

SANITARY REGULATION EXPERTS

Regulatory Affairs Consulting

Let us do what we do best: Your Sanitary Regulation



PAŠARINI
REGULATORY AFFAIRS

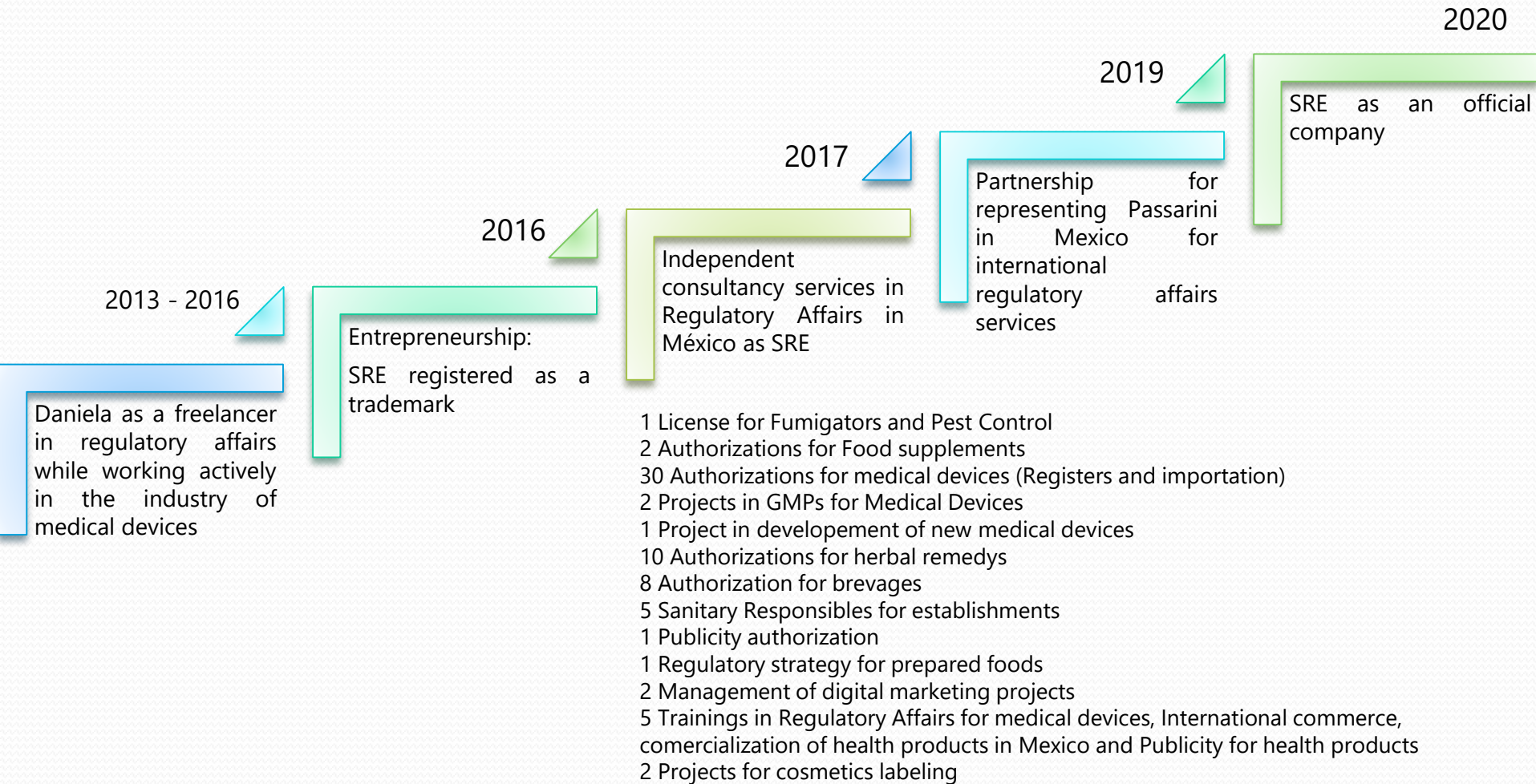
SANITARY REGULATION EXPERTS



