Pharma Consulting®
specialized pharmaceutical consulting

ABOUT OUR CEO

Dr. Rosa Paredes, PharmD
Pharmacist and manager of Pharma Consulting

Dr. Paredes did her undergraduate training in Pharmacy and Biochemistry at the Main National University of San Marcos and obtained her graduate degree in Quality Management from the Pontifical Catholic University of Peru. Dr. Paredes has also completed postgraduate specialization courses in Total Quality Management at Kenshu Kiokay Center of Osaka, Japan and Regulatory Affairs at the Escuela de Estudios Farmacéuticos (ESEF). She has a solid background in the fields of Technical Management, Quality Assurance and Regulatory Affairs.

ABOUT US

Pharma Consulting is a specialized Regulatory Affairs consulting firm based in Lima, Perú. We provide consultancy services in Regulatory affairs (RA) and Good Storage Practices (GSP) to pharmaceutical establishments such as drugstores, laboratories, specialized warehouses and more.

We guide our clients through the drug establishment (drugstores, laboratories, specialized warehouses, pharmacies) license application process with the Dirección General de Medicamentos, Insumos y Drogas (DIGEMID) - our country's regulatory authority.

We also assist our customers in registering, importing and commercializing:

- **Pharmaceutical products**: drugs, herbal medicinal products, sugar substitutes, biologics, galenical, diet and nutritional products;
- **Medical Devices and Sanitary Products:** cosmetic and personal care products, child care articles and household cleaning products;

And managing the registration of: toys, office supplies, disinfectants and pesticides with the Dirección General de Salud Ambiental e Inocuidad Alimentaria - DIGESA.

Our team is composed of experts from a range of disciplines. Pharmacists, Dental Surgeons, Nurse Practitioners and other healthcare professionals work seriously, diligently and ethically to give our clients a personalized service in order to help them achieve compliance as efficiently as possible.

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Pharma Consulting®
SPECIALIZED PHARMACEUTICAL CONSULTING

MISSION

Our mission is to provide our clients with feasible solutions on Regulatory Affairs within the legal, technical and sanitary framework of our country.

VISION

Effectively position our firm in the market and build lasting business relationships with clients.

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OUR SERVICES

Medical Device Registration and Sanitary Notification :

A Registration Authorization (Registro Sanitario) is a document emitted by Peruvian National Authorities after the evaluation of the products technical documents. Registration is required by Regulatory Authorities and it allows the bearer to import, market and distribute medical devices through national territory.
The registration has a validity period of five years.
Our service includes:

- Preparing and submitting your registration dossier for Pharmaceutical Products (drugs, herbal medicinal products, sugar substitutes, biologics, galenical, diet and nutritional products), Medical Devices and Sanitary Products (cosmetics and personal care products, childcare articles and household cleaning products).
- Preparing and submitting your registration applications through VUCE (Ventanilla Única de Comercio Exterior).
- Reviewing and adapting your proposed labeling materials in spanish.
- Tracking of device license applications.
- Renewal of pharmaceutical package inserts, product brochures, labels and instructions for use.
- Technical translation from English and Portuguese to Spanish.
- Elaborating responses to notifications, observations and warning letters.

Registration Holder :

We provide in-country representation for medical device companies entering the Peruvian market. As your registration holder, we are responsible for preparing and submitting your registration dossier, including all the technical documents required by Regulatory Authorities.
The registration holder must keep a pharmacist in staff as Technical Director.
Our solutions:

- Providing your device information and documentation to Regulatory Authorities for review and approval.
- Acting as a liaison between you and National Regulatory Authorities in instances where device recalls are necessary.
-Taking into custody documents relating to the products and technical dossiers.

Quality Assurance :

Good Storage Practices (GSP) consists of practical procedures and processes that ensure the appropriate handling and storage of pharmaceutical products for medical use. All pharmaceutical establishments (laboratories, drugstores and pharmacies) are required to comply with GSP guidelines in order to ensure the quality and efficacy of the products.
Regulatory Authorities are more likely to impose sanctions on pharmaceutical establishments that not hold a Good Storage Practices certificate or do not observe the guidelines.
Our service involves:

- Good Storage Practices (GSP) implementation.
- Submitting your Good Storage Practices certification application and recertification applications to Authorities. Elaborating a Quality Manual and a GSP Manual tailored to your business.
- Pre-assessment Quality Management System (QMS) audits for both Good Storage Practices and Regulatory Affairs compliance.

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Regulatory Consulting :

In today's competitive environment, reducing time to market is important to the success of a product and, therefore, to the company. The proper conduct of its regulatory activities is of considerable economic importance to a company. Our team of experts offers a wide range of Regulatory Affairs consulting services for pharmaceutical products and medical devices.

We offer you:

- Preparing and submitting your applications for pharmaceutical establishment registration/license and transfer of facilities.
- Preparing and submitting applications for addition of locations for drug establishment's warehouse.
- Managing applications for amendments to registration/license information.
- Technical Management service for Pharmaceutical Establishments.
- Reviewing and designing regulation-compliant labeling for medical devices, pharmaceutical and sanitary products.
- Submitting inquiries to Regulatory Authorities regarding import and marketing issues.
- Elaboration of applications for an Exceptional Permit to import pharmaceutical products, medical devices and sanitary products.

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CLIENTS

We would like to thank the companies, national and foreign, that have given us the opportunity to provide our services:

› Perú

A. W. Faber-Castell Peruana
Alpes Chemie Sucursal del Perú (Royal Pharma)
Arespharma
Ariana Internacional de Comercio
Asia America Beauty 168
Athalia Farma
Bearing Corporation
Biomedic
BioProPeru
Chan & Cía
Consorcio de la Belleza
Consorcio Ming
Droguería Sandy
Eden Pharmaceutical
Elvetium Perú
Genzyme del Perú
Grupo Integral y Tecnología Médica
Hotel Risso-Hotel La Princesa
ICC Agencia de Aduanas
Infermed
Inmed Perú
Innova Medtech
Intradent
JV Holding

JJP Hospitalaria
Laboratorios AGA
Laboratorios Induquímica
Laboratorios Portugal
Laboratorios Stiefel Perú
LS Importación Dental
MIS Implant Perú
Pfizer
Ortopedia Salvador
Primus Medical
Reprain Perú
Representaciones Jenimed
Russer Perú
Sistemas Analíticos
SlimLife
Tecnología Médica Avanzada

› Argentina

Laboratorio Novocap
Laboratorios Panalab
Instituto Biológico Contemporáneo

› Chile

ITF Labomed Chile
Inmed Medical
Laboratorio Maver
Instituto Bioquímico Beta
Primus Medical
Laboratorio Cosmético Santepharma

› United States of America

Medgyn Products Inc.
Intralock International
Bio-Lock International
Mia Secret
Symmetry Surgical Inc.
Medical Measurements System Inc.

› Brazil

Russer Brasil
Orthometric - Industria e Comercio de Produtos Medicos e Odontologicos
Descarpack - Descartáveis do Brasil
Adlin Plásticos
Vigodent Industria e Comercio

› Spain

Proteos Biotech
JJP Hospitalaria

› Israel

MIS Implants
Adin Dental Implants System

› South Korea

STARMed Co. Ltda

› Switzerland

Hamilton Medical AG

› India

Medtech Products Inc.