LIFE-SCIENCE
SOLUTIONS


# The easy way to validation of pharmaceutical processes

## Control & Automation Solutions and their Integration

AIRPLAN

CONTROL, AUTOMATION AND INTEGRATION
OF PHARMACEUTICAL PROCESSES

# Index



**PROCESSDESIGNER**

CONTROL, AUTOMATION
AND INTEGRATION OF
PHARMACEUTICAL PROCESSES

AIRPLAN

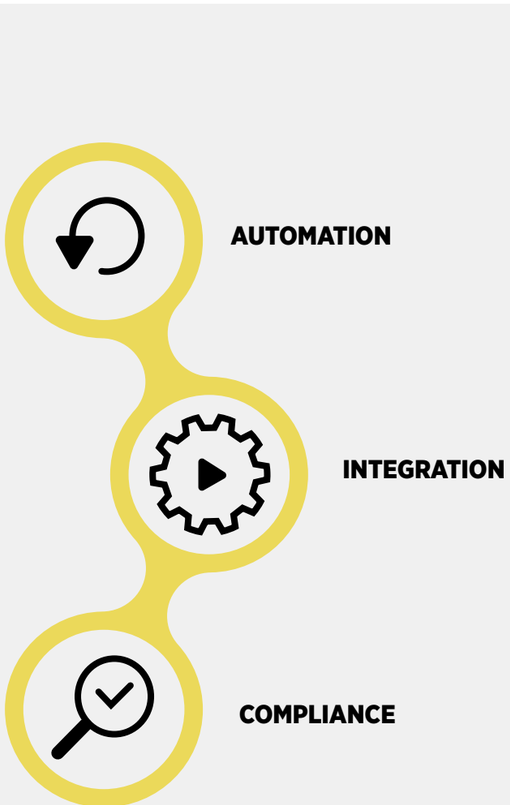
CONTROL, AUTOMATION AND INTEGRATION
OF PHARMACEUTICAL PROCESSES

# Achieve **better production results** with smart, integrated processes

**At Airplan we help our customers achieve greater efficiency and control in their pharmaceutical processes to improve the quality of their products, increase productivity and strengthen their market position.**

We combine consolidated know-how and experience of numerous pharmaceutical process projects with an automation solution developed in-house.

And we do so by instilling intelligence in the facilities we build.


The strategy is based on **3 pillars**:

## **1.** Replicability and traceability

**Automation** is the basis for efficient, stable and consistent production.

## **2.** Smart and centralized control

System **Integration** from a Smart Tank's Sensor to the company's ERP system. One common language with shared data.

## **3.** Regulatory compliance

Quality control and monitoring, as well as comprehensive records and documentation to facilitate the **validation process** of your product.

**Enabling** the three pillars with

**★AIRPLANSCADA**

We offer **holistic end-to-end solutions** based on know-how, smart equipment and automation that result in **robust and easily adaptable processes**.

This approach is based on simple and modular automation and the integration of the different systems, in order to **improve productivity by complying with European and international regulatory standards.**

Each project is developed in **close collaboration and interaction with the client**, creating solutions aligned with their real current and future needs.

All of which provides the basis for **a simple path to validation of automated processes and systems**

ISPE GAMP · FDA 21 CFR Part 11 Compliance · CE · ASME SETTING THE STANDARD · ISA Application of ISA88 Standard for Batch Control

1.

# Process automation

## Efficiency and robustness throughout production

**Control is just as important as the mechanical operation of your new pharmaceutical plant.**

• **Get accurate, predictable and repeatable batches** with minimal human interaction, reducing risks and increasing quality.

• Control production and monitor all changes

• Continuously monitor and verify product quality

• Make staff tasks easier with pre-defined recipes

• Easily create and validate new recipes

**Thanks to its modular structure, AIRPLAN automation systems offer the adaptability and flexibility required to be a functional solution in the long term.**

### FUNCTIONS

» Modular programming according to ISA-88.

» Compliance with international regulations, FDA (21 CFR Part 11), EMA, PIC/S and ISPE (GAMP guide) of good automation practices.

» Electronic batch log (alarms, audit trail, process traceability, historical values) with related graphs.

