

Pacific Biomarkers Biomarker Testing Services Specializing in Phase I-IV Studies

Biomarkers have tremendous potential to affect the success rate of clinical trials, identify new drug targets and develop diagnostic assays for early detection of disease. The global biomarkers market is striding forward rapidly due to increased healthcare expenditure, R&D spending, and the enhanced utility of biomarkers for drug-development and diagnostics. Drug firms seek solutions to enhance efficiency and productivity by streamlining development timelines. Seattle-based Pacific Biomarkers has emerged as a biomarker testing laboratory provider supporting phase I-IV studies. “We help drug developers understand the impact of the investigated drug on disease target by measuring specific biomarkers that clarify disease pathology. This provides a competitive edge for the drug developer due to differentiation in the market space,” says Amar A. Sethi, President and CSO, Pacific Biomarkers.

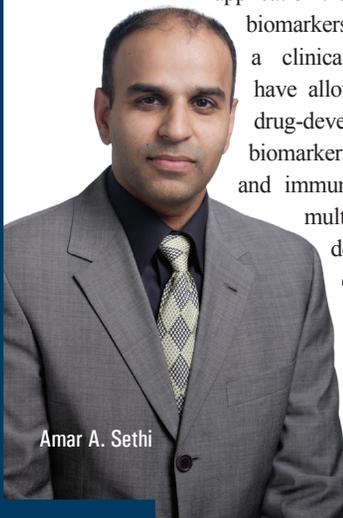
Over the years, Pacific Biomarkers has evolved into a high-quality (College of American Pathologists accredited and Clinical Laboratory Improvement Amendments certified) laboratory performing biomarker testing and consultation for pharmaceutical organizations and diagnostic manufacturers. “The collaboration with diagnostic manufacturers provides us with significant advantages due to early access to novel markers, which we can integrate into clinical trials for the advancement and differentiation of drug development. Our esoteric markers are validated to the highest threshold of regulatory compliance,” cites Sethi. The company has established a growing, diversified biomarker portfolio covering therapeutic areas from cardiovascular diseases to oncology. To help decipher the biomarker menu, in 2015 the company launched its mobile application that helps select the most appropriate biomarkers (Biomarker Navigator™) for a clinical trial. Current market trends have allowed the company to enter novel drug-development fields, such as safety biomarkers for drug-induced organ-injuries and immuno-oncology. Both areas demand multiplexing capabilities that can detect circulating biomarkers cost-effectively. “We offer multiplexing technologies, which combined with our high quality standards for analytical validations provide a new edge in this arena,” cites Sethi. Pacific Biomarkers recently launched multiplex

panels for cytokines and chemokines with improved performance allowing drug-developers to assess trends as well as minor changes associated with drugs. This benefits data interpretation and solidifies the effect of the drug early, which is important for immuno-oncology studies where the immune response already is complex rendering a shot-gun approach unreliable.

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We offer uncommon esoteric markers, which are validated to the highest threshold of quality and regulatory compliance

Pacific Biomarkers is a platform agnostic company that offers multiple podia to support client requirements. Current portfolio includes multiple specialized technologies along with random access platforms that support high-throughput analysis for immunoassays. “Each platform complements our menu with different performance characteristics such as improved sensitivity, broader dynamic range, real-time testing, high-throughput and multiplex analysis. This empowers us to customize each client’s needs with optimal testing matching the clinical protocol.” Being focused on customer requirements, the company has assisted several clients who were unable to achieve quantitative data due to inadequate methods or platforms used. On such occasions Pacific Biomarkers would carefully examine any pre-analytical factors related to biomarker collection, its stability, and utility for the intended purpose before sample testing. “We have performed several ‘rescue’ studies for clients where data analysis resulted in FDA approvals for drugs that were initially doomed,” cites Sethi.

The company is currently involved in a major initiative of developing more sensitive biomarkers of drug-induced Acute Kidney Injury (AKI) with the Predictive Safety Testing Consortium (PSTC). The company is working closely with the PSTC and the FDA to clinically qualify its novel markers for AKI. “We are conducting prospective clinical trials that will support the clinical qualification of AKI markers so future drugs in development are safer and developed faster with a reduced overall cost,” cited Sethi. Drugs associated with AKI would either be cancelled early on or monitored carefully using these novel markers. **CR**



Amar A. Sethi

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The Navigator for Enterprise Solutions

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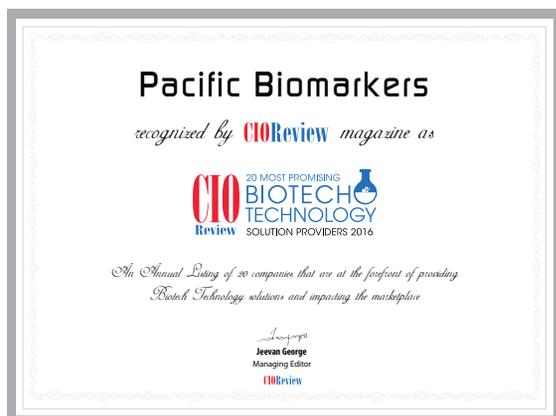
20 Most Promising Biotech Technology Solution Providers 2016

The biotech industry is booming—emerging as an area that has a remarkable effect on virtually every domain of human welfare. Innovative biotech is pushing the traditional boundaries of clinical data collection by gathering and analyzing data from initial diagnosis through long-term treatment. This data is used to measure quality of life as well as improve existing therapies or develop entirely new ones.

Today, the population is actively taking role in monitoring and improving their health. Simultaneously, therapy advances are driving biotech organizations closer to the patient. These trends are inevitably creating a paradigm shift in the ways in which patients and healthcare providers interact. Whether it is for enhancing communication, deciphering the secrets of genetics, defining better drug targets, speeding up the

drug discovery process or improving clinical diagnoses, biotechnology organizations needs to leverage sophisticated computing platforms, and new technologies to stay ahead of the competition.

In this edition of CIO Review, we present you the “20 Most Promising Biotech Technology Solution Providers of 2016,” featuring the best solution providers offering tools and services in the biotech landscape. The companies compiled in this issue have exhibited extensive business process knowledge, along with in-depth, integrated, and innovative strategies. The listing provides a look into how the solutions and services work in the real world so that organizations can gain a comprehensive understanding of what technologies are available and how they shape up against the competition.



Company:
Pacific Biomarkers

Description:
Provider of extensive scientific, regulatory, and technology expertise to drug manufacturers for developing drugs quickly and cost effectively

Key Person:
Amar A. Sethi,
President & CSO

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pacbio.com