



RAF Consulting



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Navigating Mexico's Regulatory Landscape with Expertise and Precision

Breaking into Mexico's healthcare market is no small feat. For international manufacturers, Mexico's COFEPRIS—Federal Commission for the Protection against Sanitary Risk—regulations are a moving target. The evolving regulations and shifting requirements routinely slow approvals and disrupt timelines.

RAF Consulting makes the process seamless. Founded by Gloria Frias, a veteran of multinational pharma, the firm brings over two decades of experience helping companies not just meet compliance, but accelerate entry and growth. RAF Consulting delivers more than regulatory filings; it offers strategic guidance, local insight, and hands-on navigation of every step, from strategic planning, product registration to market launch, and support during all product life cycle.

"For manufacturers eyeing Mexico, RAF isn't just a consultant—it's the difference between getting stuck in the process and getting to market fast," says Frias, CEO and founder.

Its deep knowledge of COFEPRIS regulations and criteria gives the company a natural edge in tailoring regulatory strategies that benefit clients' specific needs. RAF Consulting's offerings include regulatory intelligence and strategy, which are critical for companies looking to enter the Mexican market. This service covers everything from product classification and regulatory pathways to risk assessment, ensuring that clients are well-prepared and positioned for success.

In addition to this strategic support, RAF Consulting provides extensive dossier preparation and submission services, covering a broad spectrum of products including pharmaceuticals (biotech, generics, new drugs, and herbal products, among others), medical devices, food supplements, and cosmetics. By managing all aspects of the regulatory submission process, the firm helps companies streamline their efforts and avoid the common pitfalls that often lead to delays or rejections.

A notable strength of RAF Consulting is its ability to act as a registration holder for medical devices. The firm currently holds over 150 registrations for about 30 companies worldwide, providing foreign manufacturers with a reliable and independent partner with no commercial ties to product sales, ensuring full regulatory focus and impartiality. This is a crucial service for companies that want to maintain focus on their core business operations without being bogged down by the intricacies of regulatory or conflict of interest obstacles.

RAF Consulting also provides legal representation for pharmaceutical products in Mexico. While the GMP-compliant manufacturer holds the registration, it manages all aspects of the registration process and regulatory responsibility, and ensures continued compliance with Mexican regulations. This is particularly valuable for companies seeking a reliable partner that complies with the infrastructure required, so they need not establish their own and focus on their global operations.

Since being authorized by COFEPRIS in 2013, RAF Consulting has played a key role in pharmacovigilance and technovigilance. The firm manages adverse event reporting, periodic safety update reports (PSURs), and compliance audits, ensuring that companies meet all mandatory Mexican reporting requirements. With licenses from MedDRA and WHODrug, RAF Consulting remains at the forefront of ensuring that clients meet all safety and vigilance standards.

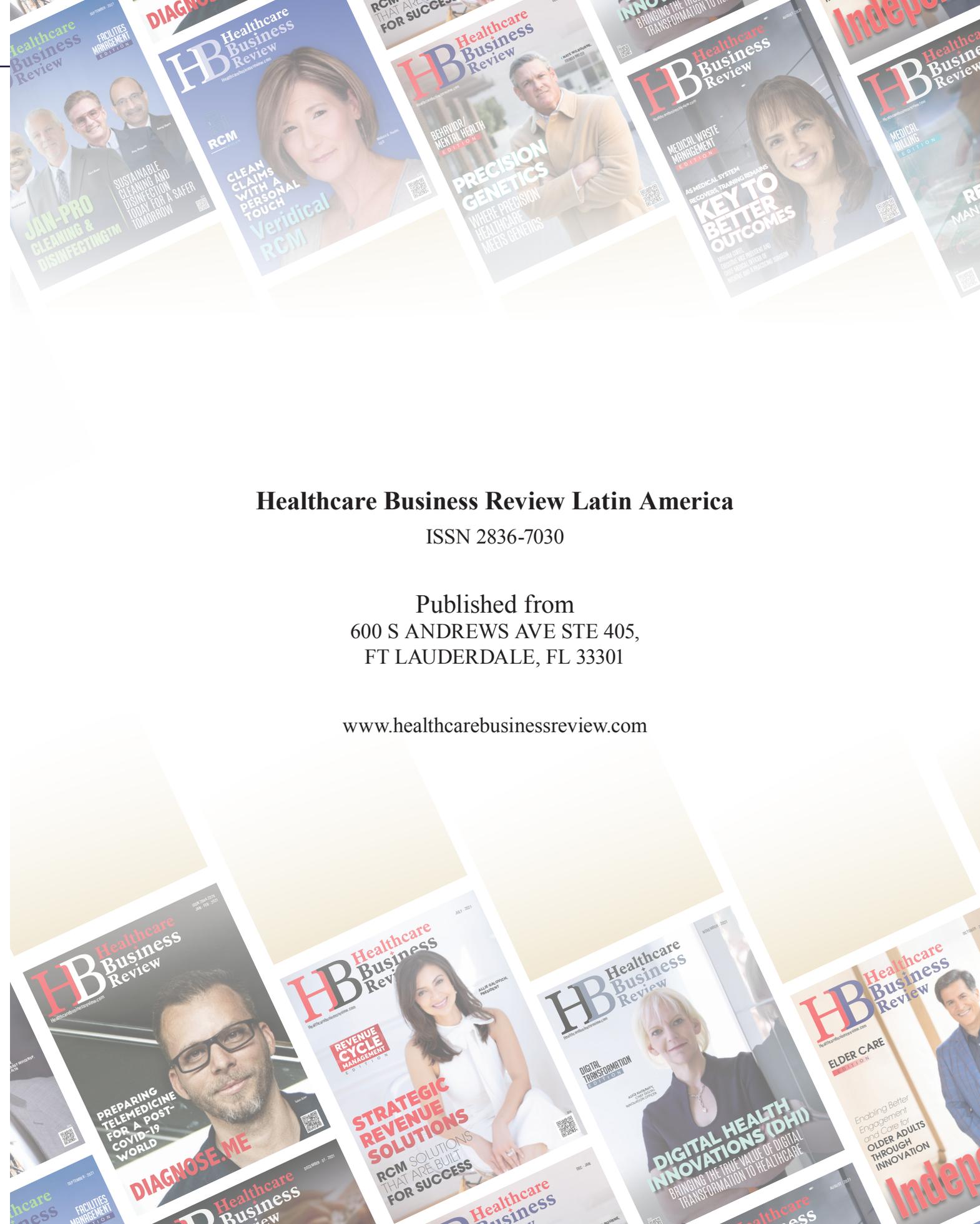
One of the company's most impressive capabilities is its ability to offer regulatory lifecycle support, which includes variations, renewals, labeling, and advertising compliance. This ongoing support ensures that clients' products remain in full compliance throughout their entire lifecycle in the Mexican market.

RAF Consulting's commitment to keeping its clients informed about the latest regulatory changes is another reason why it is highly valued by its clients. The company's team continuously monitors regulatory updates, integrating them into their processes in real time. This proactive approach ensures that clients remain compliant, even as the regulatory landscape evolves. Raf consulting has already integrated recent regulation updates, like the new equivalence agreement that marks the start of Mexican regulation towards Reliance.

For companies seeking a trusted partner to help them navigate Mexico's regulatory landscape, RAF Consulting offers an unparalleled combination of expertise, dedication, and practical support. With end-to-end services throughout the entire product lifecycle, the firm empowers international manufacturers accelerate market access, swiftly, securely, while ensuring full regulatory compliance. This strategic approach lays the foundation for sustained growth and long-term success. **HB**



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