

## ISA HEALTH

### Regulatory Affairs Consultants | Mexico

**ISA Health** and ISA Ambiental are partner companies, **ISA Health** created exclusively to handle Regulatory Affairs business in Mexico. ISA Ambiental was first established in 1996 to provide consultancy on Environmental, Health and Safety regulation compliance, 6 years later, the Regulatory Affairs field became an important part of our services.

**On this Regulatory Affairs branch, our main services are:**

- **Regulatory assessment**

We offer continuous assessment on regulatory compliance requirements based on the Mexican Health General Law and regulation updates.

- **Product Registration in Mexico**

**ISA Health** has wide experience on registration process of products with the Mexican regulatory authority COFEPRIS (*Comision Federal para la Proteccion contra Riesgos Sanitarios – Federal Commission for Protection against Sanitary Risks*).



We have successfully registered in Mexico variety of products including:

- ♦ Toxic substances
- ♦ Medical Devices (Class I, II & III)
- ♦ Medicines  
*(2 members of our team exclusively for this group)*

○ **License Hosting Service (for foreign Manufacturers)**

Foreign manufacturers must have a Mexican legal entity (its own representation office, a distributor or a consultant firm) to market devices in Mexico. The License Holder is a person/company responsible for the health care device registrations, which acts as a liaison between the manufacturer and the Ministry of Health. Choosing a License Holder as representative who manages the registration process, the distributors easily access to the documents to import and sell the products in Mexico.



○ **Certificates**

- ♦ Good Manufacturing Practices Certification
- ♦ Free Sales Certificate

○ **Importation Permits**

○ **Licenses Renewals**

○ **Assigned Technical Representatives**

Outsourcing service for Sanitary Responsible consider the assignment of a technical responsible (Chemical professional) from our staff for supervision of health care supplies establishments, as required by the government.

Our clients are **health care products** manufacturers and distributors that bring to Mexico products from all around the world.

We offer our services through our team of 4 chemists, 1 chemical engineers and 1 pharmacist to assess health care business development in Mexico.

***Mrs. Yanira Galvan***



Chemical Engineer (ITESM Mexico, 1992)  
Founder of ISA HEALTH, has been working for the last 10 years as consultant on Environmental, Safety & Health regulations compliance. Expertise areas: Medical Devices Class I, II, III & Hazardous Materials.

We have two offices, located at Monterrey city and Mexico city.

For more information please contact us, we will be glad to assist you.

**Yanira Galvan**  
***Project Manager***

**ISA Health**

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