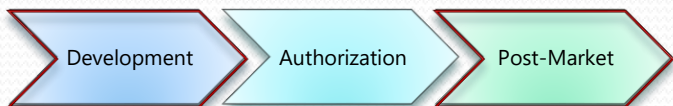
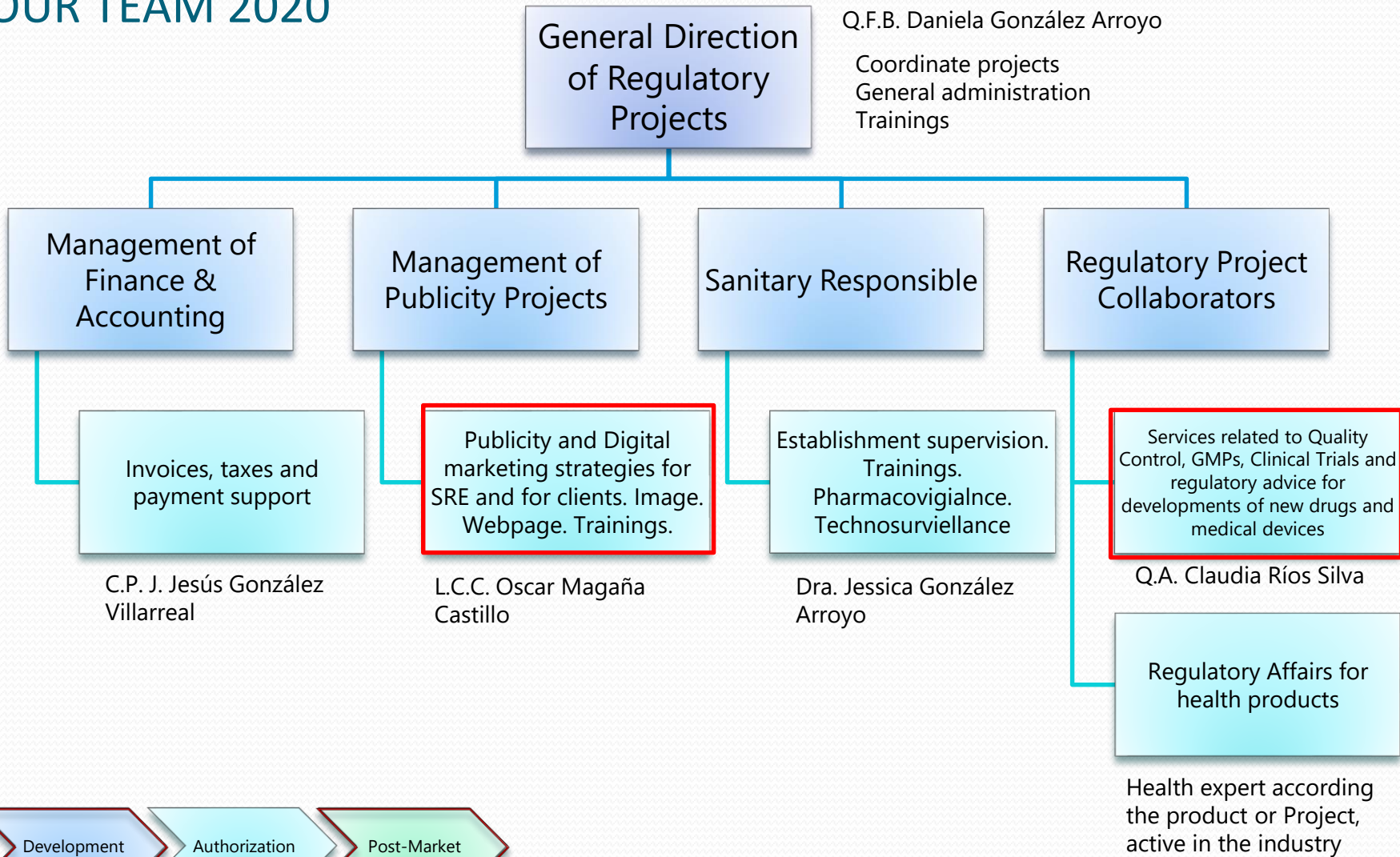
We are a consultancy that focuses on helping you place your health products and services in the Mexican market through the advice and management of your regulatory compliance.

