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What began as a focused effort has become a multifaceted operation grounded in strong values and a collaborative spirit.

22.05.2025

Tags: Puerto Rico, Rebexa Group

As regulatory expectations grow more complex and regional fragmentation persists, navigating Latin America's life sciences landscape requires more than technical know-how; it demands agility, strategic insight, and trusted local partnerships. Rebexa Group, founded in Puerto Rico, has emerged as a key player in bridging this gap for pharmaceutical and medical device companies worldwide. In this interview, President Arnaldo Hernandez and Vice President Naiomi Chardon share how the company is leveraging digital innovation, regulatory expertise, and regional reach to deliver seamless market access.

What inspired the foundation of Rebexa Group, and how did your previous experience in the pharmaceutical industry shape its trajectory?

Arnaldo Hernandez (AH): The establishment of Rebexa Group was a direct response to evolving dynamics within the pharmaceutical industry. During my 13-year tenure with Merck Animal Health, I observed the company undergo several transformations in ownership and operational strategy. Around 1999-2000, a series of administrative reforms aimed at enhancing efficiency led to the closure of regional offices previously tasked with overseeing regulatory registrations. This shift created a distinct gap in the market: the absence of independent entities capable of managing

regulatory affairs outside the scope of commercial distributors. When no suitable provider emerged, I proposed to my superiors the creation of a legal structure to fulfil this need, transitioning from employee to contractor. By then, Merck Animal Health had been merged with the veterinary division of Rhone Poulenc to form a separate company called Merial. Thus, we took Merial as our first client. What began as a practical solution evolved into a comprehensive business initiative, formalised through a robust business plan which we submitted to a competitive programme led by Grupo Guayacán and McKinsey & Company. From its inception, Rebexa was designed not only to serve the veterinary sector but also to expand into human pharmaceuticals, an ambition that was firmly embedded in our growth strategy. In this way, the company was born out of both necessity and foresight, grounded in first-hand industry experience and a clear understanding of regulatory complexity.

In what ways does Rebexa streamline regulatory access for life sciences companies operating across fragmented Latin American and Caribbean markets?

Naiomi Chardon (NC): Rebexa Group was founded with a clear purpose: to simplify and professionalise the regulatory journey for life sciences companies operating in some of the world's most complex and fragmented markets. Regulatory affairs across Latin America, the Caribbean, and certain Andean countries are often viewed as a significant operational burden, requiring extensive local knowledge and constant alignment with evolving national frameworks. We position ourselves as a strategic partner, serving as a single, central point of contact between manufacturers and regulatory authorities, offering clients not only executional efficiency but also peace of mind. By managing the full scope of regulatory submissions and lifecycle maintenance on their behalf, we enable our clients to direct their resources where they are most impactful: research, commercial strategy, and market engagement. Ultimately, our work translates into measurable operational gains and a smoother path to market access.

AH: As we often say in Puerto Rico, '*en arroz y habichuelas',* in plain terms, we are a comprehensive regulatory solution for the 16 countries we serve. Our clients are not required to build internal teams or navigate each jurisdiction independently. They entrust us with the complexity so they can focus on innovation and growth. While the task is far from simple on our side, the value we offer lies in making the experience feel seamless for those we support.

How does Rebexa manage the regulatory diversity of the region while ensuring consistency in client submissions?

AH: Managing regulatory affairs across such a heterogeneous region requires more than procedural knowledge; it demands structure, consistency, and trust. From our headquarters, we coordinate the entire process on behalf of clients based in Europe, North America, and other global markets, carefully distilling each country's unique requirements into a clear and manageable pathway. Our clients are only asked to provide the core documentation necessary to assemble a registration dossier, which we then tailor to each jurisdiction in collaboration with our local associates. These partners take on all in-country responsibilities, from executing official translations and paginating documents in line with national standards to indexing and submitting the dossier to the appropriate regulatory body. They also handle required government payments and closely monitor the process through to final approval.

Equally important is our sustained engagement with senior regulatory officials across the region. Naiomi and I actively participate in conferences, policy forums, and bilateral meetings to cultivate long-standing relationships with decision-makers. These connections allow us to step in when needed to facilitate resolution for any issues, such as delay or miscommunication. Interestingly, regulators are often more responsive when approached by someone perceived as an external expert, even when the message mirrors what local consultants may have already conveyed. We do not view this dynamic as a privilege, but rather as a natural aspect of human interaction, one that we navigate respectfully to ensure the continuity and success of our clients' submissions.

How is Rebexa Group's operational model structured regionally, and what role does Puerto Rico play in serving your international clientele?

