

# **SANITARY REGULATION EXPERTS**

Regulatory Affairs Consulting

Let us do what we do best: Your Sanitary Regulation



# SANITARY REGULATION EXPERTS



We are a consultancy that focuses on helping you place your health products and services in the Mexican market through the advice and management of your regulatory compliance.

Thanks to the fact that our team is made up of health professionals and health regulation experts, we are your key ally to develop regulatory strategies according to the particular characteristics of your product and aligned with your commercial strategy.

# OUR CLIENTS: INDUSTRIES REGULATED BY

Comisión Federal para la Protección  
contra Riesgos Sanitarios

We have the ability to support from entrepreneurs, new manufacturers, importers and distributors; even large local and foreign companies.

Food and Beverages

Consulting rooms  
and  
medical/cosmetic  
clinics

Cosmetics

Medical Devices

Drug Stores

Fumigators and Pest  
Control

Drugs

Tattooists,  
Perforators,  
Micropigmenters

Herbal Remedies

Food supplements

## OUR PROFILE



### MISSION

We are committed to support our customers in the introduction of their products to the Mexican market through a specific regulatory diagnosis and solutions attached to current health standards.



### VISION

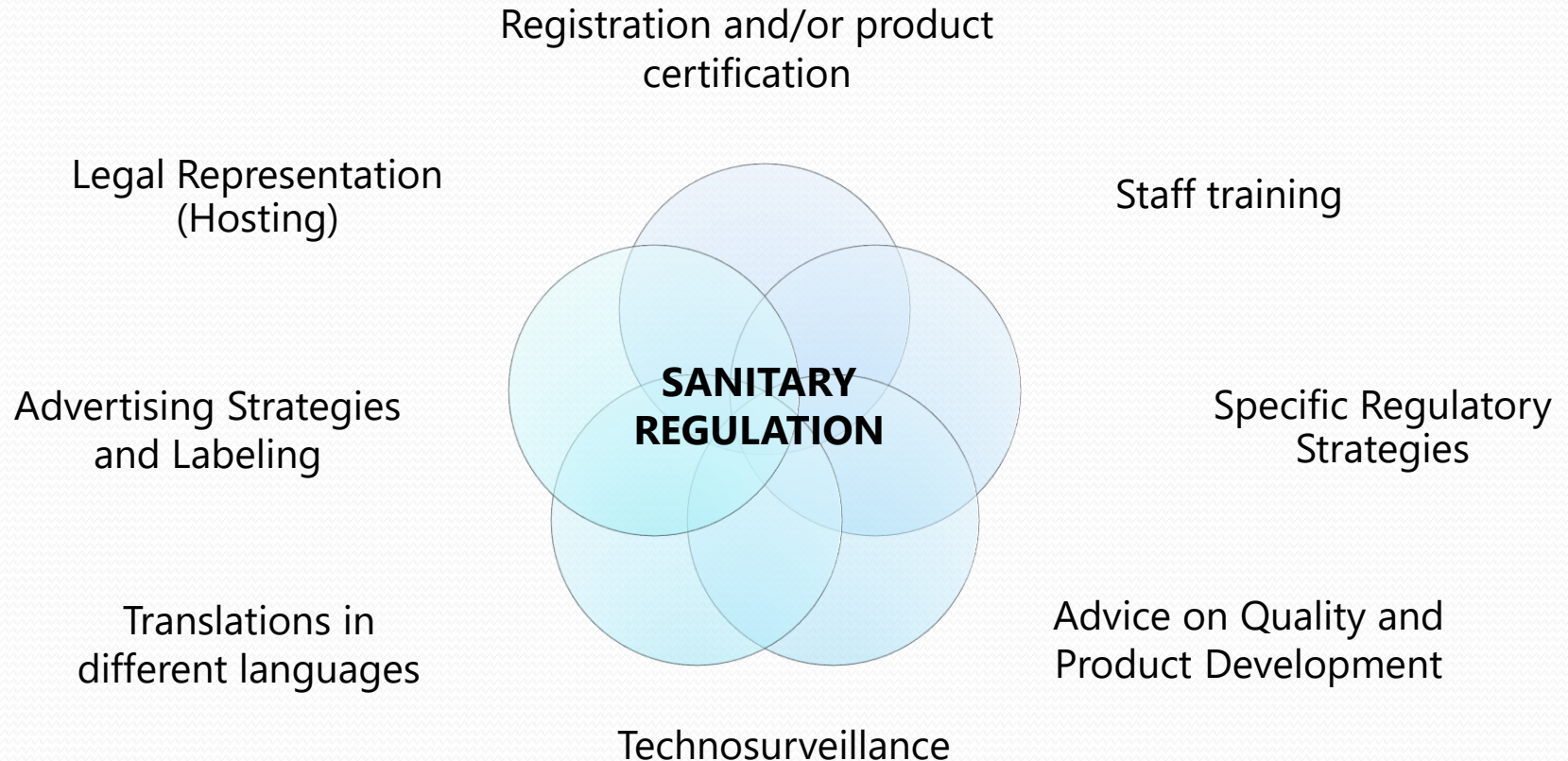
Become the key digital support point for companies, contributing to the improvement of health services and encouraging investment in health products.



