



# Ar Santé

Leading company in the regulatory area, dedicated to the pharmaceutical and chemical sector.





# Service Areas Ar Santé

## HEALTH ESTABLISHMENTS

Advice for the authorization of installation and operation of:  
Pharmacies  
Factories or workshops for the production of cleaners, detergents and/or disinfectants  
Drugstores  
Warehouses (cosmetics, DM, food and hazardous substances)  
Low-Risk Cosmetic Laboratories  
Medicine Cabinets  
Procedure Room  
Audits of establishments.  
Audits to verify compliance with  
Good Practices.  
Advice for the authorization of fractionation area in pharmacies.  
Advice for obtaining authorization for electronic commerce for pharmacies.

## COSMETICS

Registration of cosmetic products  
Registration of HBO products (Hygiene, Low risk, Odorants)  
Modifications to health records  
Transfers of health records  
Organization of cosmetics maquilas  
Registration of the establishment for the GICONA platform  
Design of cosmetic formulations

## PHARMACEUTICAL

Registration of chemically synthesized pharmaceutical and biological products  
Regulatory audits of companies  
NCh-ISO/IEC quality audits  
17025:2017  
Registration of the establishment for the GICONA platform

## DISINFECTANTS

Registration of disinfectant products / Cleaners  
Disinfectants / Sanitizers  
Preparation of Safety Data Sheets in accordance with current national regulations NCH2245:2021  
Manufacturing of disinfectant / sanitizing products.  
Registration of the establishment for the platform  
GICONA  
Design of formulations





# About us

## Leaders in Regulatory Areas Pharmaceutical and Chemical

At Ar Sante we have a multidisciplinary team with vast experience in the regulatory area whose main objective is to provide a comprehensive, timely and confidential service to your company.

At Ar Santé we generate a combination of technical, regulatory and managerial experience. This combination of experience allows us to help companies comply with applicable regulations and protect public health.

Since 2006, Ar Sante has supported companies in the mining, industrial and health sectors to optimize their performance, through advanced pharmaceutical technology solutions through a global network of experts, focusing on obtaining results.



# About us

## Mission

To be a global consulting company, with a promotional focus on quality of life and renewed primary health care, committed to innovation, quality and the environment, which encourages family conciliation, following the synergies undertaken by our own workers, by experts, orienting ourselves towards obtaining results.

## Vision

To be recognized within our consulting sector as a company that maintains stable and long-lasting relationships with our clients, by fulfilling their needs and expectations, as well as with our external and internal collaborators.

We will be a company with social profitability by applying effective and transparent public management, with a multidisciplinary team and a participatory community, that manages comprehensive responses to health needs, supported by the network, through quality services.





# Value Proposition

This value proposition is based on the experience, knowledge and networks of regulatory leaders.

**Expertise:** Regulatory leaders have extensive experience with regulations applicable to the pharmaceutical and chemical industry. This allows them to understand regulatory requirements and how to comply with them efficiently and effectively.

**Knowledge:** Regulatory leaders are up to date with the latest regulatory developments. This allows them to provide companies with the information and resources they need to stay current with the latest regulations.

**Networking:** Regulatory leaders have a wide network of contacts within regulatory agencies. This allows them to help companies navigate the regulatory process and resolve any issues that may arise.

Ar Santé's additional value proposition is based on its knowledge of Chilean regulations. This allows them to help companies comply with Chilean regulations efficiently and effectively.

Advising companies on applicable regulatory requirements.

Assisting companies in developing regulatory compliance plans.

Representing companies before regulatory agencies.

Keeping companies informed of the latest regulatory developments.



# Our Services

Our company specializes in providing Regulatory Consulting services for Pharmaceutical Products, Medical Devices, Personal Protective Equipment, Cosmetics, Dietary Supplements, Food, Household Cleaning and Hygiene Products, and Disinfectants. We provide advice on Imports of Medical Devices and authorizations for Health Establishments, in accordance with current legislation and regulations.

## IMPORTS

Advice for obtaining Customs Destination Certificates (CDA) and Certificates of Use and Disposition for the importation of products:

- Disinfectants
- Cosmetics
- Foods
- Medical devices with/without health registration
- Personal Protective Equipment (PPE)
- Pharmaceutical products

Coordination in import logistics

Advice in case of customs retentions

## MEDICAL DEVICES

Registration of medical devices that must have a health registration for their commercialization.

