

PRESENTATION MEDICINAL CANNABIS SECTOR















IFMICAL

BIOTECH

VETERINARY



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1. INGELYT PRESENTATION

1.1 Who we are?

INGELYT is a Company 100% spanish capital, which since its creation more than 25 years ago is dedicated exclusively to the design, engineering and installation of clean rooms for all types of companies in the pharmaceutical, chemical, cosmetic, biotechnology, veterinary, aerospace, microelectronics and other related sectors that require controlled environments.

The activity arises as a response to the need that mainly pharmaceutical companies had to control the environment of their manufacturing areas to ensure that the products obtained in their processes reached the quality and safety specifications set by the most demanding regulations (EU GMP, FDA, among the most important).

Thus, began to be built these rooms, as environments free of pollution that include not only the enclosure in which the operations are carried out, but also the air treatment system that controls its atmosphere and the personnel involved in the processes that are carried out.

According to this, we can define cleanrooms as rooms specially designed to achieve low levels of pollution, through the strict control of environmental parameters such as particles in air, temperature, humidity, air flow, indoor air pressure, etc ... For this, both the enclosures, the air treatment and the personnel involved in the processes must be designed and / or educated for the non-generation of pollution.



Founded in 1995, as part of the group of companies of LAPEYRA & TALTAVULL, a company located in Barcelona leader in the representation of machinery for the industry, INGELYT has experienced a remarkable growth to currently have a delegation in Madrid and Barcelona, manufacturing plants in Vitoria Gasteiz and Navarra and reach an average turnover in recent years of 7 million euros.



This evolution has allowed us to consolidate in the execution of this type of facilities, not only in the Spanish market but abroad and more specifically in Latin America where we are backed by a large number of installations carried out and extensive experience, which has even represented 30% of our total annual turnover.

With the experience and knowledge that our references in the sector give us, we offer an innovative and personalized detailed engineering, providing customized solutions for the improvement of processes and facilities according to the specifications and needs of each client.

Definitely, the consolidation of values such as innovation, dynamism, and spirit of service, allow us to provide your facilities with quality, from the initial design phase to the final delivery, required by current regulations, making INGELYT a benchmark in the sector in the execution of this type of projects.

Since 2016 INGELYT begins to bet on the medical cannabis sector, investing resources with specialists in Spain and Colombia, developing GACP/EU GMP advisory projects in different phases of project and production, both in conceptual design and in basic engineering, detail and execution of projects.



Our activity is organized into two divisions that complement each other to respond to "turnkey" projects in clean rooms: Architecture and Facilities, where it begins with the realization of the engineering and basic design of the project until concluding with the execution of the same going through:

- <u>- Internal Architecture:</u> Realization of the interior enclosure system (walls, ceilings, doors, windows, floors, accessories) and own manufacture of all the constructive elements of the rooms.
- <u>-Facilities. HVAC:</u> Design and execution of the air treatment system for the environmental control of the rooms, auxiliary equipment, process facilities...

Advantages of clean rooms with INGELYT:

- Turnkey integral projects.
- Own manufacture (without intermediaries) and custom projects.
- Fast delivery of projects. Flexibility and adaptability.
- 100% Spanish company. Technical team with high technical qualification.



1.2 Our Services



Cleanroom architecture: Tecnipure System

Ingelyt develops the "TECNIPURE SYSTEM" as a global system of interior enclosures focused on the non-generation of contamination and easy cleaning.



HVAC

A good design and operation of the Air Treatment System is one of the critical factors when designing, building and validating a clean room installation.



Critical fluids

Special fluids require a very specific treatment and must be designed and installed according to very strict regulations and procedures.



Industrial facilities

Clean rooms are a very specialized nucleus that needs an industrial environment that provides services, energy and supplies.



Decontamination systems

Periodic cleaning and decontamination of areas, systems and equipment is a necessity that must be considered and planned from the beginning of the design..



Specific cleanroom solutions

Clean rooms have many applications that require very specialized solutions, adapted to their particular conditions of use and exploitation.



Modular cleanroom solutions in containers

Constructive solution through modular containers for implementation both indoors and outdoors. 100% configurable to the needs of each project in one or several heights.



Modular Drying Solutions for Medical Cannabis (MOCAME)

Portable module that optimizes the time and thermal and humidity conditions for the drying of the medicinal cannabis flower.



