

INTEGRAL SOLUTIONS FOR **LIQUID PRODUCTION LINES**



LIQUIDPROCESS

PRODUCTION OF INJECTABLES, SERUMS, FERMENTED SOLUTIONS AND SYRUPS



THE **PROPREP** SYRUP
SYRUP PROCESS VESSEL



GLOBAL PROVIDER FOR **TAILOR-MADE SOLUTIONS**

For more than 50 years, AIRPLAN has been integrating design, engineering, consulting and installation solutions to create turn-key projects focused on meeting the needs of our clients.

The Process Department was created in response to our clients' growing needs for process solutions. Backed by our know-how in the field of industrial turnkey projects, we develop equipment and integrated process lines offering unique features, which are later assembled in our own manufacturing plant.

The Process Department is currently the fastest growing division at AIRPLAN.

LIQUIDPROCESS

Our process lines are just like our clients: unique

We conceptualize and design integrated solutions, customized to meet your needs. Our liquid process lines are designed to meet the requirements of a wide range of industries, such as the pharmaceutical, biotechnology, cosmetic and food processing industries.



THE **PROPREP** BIO
BIOPROCESS VESSEL



WE TRANSFORM YOUR IDEAS INTO A VIABLE BUSINESS

Know-how

A team of experts in chemical, process, mechanical and electrical engineering will be dedicated to bringing your idea to fruition, engaging in a continuous, dynamic dialogue and sticking to the budget and established deadlines.

Integrated solutions

From initial consulting to the final certification of your equipment, we understand the industry and its regulations, and we guide our clients throughout the entire process. The components of each line are perfectly integrated to ensure smooth operation.

Compliance with international standards

We know and abide by both international standards and the legal framework in each country where our projects are implemented. Our process lines and equipment comply with all applicable directives, such as the European Machinery Directive (2006/42/EC), the European Pressure Equipment Directive (97/23/EC), standards such as ASME BPE ("Bioprocessing Equipment" certification issued by the American Society of Mechanical Engineers) and regulations including cGMP, ISO14644 and 21 CFR Part 11 (FDA). We have also earned the accreditation required to certify our pressure equipment with certification designation "U", according to the ASME BPVC (Boiler and Pressure Vessel Code).



Flexibility at competitive prices

The customization of process lines and equipment begins at the design stage. We meet specific needs with specific designs, as opposed to merely adapting standard mass-produced models. The fact that we have our own production plant ensures that manufacturing remains true to the original design, with no intermediaries and at competitive prices. It also means that we have the capacity for immediate response to the needs of our clients.



Assembly plant at AIRPLAN, Spain, complete with a FAT (Factory Acceptance Test) zone and quality control



A vessel being packaged for maritime transport to America



Orbital welding of pipes



LIQUID PROCESSING WITH **RELIABLE RESULTS**

High-tech components

The components of our process lines have been carefully selected to meet our quality standards. We only work with components from leading industry manufacturers that supply us with state-of-the-art accessories.

Replicable processes

Thanks to the software designed by AIRPLAN, clients can automate recipes, prepare reports and manage data from the control panel interface built into the process line. In addition, it is possible to view critical process variables in real time and adjust the parameters either manually or automatically.

Examples of implemented liquid production plants

Left photo

Production units seen from
technical area.

Right photo

Syrup production area in ISO 8
Class environment.



Smart design

As the result of a careful study of personnel and product flows, as well as storage needs, our process lines maximize the performance of your production cycles. Our vessels guarantee processes with no *dead-zones* and can be complemented with CIP/SIP (Clean-in-Place / Sterilize-in-Place) systems.



THE PROCOMPACT

MOBILE PRODUCTION UNITS FOR LIQUIDS OF 150 LITRES EACH (40 US GAL)

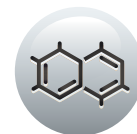


SELECTION OF AVAILABLE MODULES FOR YOUR CUSTOM PROCESS LINE

- ▶ Process lines for the pharmaceutical, biotechnology, cosmetics and food processing industries.
- ▶ Process equipment or complete production lines for sterile liquids, serums and suspensions, fermented solutions and cultures, syrups, etc.
- ▶ Objective advice for determining the best option.