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 STORY



OUR TEAM 2020



OUR TEAM 2020



Daniela

BD: Chemist Pharmaceutical Biologist

- 7 years experience in Regulatory Affairs
- 7 years: MD
- 4 years: HP in general and GMPs
- Diplomas: FV & TV, Regulatory Affairs, Biochemistry and Molecular Biology, Humanism and Profession
- Curses: Quality, Entrepreneurship, Intellectual property, Tariff Classification, ISO 9001, ISO 13485, Internal Audits, Proteomics, DM classification, Drugs & MD Importation, Checklist for registering MD



Jesús

BD: Accountant

- 40 years of experience as accountant
- Extensive experience in the accounting, financial, and tax area
- Collaborated in both private and public industry (Mexican government)



Oscar

BD: Communication Sciences

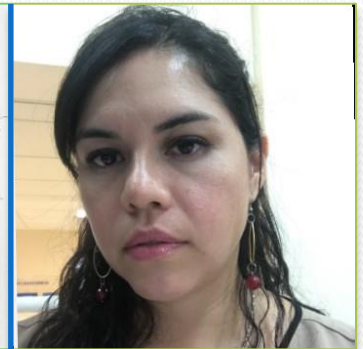
- 8 years of experience in communication and creation of digital content
- Master degree in communication with digital media



Jessica

BD: Medicine

- 3 years of experience as general doctor
- 1 year: RA
- Diploma: Humanism and Profession
- Curses: Security in Drugs Prescriptions (FV) Advanced Cardiac Life Support, Basic Life Support, Cardiovascular Urgencies, Neonatal Cardiopulmonary Reanimation, Advanced Burn Life Support