» Electronic signature that associates a user with a given action.

» Automatic backups by default.

» Optional equipment with UPS power supply, which can continue to record process values and protect HMI / SCADA data to avoid loss in case of blackout

» The system allows three operating modes: *Automatic* (standard manufacturing mode), *Semi-automatic* (recipe design test) and *Manual* (especially for maintenance).

## Automated recipes and batches:
## the bedrock of quality and regulatory compliance


**There can be no efficient production without automated recipes.**

### ★AIRPLANSCADA

### Easy recipe and batch management:

- **Facilitates product and batch validation**
- **Ensures repeatability in manufacturing**
- **Prevents errors in operations**

## Traceability for maximum control

Batch operation allows traceability of user actions and production status changes.

Along with alarm and historical reports, the complete execution of a manufacturing batch can be diagnosed and validated.

The entire process and its metrics are automatically recorded in a protected SQL database. The data associated with the electronic record (alarms, audit trail, process history, historical values) cannot be modified or deleted. Daily and monthly backups are made by default.

2.

# Vertical Integration

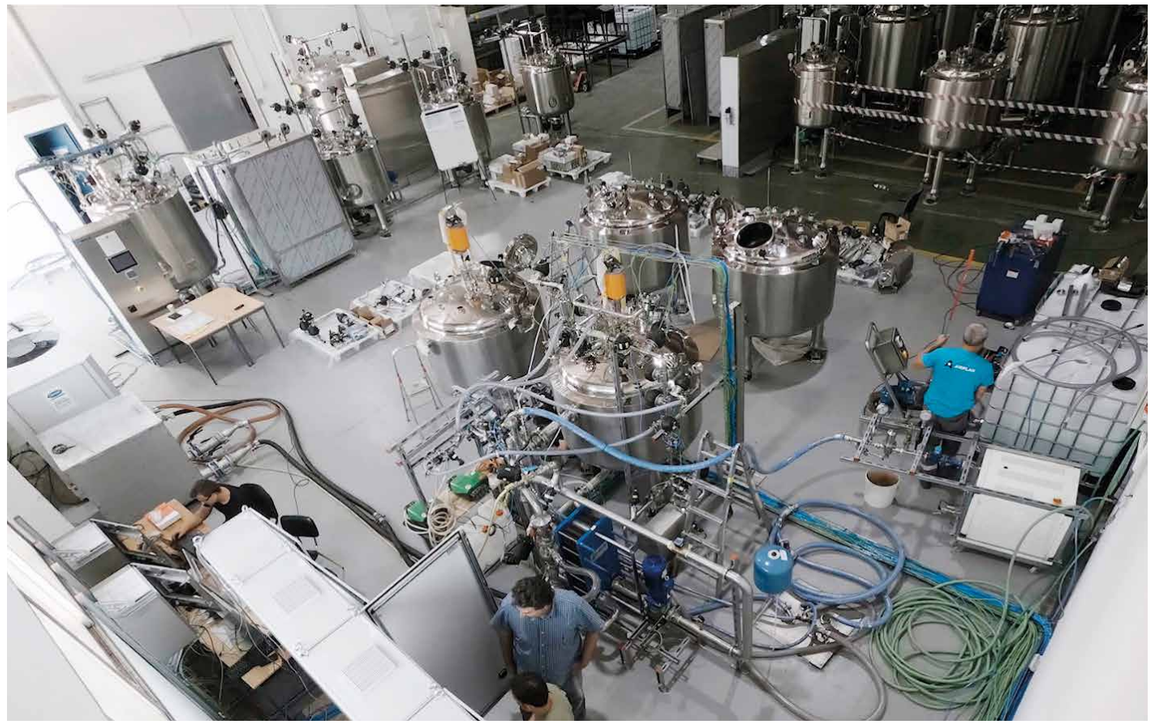
## with operational company management systems (ERP / MES)

**We connect AIRPLAN SCADA with the MES system or with the company's ERP to share necessary production information and thus be able to manage the needs of the company and its departments more easily (for example, purchasing, logistics, production, processes, maintenance, etc.).**