PHARMACEUTICALS



BIOTECHNOLOGY



COSMETICS



FOOD

| POSSIBLE PROCESS PHASES | REQUIRED EQUIPMENT | AIRPLAN EQUIPMENT | PAGES |
|--|---|--------------------------------|-------------|
| Product preparation (product loading/unloading, different control functions, etc.) | Vessel for the preparation of | | |
| | ▶ sterile liquids | THE PRO PREP INJECT | 10 - 14 |
| | ▶ serums and suspensions | THE PRO PREP SERUM | 10 - 14 |
| | ▶ fermented products, bacterial culture and cell culture | THE PRO PREP BIO | 10 - 13, 15 |
| | ▶ syrups | THE PRO PREP SYRUP | 10 - 13, 15 |
| | Other applications at the client's request | | |
| Temperature control | Temperature control skid | THE PRO SKID THERMO | 11 and 16 |
| Transfer | Transfer unit | THE PRO PUMP | 16 |
| Liquid filtration | Filtration unit | THE PRO FILTER | 16 |
| Product storage | Storage tank for liquids, syrups or alcohol | THE PRO TANK | 15 |
| PW/HPW/WFI water and pure steam generation | System for generating, storing and distributing (<i>water loop</i>) | | |
| | - PW/HPW water - (<i>Highly</i>) Purified Water | THE PRO WATER PW/HPW | 17 |
| | - WFI water - <i>Water for Injection</i> | THE PRO WATER WFI | 17 |
| | - pure steam | THE PRO WATER PURESTEAM | 17 |
| Self-cleaning and self-sterilizing equipment | CIP (<i>Clean-in-Place</i>) system | THE PRO CLEAN CIP | 18 |
| | SIP (<i>Sterilize-in-Place</i>) system | THE PRO CLEAN SIP | 18 |

THEPROPREP

VESSEL CONFIGURATION AND CUSTOMIZING



For each process, we help you determine the required equipment specifications, complementing it with the necessary accessories.

I. GENERAL SPECIFICATIONS

Material

Interior: All parts in contact with the product are made of AISI 316L stainless steel or other similar materials, finished according to client requirements (standard polishing up to $Ra \leq 0.5 \mu m$ / $\leq 20 \mu inch$; optional electropolishing and finishes up to $Ra \leq 0.2 \mu m$ / $\leq 8 \mu inch$).

Exterior: The parts that are not in contact with the product are made from AISI 304L stainless steel or other similar materials.

