



AIRPLAN
Cleanroom & Process Solutions

CLEANROOM

TURNKEY SOLUTIONS

CLEANROOMCUSTOMIZER

COMPREHENSIVE SOLUTIONS FROM CONCEPT TO COMPLETION





EXPERTISE

IN LIFE-SCIENCE INDUSTRY PROJECTS



For more than 50 years AIRPLAN has integrated design, consultancy and installation solutions for turnkey projects to meet the needs of our clients around the world.

We have carried out 2,000 engineering, modular cleanroom and process line projects in industries as diverse as pharmaceutical, biotechnology, cosmetics, hospital, chemical and food.

CLEANROOMCUSTOMIZER

CLEANROOM CUSTOMIZER is the result of years of experience dedicated to the design and production of cleanrooms created from detailed engineering and adapted to the requirements of each project.

We have the necessary experience and capacity to propose and execute integral solutions guaranteeing compliance with regulations, delivery times and budget.





SUCCESS

IS NOT A MATTER OF LUCK

All answers from just one source

Contracting a turnkey project means dealing with a single responsible for your project. At AIRPLAN, we fully develop and manage our projects without diluting responsibilities amongst different vendors. Our goal is our client's peace of mind, taking responsibility for the successful delivery and operation of the installation - with the AIRPLAN guarantee.

CONSULTING

- Technical, economic, legal and feasibility studies
- Options research
- User requirements definition (URS)

ENGINEERING & DESIGN

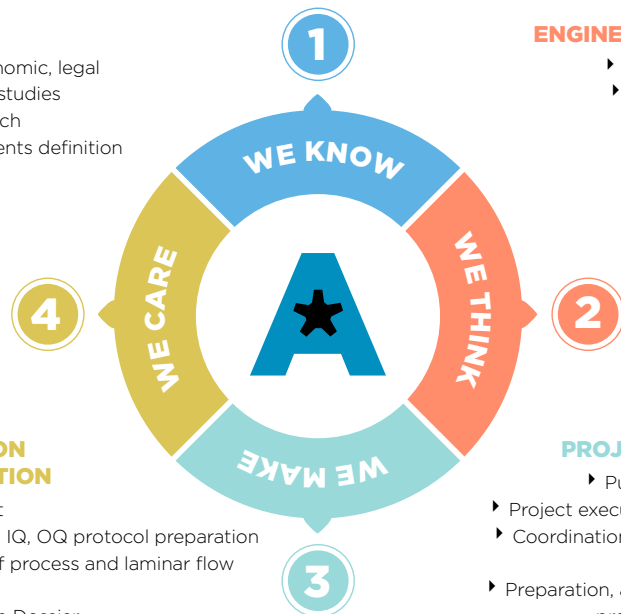
- Project management
- Process Engineering
 - Concept design
 - Functional design
 - Detailed design
- Construction plans

CERTIFICATION & QUALIFICATION

- Start-up report
- FAT, SAT / DQ, IQ, OQ protocol preparation
- Qualification of process and laminar flow equipment
- Documentation Dossier
- Facility re-qualification

AFTER-SALES

- AIRPLAN CARE after-sale services program



We transform concepts into reality

Working together, we will turn your projects into productive and competitive facilities. We understand the current regulations and industry trends. We advise to make sure that legal requirements are met along with the appropriate level of technology.

Our clients are unique. So are our solutions.

Each production plant has specific challenges that require custom-made facilities. Our team of engineers analyzes the production cycles and critical factors of your project to design a functional plant, optimizing both investment costs and operation.





THE ADVANTAGES OF WORKING WITH AIRPLAN

Energy efficiency

Every engineering project is developed taking into account the technical solutions that offer optimal energy efficiency in both production and energy transport. We design projects that promote minimal consumption, generating significant primary energy savings, along with energy recovery systems.

Our Engineering Division conducts comprehensive simulations of HVAC systems and components, optimizing their performance to determine the best solution for the client.

Ask for an audit of your existing facilities to identify points of high energy expenditure and we will deliver a proposal to obtain significant energy savings.

