DR SANJIB BANERJEE

COO (Biopharma Division)
Veeda Clinical Research Limited

Dr Sanjib Banerjee is a Cell Biologist and Immunologist with 20+ years of research and industrial experience in Bioanalytical characterization of Biosimilars and Vaccines. He has been instrumental in establishing best-in-class regulated laboratories for immunological and serological characterization of Biosimilars and Vaccines. He has been in technical leadership role in Vaccine Immunology and Clinical Serology based research for regulatory submissions and CRO management of Clinical and Preclinical studies.

"Biopharma industry has seen strategic advancements in terms of technology enhancement"

Dr Sanjib Banerjee, Chief Operating Officer (Biopharma Division), Veeda Clinical Research Limited explains the latest industry trends and initiatives by his company

By **Rahul Koul**

Tell us more about the Biopharma Division at Veeda Clinical Research? How have you further strengthened the capabilities at Bengaluru facility?

Veeda Clinical Research Limited together with its subsidiary, Bioneeds India Private Limited, referred as the "Veeda Group", offers a comprehensive portfolio of drug discovery and development services to support innovator, NCEs, NBEs, biosimilar and generic drug development programs of global clientele.

In an industry where innovation is increasingly multifaceted and collaborative, Veeda aspires to be the research partner of choice for innovative pharmaceutical and biopharmaceutical companies worldwide for their critical product development programs.

With increasing regulatory focus on evaluating the totality of evidence for similarbiologics and biological products that combines non-clinical and clinical assessments, Veeda Clinical Research believes that having an amalgamation of all the biopharma services including discovery, analytical, pre-clinical/clinical bioanalyticaland clinical services will be of competitive advantage both in building integratedexpertise as well as for providing comprehensive servicing to the clients. Veeda's management team

Biopharma team of Veeda Clinical Research at its Bengaluru facility.

decided to consolidate the biopharma capabilities for meeting such requirements by providing a one-stop-solution under the Veeda Group.

Kindly explain your technical and business capabilities for Process Development, Discovery Biology, Analytical Characterization and Clinical Bioanalysis of Biosimilars and Vaccines?

The Process Development area is approximately 5000 sq. ft. built-up area with separate labs for molecular biology, upstream, downstream activities, and has state-of-the-art instruments to undertake early-stage drug development. The vertical along with the analytical and assay biology verticals is very well positioned to undertake the biologics/biosimilar drug development program.

The Discovery Biology lab provides assay development and screening solutions to support early stage small molecule drug discovery and lead

optimization stages along with characterization assays for large molecules, vaccines and drug products.

Analytical characterization focuses on physico-chemical and structural characterization of new biological entities (NBEs), biosimilars and vaccines. Equipped with cutting-edge technologies and state-of-the-art facilities, a power-packed analytical data right from primary structure analyses to higher-order structure of biotherapeutics form the core.

The Clinical Bioanalysis Lab uses immunoanalytical techniques such as ELISA, LC-MS and Electrochemiluminescence (ECLA) which are critical for the analysis of large protein molecules and antibody drugs, including biosimilars. In addition, it also offers state-of-the-art technologies such as Flow Cytometry, qPCR and ELISpot assays in a highly regulated environment to support clinical studies.

How do you see the current trends in biopharma shaping the industry's future? What strategies do you employ to ensure the company remains competitive in the rapidly evolving industry?

The key drivers of the growth include the rising investment in pharmaceutical research and development (R&D), the number of clinical trials, drugs, and biologics market despite the COVID-19 pandemic, demand for specialized testing services among end users, and the need for novel clinical trial designs for complex cell and gene therapies. The high cost of in-house drug development has also resulted in biopharma companies increasingly choosing to outsource the research work to CROs.

Since the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, a globally recognized intellectual property pact, the drug industry's interest in India for cheap access to highly qualified scientists and the potential for selling patented drugs in India has significantly increased. Now, India's top CROs and CDMOs are asserting themselves on the global stage. They are courting biotechnology companies by setting up satellite labs in the US and Europe, hiring managers with bioharma or chemical experience to initiate and drive processes. Their goal is to compete the global CROs while becoming less of an assistant and more of a partner for their drug industry clients.

We understand that to become a successful CROs we have to keep up with globally recognized processes, quality standards, and operating models to compete in the world market, taking into considerations that, state-of-the-art facilities and top-notch teams may not compatible with offering low-cost services. Even then, large pharmaceutical companies turn to India to fill a gap between the type of R&D that they need and the number

optimization stages along with characterization assays for large molecules, vaccines and drug products.

Analytical characterization focuses on physico-chemical and structural characterization of new biological entities (NBEs), biosimilars and vaccines. Equipped with cutting-edge technologies and state-of-the-art facilities, a power-packed analytical data right from primary structure analyses to higher-order structure of biotherapeutics form the core.

The Clinical Bioanalysis Lab uses immunoanalytical techniques such as ELISA, LC-MS and Electrochemiluminescence (ECLA) which are critical for the analysis of large protein molecules and antibody drugs, including biosimilars. In addition, it also offers state-of-the-art technologies such as Flow Cytometry, qPCR and ELISpot assays in a highly regulated environment to support clinical studies.

