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ASIA EDITION

YD Bio partners with YC Biotech to establish Taiwan-US dual-core regulatory platform

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Through deep integration of YC Biotech's execution capabilities in Asia and YD Bio's experience in engaging US regulatory authorities



YD Bio Limited, biotechnology company advancing DNA methylation-based cancer detection technology and ophthalmologic innovations, has announced that its subsidiary YD Bio USA has entered into a Master Strategic Alliance Agreement with Taiwan-based YC Biotech.

This partnership represents a pivotal advancement in the company's mission, establishing YD Bio USA as the official strategic hub and exclusive US Agent for regulatory applications to the US Food and Drug Administration (FDA) for YC Biotech's Contract Research Organization (CRO) clients in Asia.

Pursuant to the agreement, the partnership will cover FDA-related projects, including Investigational New Drug (IND), New Drug Application (NDA), and Biologics License Application (BLA) submissions, which will provide clients with a streamlined, integrated approach to navigating the complexities of the regulatory landscape.

Through deep integration of YC Biotech's execution capabilities in Asia and YD Bio USA's experience engaging US regulatory authorities, the companies will establish a "Taiwan-U.S. Dual-Core" regulatory platform.

Under the terms of the agreement, YD Bio USA will serve as YC Biotech's exclusive US Agent and formal liaison with the FDA. In this role, YD Bio USA will manage official communications and correspondence with the FDA, represent sponsors in preÃ¢â?¬â??IND and other formal regulatory meetings, provide highÃ¢â?¬â??level US regulatory pathway strategies and positioning advice, and serve as compliance risk advisor.

YD Bio USA will also coordinate FDA inspection readiness efforts to facilitate compliance with applicable US regulatory requirements.

YC Biotech will lead project acquisition and technical execution for clients with US regulatory requirements and provide support for regulatory submissions. YC Biotech's responsibilities will also include preparation and drafting of comprehensive submission documentation, integration and scientific compilation of CMC (Chemistry, Manufacturing, and Controls) data, development of clinical protocols and regulatory content, overall project management to maintain timelines, and assembly of complete submission packages.