Pressure

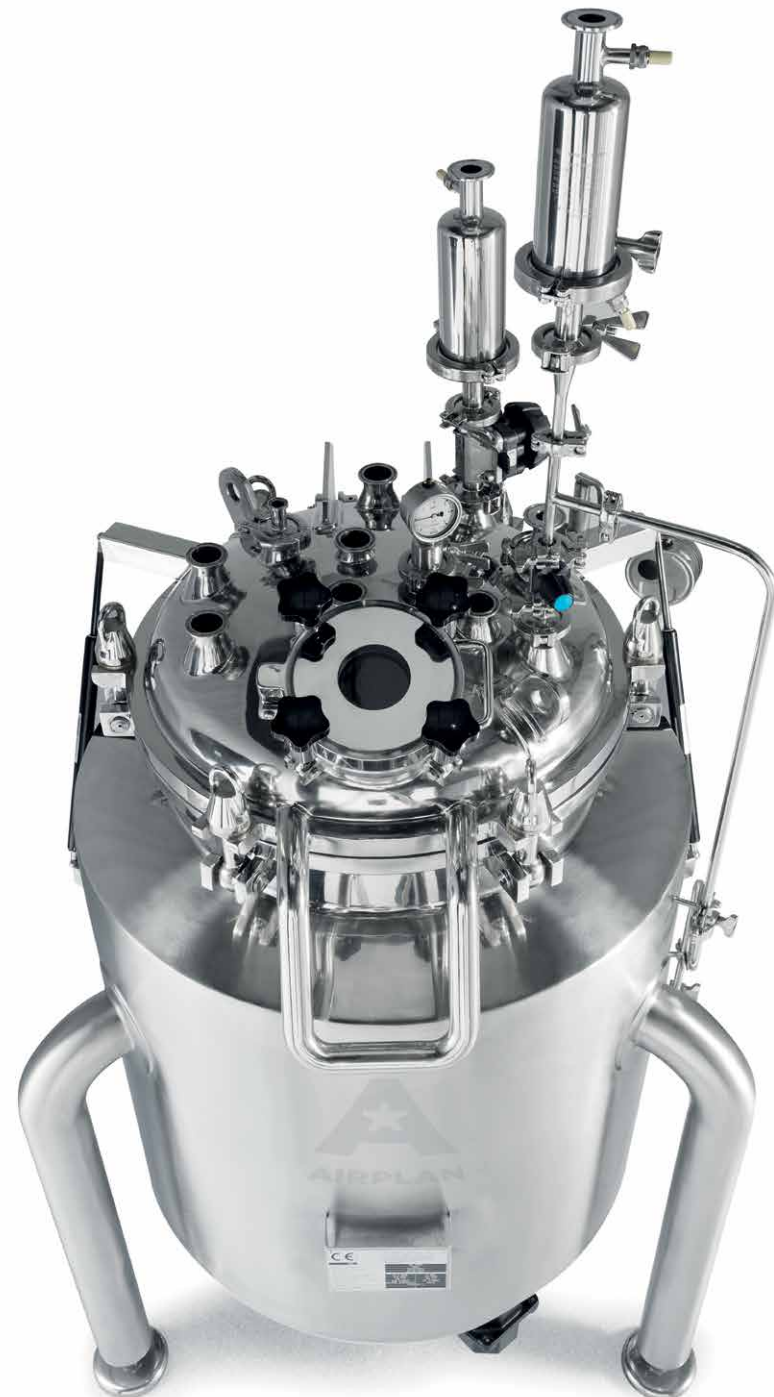
Generally speaking, the equipment is certified as pressurized equipment according to AD Merkbblätter and ASME BPE standards. Our equipment is built according to European Directive 97/23/EC governing pressure equipment and **is supplied with the CE mark (PED).**

We have also earned accreditation that allows us to certify **our pressurized equipment with the “U” mark, according to ASME BPVC**, at the client's request.

Likewise, our equipment is designed to operate under vacuum conditions up to -1 bar.

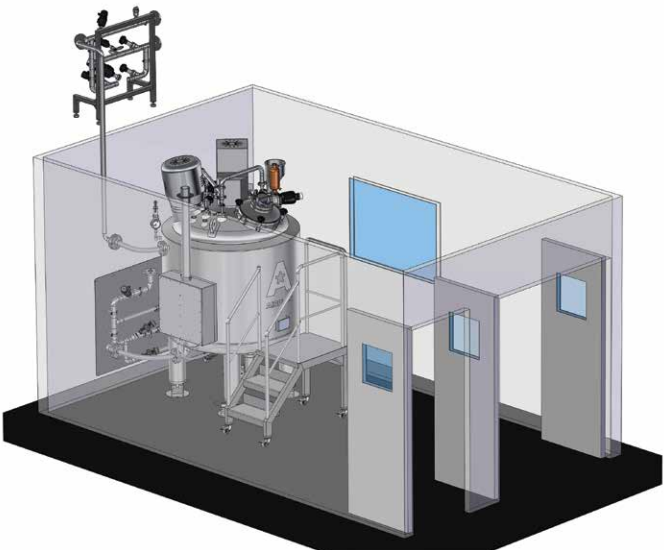
Capacity

Based on the client's needs.