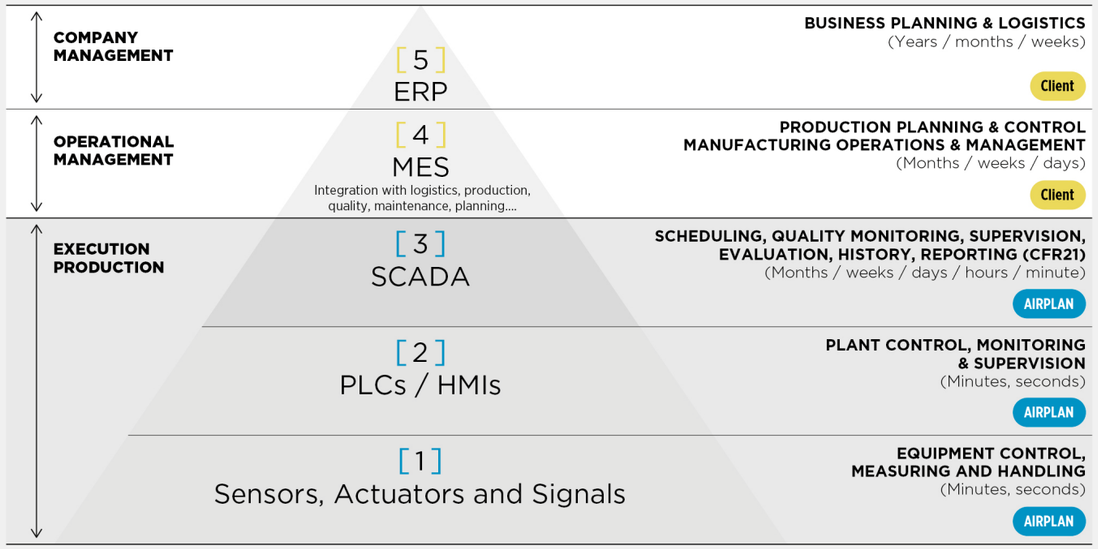
AIRPLAN SCADA systems connect, collect and distribute information among operators and allow process control from a single point. They are based on database systems, which have the advantage that they facilitate integration with the operational management systems of a pharmaceutical plant.

### FUNCTIONS & OPTIONS

- » Centralized user management, historial and recipes (SQL)
- » Reporting, database creation and storage
- » Sharing settings in the product definition
- » Production planning
- » Documentation, evaluation and validation of manufacturing batches
- » Raw material requirements and preparations for smooth internal logistics
- » Maintenance management for process equipment



## Connect enterprise management levels




### ERP

Company-level **department management system** (planning, purchasing, warehouse, logistics, etc.). Communication is often needed with the factory process to access certain plant data.
(ERP = *Enterprise Resource Planning*)

### MES

MES (*Manufacturing Execution System*) can be seen as an intermediate step between the company's ERP System and production control systems (SCADA/HMIs). It processes information and control of all plant operations: logistics, production, quality, maintenance, planning...

### SCADA

Software that **collects and distributes information between operators and process control**. We work with a SCADA (*Supervisory Control And Data Acquisition*) instead of HMI in the case of production systems with more than 4 reactors, or for more complex integrations with MES or ERP systems.

### HMI

**An HMI (*Human-Machine Interface*) is a touch screen computer for PLC control**. It can also handle important tasks as recipe management, reporting and creation and storage of a database.

For lines of up to 4 PLCs it can replace the SCADA system. Our HMIs can be connected directly to a MES or ERP and hence to the other departments at the plant, such as warehouse and logistics, purchasing, quality and maintenance.

### PLC

The control panel of each reactor. It acts like a brain, giving machines their operating instructions.
(PLC = *Programmable Logic Controller*)

### Engineering Station

Recommended in the case of an installation with many systems to generate live back-ups of programs and systems, which facilitates maintenance.

# Which systems can you integrate with ★AIRPLANSCADA ?

**Link different operational systems that share information and routes. Centralized control for greater efficiency.**


# Horizontal Integration
## with other equipment that are part of the production line

**The objective of horizontal integration is the connection of different process equipment from different suppliers in the same SCADA system.**

Our **own equipment** designed by AIRPLAN, is fully integrated natively in the AIRPLAN SCADA application.

