



# BUOYANT PR CDMO LLC

TRANSFORMING LIVES WITH INNOVATIVE HOPE AND PRECISION MEDICINE FOR RARE  
DISEASES

**Presented By :**  
**Mayra Liz Guzman-Kaslow,**  
**Founder and CEO**

*farmaforum*

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*Confidential*



**BUOYANT PR CDMO LLC**

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### Executive Summary

**Buoyant Pharma and Device Manufacturers LLC “BUOYANT FL”** is a 2-year-old new LLC corporation, registered in the State of Florida USA, and **Buoyant PR CDMO “BUOYANT PR”** the Siter Company Registered in Puerto Rico, USA with operation for services for Contract Development and Manufacturing Operations (CDMO) and Contract Manufacturing Organization (CMO).

Headquartered in Lake Nona Medical City, Lake Nona - Orlando, Florida within walking distance of UCF Cancer Research Institute and immediate access to UCF School of Medicine, Buoyant Pharma operates corporate offices and state-of-the-art Research and Development Laboratories. Our Small-Scale Manufacturing/Pilot Plant reflects our commitment to innovation and excellence.

Buoyant Pharma and Devices Manufacturer specializes in the contract development and contract manufacturing of that develops and will manufacture Biologics, Biosimilars, Cell & Gene development, and pharmaceutical drugs. As well as the Development and Manufacturing of Drugs, Biologics, and Medical Devices to treat Rare Diseases and Rare Types of Cancer.

In addition, we provide professional regulatory compliance consulting services that combine experience and resources with exceptional quality, optimized solutions to our life sciences and consumer product customers by delivering a full range of planning, facility development, and validation services. a team of regulatory compliance experts to work closely with our clients to develop comprehensive validation programs for their facilities to ensure they meet all applicable regulations.

Buoyant PR CDMO provides Contract Development Manufacturing Operation, Contract Manufacturing, and Contract Packaging (CDMO/CMO/CP) Services for Pharmaceuticals, Hormones, Biotechnology, Medical Devices, and Cosmetics including Brand, Generics, and OTC products.

We have experience with compliance for all aspects of our work, assuring that all systems, processes, and equipment that can affect quality or integrity are qualified and validated. Our program is consistent with industry standards and practices, cGMPs, and any other appropriate FDA guidelines, ISO Standards, and/or other policies



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## **Management Team**

Mrs. Mayra Guzman Kaslow, Sole Owner, Founder & CEO of Buoyant Pharma and Device Manufacturer, has had a distinguished career in the pharmaceutical and medical device industries. She began her journey in her early twenties after graduating with two bachelor's degrees in Chemistry and Chemical Engineering from the University of Puerto Rico, and a Master of Science in Thermodynamics and Materials Science Engineering from the University of Cincinnati, OH.

With over 35 years of experience, Mrs. Guzman has worked for top pharmaceutical companies and supported the FDA in various activities. Her expertise includes regulatory compliance, quality, design, engineering, operations, and the manufacturing of pharmaceutical products and medical devices. She also has extensive experience in startups, project management, and business development across the U.S., Latin America, Europe, and Asia. In her consulting roles, she has completed over fifteen startup facilities worldwide for pharmaceuticals, biotechnology, and commercial manufacturing.

As a Scientist, during the COVID-19 pandemic, Mrs. Guzman-Kaslow developed a COVID-19 molecular test which was approved by the FDA.

In 2020, Mrs. Guzman-Kaslow was honored to be featured in an article by Forbes Magazine.



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## **Our Mission**

Our Mission is to provide the highest quality and affordable medicines and devices on the market to treat those rare diseases give hope and inspire changes in the industry.

As an emerging player in the generic drug/biosimilar sector, we are committed to providing widespread access to affordable medicines.

By providing innovative, sole solutions, custom medicines, and devices, we aim to revolutionize the orphan drug market by making it easier and affordable for patients and giving them the care, they deserve.

While focusing heavily on philanthropic efforts, the foundation of our success depends on how many people we can help.



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## **Our Philosophy and Vision**

### **We Believe in:**

- **INNOVATION** – We are always ahead of the curve.
- **INTEGRITY**- Our motto: “Quality over Quantity”.
- **COMPASSION** - Empathy for those in need
- **DIVERSITY** – Diversity, and inclusion are embraced
- **BOLDNESS** - We win as a team
- **SUSTAINABILITY** - We stand behind our work 100%.
- **CUSTOMER SATISFACTION** - We aim to exceed the expectations of our industry and our customers. Customer satisfaction is paramount to us.