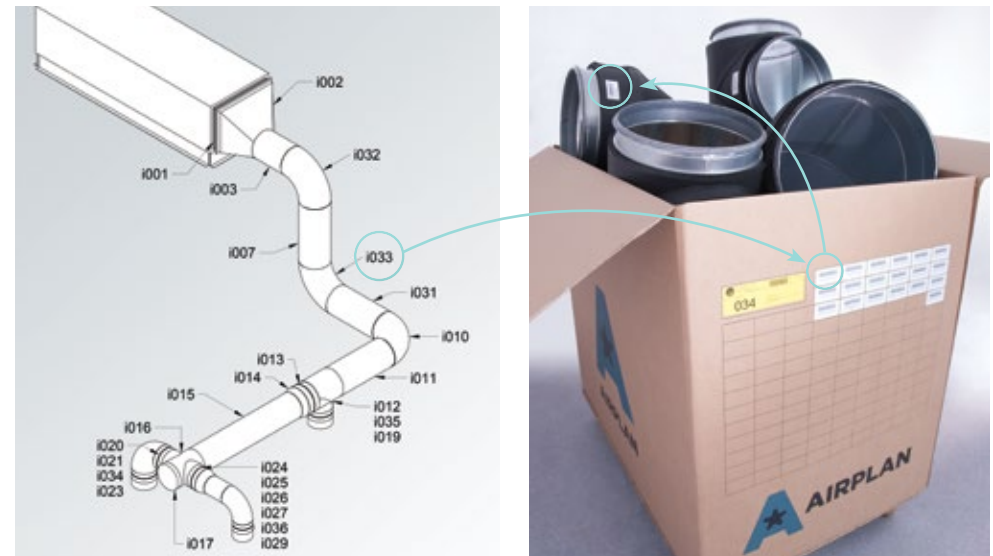
Personalized assembly

Whether you want AIRPLAN to assemble your project or you prefer to use your own staff, we have the solution for you. We can train your staff to carry out the assembly under AIRPLAN supervision, which enables you to perform your own maintenance without external intervention. By using your own staff, you can reduce investment and maintenance costs.

Assembly without surprises

Good preparation is crucial for a smooth and clean assembly. During the engineering phase, each component receives a unique code which then appears on the piece and its packing box. Thanks to this tracking system, the exact location of all the components can be established at any moment. We follow an assembly protocol to guarantee that this process is quick and organized.

Materials are sent ready to be assembled in our clients' facilities, guaranteeing their clean and precise integration. We avoid cutting or welding, and changes in civil engineering especially, for quick and easy assembly that doesn't generate dust, noise or unexpected expenses.





COMPREHENSIVE AND INTEGRATED SOLUTIONS

Our comprehensive design + construction + validation programs for cleanrooms:

▶ ▶ ▶ STUDIES

ENGINEERINGPARTNER

PHASES

ENGINEERINGCONCEPT - Concept design
ENGINEERINGFUNCTIONAL - Functional design
ENGINEERINGDETAIL - Detailed design

▶ ▶ ▶ EXECUTION

CLEANROOMCUSTOMIZER

CLEANROOM SOLUTIONS

CLEANROOMENCLOSURE - Modular paneling, flooring
CLEANROOMUTILITIES - Critical utilities
CLEANROOMLAB - Laboratory solutions
CLEANROOMHVAC - Air treatment

AIRSPECIALIST

LAMINAR FLOW PRODUCTS AND SOLUTIONS

THEAIRBOOTH - Downflow booths
THEAIRFFU - Fan filter units
THEAIRLAMINAR - Tailor-made laminar flows

PROCESSDESIGNER

PRODUCTION LINES

LIQUIDPROCESS - Liquid process lines
SEMISOLIDPROCESS - Semi-solid process lines
SOLIDPROCESS - Granulation process lines
WATERPROCESS - Water for production

▶ ▶ ▶ AFTER-SALES

AIRPLANCARE

AFTER-SALES SERVICES

REMOTE CARE - Remote system monitoring
PREVENTIVE CARE - Preventive maintenance
DIRECT CARE - Corrective maintenance
RENEW CARE - Spare parts packs
VALUE CARE - Qualification and re-qualification

AIRPLANSERVICES

COMPLEMENTARY SERVICES

AIRPLANS CADA - Supervisory control system
AIRPLANDOCS - Project documentation
AIRPLAN START-UP - Start-up service
AIRPLAN TRAINING - Staff training

During the past 45 years, we have evolved side-by-side with our clients. With our training, experience, regulation knowledge and know-how in the field of applied engineering, we know which approach is the best for your project.