### VALUES

Honesty  
Confidentiality  
Quality  
Commitment  
Empathy  
Continuous preparation  
Punctuality  
Strategy  
Full Vision

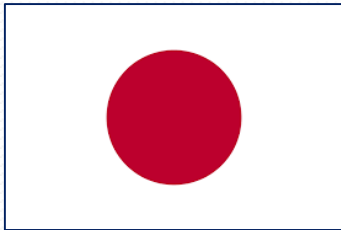
# REGULATORY SOLUTIONS



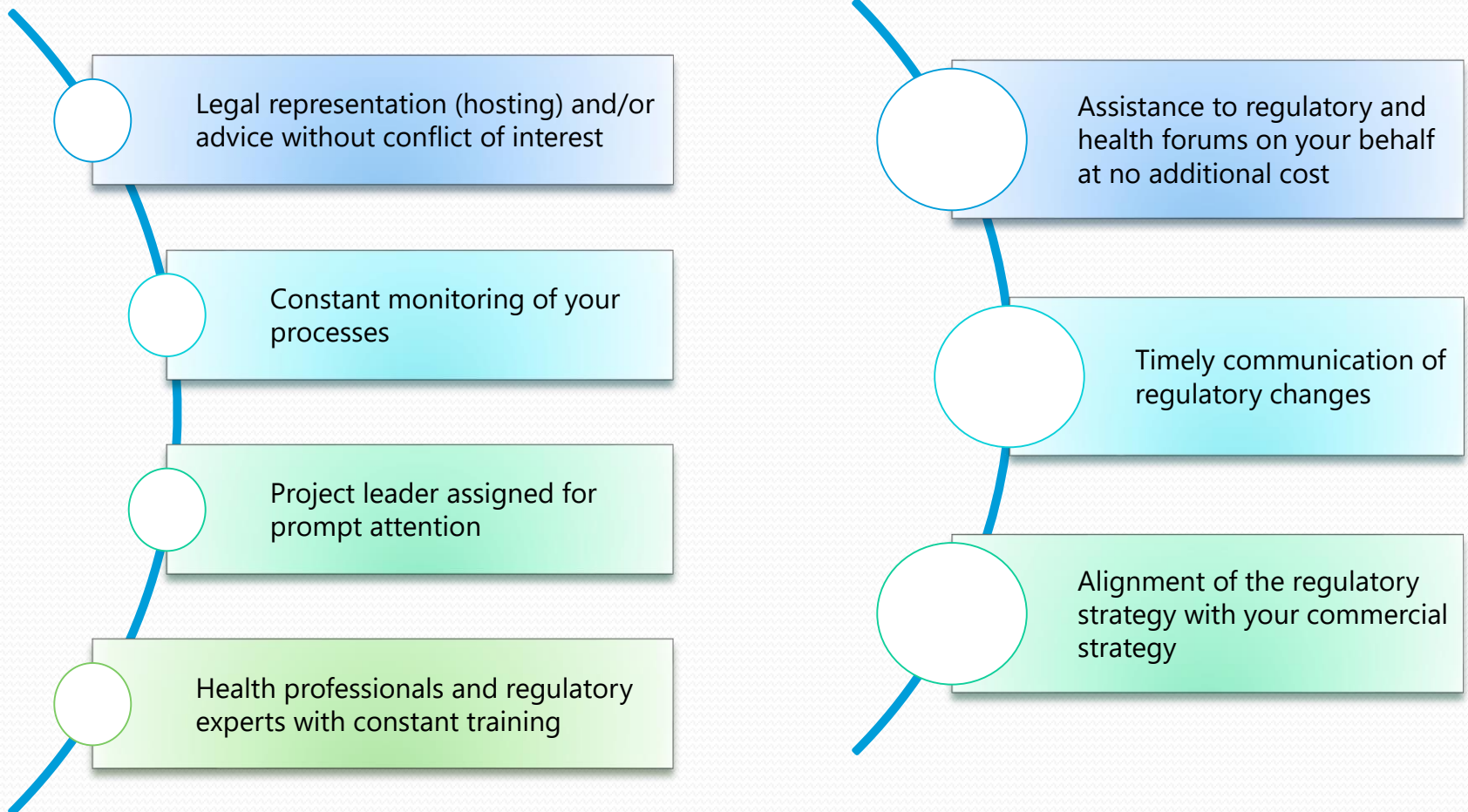
We implement specific strategies for your product so you can start selling it in the market that best suits you, complying with all the applicable regulations.