II. HEATING AND COOLING SYSTEMS

| | |
|-----------------------------|--|
| Designs | <p>Heating/cooling through:</p> <ul style="list-style-type: none">▶ jacket▶ half-tube▶ dimple jacket <p>In addition: Insulation provided by a welded jacket with mineral wool filler, as specified by ASME BPE/FDA, and outer plating in polished stainless steel, welded to the main body.</p> |
| Process temperature control | <p>A stand-alone temperature control skid is also available (THE PRO SKID THERMO, page 17). The temperature is controlled on the same touchscreen used for the entire rest of the process (IV. Control System).</p> |



Integration of an Injectables Vessel with Temperature Control Skid
The decision was made to install the part of the skid in the technical area above the false ceiling due to the limited space available in the cleanroom.

III. MIXING SYSTEMS

The choice of mixing systems is made based on the client's needs and the product to be manufactured. Our agitators can be controlled by a speed regulation system on the control panel.

All agitators are designed according to ASME BPE sanitary criteria, maintain seal tightness under pressure and vacuum conditions and are prepared for CIP/SIP.

Standard mixers:

| | |
|-------------------------|---|
| Magnetic agitator | Designed for solutions such as sterile injectable and parenteral substances. Its head can be easily removed to facilitate cleaning the inside of the vessel and inspection. |
| Homogenizer / disperser | Designed for the production of syrups and suspensions, they favor the proper homogenization of the end product. |
| Others | <ul style="list-style-type: none">▶ Anchor▶ Propeller▶ Paddles▶ Cowles <p>Other models available on request.</p> |



Magnetic agitator



Homogenizer



Anchor



Blades

IV. LOADING AND DOSAGE

Our equipment is designed to adapt to different raw material loading and dosage strategies.

| | |
|------------------------|---|
| Loading options | <p>The equipment is designed to operate using various loading systems, for example:</p> <ul style="list-style-type: none">▸ Vacuum▸ Gravity▸ Pipes▸ Pneumatic or mechanical lifts▸ Through the inline mixer, etc. |
| Dosing options | <p>Optional accessories such as weighing cells, flow meters, level sensors, etc., can also be included in the vessel.</p> |



Weighing cell in one of the feet of the vessel, along with its corresponding section in the software program, essential components of the automatic dosing system.

V. PROCESS CONTROL

| | |
|--|--|
| Control system | <p>Thanks to customized software developed by AIRPLAN, users can automate production recipes, generate reports and manage and record different process variables. The software is programmed and customized for each equipment.</p> |
| Title 21 CFR Part 11 | <p>We also offer optional compliance with regulation Title 21 CFR Part 11, including the specific license.</p> |
| Optional monitoring systems | <p>Options:</p> <ul style="list-style-type: none">▸ Integrated equipment control via a SCADA system▸ Remote control (telecontrol) and maintenance through a VPN router |
| Instrumentation and accessories | <p>The equipment is supplied with all the connections and accessories the client needs, such as:</p> <p>Product inlet with illuminated sight glass, rupture disk, pressure transmitter, sterile vent filter, sampler, sparger (N₂), temperature probe, pH meter, etc.</p> <p>The control panel displays critical process variables in real time and allows parameter adjustment such as: temperature, pressure/vacuum, pH, dissolved O₂ concentration, product weight, stirring system speed, etc.</p> |
| Compliance | <p>Delivered with CE or UL mark</p> |



The control panel includes customized software for an easy and complete process control



The connection type and the location are specifically designed for each project

VI. UNLOADING

Unloading material

We manufacture our standard vessels with pharmaceutical grade sanitary bottom valves. We ensure that the vessel can be completely emptied during drainage tests, as required by ASME BPE standards.

