www.globalactive.com.mx

GLOBAL ACTIVE, SA DE CV

GLOBAL ACTIVE (GAMx)

Has served the national or international manufacturers and importers of health industry since 1966, focuses on and offers support services that enable manufacturers, importers and distributors to effectively meet stringent requirements across diverse regulatory mandates under the scope of the Mexican Health Agency (COFEPRIS).

GLOBAL ACTIVE (GAMx), offers a comprehensive regulatory affairs service, thanks to our experienced team comprising pharmacists, legal and regulatory specialists. This service covers all aspects of compliance with Mexican law related to the importation and distribution of pharmaceutical, medical devices, diagnostic, scientific, medical controlled substances , nutraceutical products, food & beverages, cosmetics, chemicals, fertilizers and pesticides.

All non-Mexico medical device and pharmaceutical country manufacturers must appoint a local legal address, a well accredited warehouse (in regulatory compliance) or 3PL and notice a Regulatory Affairs Responsible (a local professional as Authorized Representative into the Mexican Health Agency -COFEPRIS- according to the current regulatory law in Mexico) to be able to submit the Sanitarian Registration and/or any request of commercial authorization of the health product and apply for an import permits. If you are a non - Mexico manufacturer and wish to market your device in Mexico, Global Active can act as your Authorized Representative & Registration Holder.

Our Services include: registration of products with regulatory authorities; permits and licensing for importing, warehousing, packing and selling; quality assurance, adverse drug reaction and product complaint assessment and reporting; review of marketing and advertising material.

Planning & Development Division
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What we can do tailored or with individual services on demand:

- Act in Mexico as your Authorized Representative & Registration Holder (Pharm & Medical Devices)
- Regulatory Labeling review
- Data & Info Management
- Regulatory Consulting
- Regulatory Supporting
- Marketing Authorization Applications,
- New Medicine or Medical Device Application: preparation and submissions
- Handling and maintaining notification process
- Crisis assistance. End-to-end assistance with investigation of medical device adverse events and reports.
- Cosmetic Regulatory Services
- Food & Beverages Regulatory Services
- Chemical Regulatory Services
- Fertilizers and Pesticides Regulatory Services
- Medical Devices Regulatory Services
- Due Diligence
- Legal support
- Brand Registration, Industrial Property and Copy Rights
- Warehousing & Distribution
- Administrative services

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Authorized Representation

Mexican Health Agency (COFEPRIS) insist on product licenses being held by a legal entity domiciled within the market – typically a registered Company-. The local entity is usually known as a Distributor, Authorized Representative or Sponsor. It takes responsibility for the product in the market (legally & accreditations), files regulatory submissions and conducts communications with the regulator on behalf of the manufacturer.

GLOBAL ACTIVE (GAMx) offers market representative and Agency services for all your Pharmaceuticals (OTC, Bio Tecnologicals, Orphan Drugs, etc) & Medical Device Registration, Alternative and Health Product's (not all food supplements in other countries have the same classification in México and could be reclassified as medicines), Food & Drinks, Cosmetics, Chemicals, Fertilizers & Pesticides. This is more than an administrative solution – we take care of the entire regulatory process of ongoing compliance (accredited in regulatory compliance warehouse, logistics, post marketing surveillance, etc) so that you can focus on building your business, marketing and sale force in Mexico.

Why shouldn't I just use a regular commercial distributor as my Authorized Representative with the Mexican Health Agency (COFEPRIS)?

The selection of representative/license holder is critical to the orderly continuation of supply. Use of the distributor as representative is not recommended because:

- Distributors are focused mainly on sales and marketing and don't have the regulatory skills and capacity operation to manage product compliance (in the warehouse, logistic operations, SOPs, reports, etc).

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- If a distribution contract is terminated, then the original distributor can cause disruption to continuity of supply and delay the transfer of sponsorship to the new entity. This may even force the supplier to obtain a completely new regulatory approval with substantial interruption to business.

As your Authorized Representative Global Active (GAMx) takes responsibility for the regulatory compliance and provides the interface with regulatory authorities, the manufacturer and the GBU. This provides the PEACE OF MIND of management about the regulatory compliance according to the risk of the health products, while sales arrangements can be independently structured for maximum commercial benefit.

We are here to listen, understand, guide, classify, create or comply with health regulatory affairs and legal conditions in Mexico to represent the GBU and/or manufacturer.

Talk to us today and see how we can help you as regulatory affairs advisor and strategic partner to get your product into the Mexican market.

Best regards/Mit freundlichen Grüssen/Un saludo

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