Additional benefits

Detailed engineering, concise drawings, standardized work processes. Key points that facilitate a project's transition from paper into reality. The fluidity of assembly, installation and start-up of a cleanroom with its thousands of components demonstrates whether or not a project has been thoroughly planned.

Additionally, our 3D project plans allow you to follow the progress of your project in real time, documented weekly using photographs and interactive plans with detailed views and even *virtual tours* in video format.

Our engineering process comprises 3 phases:

ENGINEERINGCONCEPT

Concept Design

- ▶ User Requirements Definition (URS)
- ▶ Production diagrams
- ▶ Production layout
- ▶ Study of alternative services
- ▶ Total energy balance
- ▶ Air balance
- ▶ Equipment lists
- ▶ Airflow diagrams
- ▶ Utility diagrams
- ▶ Cost estimation
- ▶ Planning

ENGINEERINGFUNCTIONAL

Functional Design

- ▶ Technical memory
- ▶ Process & material flow diagrams
- ▶ Piping & Instrument Diagrams (P&ID)
- ▶ Room-book (utilities requirements per room)
- ▶ Technical sheets of process equipment
- ▶ Utilities' line diagrams
- ▶ Equipment and materials' technical specifications
- ▶ Floor Plans

ENGINEERINGDETAIL

Detailed Design

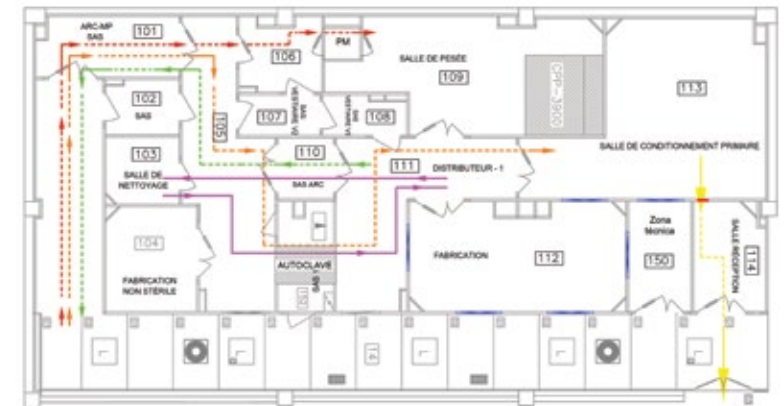
- ▶ Technical memory
- ▶ Electrical diagrams
- ▶ Control diagrams
- ▶ Calculations and specifications
- ▶ Equipment location
- ▶ Routing of air and utility ducts
- ▶ Isometric drawings and material lists
- ▶ Construction drawings
- ▶ Bill of quantities

We comply with international guidelines and regulations and their interpretation at the local level, including cGMP, ISO 14644, 21 CFR Part 11 (FDA), etc.



EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH.

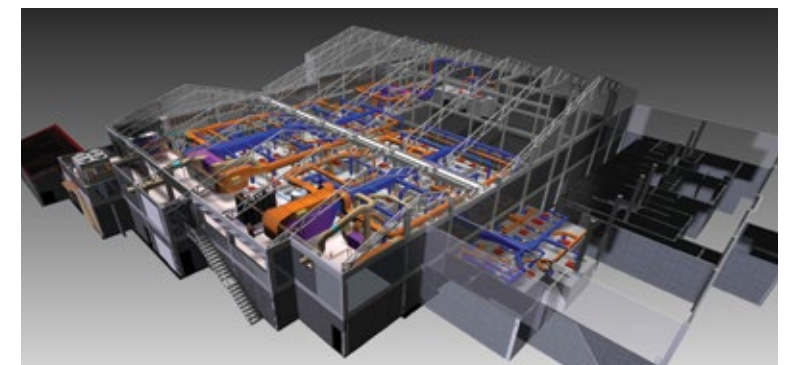
ENGINEERINGCONCEPT



ENGINEERINGFUNCTIONAL



ENGINEERINGDETAIL



CLEANROOM ENCLOSURE

Paneling, Enclosures, Flooring

With our modular paneling system, you can create personalized rooms according to your needs, and in compliance with current local and international regulations. We propose specific and validable solutions for all cleanroom area classifications built with materials that comply with ISO 14644 guidelines.

