

Looking to expand your contract manufacturing activities in Latin America?

Dear Readers,

At Fresenius Kabi we continue to accelerate the growth of our business across products and markets, demonstrating the power of our strategy fueled by our diversified portfolio.

We proved that we can deliver high-quality products designed to exceed patients' and health care professional's expectations. We showed that we can pivot our presence in emerging markets by bringing high-quality products to new consumers around the world.

In this new issue we would like to give you an overview of Fresenius Kabi Product Partnering activities in our Latin American sites.

Latin America pharmaceutical Contract Manufacturing market is anticipated to reach USD 21.0 billion by 2025.⁽¹⁾ Low drug registration cost and continuous economic growth in Latin American countries are the key factors contributing to progress in this region. These countries are perceived to have great potential for pharmaceutical development. Brazil, Mexico, and Chile have ranked in the top 20 countries for financial attractiveness, people skills, and business environment for offshore options.⁽²⁾ Furthermore the same have surpassed China in English proficiency.⁽³⁾

Fresenius Kabi has provided contract manufacturing services for decades and is committed to further expanding these activities in Latin America. Spread across four production sites in Latin America, compliant with cGMP and local standards, our operations are equipped to become our partners' manufacturing platforms. Fresenius Kabi constantly invests in its manufacturing sites to maintain them at the cutting edge of technology and staffed with well-educated and highly motivated people.

Fresenius Kabi Product Partnering core competencies allow our partners to have access to trained and professional people, state-of-the-art production facilities and capabilities in Latin America thus simplifying product's path to market while meeting partner's manufacturing needs. Fresenius Kabi has an established quality, regulatory and supply-assurance track record, along with robust manufacturing expertise. Our portfolio offers products that are synonymous with quality, consistency and reliability.

The customized approach and flexibility allows the opportunity to offer tailored solutions for unique, specialized requirements. Once the development work is complete, we will formulate, fill/finish, label, and package your product to your specifications.

Our focus is always the success of your product, so contact us or meet us at one of the exhibitions below to start talking about the optimal solution for you!

Thank you for your continued confidence,
Laura Pandolfi

References:

⁽¹⁾ Grand View Research - Latin America Pharmaceutical Contract Manufacturing Services Market

⁽²⁾ 2016 A.T. Kearney Global Services Location Index

⁽³⁾ EF English Proficiency Index 2015

Exhibitions

- Contract Pharma Table Top - September 27, 2018, New Jersey, USA
- CPhI Worldwide - October 09 - 11, 2018, Madrid, Spain
- Bio Europe - November 5-7, 2018, Copenhagen, Denmark



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In this issue

Editorial

In the Spotlight:
Fresenius Kabi Contract
Manufacturing Services in
Latin America

Our capabilities for sterile
products in Latin America
at a glance

In the Spotlight: Fresenius Kabi Contract Manufacturing Services in Latin America

Fresenius Kabi Product Partnering is dedicated to provide our partners with solutions precisely tailored to meet the unique requirements of their products and businesses. In Latin America we offer contract manufacturing services in our production facilities in Santiago de Chile, Chile, Aquiraz and Anápolis, Brazil and Guadalajara, Mexico. Outsourcing with us in Latin America means access to our advanced technologies and optimized processes to streamline your product pipeline and benefit from our expertise in facility design, construction, equipment selection, process development and technology transfers to ensure you have exactly the commercial product supply you need to succeed.

Throughout our facilities we provide analytical competence in the physicochemical & microbiological testing of production processes and materials (e.g. analytical HPLC, GC, AA, sterile testing etc). Furthermore, we have in-house Engineering/Validation, Documentation, Quality Control, and Quality Assurance teams to support our partners. Our customized approach and flexibility allow us to offer our partners tailored solutions for unique, specialized needs in a wide range of volumes and packaging systems.



Anápolis (Brazil)

The production site in Anápolis (state of Goiás), located in the second biggest hub of pharmaceutical industry in Brazil, was founded in 1994 as a specialist for small volume parenterals and acquired by Fresenius Kabi in 2014. The facility has 6 dedicated production areas according to technologies used and therapeutical class of the final product. The plant produces a variety of small volume parenterals, i.e. liquids (glass ampoules 1-10 ml) and powders (glass vials 0.1-4.5 g) through aseptic processing or final sterilization focusing on Antibiotics, Glucocorticoids, Analgesics and Catecholamine. The facility employs about 500 people and has its own quality, logistics and administration departments including an onsite warehouse.