2. INTERNAL ARCHITECTURE, TECNIPURE SYSTEM



As a fundamental part of a clean room installation INGELYT takes care of the entire system of interior enclosures of the same.

The need to focus its design and construction on the non-generation of pollution has required the development of a system that, through the use of specific materials and solutions, achieves ideal finishes and a total integration of the rest of the facilities.

In this sense and based on the applicable regulations, INGELYT creates the "TECNIPURE SYSTEM", thought as a whole as a global system of enclosures (walls, ceilings, doors, windows, floors and accessories), which allows to offer the most innovative and appropriate technical solutions in a Clean Room installation.

It is a modular construction system, self-supporting, adaptable to the specific needs of each installation and transformable, so it facilitates subsequent extensions or modifications resulting from the production process without having to go to new construction.

Due to the development of specific solutions, it also allows the integration of the rest of the necessary installations, air conditioning, filtration, lighting, fluids... giving rise as a whole to premises typified according to international regulations.

The "TECNIPURE SYSTEM" is applicable in the pharmaceutical, biotechnology, cosmetic medical cannabis, veterinary ... as well as in the hospital and research sector to cover health needs of conflict areas such as operating rooms, animal husbandry, laboratory, containment and biosecurity areas, etc...





For years, our R&D Department has focused on the search for specific materials for the creation of innovative products, and in this sense continues to adapt and implement in them, all the changes and improvements that the regulations and the demands of the production processes are generating.

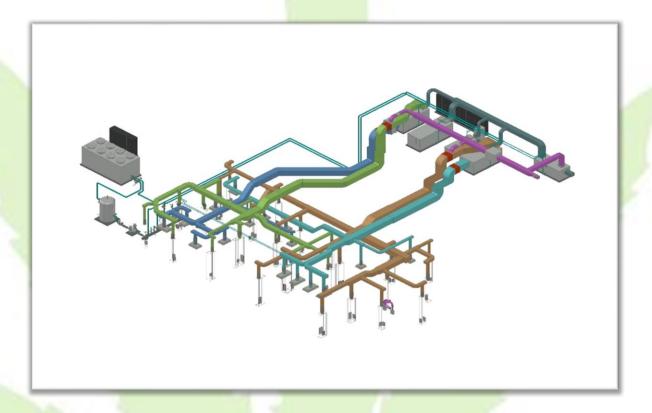
The result of this work is the manufacture of materials certified and tested by reference bodies with total guarantees of quality, functionality and reliability.

The set of enclosures includes the walls made with pharmaceutical sandwich panels with different finishes, recordable watertight ceilings, passable ..., sanitary profiles, specific flush doors for critical areas, windows, floors, lighting and accessories such as lockers, shoemaker benches, SAS materials





3. FACILITIES / HVAC



INGELYT's facilities engineering and HVAC Department is responsible for carrying out the rigorous environmental treatment required in clean rooms and critical areas.

To this end, it is responsible for designing, calculating and executing the air conditioning system in order to:

- Control the environmental parameters determined by the regulations and by the requirements of the production process itself such as suspended particles, temperature, relative humidity, air flow, differential pressures, pressure scaling, etc..
- Reduce and control the introduction, generation and retention of any type of contamination in the rooms: microbiological, dust particles, cross between products, or any other external contamination, including that which may be produced by the operators themselves.
- Create ventilated and / or air-conditioned rooms in an effective way, with air control facilities appropriate
 to the products handled, the operations carried out and the external environment.
- Obtain a customized and sized installation according to the criteria set by the URS.
- Optimize energy efficiency in equipment selection and facility design.
- Minimize the footprint of CO2 emissions, both in the manufacturing phase of equipment and goods and in the construction of facilities.





Our facilities include all the necessary equipment:

- Special clean room AHU's (Air Handling Units).
- Production systems for air conditioning fluids (cold water, steam, hot water) and their distribution.
- Air distribution and extraction pipelines.
- Humidity control systems (humidification and dehumidification).
- Absolute filtration.
- Energy recovery systems.
- Particle monitoring systems.
- Control systems (compliance GMP Compliance 21 CFR part 11)

All this equipment is usually associated with a control and monitoring system that allows managing and visualizing the status of the variables that are decisive for the installation and its subsequent validation.