Claudia

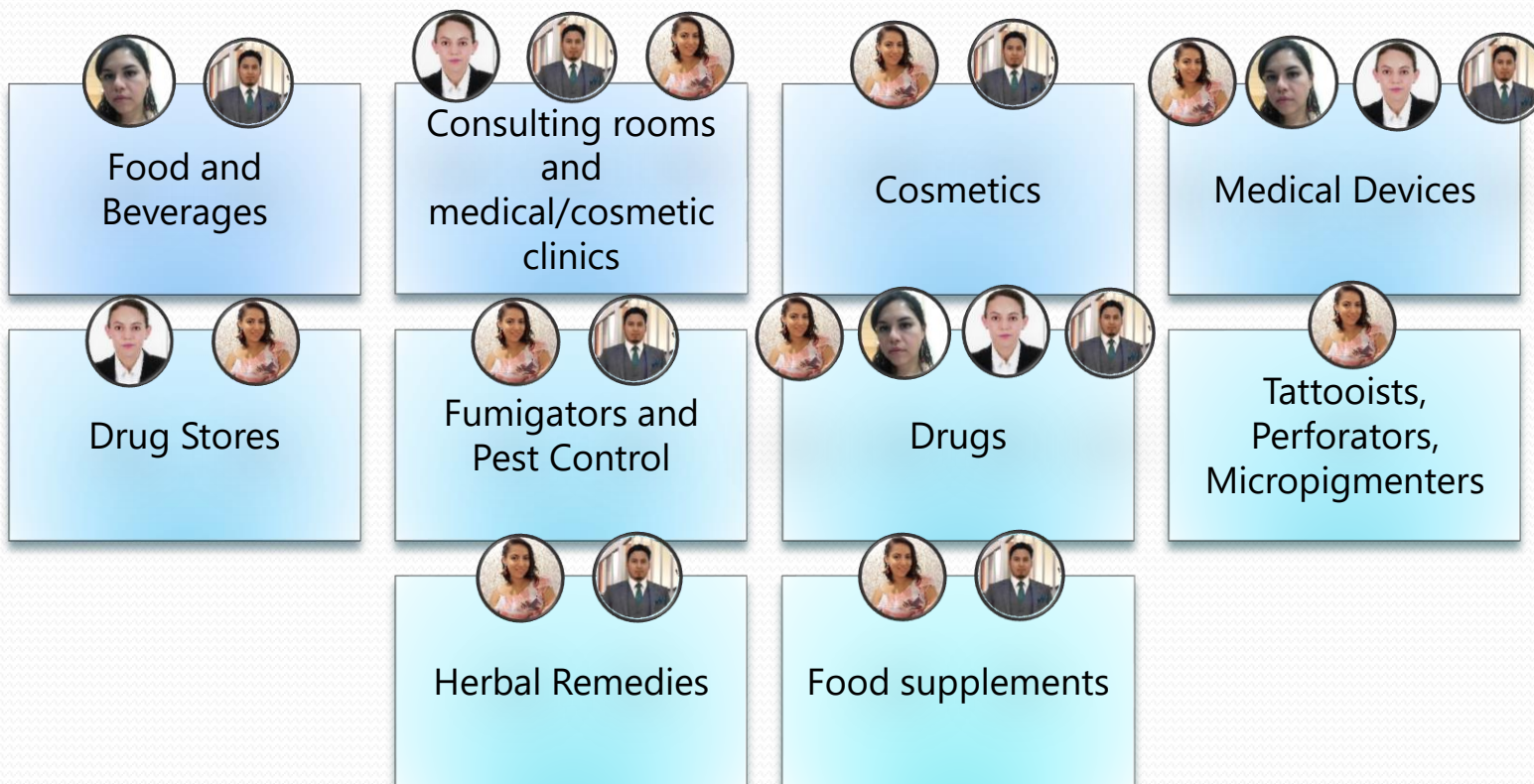
BD Food Chemist

- 10 years of experience in the pharmaceutical industry
- 2 years: QA, QC, GMPs
- 3 years: Clinical
- 5 years: RA
- Specialty: Statistics and Quality
- Diplomas: Pharmaceutic medicine, clinical Trials, Regulatory Affairs

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.



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

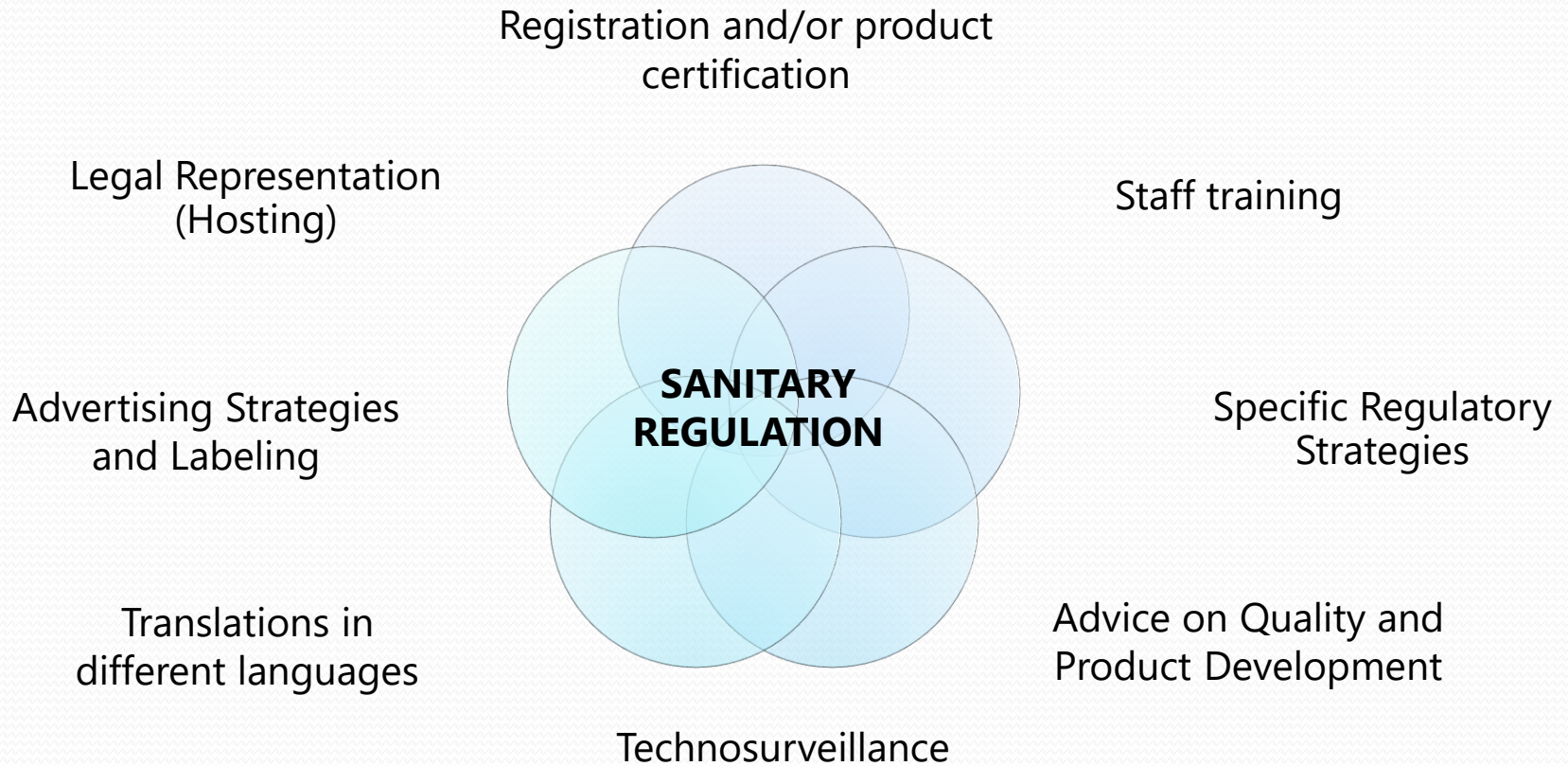
Become the key digital support point for companies, contributing to the improvement of health services and encouraging investment in health products.