All **equipment designed by other providers** require the development of a **horizontal integration strategy** tailored to each case.

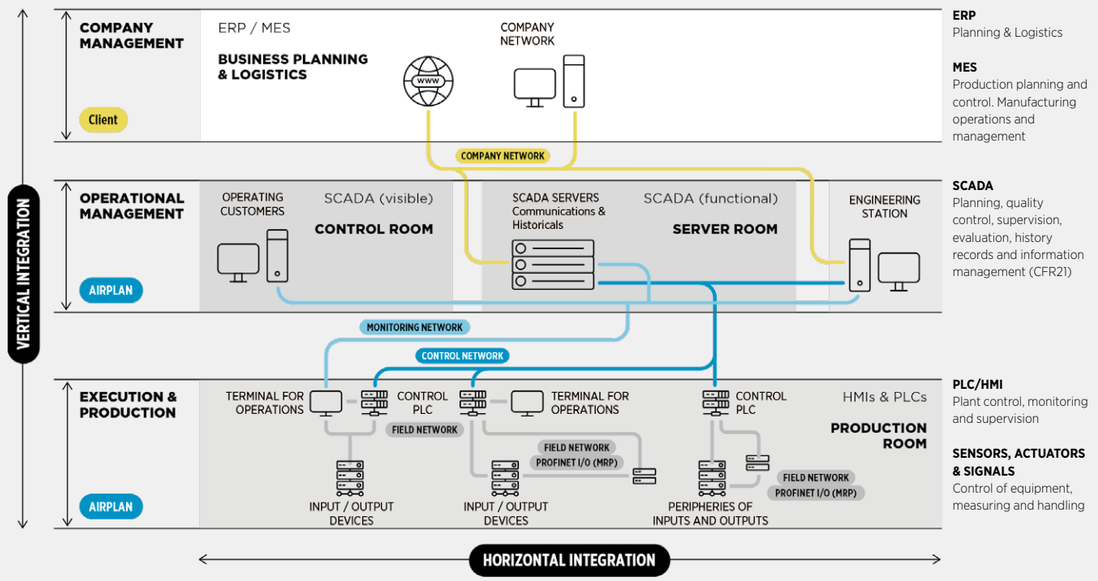
### OPTIONAL HORIZONTAL INTEGRATION STRATEGIES

» **Nivel 0: Funtional (mandatory)**
**To execute shared tasks in a synchronized and secure way between one's own computer and another external one.** Suitable for simple equipment and processes that depend on their own equipment or process and are not relevant to the batch in production or to process validation.

» **Nivel 1: Monitoring**
**To monitor and record relevant information for process validation on an external computer.** Applicable for independent equipment and processes operated locally by HMI. Registration of relevant information for process validation.

» **Nivel 2: Operational**
**Operation of external equipment with AIRPLAN SCADA in a centralized way.** It allows the management of external and internal equipment in the same way and the execution of all functions, from commands and settings to reports.

### Connect company management and production levels



3.