Declaration of medical devices by the ISP

Advice for the evaluation of medical device background

Registration of the establishment for the GICONA platform

Registration of the company in the ISP as an

importer/exporter/distributor and marketer of medical devices.





# Our Services

## FOOD

Advice on food classification according to its qualitative-quantitative composition.

Labeling

Maquilas of food supplements

Registration of the establishment on the AS DIGITAL platform.

## PHARMACEUTICAL

Registration of chemically synthesized pharmaceutical and biological products

Regulatory audits of companies

NCh-ISO/EC 17025:2017 quality audits

Registration of the establishment for the GICONA platform

## PROYECTOS

Corfo project formulations.

Preparation of state-of-the-art reports.

Corfo Project Management

Consulting on Corfo project evaluations

Client database management

## DISINFECTANTS

Registration of disinfectant products / Disinfectant Cleaners / Sanitizers

Preparation of Safety Data Sheets in accordance with current national regulations NCH2245:2021

Manufacturing of disinfectant / sanitizing products.

Registration of the establishment for the GICONA platform

Design of formulations

## COSMETICS

Registration of cosmetic products

Registration of HBO products (Hygiene, Low risk, Odorants)

Modifications to health records

Transfers of health records

Organization of cosmetics maquilas

Registration of the establishment for the GICONA platform

Design of cosmetic formulations



# Our Services

## **FAMILY ESTABLISHMENTS**

Advice for the authorization of installation and operation of:

- Pharmacies
- Factories or workshops for the production of cleaners, detergents and/or disinfectants
- Drugstores
- Warehouses (cosmetics, DM, food and hazardous substances)
- Low-Risk Cosmetics Laboratories
- Medicine Cabinets
- Procedure Room

Audits of establishments.

Audits to verify compliance with Good Practices.

Advice for the authorization of fractionation area in pharmacies.

Advice for obtaining authorization for electronic commerce for pharmacies.

## **TRAINING**

Development and implementation of programs according to the company's specific requirements.

In-person and streaming training

## **ERP**

Company registration with the ISP as an importer/exporter/distributor and marketer of Personal Protective Equipment (PPE).

Registration of PPE with the ISP





# Our Services

## **REPRESENTATION AND DEFENSE AGAINST SANCTIONS AND/OR MEASURES APPLIED BY THE SEREMI OF HEALTH**

By filing administrative appeals, we are able to nullify or, alternatively, reduce to the minimum possible those fines that the health authority may apply after an inspection.

Our work with the Seremi de Salud consists of defending the alleged offender, through actions aimed at preventing a fine from being applied (discharges) or, having been imposed, that it be nullified; replaced by a warning; or reduced to the minimum possible (appeals).

We achieve excellent results without having to resort to legal proceedings (claiming a fine in a civil trial), saving time and money for the alleged offender.



# Areas of Experience

At Ar Santé we aim to be a global consulting company, with a promotional focus on quality of life and renewed primary health care, committed to innovation, quality and the environment, which encourages family conciliation, following the synergies undertaken by our own workers.

**Product Regulation:** This area focuses on compliance with regulations applicable to pharmaceutical and chemical products, from development to commercialization. Leaders in this area must have a deep understanding of the science and technology of pharmaceutical and chemical products, as well as the regulations applicable to these products.

**Process Regulation:** This area focuses on compliance with regulations applicable to the manufacturing processes of pharmaceutical and chemical products. Leaders in this area must have a deep understanding of the manufacturing processes, as well as the regulations applicable to these processes.

**Safety Regulation:** This area focuses on compliance with regulations applicable to the safety of pharmaceutical and chemical products. Leaders in this area must have a deep understanding of the risks associated with pharmaceutical and chemical products, as well as the regulations applicable to the management of these risks.

**Quality Regulation:** This area focuses on compliance with regulations applicable to the quality of pharmaceutical and chemical products. Leaders in this area must have a deep knowledge of quality management systems as well as the regulations applicable to these systems.



Mining



Industrial



Health



# Our Clients



# Our Clients



ZACHARY  
PERFUMES



DOC JOHNSON



beauty.plus

ENFLEX

FUTURE  
fashion

AlphaLab  
SECRETARIO MAGISTRAL



ris

PISCO INDEPENDIENTE  
MALPASO  
... VALLE DEL LIMARI ...





# Ar Santé

Av. Kennedy # 5600 Vitacura,  
Santiago

Of. 1009

+56 2 24710338

+56 9 68377263

Contacto@arsante.cl