VALUES

Honesty
Confidentiality
Quality
Commitment
Empathy
Continuous preparation
Punctuality
Strategy
Full Vision

REGULATORY SOLUTIONS

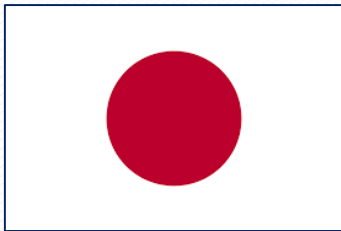


We implement specific strategies for your product so you can start selling it in the market that best suits you, complying with all the applicable regulations.

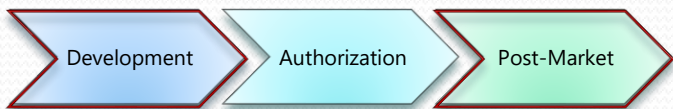
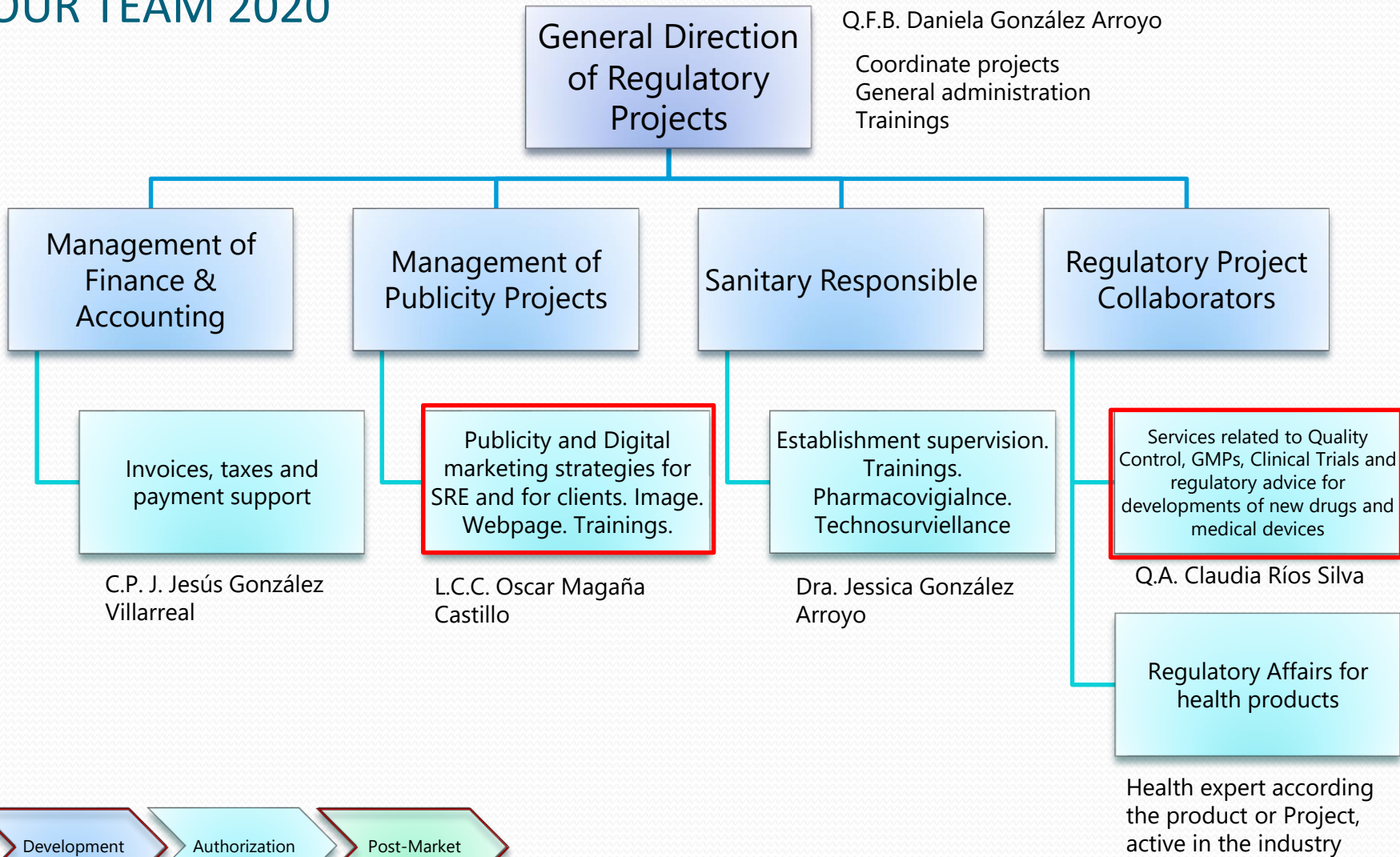
GLOBAL PRESENCE PASARINI

