

MOLECULAR DESIGNS COLLABORATES WITH DLS TO FACILITATE SMALL PHYSICIAN-OPERATED LABORATORIES FOR IN-HOUSE MOLECULAR DIAGNOSTIC TESTING



Homero Rey is Director of System Integration and Support at Molecular Designs, a small molecular diagnostics company started by a couple of physicians in Birmingham, Alabama. They've been in business about 10 years, slowly growing into the molecular diagnostics space by serving small physician-operated laboratories (POLs) where in-house diagnostics (assays) can be performed. They provide workflows using qPCR (quantitative PCR) technology. Rather than sending out samples to central laboratories, they enable POLs to run assays in-house. It's a shortened turnaround time for both physicians and patients, so they can get results much sooner than they otherwise would.

THE BACKGROUND

Homero has been in the molecular diagnostics field for over 25 years and has a bachelor's degree and a PhD in molecular and cell biology. He has mostly worked with small companies in the Bay Area, and has also worked with larger corporations like Thermo Fisher Scientific, Applied Biosystems, as well as various other companies.

Homero was introduced to DLS very early in his career. He was working on one of the first PCR systems for a leading biotech instrument and reagents manufacturer located in "Biotech Bay" where he met Bruce DeSimas (DLS co-founder) who had been contracted for software development and product testing. Homero and Bruce worked closely together. Homero said, "We were very successful in developing and deploying the system, including the software. That was my first experience with Bruce and DLS, and it was very positive. It always stood out in my mind as a very productive collaboration."

THE CHALLENGE

Today, Molecular Designs builds software that adds value to other companies' instruments, specifically instruments that do PCR analysis. They intend to submit a new product for FDA approval that deals with testing for COVID and other respiratory viral target. Typically, these clinical systems or platforms require software so that the laboratory technician does not have to make a judgment call on the assay results. Software provides a more systematic determination. Molecular Designs knew it needed software for this new device which would interpret PCR results and make a calculated determination of "Test Positive" or "Test Negative" based on the PCR analysis.

Software development for this new product had to be contracted out since Molecular Designs does not have their own software development group within the company. Homero said, "At first, we looked at a few vendors that my VP was familiar with. Then one day someone suggested DLS. My VP and I had very positive experiences with DLS. In addition, DLS had already developed necessary software components that they could bring to the table to reduce development time."

MOLECULAR DESIGNS COLLABORATES WITH DLS TO FACILITATE SMALL PHYSICIAN-OPERATED LABORATORIES FOR IN-HOUSE MOLECULAR DIAGNOSTIC TESTING



“Bruce DeSimas immediately understood what we were trying to do, why we were trying to do it, and how we were trying to do it. It was very easy to work with DLS because they understand the molecular diagnostic space quite well.”

Homero Rey

Director of System Integration and Support

THE CHALLENGE

Large portions of this software must adhere to an FDA regulation called “21 CFR Part 11,” which provides guidance for in vitro diagnostics (IVD) products. DLS already had FDA-certified “21 CFR Part 11” components for electronic records traceability and tamper-proofing. These components monitor who logged into the system and who does what when. All the pieces of software that go into IVD products need to adhere to it, and DLS had already developed it for other projects.