## GLOBAL PRESENCE

Thanks to our incorporation into a “Partnership” system, we offer regulatory services, such as registration or legal representation (hosting), in different regions. In this way we support you to have presence in the markets of your interest.



# OUR COMMITMENT WITH EACH PROJECT





# SANITARY REGULATION EXPERTS

Registros Sanitarios - Permisos de Importación - Licencias Sanitarias - Traducciones - Publicidad - Capacitaciones  
Dispositivos Médicos - Medicamentos - Cosméticos - Suplementos - Herbolarios  
Servicio de Control de Plagas - Tecnovigilancia - Farmacias - Consultorios Médicos - Procedimientos - Almacenes



55 77 67 76 21



info@sanitaryregulationexperts.com



sanitaryregulationexperts

[www.sanitaryregulationexperts.com](http://www.sanitaryregulationexperts.com)



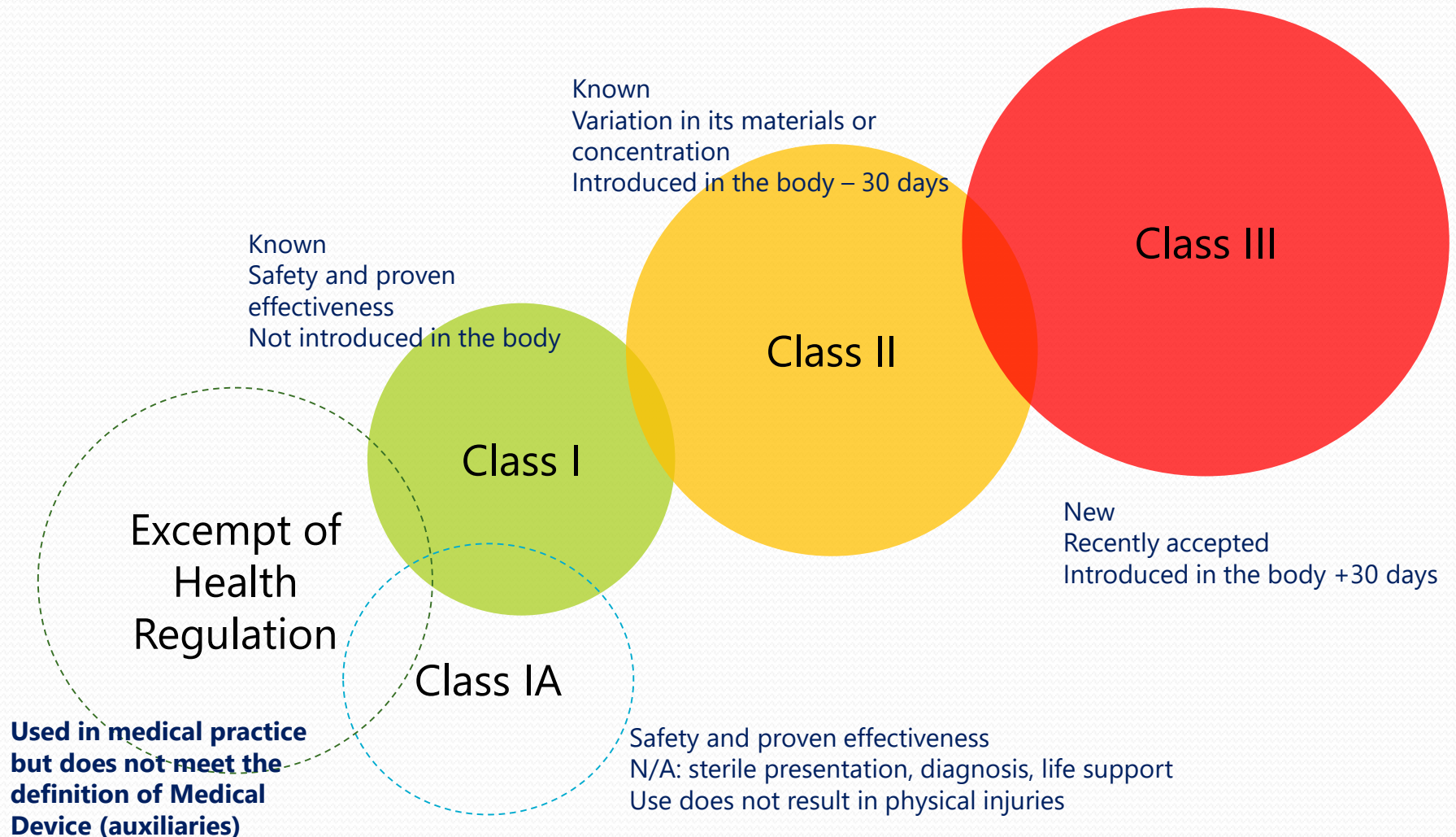
# **SANITARY REGULATION EXPERTS**

## **MEDICAL DEVICES CLASIFICACION IN MEXICO**

Source: Suplemento de Dispositivos Médicos de la Farmacopea de los Estados Unidos Mexicanos



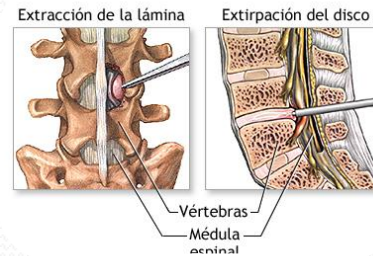
# CLASIFICACION: RISK LEVEL



# CLASIFICACION: FUNCTION / INDICATION OF USE



Medical Equipment