REGULATORY AFFAIRS

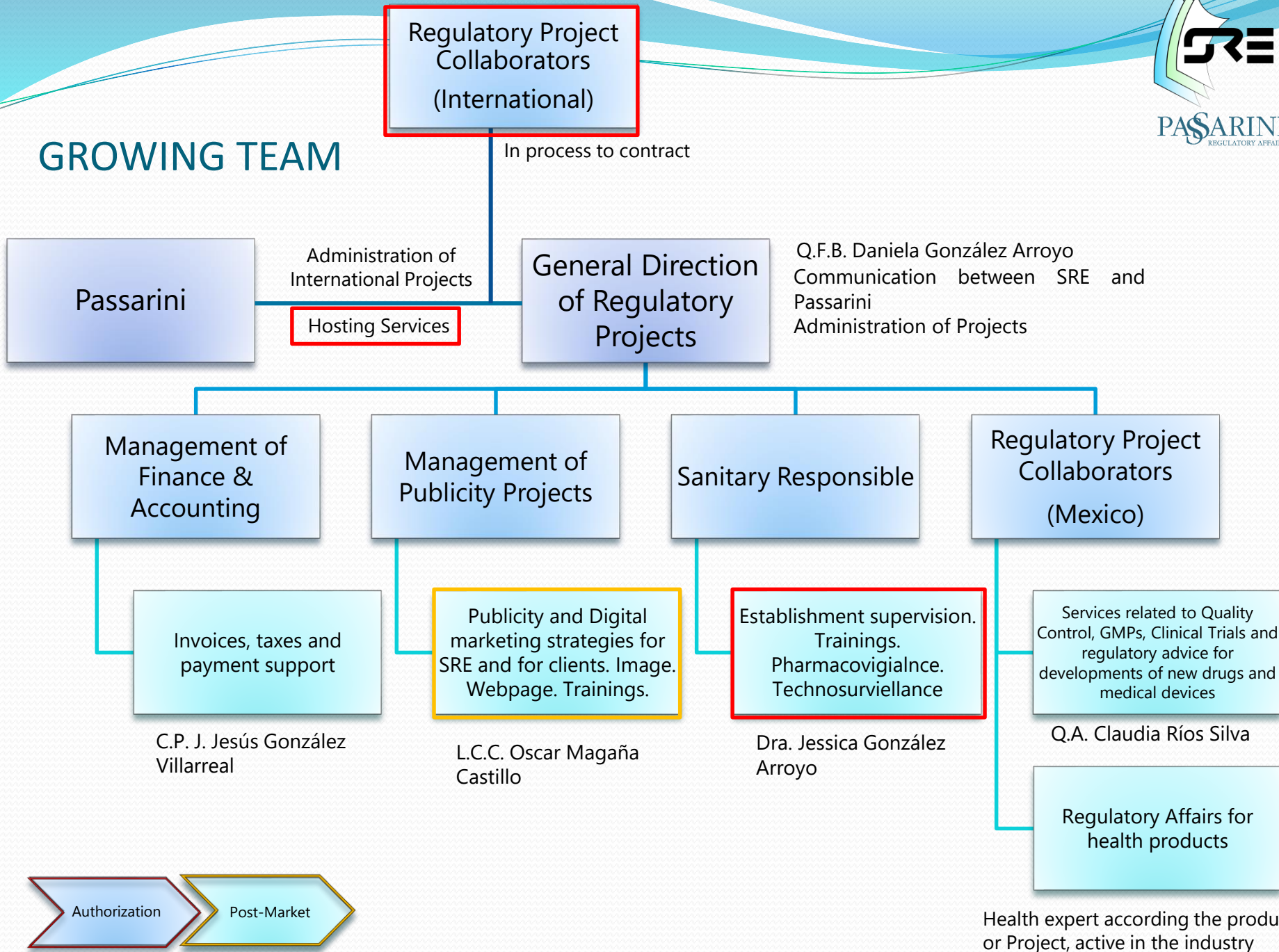
Thanks to our incorporation into a “Partnership” system with Passarini, we offer regulatory services, such as registration or legal representation (hosting), in different regions. In this way we support you to have presence in the markets of your interest.