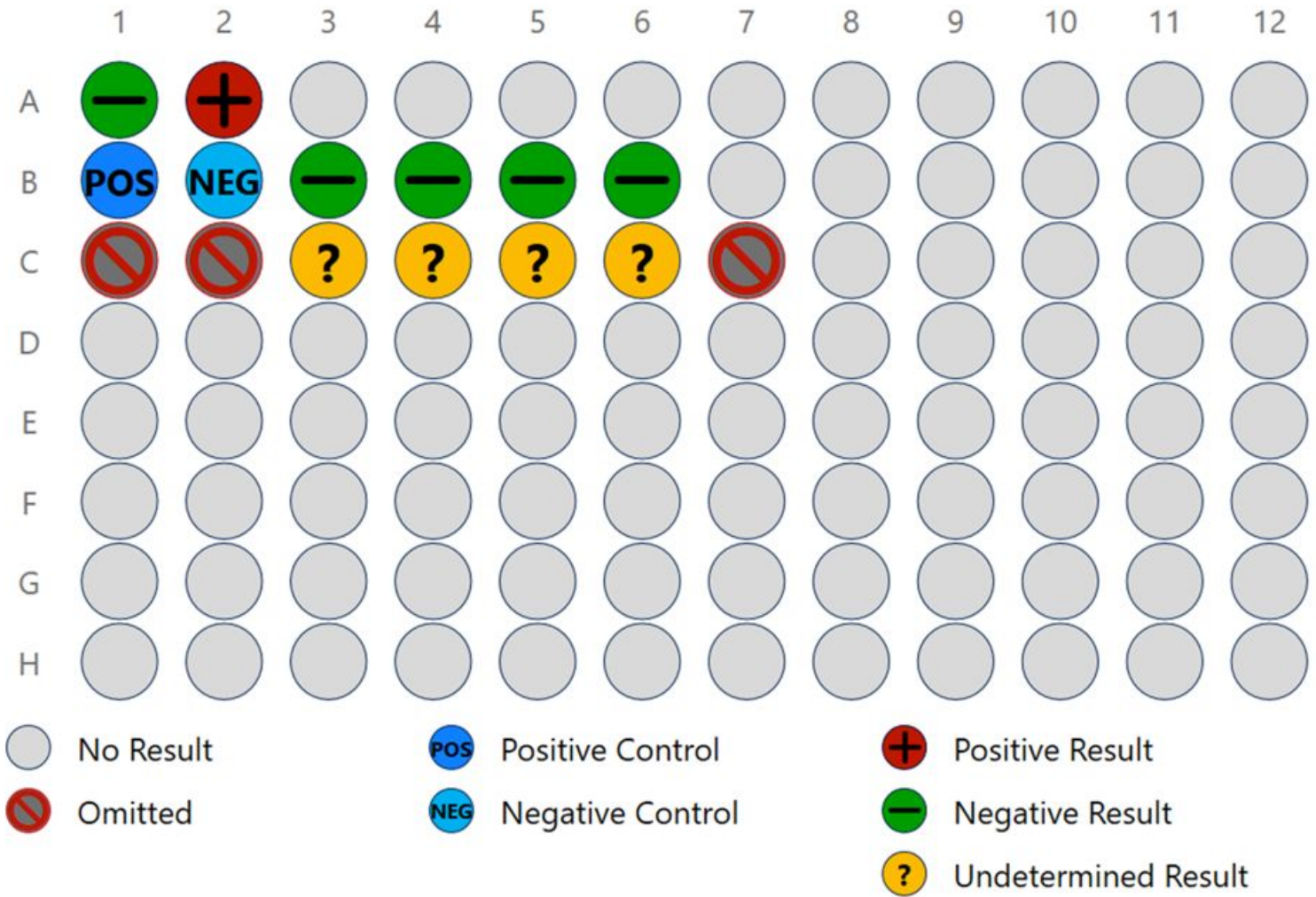
Homero elaborated. “We narrowed our search to DLS and one other company. The other company was bigger than DLS so, in my mind, DLS could be more nimble, and, if needed, move very quickly. Our timeline was somewhat compressed, so we couldn't have a protracted development project. I knew that DLS could work quickly and efficiently without sacrificing quality, being able to work in a lean fashion and be very responsive. Both companies had experience in this space but we already knew, having worked with Bruce, that he had a very deep background in the field of quantitative PCR. So, coming up to speed in terms of the underlying technology was a non-issue.”

Homero continued. “Bruce immediately understood what we were trying to do, why we were trying to do it, and how we were trying to do it. It was very easy to work with DLS because they understand the molecular diagnostic space quite well.”

DECISION FACTORS

Major decision factors were cost, nimbleness, technical knowledge, and existing components. These factors allowed Homero and his team to focus on the core of the software that still had to be built. Homero said, “We were building software on top of pieces that were already there. With DLS, there were advantages across the board. They brought significant expertise to the table; they were able to understand quickly what we needed to do and were able to rapidly engage in the new development process.”

MOLECULAR DESIGNS COLLABORATES WITH DLS TO FACILITATE SMALL PHYSICIAN-OPERATED LABORATORIES FOR IN-HOUSE MOLECULAR DIAGNOSTIC TESTING