# Process validation

Regulatory compliance as the basis of quality

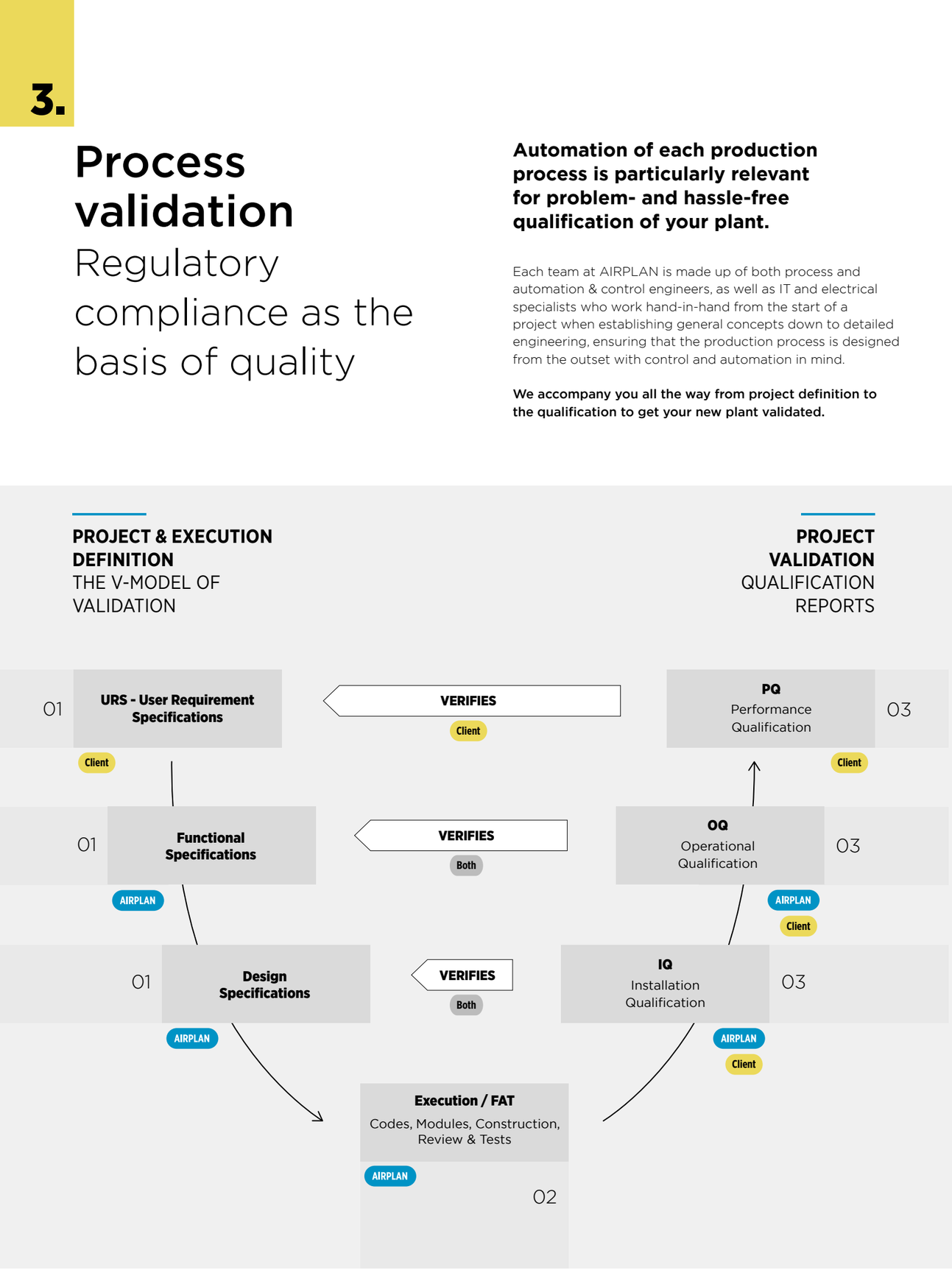
**Automation of each production process is particularly relevant for problem- and hassle-free qualification of your plant.**

Each team at AIRPLAN is made up of both process and automation & control engineers, as well as IT and electrical specialists who work hand-in-hand from the start of a project when establishing general concepts down to detailed engineering, ensuring that the production process is designed from the outset with control and automation in mind.

**We accompany you all the way from project definition to the qualification to get your new plant validated.**

**PROJECT & EXECUTION DEFINITION**
THE V-MODEL OF VALIDATION

**PROJECT VALIDATION**
QUALIFICATION REPORTS




01

## Project definition and solutions

We work with you to achieve an **automated pharmaceutical plant** aligned with your URS, advising and providing you with a solution that is:

- **Bespoke**
Because no two companies are the same, we offer you understanding and flexibility in design.

- **Consistent**
The automated installations you need, no more, no less, whether simple or highly complex.

- **Secure**
With a precise methodology proven over 50 years of experience. We perform process simulations starting with the conceptual phase.

02

## Manufacture and installation

When we accompany you on a project from start to finish, we understand the process and its components better than anyone, because we design it, manufacture it and install it on your production site.

Which ensures that your process line and the control and automation system are working according to project specifications.