OUR TEAM 2020



GROWING TEAM



OUR COMMITMENT WITH EACH PROJECT

Legal representation (hosting) and/or advice without conflict of interest

Constant monitoring of your processes

Project leader assigned for prompt attention

Health professionals and regulatory experts with constant training

Assistance to regulatory and health forums on your behalf at no additional cost

Timely communication of regulatory changes

Alignment of the regulatory strategy with your commercial strategy

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



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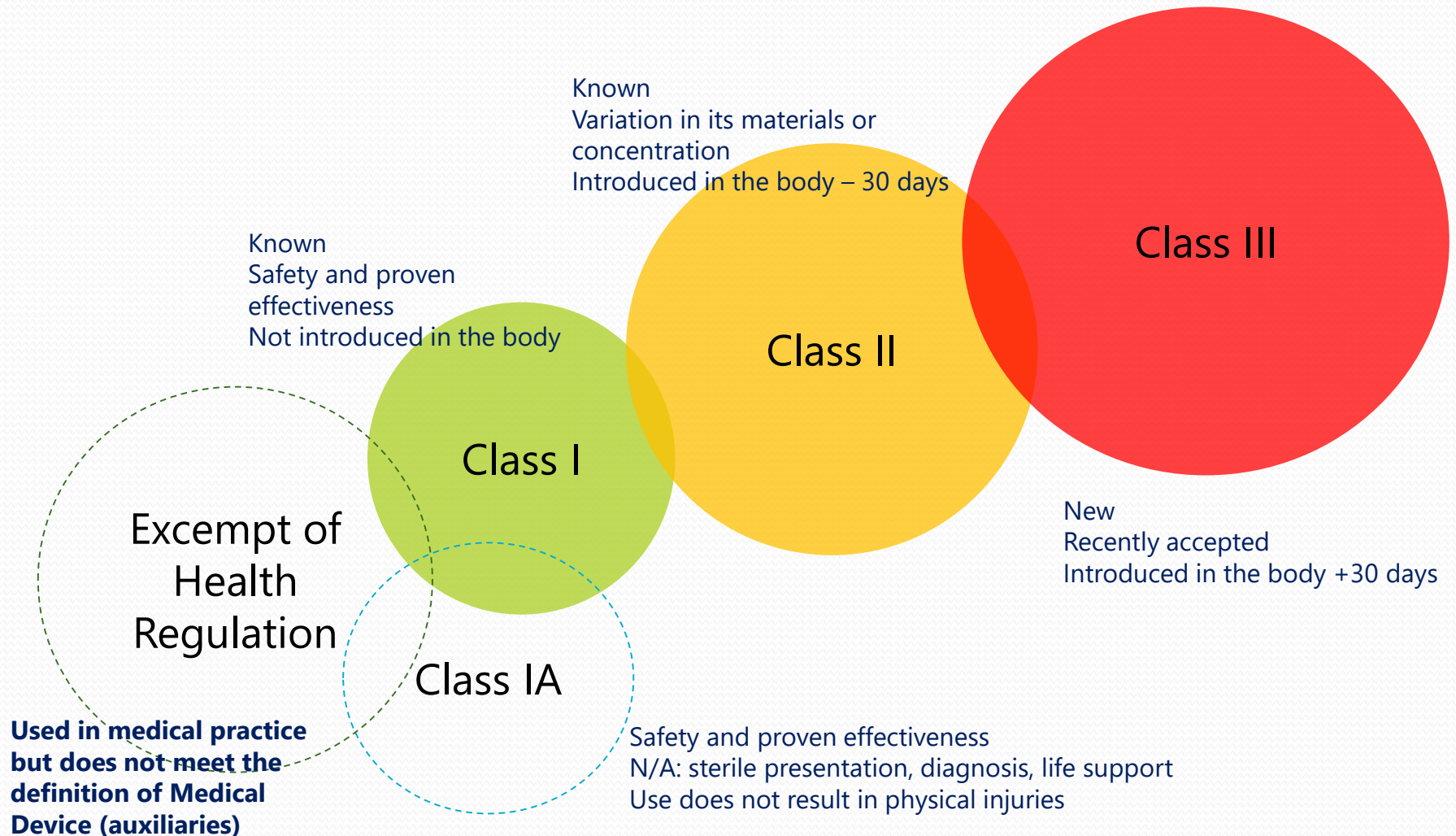
MEDICAL DEVICES CLASIFICACION IN MEXICO

