GRA

GLOBAL **REGULATORY** AFFAIRS

Pharmaceuticals | Medical devices | Biotechnological
Biosimilars | Dietary | Cosmetics | Food | Veterinary

www.gra.com.pe

ABOUT US

Global Regulatory Affairs (GRA) is an international consultant firm that began activities in Peru on 2014 as an initiative to support multinational and local pharmaceutical companies to obtain Marketing Authorizations in Peru. Nowadays, pharmaceutical, biological, medical devices, cosmetic, hygiene and food companies are supported by GRA to focus on their core business trougout an expert advice, guidance, training & recruitment services in Regulatory Affair

The regulatory activity represents a series of challenges that must be resolved quickly in order to avoid delays in getting products to consumers; for that reason, GRA is comprised of senior regulatory professionals with extensive experience in Peru and Latin American sanitary legislation so that we can help your organization to handle the entire regulatory process, from the initial submission to post approval activities, saving time and resources by avoiding re-submission due to rejections.

Global Regulatory Affairs

Global
Regulatory
Affairs

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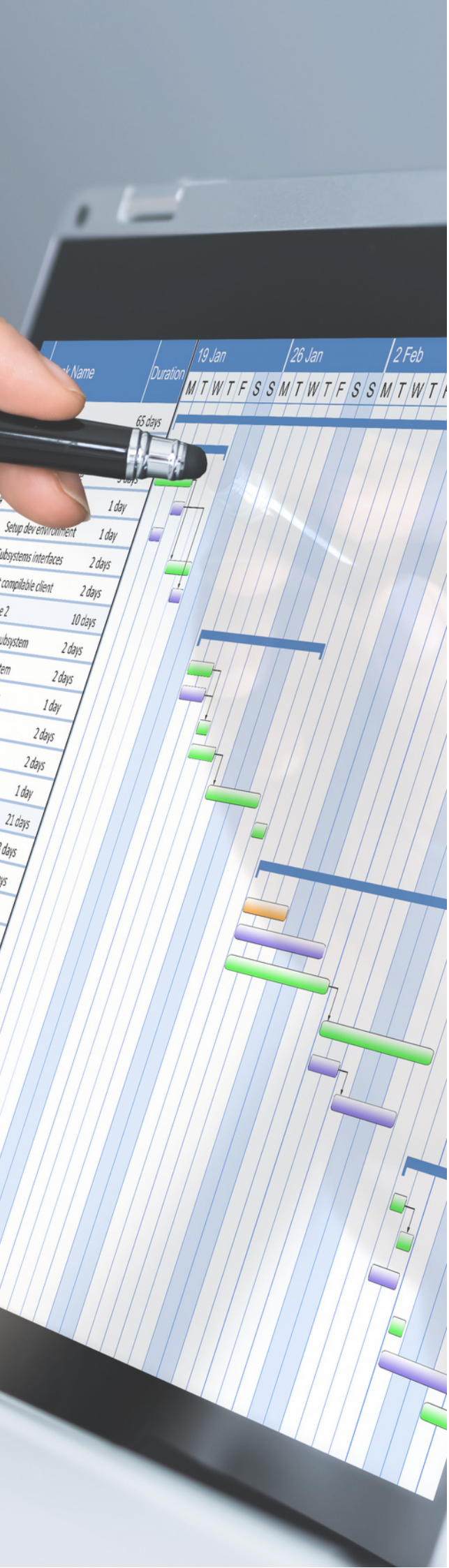

Regulatory Affairs

Global Regulatory Affairs offers scientific, regulatory and operational expertise to help you achieve regulatory approvals and quick market access for your product.

Our strategic regulatory services span the full spectrum of activities and technical functions including regulatory CMC,, lifecycle management, regulatory strateg and full-service regulatory partnerships.

Our end-to-end solutions assure regulatory compliance throughout the entire product lifecycle .

We work closely with you to develop the regulatory strategy needed, preparing and submitting the regulatory documentation, helping to guide you through the various regulatory procedures to bring your product to market quickly and efficiently.

PRACTICE AREAS

MARKETING AUTHORIZATIONS

We provide a wide range of Regulatory Affairs Consultancy services including all aspects of product lifecycle:

- Initial registrations
- Renewals
- CMC variations
- Deficiency letter response
- Labeling
- Regulatory intelligence
- Translations, etc.

GRA can handle the entire regulatory activity of your portfolio.

A regulatory project manager will be assigned to work closely with you.