Additional benefits

Modular paneling significantly reduces investment costs in civil engineering and allows for plant layout modifications and reuse of materials without production downtime, for example when entering large equipment in the future. Panels are self-supported and capable of withstanding walkable ceilings. Additionally, the paneling provides excellent acoustic and thermal insulation, which helps to maintain temperature, relative humidity and differential pressure conditions and minimize air leakage. The panels possess high mechanical and chemical resistance and are available with a variety of panel faces, such as oven-painted galvanized steel, phenolic resin, polymer-coated (PET) steel or stainless steel. All finishes comply with cGMP regulations: they do not emit particles, prevent dirt accumulation, and are easy to clean. Moreover, we provide different floor treatments, like epoxy paints, vinyl flooring, etc. available in a wide color-range.

CLEANROOM ENCLOSURE includes the following elements:

- ▶ Panels
- ▶ Doors
- ▶ Windows
- ▶ Integrated lighting
- ▶ Floors
- ▶ Walkable ceilings
- ▶ Specific accessories for every type of facility

**All elements are available
in a wide color-range**

We offer special paneling structures for exteriors.

Furthermore, we've created a ready-to-use cleanroom, **THE QUICK BOX**, that satisfies specific applications in limited spaces.



CLEANROOMUTILITIES

Critical utilities

As a turnkey provider, we offer careful planning for the different energy and technical gas installations, ensuring seamless integration of the project, avoiding conflicts between systems and optimizing the production process.

An initial design concept of total energy optimizes useful installation space, minimizes energy costs and reduces start-up time. Additionally, we provide each production plant with systems for efficient process control.

HEATING / COOLING ENERGY

- ▶ Chillers
- ▶ Boilers
- ▶ Heat pumps
- ▶ Installation of hydraulic networks:
 - > cooling / heating water
 - > steam
- ▶ Exchangers: Secondary circuits / energy recovery

ELECTRICAL ENERGY

- ▶ Power and control
- ▶ Regulation and control systems
(AIRPLAN SCADA, page 18)
- ▶ Electrical installation

CITY WATER SUPPLY

Chilled / hot municipal water

PHARMACEUTICAL WATER / STEAM

(see page 17)

INDUSTRIAL GASES

- ▶ Compressed air (industrial / pharmaceutical)
- ▶ Vacuum
- ▶ Nitrogen
- ▶ etc.

FIRE PROTECTION

- ▶ Fire prevention installation: fire detection and suppression systems
- ▶ Security installation: fire prevention control panels

We comply with the requirements established by the European Low Voltage Directive (CE), as well as the National Electric Code (NEC) and the National Fire Protection Association (NFPA) standards.

Our engineers design under MEP criteria (Mechanical, Electric, Plumbing) and we work with specialists in each field.



CLEANROOMLAB

Laboratory furnishings

Equip your lab with total flexibility using our extensive range of modular furnishings, made of high strength materials, finished with care, easy to clean, and featuring a modern look. Our modules offer excellent visual control over each area and are easily combinable. We can equip quality control, R+D, microbiology or pharmaceutical development laboratories, among others.

Additional benefits

We integrate furniture to the physical geometry of your laboratory to create a functional and aesthetic environment that optimizes space utilization in accordance with work flow and equipment. We take advantage of the existing infrastructure to avoid alterations in original civil engineering and reduce additional costs. Ergonomic design of each element encourages operator comfort, ensuring proper job execution.

CLEANROOM LAB includes

- ▶ Height adjustable, mobile, support or (anti-vibrating) weighing tables
- ▶ Safe storage in ventilated or safety cabinets for reagents, acids and bases, and flammables.
- ▶ Technical walls that allow mobile, adaptable and safe environments
- ▶ Worktops made with high-strength, certified materials
- ▶ Washing modules with incorporated sink, with heavy-duty construction against spills and splashes
- ▶ Waste separation modules
- ▶ Equipment such as fume hoods, fume cupboards, etc.



CLEANROOMHVAC

Air Treatment

We have been specialists in industrial air treatment solutions since 1968. Our systems guarantee effective control of temperature, relative humidity, pressure and environmental classification requirements from ISO 8 to ISO 1 as per ISO 14644. We offer aseptic, sterile or semi-sterile production areas, for biocontainment or biosafety, as well as suitable solutions for applications for the life-science, food, microelectronic and hospital industries or HVAC comfort for large offices and public works.