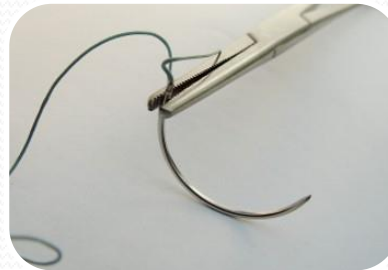
Prosthesis, Orthosis  
and Functional Aids



Diagnostic Agents  
(IVDs)



Odonatological  
Supplies



Surgical and Healing  
Material



Hygienic Products

## Cost of the main services for Mexico 2019

SERVICE	SERVICE COST (USD)	NOTES
New Application Class IA y I	\$1,421.00	COFEPRIS tax not included 50% start 50% authorization Possibility of improving price by volume
New Application Class II	\$2,105.00	
New Application Class III	\$2,684.00	
Hosting 1 – 10 applications	\$5,900 / year	Fee presented with discount for annual payment There is monthly payment option 1 <sup>st</sup> payment upon obtaining the first authorization
Hosting 11 – 20 applications	\$11,000 / year	
Hosting 21 applications onwards	\$ 15, 600 / year	
English – Spanish simple technical translations	\$6.70 / page	Cost presented with discount when contracting any other service Normal cost: \$8 / page

Other services: Modifications of registers. Renewals of registers, Technosurveillance, Hosting with warehouse, Translations in different languages, Certified translations in different languages, Labeling, Publicity Strategies, Good Manufacturing Practices, among others.