REGULATORY INTELLIGENCE

Our team bring to your organization relevant information, trends, competitors, a well as the bureaucracies and regulatory forces that drive key developments in your sector.

Once the regulatory landscape and stakeholders are mapped, Global Regulatory Affairs team supports your company with and strategic and informed inputs to minimize regulatory risks and increase the business's success.

PRACTICE AREAS

REGULATORY HOSTING & COMPANY OPENING

Entering to a new market is a complex challenge due to variety of hazards and new landscapes to explore and in most of the cases the opportunities are not duly assessed,

Global Regulatory Affairs assists companies in business & office opening in Perú by offering the service of legal & technical representation while, in parallel, your products are getting registered with us saving time and reducing error margins due rejections.

DUE-DILIGENCE

Global Regulatory Affairs provides support to companies that are looking to acquire in-license products or companies; or to out-license products, in which a high-quality decision-making need to be led by a detailed and accurate assessment of the available information & data

We rely in our highly experienced team that supports clients in such critical stage by carrying out a detailed analysis of the regulatory & GxP status to ensure a detailed due diligence process.

Global Regulatory Affairs reports the findings to highlight areas of concern, and assessing the risks and benefits of the list of products or company you plan to acquire.

PRACTICE AREAS

GxP INTERNAL AUDIT & LOCAL CERTIFICATIONS

Global Regulatory Affairs offers professional advices and preparation for quality teams and decision maker to face regulatory audit coming up,by making sureour clients are ready by having a pre-audit by one of our experienced consultants.

Global Regulatory Affairs supports organizations to manage a GMP / GLP / GWP / GDP compliance roadmap to guide them on a successful outcomes .
Global Regulatory Affairs' audit experts can work to evaluate systems at pharmaceutical, biotechnology, or medical device organization or at their vendor sites to determine if the systems in place are sufficient to meet your needs and the current regulatory standards.

As an extension of your Auditing team, we're able to conduct audits on your behalf, using our roadmap or your established audit program, whichever works best for your needs.

Global Regulatory Affairs audit preparation covers:

- ·Good Manufacturing Practices
- ·Good Laboratory Practices
- ·Good Wharehousing Practices
- Good Distribution Practices

PRACTICE AREAS

PHARMACOVIGILANCE (PV)

Global Regulatory Affairs offers Human Pharmacovigilance, including the provision of Responsible Person for Pharmacovigilance (RPPV) with the necessary tools, experience and expertise to support Sponsors, Marketing Authorization Holders and Applicants.

In accordance with the Peruvian regulation on good pharmacovigilance practices, Marketing Authorisation Holders (MAHs) are required to perform regular risk-based audits of their PV system, and can any time be inspected by the drug regulatory authority (DIGEMID).

Keep your business in compliance and avoid hazards/penalties that might put at risk your operation in Perú.

RECRUITMENT & OUTSOURCING

Our process of selection is based on the in-depth knowledge about the competencies of Regulatory Affairs & Quality professionals. GRA will identify the most skilled candidates and bring them to your organization.

Global Regulatory Affairs' role as an outsourcing partner includes working side-by-side with internal regulatory teams and other functions (e.g., Commercial / Marketing / Supply), supporting submissions, regulatory intelligence, product registration, life cycle management, launching.

GLOBAL FOOTPRINT

Our global service and active regulatory agency network provide local coverage to apply up-to-date, robust regulatory intelligence to product registration process & regulatory intelligence.

We develop preemptive solutions for potential regulatory hurdles and ensure the quality of submissions to maximize the likelihood of successful review.
Our country regulatory agency network ensures appropriate country regulatory representation, response and action to support your business growth.

Global Regulatory Affairs reached +25 clients worldwide

Perú, Ecuador, Chile, Colombia, Bolivia, Argentina, EEUU, Mexico, Canada, Guatemala. Spain, Germany, Italy, India, Tunisia, South Korea,China, Japon.

GRA team provides functional outsourcing as a customizable solution that focuses on high quality, measurable outcomes and cost savings. This dedicated business unit focuses on a full range of regulatory services,including regulatory strategy and document preparation, publishing and lifecycle management.

"WE ARE THE PARTNER OF CHOICE FOR **PATIENT-FOCUSED COMPANIES** AND STRIVE THEM IN THEIR EFFORT TO COMMERCIALIZE **PRODUCTS AND INNOVATE SOLUTIONS** THAT HELP PATIENTS AROUND THE WORLD LEAD BETTER, HEALTHIER LIVE"

CODE OF CONDUCT AND BUSINESS ETHICS

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