02

## Integrated FAT
**(Factory Acceptance Test)**

We check all the instruments and overall operation of the system, the calculations and solutions proposed and the protocols required by the client.

03

## IQ & OQ protocols

These protocols validate the pharmaceutical production project. They demonstrate that the equipment offers a high level of quality assurance and consistently delivers products that meet the established requirements.

We offer **3 management modes** of **IQ (Installation Qualification)** and **OQ (Operational Qualification)**:

1) We offer support to create all the necessary documentation, and you manage the validation.

2) We prepare the documentation, and you manage validation.

3) We prepare the documentation and manage the validation, performed by an independent external provider.

# Simulating your future process

We play safe by scheduling simulations to better develop the system from the early design phases

**With these simulations:**

• We get the best information to develop the client's system.

• We check the program and **anticipate problems and situations** in actual operations.

## Does your plant need a *revamp*?

When a plant process needs to be updated, simulations are equally useful because we can analyse and program the *update* without halting production.

With *revamping* simulations, the installation will be operational as long as possible and the **start-up** of the new system is shortened as far as possible.

## With ★AIRPLANDOCS all your documentation to hand

**We deliver your global documentation *as built* dossier in paper and digital format.**

This includes a manual engineering report for each component of the installation, drawings, operating diagrams and construction schematics, certificates and protocols and validation reports (DQ/ FAT/ SAT/ IQ/ OQ).

Everything is organised without redundancy and centralised in a single *link* easily accessible via our web service, backed up at Airplan.