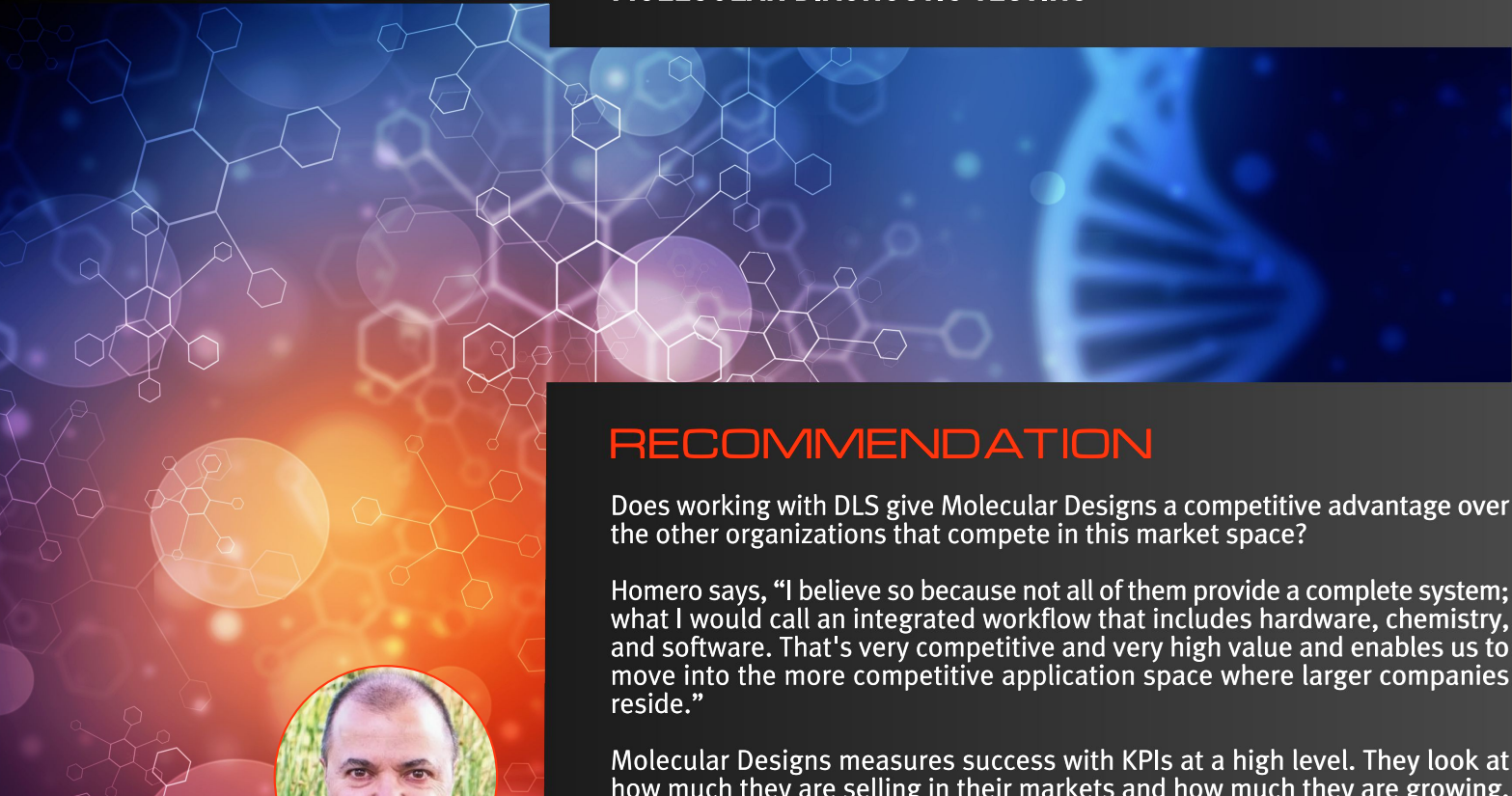
Results screen from Molecular Designs Interpretive Software

RESULTS DRIVEN

“It’s actually very easy to work with DLS” said Homero, “and very enjoyable. I knew Bruce and so did my boss. DLS was a known quantity. The style with which Bruce and his team work is very, very focused and driven towards results. They understood how they needed to navigate because these are regulated products and there are expectations of how these products will work, the scrutiny that they will come under, and the way in which they must be developed. DLS has a good understanding of the context in which they work but are still able to work rapidly and efficiently within that.”

Homero adds, “The interaction has been mostly with myself and Bruce. We meet every week, and it is very easy for us to communicate, reach understanding and make decisions. DLS has provided a lot of creative options on how to do things and the implications of going one way or the other. Customers have expectations about how the system should operate, its ease-of-use and its robustness.”

MOLECULAR DESIGNS COLLABORATES WITH DLS TO FACILITATE SMALL PHYSICIAN-OPERATED LABORATORIES FOR IN-HOUSE MOLECULAR DIAGNOSTIC TESTING



“I don't think we would have a viable product without DLS's involvement. It's a long road to get a product cleared through the FDA and then from there, to see how it does in the market. I know that we wouldn't be as competitive without DLS's contribution.”

Homero Rey

Director of System Integration and Support

RECOMMENDATION

Does working with DLS give Molecular Designs a competitive advantage over the other organizations that compete in this market space?

Homero says, “I believe so because not all of them provide a complete system; what I would call an integrated workflow that includes hardware, chemistry, and software. That's very competitive and very high value and enables us to move into the more competitive application space where larger companies reside.”

Molecular Designs measures success with KPIs at a high level. They look at how much they are selling in their markets and how much they are growing. Are they expanding their customer base? Are they being competitive? Can they win both sales and expand their base?

Homero adds, “There are considerations like being able to get products through the FDA approval process. This adds to our company's reputation as being a company that can build regulated products that will clear the FDA and serve the IVD market.”

Would Homero recommend DLS to other companies?

“I would highly recommend working with DLS,” said Homero, “particularly if it is a smaller company like us that doesn't have a large software development team. Larger companies that have their own software development teams may still need a company like DLS when there is domain-specific knowledge or expertise that they don't have in-house.”

“So, I think it is critical to be able to work with a company like DLS that can really scale to whatever the need is and bring all their knowledge and experience to bear. It's as if we have our own software development group in DLS.” Homero concludes, “Working with DLS has been a very positive experience. We know that there's a long-term need for support and ongoing development that they are perfectly suited to engage in when the time comes. We look at our relationship DLS as a long-term partnership. We have a lot of confidence in what they're building for us.”