Additional benefits

We also provide special solutions, such as cleanrooms with ISO 7 classification at temperatures that range from $-10^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ($14^{\circ}\text{F} \pm 4^{\circ}\text{F}$) to $60^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ($140^{\circ}\text{F} \pm 2^{\circ}\text{F}$), maintaining the temperature in any place within the room, as well as the areas with a relative humidity of 1%. The critical elements of the air conditioning systems are made according to the AIRPLAN design: air ducts, room extraction structures, HEPA filter drawers/boxes, diffusion elements in stainless steel, etc. Moreover, we offer centralized systems for dust collection (THEAIRDUST) and gas and fume extraction (THEAIRFUMES).

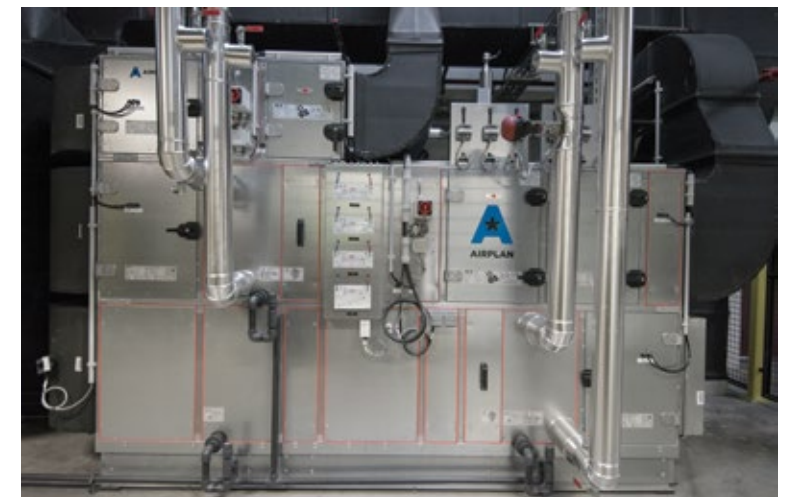
1) Collection



2) Suction, transport and extraction



3) Filtration (opt. HEPA) prior to discharge



Solutions for laminar flow environments

THE**AIRBOOTH**, THE**AIRFFU**, THE**AIRLAMINAR** equipment from AIRPLAN uses our extensive experience in air treatment for controlled environments, offering sterile areas with laminar ISO 5 classification according to current regulations. Our models are the result of intensive conceptualization, engineering and design, and are based on the specific requirements of our clients.

Additional benefits

Regardless of the available space and infrastructure in your facility, the geometry of the room or the required environmental classification, we can offer a customized solution. Choose from our standard products, their adaptable versions or a custom-designed solution just for you.



THEAIRBOOTH****
Dispensing and weighing booth

Get the necessary containment for raw material during the dispensing and weighing processes, avoid cross-contamination and protect your workers from harmful particles.



THEAIRFFU****
Fan Filter Unit

A fan and filter unit ready to use, providing an ISO 5 classification at particular areas within the cleanroom. Ideal for creating specific clean zones within a controlled environment, such as filling points.



THEAIRLAMINAR****
Customized Laminar flow

To create a homogeneous air flow that covers large and/or geometrically-irregular areas. Installation with diffuser membrane allows this system to adapt to any dimension or size, providing laminar flow air in all corners of the room. Available in horizontal or vertical format, or incorporated into workbenches.

All equipment has been specifically designed to be installed in classified environments, according to FDA (Title 21 Part 11), EU GMP (Vol 4) / cGMP ISO 14644, ASHRAE, etc. regulations.