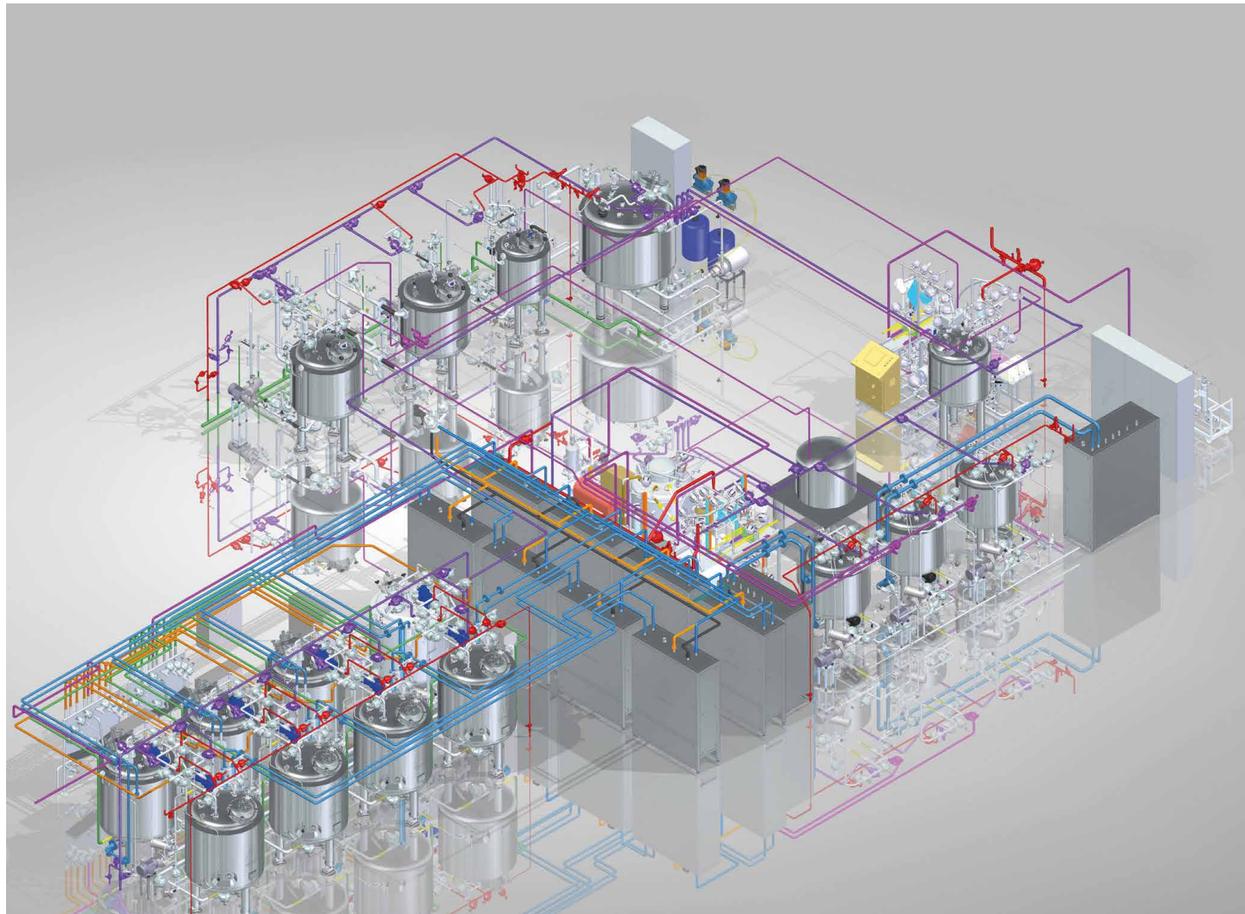

# What is your ideal solution?

We provide unique automation and integration solutions for every business

**No fashions or trends**: we adapt our programs to give companies what they need, based on their situation, characteristics, and production needs.

**On the following pages you will find 4 proposals of control, automation and integration solutions which will be tailored to your specific needs.**

## Which is yours?

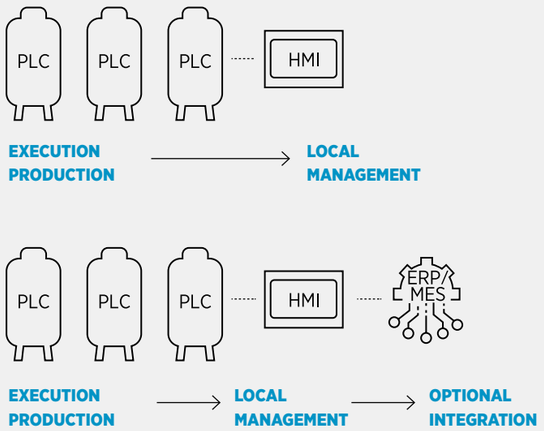


Solutions for

# Local Management

**For production plants with single equipment or small production lines and simple processes that do not require extensive management.**

In the “Plus” version, the PLCs of the Smart Vessels are managed by an Advanced HMI with a database that is compatible with the company’s ERP system.




| | ★AIRPLANCONTROL | ★AIRPLANCONTROL PLUS |
|---|---|---|
| Hardware | **Confort 9”**<br>(Simple HMI) | **PC 12” Panel**<br>(Advanced HMI) |
| Benefit | **The best solution for a production plant without expansion plans and that won’t be connected to other departments. It is the most economical solution in full compliance with the FDA.** | **An advanced HMI to control more complex processes. Your database allows connection to the network of the plant and the other departments. It is an easily expandable solution.** |
| User Management | Application users | Application users |
| Reports | · Without filtering options<br>· Alarm History and Audit Record Reports in CSV format<br>· Local storage<br>· Without display tool | · Report filtering by date or by batch<br>· Alarm History Report<br>· Audit Record Report<br>· Process Traceability Report<br>· Process Values Graphics Report<br>· Configuration Parameters Report<br>· Master Recipe Report<br>· Local storage in MS SQL Database<br>· Display viewing using MS Reporting Services |
| Recipe Management | Without recipe management functions | · Local management<br>· Status (edition, obsolete production) and version<br>· Master Recipe Report<br>· Local storage in MSSQL Database |
| CFR 21 part 11 | Electronic registration in local and encrypted text files, with file integrity verification software | Local electronic registration in MS SQL Server protected against unauthorized access and administrator negligence |
| Options of Integration | · Transfer of files by USB, shared folders or Web Server<br>· Remote operation via SmartClient | · Easy connection with basic SCADA System<br>· Double connection for back-up with Advanced SCADA<br>· Remote operation with SmartClient or remote desktop |