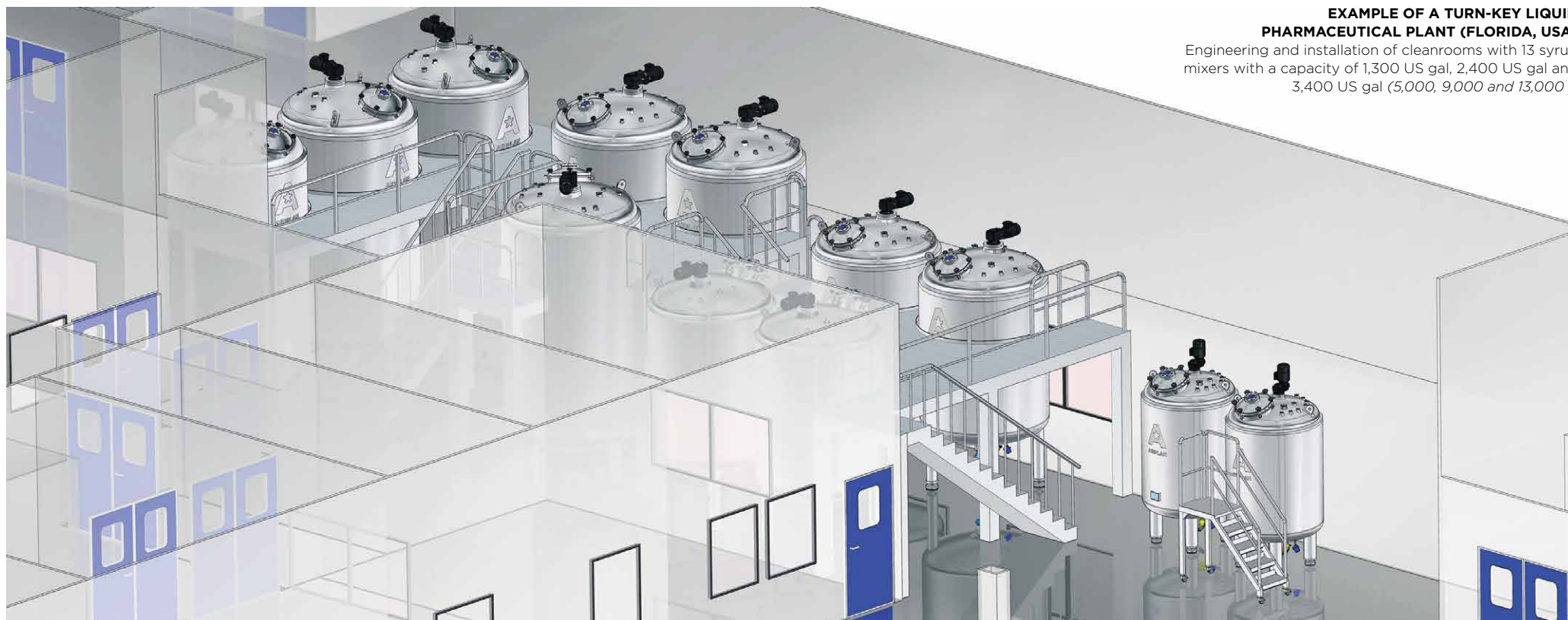


Bottom valve

VII. CLEANING SYSTEM

CIP/SIP system

CIP/SIP (Clean-in-Place/Sterilization-in-Place) cleaning systems (THE PRO CLEAN, page 18) are also available.



EXAMPLE OF A TURN-KEY LIQUID PHARMACEUTICAL PLANT (FLORIDA, USA)

Engineering and installation of cleanrooms with 13 syrup mixers with a capacity of 1,300 US gal, 2,400 US gal and 3,400 US gal (5,000, 9,000 and 13,000 l)

COMPETITIVENESS IN EACH INDUSTRY

WITH CUSTOMIZED PROCESS EQUIPMENT

We present our five types of vessels, commonly used in different industries. We create unique equipment and customized process lines, providing objective advice on the steps to develop the best solution.