Our business and project management expertise covers every level of Development, Manufacturing, and compliance assistance for U.S. and non-U.S. companies in the pharmaceutical, biotechnology, medical device, and related industries.



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# Core Offerings



Buoyant PR CDMO offer Contract Development and Manufacturing Organization (CDMO) services and Contract Manufacturing Organization (CMO) services to other companies helping to increase their commercial capabilities.



CMO Services for Oral Solid Dosages, Oral Gels, fill and finished capabilities for syringes, vials, and cartridges injectables



Cell & Gene Development, Manufacturing and Commercialization



We will collaborate with Brand-Name Manufacturers to support their commercial capabilities for the type of product presentations.



Contract Packaging



In the industry, aiding in the development and manufacturing of Orphan drug products for the treatment of Rare Diseases and Rare Types of Cancer.



Stability Services



Buoyant Regulatory Compliances Services, provides Regulatory Compliance, Regulatory Affairs, Quality Audits, Remediation Plans, Validation, and Engineering Consulting Services to all regulated health care product industries:

- ✓ Pharmaceuticals / Biotech
- ✓ Biosimilar and Cell & Gene
- ✓ APIs
- ✓ Cosmetics
- ✓ Medical Device and Diagnostic



Analytical Methods Development Services



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# Pioneering Solutions for Rare Diseases and Cancer Care."



Buoyant Pharma & Device Manufacturers LLC and Buoyant PR CDMO is dedicated to advancing healthcare through the development, manufacturing, and distribution of specialized pharmaceuticals, biological products, and medical devices, focusing on Rare Diseases, including Rare Types of Cancer. Our unwavering commitment to patient-centric drug development and manufacturing ensures success throughout the entire journey.



Prioritizing patients' well-being and needs, we empathize with the distinctive challenges they face in dealing with Rare Diseases and Rare Types of Cancer. Our commitment translates into pioneering, personalized solutions, including custom medicines and devices, aiming to transform the orphan drug market for improved patient access and affordability.



Whether guiding the journey from molecule development to Cell & Gene Therapeutic or overseeing the comprehensive commercialization of Biosimilars, we serve as a dedicated, trustworthy, and experienced partner. Our tailored solutions demonstrate a commitment to understanding and addressing the intricate needs of patients.





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# Why PUERTO RICO?

**BUOYANT PHARMA AND DEVICE MANUFACTURERS**

**BUOYANT PR CDMO**

**OUR CEO PROUDLY BORN IN PR**



**Strategic  
Geographic  
Location**



**Favorable  
Regulatory  
Environment**



**Outstanding  
Human Capital**



**World Class  
Business  
Environment**

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## **Buoyant Pharma: Expanding to Puerto Rico with a New State-of-the-Art Facility**

Buoyant Pharma is excited to announce a significant milestone in our growth journey—the acquisition of a state-of-the-art cGMP (Current Good Manufacturing Practice) manufacturing facility in Puerto Rico. This facility will enable us to significantly expand our Research & Development capabilities, including Product Development, Technology Transfer, OSD (Oral Solid Dose) Formulation, and offering CDMO/CMO services for Fill and Finish, as well as Commercial Manufacturing.

This strategic expansion aligns with our long-term vision of establishing a powerful presence in Puerto Rico, furthering our mission to deliver high-quality, affordable healthcare solutions to those who need them most. Through innovative collaboration and an unwavering commitment to accessibility, we aim to make a lasting impact in the treatment of rare diseases—bringing hope to patients worldwide.

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## **Contact Information**

**MAYRA LIZ GUZMAN-KASLOW**

Founder & CEO



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✉ [mayra.guzmankaslow@buoyantprcdmo.com](mailto:mayra.guzmankaslow@buoyantprcdmo.com)

☎ +1. 609.902.4666

📍 Union St Rd 195 Km 1.1  
Fajardo, PR, 00738

[www.buoyantprcdmo.com](http://www.buoyantprcdmo.com)

***“THE SKY IS NOT THE LIMIT, IT'S JUST  
THE BEGINNING”***

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