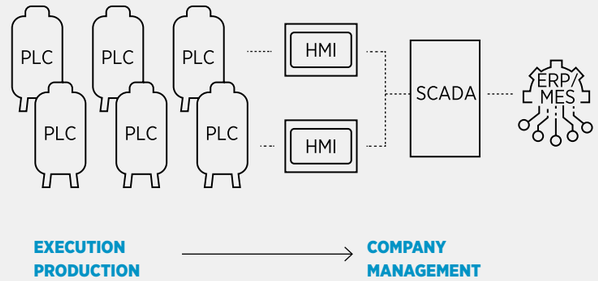


Solutions for

# Centralized Management

**For production plants that require integrated equipment and centralized control management for their complex processes.**

The PLCs of the Smart Vessels are managed with HMIs that are integrated by SCADA and allow direct communication with the company’s ERP or MES.




| | ★AIRPLANSCADA | ★AIRPLANSCADA PLUS |
|---|---|---|
| Hardware | **SCADA (Basic)** | **SCADA (Advanced)**<br>(Additional licenses for integration with other systems) |
| Benefit | **This solution compared to AIRPLAN CONTROL PLUS extends functions and goes from a local to a centralized system that facilitates information management.** | **The hardware is the same as in the SCADA BASIC version. Through additional licenses we extend functions that allow integration with more systems.** |
| User Management | Application users | · Application users<br>· Windows users<br>· Domain users |
| Reports | · Report filtering by date or by batch<br>· Alarm History Report<br>· Audit Record Report<br>· Process Traceability Report<br>· Process Values Graphics Report<br>· Configuration Parameters Report<br>· Master Recipe Report<br>· Local storage in MS SQL Database<br>· Display viewing using MS Reporting Services | · Report filtering by date or by batch<br>· Alarm History Report<br>· Audit Record Report<br>· Process Traceability Report<br>· Process Values Graphics Report<br>· Configuration Parameters Report<br>· Master Recipe Report<br>· Local storage in MS SQL Database<br>· Viewing using MS Reporting Services |
| Recipe Management | · Local management<br>· Status (edition, obsolete production) and version<br>· Master Recipe Report<br>· Local storage in MSSQL Database | · Local management<br>· Status (edition, obsolete production) and version<br>· Master Recipe Report<br>· Local storage in MSSQL Database |
| CFR 21 part 11 | Local electronic registration in MS SQL Server protected against unauthorized access and administrator negligence | Local electronic registration in MS SQL Server protected against unauthorized access and administrator negligence |
| Options of Integration | · MS SQL Server (databases) and client IT systems (maintenance, warehouses, planning...)<br>· Remote operation with SmartClient or remote desktop<br>· Engineering station for programming and remote access | · MS SQL Server (databases) and client IT systems (maintenance, warehouses, planning...)<br>· Engineering station for programming and remote access<br>· PC exclusively destined to SCADA client, including application and licenses<br>· Web server for reports and operation on mobile devices and tablets |

# About us

Helping you overcome challenges in the Life Science industry with tailored solutions for your pharmaceutical and biotech projects

**Achieve validation with automated, integrated systems to drive efficiency, improve quality and facilitate control and production in pharma and cosmetics.**

### ADAPTABILITY

We reject trends and rigid patterns.

Your project, the way it should be. Bespoke.

### EXPERIENCE

3000 projects in 48 countries on 5 continents.

We know what you need, what you have to fulfil in your country, and how to achieve it.

### 100% LIFE SCIENCE

We understand your challenges and needs in the pharma industry.

Since 1968 we have been dedicated to the design and creation of installations and processes in the sector.

### COMMITMENT AND LOYALTY

We accompany you all the way, and listen to you.

80% of our annual revenue comes from repeating customers.

**SIEMENS** **Our technology *partner* for hardware**


Contact us to find out how we can help you with your **process automation, control and validation**


AIRPLAN HEADQUARTERS
C. Vallcebre 13 – 19
Sant Fruitós de Bages
08272 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 Lisbon
Portugal
Tel: +351 210 948 855

AIRPLAN MX
Avda. Américas 1254 P10 Int1
44610 Country Club
Guadalajara Jalisco
Mexico
Tel: +52 33 2101 0478


AIRPLAN