INJECTABLES

THEPROPREPINJECT - STERILE SOLUTION PRODUCTION VESSEL

| | |
|-----------------|---|
| Use | Sterile preparation of liquids such as ophthalmic solutions, injectables, etc. |
| Benefits | <ul style="list-style-type: none">▶ Allows working with a wide range of partial capacities, from 10-15% up to 100% of the nominal useful vessel volume▶ Easy application of CIP/SIP process in all our vessels |
| Mixer | Magnetic agitator especially designed for the preparation of easy-to-clean sterile solutions. |

SERUMS

THEPROPREPSERUM - LARGE VOLUME TANK FOR PARENTERAL SOLUTIONS

| | |
|-----------------|--|
| Use | Preparation of all types of parenteral solutions |
| Benefits | <ul style="list-style-type: none">▶ Capacities of up to 4,000 US gal (15,000 l)▶ Easy application of CIP/SIP cleaning processes |
| Mixer | Normally with a magnetic agitator located at the bottom of the vessel. Other mixing systems may be implemented at the request of the client. |



THEPROPREPINJECT

Sterile Solution Vessel - 105 US gal (400 l)
Client: New Stetic / Colombia / 2013



THEPROPREPSERUM

Two Serum Vessels - 4,000 US gal (15,000 l)
Client: Biogalenic / El Salvador / 2011



THEPROPREPSERUM

Two Serum Vessels - 400 US gal (1,500 l)
Client: Bonin / Guatemala / 2010

BIOCHEMICAL PROCESSES

THEPROPREPBIO - BIOVESSEL

| | |
|-----------------|--|
| Use | For use during fermentation processing, growth and control of biological cultures |
| Benefits | <ul style="list-style-type: none"> ▶ Versatility and easy adaptation to biological processes ▶ Control of suitable environmental conditions for the process (temperature, pressure, pH, O₂ concentration, etc.) ▶ Easy application of CIP/SIP cleaning processes |
| Mixer | As appropriate for each biological process. Magnetic agitator available, installed at the bottom of the vessel. |

SYRUPS AND SOLUTIONS

THEPROPREPSYRUP - SYRUP VESSEL

| | |
|------------------------|---|
| Use | Preparation of syrups, suspensions and other solutions |
| Benefits | <ul style="list-style-type: none"> ▶ Especially designed to work with solutions with high sugar concentration ▶ Capacity according to client requirements ▶ Suitable for vacuum and over-pressurization processes |
| Loading options | <ul style="list-style-type: none"> ▶ External solid raw material loading by means of in-line recirculation mixers. The system allows to make products of a wide range of viscosities. ▶ Easy loading of solid raw materials using vacuum systems. High-speed agitator enabling easy product homogenization. Optional second anchor-type agitator to facilitate processes with high viscosity solutions. |

STORAGE

THEPROTANK - STORAGE TANK

| | |
|-----------------|---|
| Use | Storage tank for liquid products |
| Benefits | <ul style="list-style-type: none"> ▶ Capacity according to client requirements ▶ Adapted to the operating conditions, temperature and pressure, and to the type of product being stored ▶ Optional stirring and control systems ▶ Suitable for operation in potentially explosive environments (ATEX / NFPA) upon request |



THEPROPREPBIO
Biovessel - 50 US gal (200 l)
Client: Microsules / Uruguay / 2013



THEPROTANK
Storage Tanks - 790 and 1,600 US gal (3,000 and 6,000 l)
Client: Provital / Spain / 2013



THEPROPREPSYRUP - Syrup Production Line - 530 US gal (3,000 l). Client: Biotech / Venezuela / 2013

OTHER PROCESS COMPONENTS

Accessories that increase the performance of the liquid manufacturing process

TEMPERATURE CONTROL

THEPROSKIDTHERMO - TEMPERATURE CONTROL SKID

Description Compact unit with the valve assembly for the automatic control of the product temperature inside the vessel.