The site is GMP certified by Anvisa and obtained a GAFO (Grupo de Avaliação e Qualificação de Fornecedores/ Evaluation and Qualification Group for Suppliers) certification.

Aquiraz (Brazil)

One of our Brazilian production sites located in Aquiraz, in the state of Ceara, was founded in 1985 as a local company, and acquired by us in 1997. The plant produces Standard and IV Solutions in Plastic Bottles (50-1000 ml). The site has its own quality, maintenance, logistics, administration departments and warehouses for finished products and raw material storage.

The facility has a highly qualified staff of about 600 employees and its products are produced to serve the Brazilian market.

The site is GMP certified by Anvisa and ISO 9001 certified.

Santiago de Chile (Chile)

Operations in Santiago de Chile in a small pilot plant making Standard Solutions in plastic bottles. Currently the plant produces a variety of products including generic IV Drugs in a large number of different containers such as **freeflex**® bags and plastic ampoules ranging in volume from 2 ml to 5000 ml. Furthermore, a high-tech integrated line for filling glass ampoules ranging in volume from 1 to 10 ml and glass vials ranging in volume from 1 to 20 ml within aseptic process or with final sterilization completes the capability of our Chilean site. Currently our "Laboratorio Sanderson" production site in Chile employs around 850 employees, and covers more than 32,000 square meters area. The production site in Santiago supports Fresenius Kabi's business with a variety of containers and a wide range of products such as Standard Solutions, Anesthetics, Analgesics and Anticoagulants delivered to almost all Latin American countries and European non-profit organizations.

Guadalajara (Mexico)

The production site in Guadalajara was founded as "Laboratorios Alpha" and acquired by us in 1996. In 2004 the site was completely renovated and since then the plant covers an area of 32,000 square meters (shared with our sister company Fresenius Medical Care). The plant produces Standard Solutions and generic IV Drugs in Blow-Fill-Seal Plastic Bottles (ranging in volume from 50 to 1000 ml) and in PVC bag containers (from 50 to 300 ml). All our IV products are terminally sterilized. The plant also has a line producing enteral nutrition products; i.e., Oral Powders in plastic containers and sachets, as well as Sip Feeds in aluminum cans. This production site is focused on providing products for the local Mexican market as well as for Peru, Argentina, Ecuador and further markets in the Central American region. Guadalajara is considered a commercial and financial center with excellent infrastructure and great connectivity to the rest of the country.

The site is GMP certified by INVIMA (Colombia) and DIGEMID (Peru) and has an ISO 9001 certification.

Our capabilities for sterile products in Latin America at a glance

		PLANT			
		Anápolis (BR)	Aquiraz (BR)	Guadalajara (MX)	Santiago (CN)
Selected Contract Manufacturing Technologies	Technology Transfer	●	●	●	●
	Laboratory Testing & Stability	●	●	●	●
	Aseptic Fill & Finish	●			●
	Small Molecule Drug Products	●			
	Blow-Fill-Seal (BFS)		●	●	●
	Terminal Sterilization			●	●
	Sip Feeds			●	
	EN Powders			●	
	Project Management	●	●	●	●
	Warehousing and Shipping	●	●	●	●
	Containers (Plastic)	Ampoules	●		
freeflex ® Bags					●
Bottles			●	●	●
PVC Bags				●	●
Canisters for Haemodialysis					●
Containers (Glass)	Vials	●			●
	Ampoules	●			●
Certifications	GMP	●	●	●	●
	ISO 9001		●	●	●
	ANVISA (Brazil)	●	●		●
	INVIMA (Colombia)			●	●
	DIGEMID (Peru)			●	●
	ISP (Chile)				●

	Primary Packaging Systems	Volumes
Plastic	Ampoules	2 - 20 ml
	freeflex ® Bags	50 - 1,000 ml
	Bottles	50 - 1,000 ml
	PVC Bags	50 - 300 ml
	Canister	5,000 ml
Glass	Ampoules	1 - 10 ml
	Vials	2 - 10 ml