4. SECTORS

Over more than 25 years, INGELYT has been forged from an experience in the design and construction of clean rooms in the following sectors:

- Pharmaceutical
- Cosmetic
- Chemical
- Biotech
- Veterinary
- Medical Cannabis
- Aerospace
- Microelectronics
- Automotion
- Food
- Nutraceutics
- Sanitary / hospital
- Research
- Glass
- Plastic

5. REFERENCES / MEDICAL CANNABIS SECTOR

Next, we will indicate the most relevant references of projects in the Medicinal Cannabis sector where INGELYT has collaborated:

















6. REFERENCES / PHARMACEUTICAL SECTOR

Below are the main references of clients in the pharmaceutical sector where INGELYT has collaborated:













































































7. INGELYT GENERAL DATA

Below are the general data of INGELYT:

- Production centers:
 - Madrid (Headquarters, warehouses, R&D center & equipment manufacturing)
 - Barcelona (Offices and warehouses)
 - Navarra (Panel manufacturing plant)
 - Vitoria-Gasteiz (Manufacturing plant furniture, carpentry and equipment)
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8. ORGANIZATION, HUMAN RESOURCES & MATERIALS

8.1 Organization chart

INGELYT has a technical team of more than 50 people divided between its headquarters in Madrid and Barcelona. From these headquarters and with the help of our commercial offices INGELYT develops its activity worldwide.



In its factories in Vitoria Gasteiz and Navarra, the materials that INGELYT uses in the architecture of its rooms are manufactured, being strategic logistics points to cover the entire national and international territory.

8.2 Materials

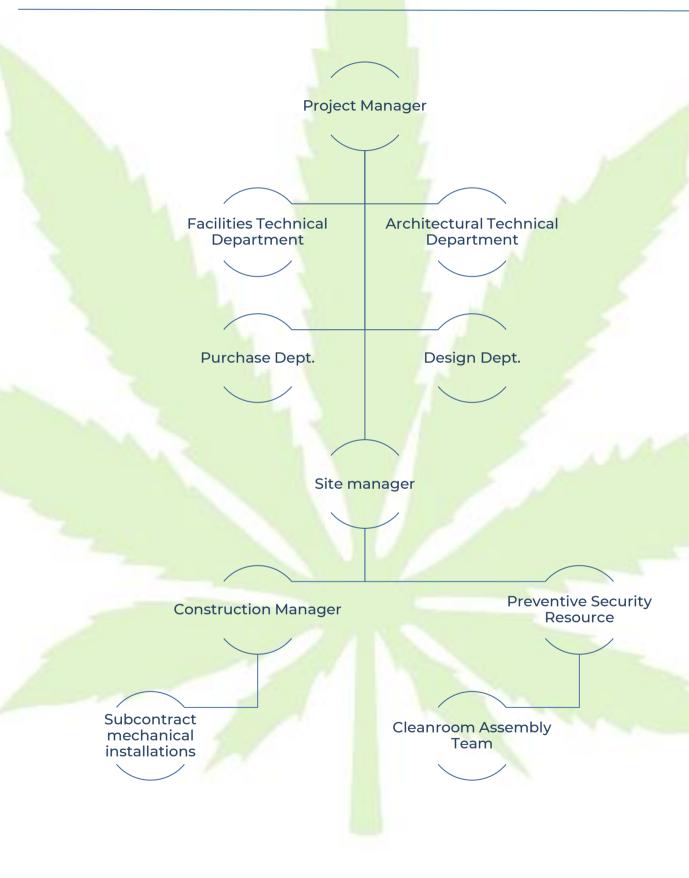
For years, our R+D+I department has focused on the search for specific materials for the creation of innovative products, and in this sense it continues to adapt and implement in them, all the changes and improvements that the regulations and the demands of the production processes are generating.

The result of this work is the manufacture of products certified and tested by reference bodies with total guarantees of quality, functionality and reliability.

The set of TECNIPURE enclosures includes sandwich panels with different finishes and insulation, recordable, passable watertight ceilings ..., sanitary profiles, flush doors specific for critical areas, windows, SAS pasamaterials, floors, lighting and accessories such as lockers, shoemaker benches ... manufactured in national territory.



8.3 Technical team





9. INTEGRAL SERVICE

From INGELYT we put at your disposal a comprehensive service of design and installation of controlled environments:



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