Benefits **Integrated and complete.** Designed and manufactured at AIRPLAN, where it is subjected to strict quality controls. Fast, clean assembly.

THEPROSKIDTHERMO

Temperature control skid
(top photo with protective covers;
bottom photo without covers)



THEPROPUMP

Transfer Pump



TRANSFER

THEPROPUMP - TRANSFER PUMP (PORTABLE OPTION)

Description Sanitary pumps to transfer liquids, designed for in-situ cleaning (CIP, with SIP available).

Benefits **Compact design.** Optional mobile cart for easy moving around. Electric panel with built-in control panel for system control. It may be used as a recirculation pump in CIP systems.

THEPROFILTER

Filtration unit



LIQUID FILTRATION

THEPROFILTER - FILTRATION UNIT (PORTABLE OPTION)

Description Equipment for filtering liquid products.

Benefits **Compact design.** Adaptable to each process. Designed for CIP/SIP cleaning. Optional built-in mobile cart for easy moving around.

THEPROACCESS

Platform



ACCESS

THEPROACCESS - PLATFORM WITH STAIRS

Description Stainless steel operating platform for easy access to the equipment.

Benefits **Customized design:** The platform and ladder are custom made to match the equipment dimensions and the geometry of the room where it will be used.

CLEANING

THE **PROCLEAN** CIP/SIP MOBILE - "IN SITU" CIP/SIP CLEANING SYSTEM

Description "In situ" cleaning system CIP (clean-in-place)/SIP (sterilize-in-place) that makes it possible to manage the four key factors in cleaning operations:

- ▶ **Mechanical.** The impact produced by the flow and pressure of water and detergent
- ▶ **Chemical.** Concentration and type of detergent solution
- ▶ **Thermal.** Temperature control
- ▶ **Time.** Different phases of the production programs

Benefits

- ▶ **Replicable process.** Consistent results from each cleaning cycle
- ▶ **Automatic.** Automated cleaning process with confirmation via software
- ▶ **Certifiable.** Designed according to international standards
- ▶ **Guidelines.** Practical instructions for cleaning processes
- ▶ **Data protection.** Information is protected by multiple password levels
- ▶ **Environmentally friendly.** Low energy, water and detergent consumption
- ▶ **Flexible.** May be operated manually or automatically
- ▶ **Manageable.** Easy to move around
- ▶ **Time-saving.** Fast cleaning process
- ▶ **Safety.** Prevents cross-contamination

THE PRO CLEAN CIP systems are available as mobile or fixed systems.



THE PORTABLE **PROCLEAN** CIP MOBILE with a double tank



THE **PROCLEAN** CIP MOBILE without tank



THE **PROCLEAN** CIP with single tank, fixed version



WATER FOR PRODUCTION

INSTALLATION INTEGRATED WITH THE PROCESS LINE

We offer the design, supply and complete installation of systems required for the production of water and pure steam, the essential components for each process, including manufacturing, cleaning and sterilization.

WATER PRODUCTION

THEPROPW / THEPROHPW / THEPROWFI / THEPROPURESTEAM

Description Technology for the production of:

- ▶ **(Highly) Purified Water (PW/HPW):** reverse osmosis equipment (OI, RO, RORO) and electrodeionization equipment (CEDI)
- ▶ **Water for Injectables (WFI):** distillers suitable for producing water for injectables
- ▶ **Pure Steam:** pure steam generator for sterilization