AH: Rebexa Group operates from a single, centralised office in Puerto Rico, which serves as the nucleus for all coordination and communication. While we do not maintain physical offices across the region, we have established legal entities wherever required to comply with local regulatory frameworks. These entities function virtually, enabling us to maintain the necessary authorisations to represent clients before Ministries of Health. Supporting this structure is a network of approximately 60 experienced associates across Latin America, each contributing country-specific expertise under a tightly coordinated model.

Although our headquarters are in Puerto Rico, around 90% of our clients are based internationally. The island once played a more prominent regional role, but over time, many multinationals have

shifted their Latin American operations to locations such as Miami, Bogotá, or Mexico City. Today, Puerto Rico remains a strategic operational hub rather than a commercial centre. While local events like hurricanes may cause temporary logistical challenges, our geographically dispersed client base and virtual infrastructure ensure continued service delivery with minimal disruption.

What distinguishes Puerto Rico's regulatory environment, and how does its alignment with the United States Food and Drug Administration (FDA) influence market access?

NC: Although Puerto Rico operates under the regulatory framework of the FDA, it also enforces local requirements to safeguard public health. International clients often ask why separate registration is necessary if the FDA approval has already been granted. The answer lies in the Puerto Rico Pharmacy Act, which mandates that all pharmaceutical products marketed locally be registered with the Department of Health and that distributors maintain valid certifications. Since there are no customs inspections for goods arriving from the US mainland, compliance oversight depends on the diligence of manufacturers and distributors. At Rebexa, we play an active role in advising clients on these obligations and ensuring their alignment with both federal and territorial requirements.

AH: Importantly, registration in Puerto Rico is not a technical evaluation of safety or efficacy but rather a mechanism for traceability. Authorities seek to understand where a product is made, who distributes it, and how it reaches the market. This approach allows for rapid response in the event of a recall and ensures accountability across the supply chain. Similar systems are found in several US states to manage interstate commerce, particularly as products can be transported freely or purchased online. By licensing pharmacies, distributors, and products, Puerto Rico reinforces regulatory integrity while maintaining its position within the broader FDA-regulated framework.

What regulatory hurdles do pharmaceutical companies face when seeking to bring products to market across Latin America?

AH: As regulatory systems across Latin America evolve and align with global standards, the complexity of market entry has increased markedly. Where once product registration required only basic labelling and general information, today's submissions demand detailed evidence of safety, efficacy, raw material sourcing, and manufacturing processes. However, while the regulatory burden has intensified, government agencies often remain understaffed and under-resourced,

lacking the capacity and continued training necessary to process this growing workload efficiently. These constraints result in extended delays, not because of bureaucratic resistance, but due to structural limitations within public institutions.

For multinational companies, this environment presents a cost-benefit dilemma. While markets like the United States, Europe, or Japan offer expansive returns from single regulatory approvals, Latin America's fragmented landscape requires navigating multiple national processes to access significantly smaller markets. In some cases, companies opt out entirely, limiting access to innovative treatments. At Rebexa, we actively encourage our clients to remain committed to the region, especially given the clear and often unmet medical need. Although the generics space is increasingly supported by local players, access to cutting-edge therapies continues to face structural obstacles that demand long-term engagement and strategic persistence.

How are regulatory frameworks in Latin America adapting to the rise of biosimilars, digital health, and other advanced therapies?

AH: Across Latin America, regulatory frameworks are evolving, but often at a slower pace than the technologies they aim to govern. When companies introduce innovations such as digital health platforms or medical devices that combine electronic and therapeutic components, they frequently find that current legislation does not yet accommodate these models. In such cases, regulatory pathways must be negotiated individually, with companies and authorities working together to define an appropriate approach. While the absence of regulation does not necessarily block market entry, it does demand flexibility and cooperation. A case in point involved a company seeking to commercialise pre-standardised hormonal pellets initially produced through compounding. Because these products did not fall under existing rules, and the authorities lacked a legal mechanism to assess them, registration was effectively impossible, despite the company's full willingness to comply.

NC: These challenges are exacerbated by systemic limitations within the regulatory bodies themselves. Many agencies remain under-resourced, and even those with sufficient staff often suffer from high turnover and limited continuity in dossier review. A submission may be evaluated by several officials in succession, each applying different interpretations and raising new queries, which significantly delays the process. As regulatory demands increase, driven by scientific complexity and public health needs, the capacity gap within institutions becomes more pronounced. Without greater consistency, investment in training, and procedural clarity, the

promise of next-generation therapies in the region risks being undermined by administrative bottlenecks.

How is digital transformation influencing regulatory environments in Latin America, and in what ways is Rebexa Group adapting its own operations in response?

