

Interview: Andrés Soto & Luis Baez â?? Co-Founders, ISPV, Puerto Rico



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Andrés Soto and Luis Baez co-founded ISPV (Integrated Services for Productivity and Validation) in 2007. As a relative latecomer to the validation market of Puerto Rico, they explain how they capitalized upon their previous experience to become one of the fastest-growing service providers in the Puerto Rican pharmaceutical and food industries.

What are the main priorities of ISPV today?

AS: ISPV is a servicing company. Our major services include contract support, resource management and provision of equipment to the pharmaceutical industry. In terms of contract support, those are the main projects associated with complete validation of a project. For resource management, we provide specific technical contractors to the industry based on their needs, such as principle engineers, quality or CAPA experts, or specific engineering task, documentation, or process experts. As an equipment provider we have a platform of solutions where we distribute products. We have equipment for sealing to increase productivity, complete packaging lines, particle counters and enclosures for containment packaging with HEPA filters. Our mission is to become a one-stop provider of services. ISPV creates a strong relationship with customers; whatever they need we will provide a solution. Our vision is to become the best in our area. In seven years, ISPV has become one of the fastest growing companies in the validation and productivity area.

LB: In 2013, we were selected by our clients as an award-winning service company. In 2014, we were the top validation company at Amgen out of 42 companies. We have been servicing Amgen since 2009; since then we have always been among their top five validation companies annually. We take pride in all of our work. There is no small job at ISPV; we can take a 100 hour project or 10,000 hour project and apply the same energy.

What is so innovative about the validation solutions that ISPV offers?

AS: We offer turnkey solutions in terms of a solid platform of equipment from our original equipment manufacturers. We value quality, time and cost. We base all our projects on all three of those attributes, whereas most competitors can only provide two of the three. ISPV runs a locally authorized calibration lab where we calibrate equipment to the highest standards of technology. We are not yet servicing in-house calibration, but we are moving into that area. The company will move the technology into a new facility soon. For this, we always look to emerging markets. We are certified in just about every market for pharmaceutical and food companies, but we also look forward into other markets like Dominican Republic, Costa Rica, Mexico, Cuba, Panama and mainland US. We are moving from Puerto Rico to the US, not only for growing but also providing a solution to the people for who are responsible.

Two of our partners are in Canada, the rest are in the US. We have been contracted for all the projects we service (i.e. project management, technology transfer). When companies start downsizing and consolidating their operations into different companies, sometimes they have the best technology in one plant and want to move it to another plant. They hire us to make the movement from that company in terms of moving everything from that plant to the next. ISPV makes

the assessment and provides the movement and validation of the process. Some hire us just for turnkey solutions. Ultimately, we get the whole project, provide a specific solution to their needs, and provide equipment to the industry.

You established ISPV in 2007, at a time when the marketplace was already saturated with similar service providers. What did you feel you could contribute that would be new?

AS: We have been contractors in the industry for over two decades. Luis and I have known each other from working on the same projects in different pharmaceutical companies over the years, and we know the industry inside out. After a while, we decided to incorporate ISPV, but we needed to provide a different solution. What is our competitive advantage over everyone else? A one turnkey solution. We will be your guide, providing expert access to technology, why that technology is best for you and why it makes you more competitive and saves costs.

LB: I went on my own as an individual contractor in 2004. In 2006, Andr s did the same. Between 2006 and 2007 our paths crossed on projects for three different sites. But we have known each other since university. Being on our own reduces our market share, so by forming a company we became more competitive together. When the two of us started receiving more requests to do jobs or projects than we could manage ourselves, we started outsourcing and hiring contractors. In 2007, the big companies were already there so it was hard competing. But after 15 years of hard work and networking, by 2007 we had already opened many doors. We knew what customers wanted because we had always been in their shoes in the past, and could easily relate to them.

Quality is a necessity to survive nowadays. What separates your quality from others?

LB: Time is relative depending on the work. After the manager of Pfizer s Carolina plant hired two of our resources, leaving out two other companies, they told us that even they had problems choosing which of ISPV s employees not to hire! We provided everything they needed, unlike the other companies which sent them countless resumes. We tailor the contract or who serves the client to the site s specific needs. In terms of the type of business or urgency or management style, not everyone can handle that. Pfizer might ask me for a project manager and a specific engineering task; perhaps I have three employees fit for the task but maybe not all three can go there. We don t just go to an electronic file and send resumes. We specifically send people who will fit the customer and the site. We have 27 professionals today, with an average time at ISPV of three years and a very low turnover rate.

AS: It is the whole mapping of a process, in terms of doing the diligent interview process and preparation for each candidate to fit the necessity. Once you do the work, the quality is there. It does not matter how many hours you put in the process, you always need the preparation for any process. Quality is a result of work done, time and preparation.

How do you see your international growth expanding in the future?

AS: Everything is changing too fast and we are learning the market. Regarding our expansion within the mainland, we hired five people and we have other contractors working now, so in terms of resource management there is some potential in the mainland. With other Latin American and Caribbean markets, we are looking forward to grow more. There is nothing concrete, since each country provides specific restrictions and conditions, so maybe we will not expand there as one solution but rather another one of our solutions.

LB: Ideally we would like to see 50 percent of our revenue come from outside Puerto Rico, but we cannot underestimate our local clients despite the hard times. There are specific tasks and activities that have taken us abroad in terms of exporting or internationalization. For example, we have done

work in Costa Rica, and we have visited Panama, Cuba, and the Dominican Republic. We recently received a contact through Global Vision in Montreal with 30 companies in Central and South America for a project that we were referred to by GSK. If we do 50 or 75 percent of those companies, it will be ideal. Over the next few months we will commit to those customers. Global Vision has other partners and companies that represent them worldwide â?? ISPV was selected because we are very flexible with our approach to business. They already know we have been outside of Puerto Rico and there is no language barrier. If you do not put the effort, you will not know if you get a return. Global Vision has represented us in Mexico, Brazil and Costa Rica.

AS: Our business is one of uncertainties; our duty is to make those uncertainties realities. Each uncertainty is an opportunity waiting to be captured. We have 30 customers in Latin America and we were recommended to be the main provider for those services. We do not know how many we will get but we will do our due diligence to obtain them.

It also makes sense to use a Puerto Rican company since the regulation there is better.

AS: We have always been working under a regulated environment, subject to regulations. With our experience we know the important things to recommend our customers to prevent observations.

How do you perceive the evolution of the Puerto Rican service provider industry?

AS: I see it evolving through the expertise in the regulated environment. We have always been subject to those regulations and that is our competitive advantage with those countries that want to sell to the US.

What are your expectations for ISPV in the future?

AS: We have a strong presence not only in Puerto Rico but in the mainland, and by 2020 we should be 50/50, having doubled in size and with solid performance and customer relations.

LB: We have already demonstrated our value to our customers; but we do not sleep on that. We canâ??t stay in the comfort zone. Every time we see a customer, it is like the first time. You will be hearing from us with new projects in 2020, and we will probably have a manufacturing building. You have to diversify based on the needs of your clients. As the market changes, so must you, otherwise you will be out of the market.

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