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



PA\$ARINI
REGULATORY AFFAIRS

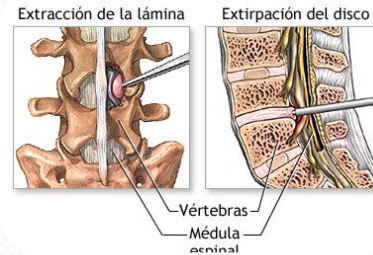
CLASIFICACION: RISK LEVEL



CLASIFICACION: FUNCTION / INDICATION OF USE



Medical Equipment



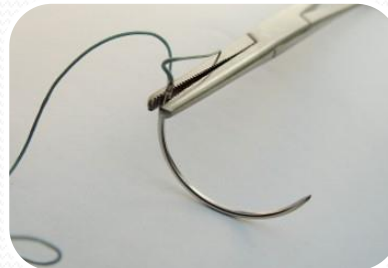
Prosthesis, Orthosis
and Functional Aids



Diagnostic Agents
(IVDs)



Odonatological
Supplies



Surgical and Healing
Material



Hygienic Products

SANITARY REGULATION EXPERTS

FAMILY GROUPING FOR MEDICAL DEVICES

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



PA\$ARINI
REGULATORY AFFAIRS

DIAGNOSTIC AGENTS (IVDs)

1. REAGENT KIT OR PACKAGE



Group:

- Reagents
- Controls
- Calibrators
- Buffers
- Solutions

Criteria:

- Same determination / identification
- For the same analyte or parameter
- Same analysis method (clinical chemistry, colorimetric, spectrophotometry, etc)

DIAGNOSTIC AGENTS (IVDs)

2. GLUCOMETERS AND OTHER DIAGNOSTIC EQUIPMENT



Group:

- Test strips
- Control
- Calibrator

Criteria:

- Only if all of them are used in the same equipment

Cannot group:

- Lancets (Medical Instruments)
- Glucometer or self diagnostic equipment (Medical Equipment)

If you want to assemble the kit, first each component must have its separate authorization and then apply for a new application asking for grouping them in a kit

DIAGNOSTIC AGENTS (IVDs)

3. CULTURE MEDIUM



Group:

All the nutritional material in which you can:

- Recover
- Multiply
- Isolate
- Apply susceptibility test

Criteria:

- Same composition or formula
- Same physical appearance

DIAGNOSTIC AGENTS (IVDs)

4. CONTROL MATERIAL (CHECKERS)



Group:

Preparations that evaluate:

- Accuracy
- Precision

Criteria:

- Same speciality

MEDICAL INSTRUMENTS

Group:

Variety of types or models of medical instruments

Criteria:

- Same type of instruments, including their different presentations or models, as long as they are of the same material and have the same indication of use

or

- Different instruments used in the same indication of use / technique or specific surgical procedure



HIGIENIC PRODUCTS

Group:

Variety of presentations

Criteria:

- Same formula (the weight or amount of content may differ)
- Dyes, flavorings or perfumes may differ, as long as their general physicochemical characteristics are preserved



PROSTHESIS, ORTHOSIS AND FUNCTIONAL AIDS

Group:

- Same type of product with its different presentations or models

Criteria:

- Same material
- Same formula or composition
- Same indication of use

If you want to assemble the kit or system with several kind of components, they must be for the same indication of use



Instruments are registered separately

MEDICAL EQUIPMENT

Group:

Medical equipment+ **accessories**

Criteria:

- They are part of the same medical equipment

Group:

Different **models** of medical equipment

Criteria:

- Same technology
- Same indication of use



GENERAL CRITERIA

- Same manufacturer or its subsidiaries or authorized external manufacturer
- The product, from the generic point of view, should have the same commercial or distinctive denomination with the same indication of use
- Keep the sale distinctive name in case of products for distribution in different commercial chains