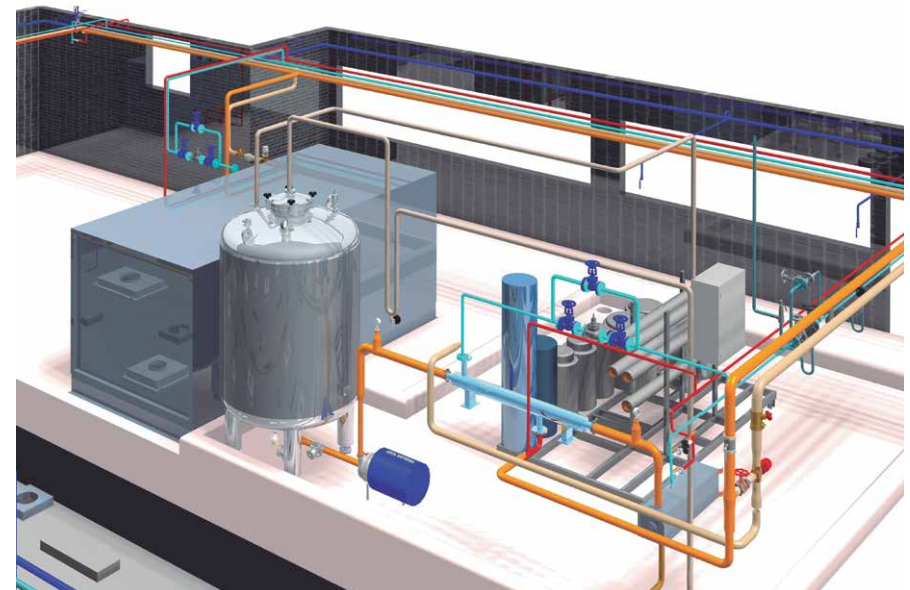
Benefits We work with our clients to find the best solution in terms of their specific needs, applicable regulations, process and environment. Water installations are delivered as a modular skid that only needs the loop and storage tank to be put into use.

PURIFIED WATER DISTRIBUTION

THEPROLOOP

Description **Water loop** for the distribution of production water.

Benefits Thoroughly engineered with prefabricated connections made at AIRPLAN to ensure perfect integration with the rest of the plant installations.



Production and distribution of purified water (PW)



Water treatment and generation of purified water (PW), including water loop and storage tank



YOUR AFTER-SALES SERVICE

AIRPLAN HELPDESK

We offer you our AIRPLAN CARE hotline to help resolve any incident you might have with your process line or equipment, providing a solution over the phone or, if necessary, in person.



+34 938 788 384



wecare@airplan-sa.com

Maintenance / Spare parts

We offer preventive and corrective maintenance plans, as well as spare part packages.

Ask for more information about our after-sales service!

Training

With our initial training, custom-planned in accordance with your specific needs and concerns, we design a training plan in which we show you how to use and maintain your installation and equipment properly.

We also provide you a customized maintenance checklist.

Qualification

Our equipment has passed strict quality controls before leaving the factory. Equipment started up by AIRPLAN personnel is delivered with a detailed report. As a complementary service, AIRPLAN offers the option to prepare and carry out FAT and SAT protocols (Factory / Site Acceptance Tests). We also design and implement IQ and OQ protocols at the client's request.

Documentation

Each process equipment and facility is delivered with its respective *Documentation Dossier*, in digital and paper format. This includes the technical documentation from the component manufacturers, the specific operating manual for the equipment or production line, electric diagrams, certificates and relevant technical diagrams.





More?

process@airplan-sa.com
www.airplan-sa.com

AIRPLAN

C. Vallcebre 13 - 19 · 08272 Sant Fruitós de Bages · Barcelona · Spain · Tel: +34 938 788 384

AIRPLAN USA

4601 Sheridan St, Unit 211 · Hollywood, FL 33021 · USA · Tel: +1 321 888 2888

AIRPLAN PT

Rua Fernando Mauricio 37A · 1950-450 Lisboa · Portugal · Tel: +351 210 948 855

AIRPLAN MX

Avda. Américas 1254 - P19 Int 19-125 · 44610 Country Club · Guadalajara - Jalisco · Mexico · Tel: +52 33 2101 2138



LIQUIDPROCESS

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