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APAC SPECIAL

PHARMA OUTSOURCING EDITION

PPD-SNBL

THE HALLMARK OF QUALITY AND RELIABILITY IN CLINICAL TRIALS

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VP and General Manager

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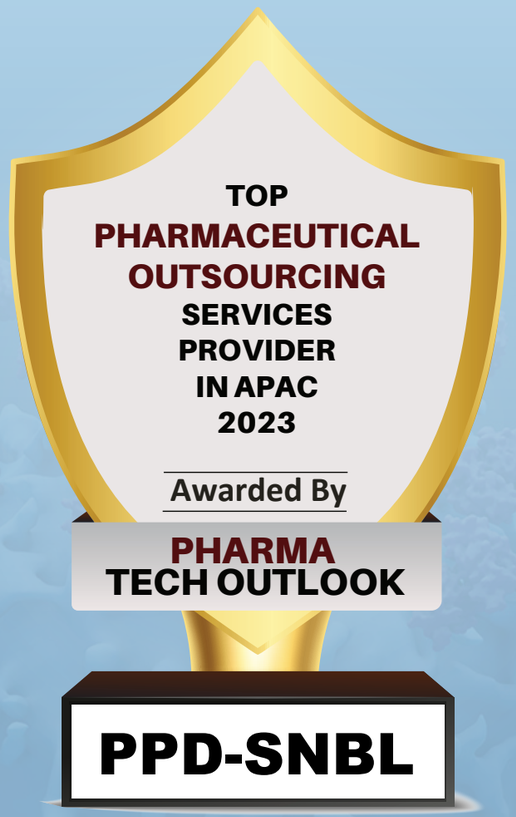

PPD-SNBL

PPD-SNBL is recognized as one of the Top of 10 companies that are at the forefront of providing Pharmaceutical Outsourcing services and impacting the Pharma industry

COVER STORY

PPD-SNBL

THE HALLMARK OF QUALITY AND RELIABILITY IN CLINICAL TRIALS

By Stacey Smith

In the pursuit of cutting-edge therapeutics that set new precedents in patient care, the need for a dependable CRO is more pronounced than ever. It is the driving force that helps pharma companies successfully navigate a dynamic and highly regulated industry, accelerating drug development timelines, ensuring compliance and ultimately ushering transformative therapies from conception to market.

PPD-SNBL embodies all the qualities of an ideal CRO by blending quality, speed and cost-efficiency to effectively serve client needs and contribute to the advancement of clinical research.

As a clinical development specialist, it provides a wide array of high-quality services, ranging from monitoring all stages of clinical development to regulatory consulting, and beyond. It helps clients seamlessly progress through the clinical trial process and secure new drug approvals from regulatory agencies.

"Our goal is to maintain the highest standards of quality in our services to turn into the most trusted CRO in Japan," says Yasumasa Kurioka, VP and general manager of PPD-SNBL.

An impressive portfolio of over 150 ongoing global studies, including nearly 30 as an In-Country Clinical Caretaker (ICCC), speaks volumes about the trust and credibility PPD-SNBL has garnered in the industry. It has also forged extensive collaborations with over 30 international pharma organizations within and outside of Japan, demonstrating its capability to cater to diverse client needs on a global scale.

Optimizing Clinical Trial Processes

Recognizing the paramount importance of meeting the dual expectations of cost reduction and expedited timelines in clinical trials, PPD-SNBL has strategically implemented a decentralized clinical trial (DCT) model. It represents a groundbreaking approach to conducting trials remotely and cost-effectively, which benefits sponsors and patients.

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This model also encourages patients to participate in clinical trials because they can do so from the comfort of their homes. It assures their undivided engagement throughout the trial and reduces the dropout rates often associated with the inconvenience of travel and site visits.

In essence, the strategic implementation of DCT contributes to an overall reduction in traditional

Yasumasa Kurioka,
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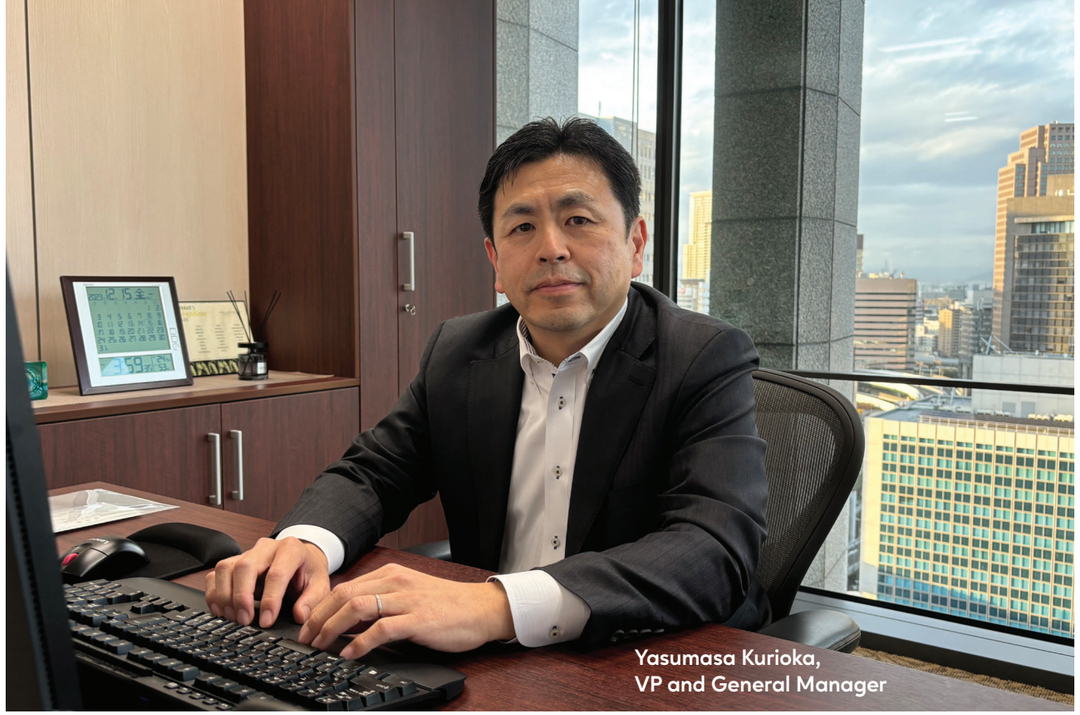