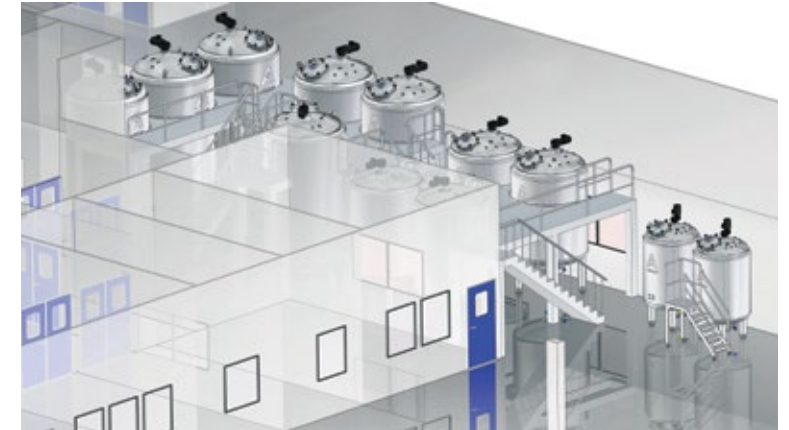
We design equipment and process lines, focused on manufacturing a wide range of your products for the pharmaceutical, cosmetic, biotechnology and food industries. From the initial concept until the final qualification of your equipment, we guide our clients through the entire process of designing a customized solution. We guarantee faithful execution to the original design with high-tech components and custom software for each piece of equipment.

Added value

We offer the ideal technological standard for each project, with optimal quality-price ratio. Our equipment and process lines are conceptualized according to the needs of production, and each piece of equipment is subjected to strict quality control before leaving our assembly plant.

As a complementary service, we can prepare and perform FAT and SAT (factory / site acceptance test), IQ and OQ protocols.

We comply with the European Directive of Machines (2006/42/CE), the European Pressure Equipment Directive (97/23/CE), ASME BPE standards and EU GMP / cGMP and 21 CFR Part 11 (FDA) regulations. We can certify pressure equipment as "U" according to the ASME BPVC (Boiler and Pressure Vessel Code).



LIQUIDPROCESS

Production lines for injectables, serums, fermented solutions and syrups

Some of the available equipment:

THE**PROPREP** - Liquid production vessels
THE**PROTANK** - Storage tanks for liquids
THE**PROSKID CONTROL** - Temperature control skid
THE**PROCLEAN** - Cleaning systems (SIP/CIP)



SEMISOLIDPROCESS

Production lines for creams, lotions and ointments

Some of the available equipment:

THE**PROCREAM** - Production vessels for semisolids
THE**PROFUSER** - Melting tanks
THE**PROSKID CONTROL** - Temperature control skids
THE**PROCLEAN** - Cleaning systems (SIP/CIP)



SOLIDPROCESS

Granulation lines for the production of granules and powders

Some of the available equipment:

THE**PROMIX** - High shear mixer-granulators
THE**PRODRIY** - Fluid bed dryers
THE**PROCLEAN** - Cleaning systems (WIP/CIP)

WATERPROCESS

Integrated installation of water for production

An indispensable commodity for every production, cleaning and eventual sterilization process, we can offer the design, supply and integral installation for water and pure steam systems. Each solution is delivered with a general control system (AIRPLAN SCADA).

WATER PRODUCTION

Technology for the production of

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

Together with our clients we will find the best solution for their specific needs. Water installations are delivered as modular skids that are ready to use requiring only to connect the water loop and the storage tank.

PURIFIED WATER AND STEAM DISTRIBUTION

Loops for the distribution of water required for production

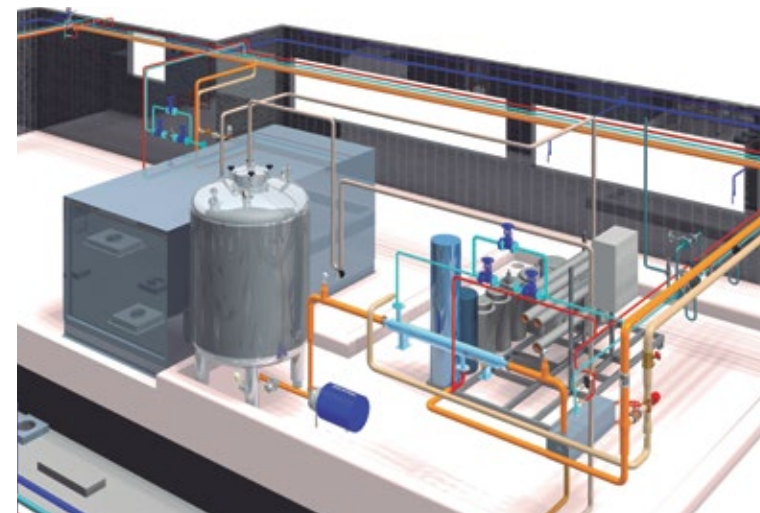
Our exhaustive engineering ensures ultra-fast assembly and perfect integration with the rest of the plant facilities.