AH: The move toward digitalisation across Latin American and Caribbean regulatory agencies marks a significant step forward in modernising the region's compliance infrastructure. While most national authorities are now implementing electronic platforms for current submissions, these initiatives are generally forward-facing, with historical records still maintained in physical format, creating fragmented systems that pose both logistical and procedural challenges. In the early stages, agencies frequently encounter issues such as unstable platforms, insufficient bandwidth, and limited cloud capacity, which can slow progress and frustrate stakeholders. Yet, countries that have taken a structured, well-resourced approach to implementation, such as Ecuador and Costa Rica, demonstrate that digitalisation, although demanding, can lead to significantly improved efficiency and predictability. When executed with institutional clarity and continuity, it becomes a transformative force rather than a temporary disruption.

At Rebexa Group, we recognise that adapting to this shift is not only a matter of responding to external demands but also of proactively reimagining how we operate. To this end, we have developed a proprietary digital platform that centralises collaboration between our internal teams, field associates, and clients, enabling a more transparent and agile approach to regulatory execution. This shared digital workspace enhances communication, reduces turnaround times, and allows us to manage complex, multi-country projects with greater precision. In our experience, approximately 70% of regulatory work is process-driven and lends itself to automation; however, the remaining 30% is governed by nuance, local context, institutional culture, and the interpersonal dynamics that underpin regulatory review. As artificial intelligence technologies evolve, we anticipate they will increasingly support these more interpretive tasks, not by replacing human judgment, but by enhancing it. For Rebexa, digital transformation is not a matter of catching up, it is integral to sustaining excellence in a region where agility, expertise, and foresight are more valuable than ever.

What are Rebexa Group's strategic priorities over the next five years, and what message would you share with companies navigating Latin America's regulatory

landscape?

AH: Over the next five years, our strategy is anchored in two priorities: accelerating our digital transformation and expanding into emerging, underserved markets. We are refining a proprietary digital platform that will function as a centralised workspace, enhancing coordination between clients, internal teams, and field associates. This tool is designed not only to increase operational efficiency but to bring greater transparency and responsiveness to the regulatory process. On the geographic front, we intend to expand our presence in smaller markets such as Paraguay, Uruguay, and Bolivia, countries where it may not be commercially viable for multinationals to establish local infrastructure, but where we can deliver high-quality regulatory support that meets or exceeds in-house capabilities. Concurrently, we are focused on strengthening strategic partnerships in key regional hubs, including the United States, Mexico, Brazil, and Argentina, to offer integrated solutions that scale across borders.

To companies evaluating Latin America, I would emphasise that establishing a local legal entity is no longer the only path to access. With the right partner, it is entirely possible to navigate complex regulatory environments efficiently, without compromising control over your intellectual property or product strategy. While individually these smaller markets may not yield transformational returns, collectively they represent a compelling opportunity, particularly for companies that have already invested in Spanish-language labelling and regional packaging.

NC: My message is simple: invest in specialised expertise. Just as you would entrust architectural work to an architect or legal matters to a lawyer, regulatory affairs demands the same level of professional precision. Focus your internal resources where they add the most value, and delegate the regulatory burden to those who know the terrain.

What final reflections would you like to share, and how has Rebexa Group evolved in terms of its service scope across human and veterinary health?

AH: The journey of building Rebexa Group has been one of perseverance, growth, and shared purpose. It has not always been easy, but it has been deeply rewarding, professionally and personally. What began as a focused effort in pharmaceutical regulatory services has evolved into a multifaceted operation grounded in strong values and a collaborative spirit. Over time, as the regulatory landscape matured and market needs shifted, we expanded our offering well beyond our initial scope. Today, we support a broad array of products across both human and animal health sectors, including pharmaceuticals, medical devices, cosmetics, diagnostic kits, biologicals,

and feed supplements. Our work encompasses all categories regulated by Ministries of Health and Agriculture, underpinned by a well-established regulatory infrastructure and deep contextual knowledge.

In the veterinary field, we have seen particular growth in the area of feed supplements, as industry practices shift away from the use of antibiotics as growth promoters in livestock. Heightened regulatory scrutiny has accelerated the move toward nutrition-based solutions that enhance animal health more sustainably. This evolution mirrors our own trajectory: continuously adapting to change, expanding our expertise, and reinforcing our role as a trusted partner in highly regulated environments. An interesting note is that we have a 93% + client retention rate. So we are in for the long haul with our clients. I would prefer not to mention names for confidentiality agreements yet even though the products that were managed by some of our first clients have changed hands several times in the past 20 years, we are still managing the portfolio.

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