Yasumasa Kurioka,
VP and General Manager

burdens, aligning with PPD-SNBL's overarching goal of reducing both time and costs in the clinical trial process.

Further distinguishing PPD-SNBL is its implementation of the evolving clinical delivery (ECD) model. Unlike the conventional approach, where one clinical research associate (CRA) is assigned to a single investigator site, the ECD model introduces a dynamic trio comprising remote, on-site and assistant CRAs.

While the remote CRA oversees investigator sites from a separate location, on-site CRAs provide hands-on support and ensure seamless execution of clinical trial activities. Coordinating with these two roles, the assistant CRAs take up the responsibility of report documentation and preparation. This strategic division enables each role to leverage its distinct expertise, fostering a collaborative and specialized approach to clinical trial monitoring. It also mitigates potential disruptions and enhances the quality, reliability and speed of clinical trials.

Tackling Local Regulatory Challenges

In 2015, the merger of PPD, a CRO with 86 offices in 47 countries, and SNBL, a prominent Japan-based CRO, equipped the newly formed company with global knowledge and local expertise. It is a distinctive strength that allows the company to address the complexities specific to the Japanese regulatory landscape and expedite clinical trials in Japan.

Adherence to global standard operating procedures (SOP) and practices is imperative when undertaking global clinical trials. However, applying these SOPs in Japan necessitates a nuanced approach due to the unique local environment. Merely adopting global SOPs without customization would be ineffective in the Japanese context.

Sidestepping a one-size-fits-all approach, PPD-SNBL tailors its processes to suit the local environment by combining the 'best of both worlds'—a strategic blend of PPD's global knowledge and practices with SNBL's two decades of local experience.

This customization extends to various aspects, including investigator sites, doctors, hospitals and site staff. An illustrative example is the feasibility survey, a critical step in selecting investigator sites for clinical trials. While the global standard involves sending surveys directly to hospitals, PPD-SNBL adopts a more personalized approach in Japan. A local CRA visits the hospital, conducts the survey, and discusses it with investigators. This adaptation of global SOPs to fit the Japanese environment has earned PPD-SNBL high praise and evaluations from clients, establishing it as a trusted and adaptable partner in Japan's ever-evolving field of clinical research.

Setting New Standards of CRO Efficiency

The depth of expertise and efficiency embedded in every aspect of PPD-SNBL's clinical trial operations is underscored by the company's meticulous adherence to good clinical practice (GCP) standards.

Undergoing thorough GCP inspections by regulatory agencies that scrutinize the processes of clinical trials, PPD-SNBL has consistently received zero critical findings, further highlighting the company's unwavering dedication to exceptional service quality. This stellar track record also signifies a seamless and robust execution of trials, instilling confidence in pharmaceutical companies that partner with PPD-SNBL.

Our commitment to retaining skilled professionals is a distinctive advantage, ensuring a stable and experienced workforce and promoting consistency in service delivery

Another notable strength that contributes significantly to the consistency and quality of PPD-SNBL's services is its low turnover rate, which heightens staff engagement and performance. By building a stable and committed workforce, PPD-SNBL has created an environment where employees are deeply invested in their roles, which maximizes their efficiency and results in uninterrupted clinical trials.

Since establishing the joint venture, the company has maintained an impressive turnover rate of around five percent, exemplifying a remarkable employee retention level where the industry average ranges from 13 to 15 percent.

"In an industry where turnover can often lead to disruptions in processes, resource allocation and knowledge transfer, our commitment to retaining skilled professionals is a distinctive advantage that guarantees a stable and experienced workforce and promotes consistency in service delivery," says Kurioka.

The company's discernible organizational structure, where percentage of women in management positions is more than 40 percent, also sets it apart from competitors. It reflects a proactive approach to empowering and involving women in key decision-making roles, upholding an inclusive and diverse workplace environment.

PPD-SNBL has been selected as a business partner by more than 10 of the top pharmaceutical companies worldwide, solidifying its industry prominence. This recognition attests to the company's trustworthiness and capability to collaborate with major players in the pharmaceutical sector.

Capitalizing on its reputation as a reliable CRO in Japan, PPD-SNBL is determined to consistently play a pivotal role in the execution and management of clinical studies, helping more pharma companies commercialize innovative therapies that can improve the lives of millions of patients worldwide.