard Health & Care offers original designs by taking the tanks and large items of equipment out of the clean rooms. Less equipment, less turbulence and deterioration of the air flow, and a smaller layout in the clean rooms lead to easier maintenance, a lower cost and efficient solution!

**Ethanol**

Our high level of knowledge of ATEX standards for storing large quantities of ethanol means we can design solutions with an excellent cost/safety ratio. Independent organisations and authorized agencies have controlled and fully validated our optimized design.
“We choose Boccard for our Biotechnology plant because we wanted an industrial integrator that was able to deliver a turnkey facility and provide us with a performance guarantee. We were particularly impressed with their expertise in the boiler-making sector. As a company that works with plasma derivatives, we have extremely precise requirements.”

S.J., Project Director, LFB
We Design, Manufacture, Qualify, Install and Maintain your facilities

Successful project completion requires bringing in expert teams in process engineering, including engineers, automation experts, qualification specialists, technicians, accurate boilermakers and welders to fully control the execution of the process and quality of the installation. In everything we do, our goal is to provide you with the best process experience now and in the future.

Project management

Whether a Greenfield plant or an upgrade to a blood plasma fractionation facility, we provide the engineering expertise to ensure that your process is reliable and compliant with specifications and regulations. As an industrial integrator, we help you to manage your project more easily. On a partnership basis and thanks to our expertise in process intelligence as in project management, we deliver efficient turnkey process solutions.

“Safety first, On time, On spec, On budget”.

Process Control

Simply and efficiently piloting your installations is essential: our automation engineers design open automated systems that communicate with your IT systems. They use the most reliable solutions on the market and work closely with your team to design ergonomic systems fully compliant with CFR21, GAMP V and ANSI/ISA-88.

Premium process vessels

Our integrated stainless steel workshops ensure manufacturing excellence for your tanks and vessels. Welding experts for stainless pressure devices, our teams produce tailor-made equipment from the 50 L pilot format to the 15,000 m³ industrial format!

International in scope

Thanks to our design offices and our 55 business units located throughout the world, we can help our clients wherever they are. Each project is designed by the Excellence Center then built and qualified by our teams who have expertise in most international codes and reference guides: ASME/BPE, DESP, GMP, FDA… Excellence… where you need it.
QUALIFICATION

Integrated qualification: your project advantage

For over 20 years, Boccard Health & Care has been making specific equipment, precisely tailored to the needs of pharmaceutical & biotechnology clients. Once equipment is made, it has to be qualified. Attentive to your expectations, we have optimised our development processes and offers Integrated Qualification. This has a serious advantage as you can start the validation of the process solution earlier while carefully respecting the GMP regulation (including change control requirements).

An Expert Qualification team

Whatever your installation project involves (production of complete workshops, tanks, skids, thawing vessels…), a Qualification team will be assigned for the successful completion. Capitalizing on our experience, respecting current GMP and relying on ASTM E2500 and ISPE Vol. 5 reference guides, the team qualifies your assemblies and equipment.

Experts in the field, the team will draw up the test protocols (FAT and SAT tests, DQ, IQ and OQ qualifications), manage any non-compliance and write up test reports. This ensures deadlines and process reliability are optimised.

Qualification starts right from the FAT, namely earlier than in a standard qualification process. Engineering tests are capitalized. This has a serious advantage: the global planning is reduced.
The experience acquired in various industrial fields has given Boccard solid advantages: the shared expertise and the procedures we follow (SHA, LEAN, CSR...) are beneficial to all our clients.

Our references
For 20 years, the largest biotechnology laboratories in the world such as LFB in France and Green Cross Biotherapeutics in Canada, have been entrusting us with their design and construction projects for blood fractionation units and the production of therapeutic proteins. Recognised and appreciated by all our clients, our ability to manage complex developments ensures your ideas will be implemented securely and reliably.

Process solutions and demanding quality manual
Our teams will work on creating global and relevant solutions to meet the challenges of your project. They study, design, manufacture, build and qualify your future equipment, while always respecting the BOCCARD MANAGEMENT SYSTEM (BMS). BMS is the commitment by BOCCARD to ensure the demanding performance of your installations: unique and precious over time.

Powerful tools and innovative technologies
To better serve our clients, our project management processes are constantly improved. To this end, our experts rely on tried and tested technologies or develop their own tools. The most iconic of these tools and technologies are: PDMS, a 3D CAD system for designing installations; E-qualification, a system designed for monitoring the FAT-SAT tests protocols and results are available in real time on a web interface anywhere in the world. Boctrack, software developed inhouse for construction traceability, Boclock smart connector or Pharmaloop are other innovations frequently used on your facilities constructions.

Associated services
Accompanying you throughout the lifecycle of the installations we carry out is more than a service. For us, maintenance of the “qualified state, managing production outages, up-grading and training are self-evident. Boccard is developing internationally in a whole range of demanding markets, and for your performance, we have expert knowledge of the codes and certifications that apply in your country: ASME/BPE, DESP, GMP, FDA... Successful, compliance projects assured!

* World Patent; 2013 CFIA Innovation Award for sensitive connections
We design, manufacture, assemble and install turnkey processing solutions for our customers worldwide who transform raw materials into products for people’s direct consumption. That is why our centers of excellence – serving Food & Beverage, Pharma & Biotech, Cosmetics & Hygiene and Brewery markets – are committed to achieving the highest levels of quality and safety in over 100 countries, while ensuring optimal productivity to serve demanding markets.

Our experts in Process Intelligence and Project Management work on a partnership basis with companies of all sizes, including major global players, to build new facilities or upgrade existing systems to meet and surpass key performance indicators: product excellence and consistency, efficient time-to-market, responsiveness and flexibility.

In everything we do, our goal is to provide you with the best process experience, now and in the future.