STORAGE

Storage tanks for liquid products

- ▶ Capacity according to the requirements of the client
- ▶ Adaptation to working conditions, temperature and pressure, along with the type of product to be stored
- ▶ Possibility of incorporating stirring and control systems
- ▶ Suitable for operation in potentially explosive environments (EU ATEX / NFPA 69), upon request

Designs according to FDA (Gamp), EU GMP / cGMP, ISPE, USP (US Pharmacopeia) and Ph. Eur. (European Pharmacopeia) regulations.



Generation and distribution of purified water (PW)



Water pre-treatment and generation of purified water, including loop for water distribution and storage tank

WE'RE BY YOUR SIDE FOR EACH STEP

START-UP SERVICE

★AIRPLANSTART-UP

We provide a personalized startup service: specific adjustments that optimize performance and avoid unnecessary wear of components while promoting savings in energy and other resources. Each start-up ends with the delivery of the respective report.

TRAINING SERVICE

★AIRPLANTRAINING

Our initial training will help your staff familiarize themselves with the installation elements in a short amount of time, facilitating the proper use of each piece of equipment and a proper maintenance routine. Training sessions are planned according to your specific needs and end with an open question and answer session.

SUPERVISORY CONTROL SYSTEM AND DATA ACQUISITION

★AIRPLANSCADA

The monitoring system is complemented by programmable PLCs (with CE or UL certificates) and their corresponding screens, as well as the SCADA system, customized to your needs. With these tools, you can monitor the main variables of the system.

If the client so wishes, we offer hardware and software in compliance with the Title 21 CFR Part 11 regulation, specific license included.

YOUR DOCUMENTATION ON-HAND WITH

★AIRPLANDOCS

We deliver a global documentation “as built”, printed and in digital format. The *Documentation Dossier* includes an engineering memory of manuals for each component of the installation, plans, operating diagrams and construction schemes, certifications, as well as validation protocols and reports (DQ/ FAT/ SAT/ IQ/ OQ). All information is organized without redundancies and is centralized in a single link easily accessible through our website. Moreover, AIRPLAN saves a back-up copy of your Dossier indefinitely.





WE SUPPORT EVERY SOLUTION WITH CUSTOMIZED SERVICE

We offer a range of after sales services to help you get the most out of your installation or equipment and care for your long-term investment.

FREE SERVICE

AIRPLAN HELPDESK

Questions? Comments? Contact us with any problems at our AIRPLAN CARE number and our team will offer a solution whether remotely or in person.



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MONITORING YOUR FACILITIES IN REAL TIME

REMOTE CARE

As part of our AIRPLAN SCADA program, REMOTE CARE allows for an objective real-time diagnosis to whatever operational issue you're having, wherever you are in the world.

Once you authorize our access, we can study the vital parameters of your equipment or installation to solve the technical problem, without the unnecessary cost of sending specialized staff to the site.

PREVENTIVE AND CORRECTIVE MAINTENANCE

PREVENTIVE CARE / DIRECT CARE

Protect yourself from unseen circumstances or solve any setback with our scheduled or corrective maintenance plans that help you maintain and tune your facilities and equipment. Timely maintenance prolongs the life of your assets and prevents unanticipated high-cost repairs or non-scheduled production downtime.

QUALIFICATION AND RE-QUALIFICATION

VALUE CARE

We can prepare FAT (Factory Acceptance Test) or SAT (Site Acceptance Test) protocols, to be performed in AIRPLAN or carried out at your facilities.

Additionally, we can edit all of the DQ, IQ and OQ protocols for the qualification of your facility, or prepare your installation for re-qualification, carrying out the necessary adjustments.

SPARE PARTS

RENEW CARE

We offer spare part packages customized to your needs. You will find a detailed list of recommended spare parts, along with replacement instructions in your *Documentation Dossier* so that your maintenance department can act quickly. Choose between the *Recommended Pack* or the *Critical Pack*.



More?

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ENGLISH
2018 / 03