How do you see the current trends in biopharma shaping the industry's future? What strategies do you employ to ensure the company remains competitive in the rapidly evolving industry?

The key drivers of the growth include the rising investment in pharmaceutical research and development (R&D), the number of clinical trials, drugs, and biologics market despite the COVID-19 pandemic, demand for specialized testing services among end users, and the need for novel clinical trial designs for complex cell and gene therapies. The high cost of in-house drug development has also resulted in biopharma companies increasingly choosing to outsource the research work to CROs.

Since the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, a globally recognized intellectual property pact, the drug industry's interest in India for cheap access to highly qualified scientists and the potential for selling patented drugs in India has significantly increased. Now, India's top CROs and CDMOs are asserting themselves on the global stage. They are courting biotechnology companies by setting up satellite labs in the US and Europe, hiring managers with bioharma or chemical experience to initiate and drive processes. Their goal is to compete the global CROs while becoming less of an assistant and more of a partner for their drug industry clients.

We understand that to become a successful CROs we have to keep up with globally recognized processes, quality standards, and operating models to compete in the world market, taking into considerations that, state-of-the-art facilities and top-notch teams may not compatible with offering low-cost services. Even then, large pharmaceutical companies turn to India to fill a gap between the type of R&D that they need and the number

of people at their companies who are qualified to do it. Veeda envisage to become the CRO that can position itself as a full-service "general contractor" of choice for biotech companies, bringing relationships, access to services, and strategic perspective, can become an invaluable development partner.

How does your company approach R&D in the biopharma space? Can you highlight any recent breakthroughs or advancements in your pipeline that you find particularly promising?

Veeda's R&D team recognizes its role as an integrator of point solutions that drive speed, quality, and stakeholder experience in product development—and build the capabilities to orchestrate the use of point solutions flawlessly. Veeda Biopharma further position itself as an end-to-end strategic partners—that is, from asset strategy to launch.

Veeda Biopharma's Discovery Biology is actively working to establish various assays in order to support the PROTAC and Biologics/Biosimilar's research and development. Developing platform methods are essential for providing rapid analytical support to biopharma industry and this mandates research and development with continuous upskilling of technical force. Veeda Biopharma now holds ready-package for physico-chemical characterization of leading monoclonal antibodies, bi-specific antibodies, peptides and other modalities. We have also established HOS laboratory equipped with globally recognized instruments, delivering high quality structural information of biopharmaceuticals. Complexity, an integral part of drug development, is where deciphering solutions are appreciated and characterization of fusion proteins has paved way for innovations.

Veeda Biopharma continues to look at unharnessed technologies such as advanced mass spectrometry and biophysical technologies to broaden the analytical outlook for biopharma industry.

How does your company navigate the complex regulatory environment in the biopharma industry? Strategies to ensure compliance with regulatory requirements while maintaining agility in product development?

Veeda is an independent Indian CRO with 19+ years of experience and has conducted over 3800+ studies working with over 200 biopharmaceutical companies around the world. It has an exemplary regulatory record when it comes to successful completion of audits from USFDA, AGES, MHRA, ANVISA, WHO, NPA, ANSM, MCC, DCGI & NPRA. Due to stringent quality norms and transparency at all stages, Veeda is considered to be a preferred partner for many

biopharmaceutical companies. We have a robust Quality Management System in place to capture any non-compliance or deviation identified during the study with an effective mechanism of corrective and preventive actions implemented.

Adequately trained staff and CFR21 Part 11 compliant systems are available to perform study related activities. All study related documents are promptly filed following OECD GLP principles (ALCOA++) and securely archived for future references. Facility readiness is ensured by continuous verification of the systems and documents by the in-house quality monitoring team for processes and documents during ongoing study. The Quality Assurance Unit also conducts facility, process and equipment based audits periodically to check the compliance with in house SOPs and study audits to verify the compliance with Study Protocol. Senior management continuously monitors the quality systems of various departments to ensure that all standard processes and practices are implemented, thereby ensuring all time audit readiness of various facilities.

"The amalgamation of all the biopharma services including discovery, analytical, pre-clinical or clinical bioanalytical and clinical services provides us a competitive advantage."

Can you discuss any recent strategic alliances or partnerships that have been instrumental in achieving your company's goals?

Biopharma industry has seen strategic advancements in terms of technology enhancement and scientific prudence. Leveraging cutting-edge technology is the key in delivering excellence, which in turns makes a healthier tomorrow. Sensing the need for a high-throughput method for routine analysis of intact-native monoclonal antibody, charge variant and many such investigations, Veeda has partnered with Biobeams and 908 devices for ZipChip technology. With this add-on, Veeda Biopharma is the only solution partner in India offering services on this micro-capillary based platform for fast and routine analyses of biopharmaceuticals. ZipChip is connected to a high-resolution mass spectrometer (QExactive), a proven combination for early stage investigations and routine monitoring.