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Building Teams and Adding Value: Matt Stroschein, CEO of **WAYS Pharmaceutical Services**





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COVER STORY

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att Stroschein, CEO of WAYS Pharmaceutical Services, is a builder but not in the typical sense of the word. He is not in the construction industry. Matt works in the life sciences industry and builds organizations. He builds the teams that make up those organizations and the processes and capabilities that keep them performing. He enjoys building things, and it is clear he continues this pursuit in his leadership role at WAYS.

Matt has always worked beyond the confines of the traditional job description. At the young age of 13, he became the custodian for a bagel shop. Every evening, he would clean the shop and prepare it for the bakers. The shop owners saw his eagerness to learn and taught him about the business, including how to make bagels, order supplies, even fix a broken oven. This experience taught him how to manage his time and look at the bigger picture.

Moving from custodian to baker changed more than his responsibilities. "I was heavily involved in sports. I played football and baseball and had to learn how to juggle academic and athletic commitments with my work obligations. It was a great lesson in discipline and time management.

During that time, I learned about inventory, planning, and equipment. I even knew how to climb inside the oven to fix a belt. When I started making bagels, my schedule changed drastically. I had to wake up at 3:00 am every day. But for the high school kid in me, that was better than spending my Friday nights cleaning the shop!"

This entrepreneurial spirit has continued throughout his career. When he started to build WAYS Pharmaceutical Services, Matt interacted with Regulatory and Leadership teams that expressed disappointment in the current Submission Management marketplace. They were frustrated with the lack of domain expertise and the service they were getting from prominent vendors.

Matt knew the marketplace and understood the challenges and gaps in existing services, particularly those aimed at small and early-stage teams. Many vendors with global capabilities were offering large-capacity production teams to handle submission publishing. However, there was a significant portion of the market that was not being served. Small and mid-size groups looking for an experienced submission management partner struggled to find a partner with the right mix of domain expertise and submission

leadership. These groups weren't big enough to require offshore or around-the-clock capabilities. Instead, they needed proficiency, guidance, and a real, live person to provide input into their submission plans.

He saw this gap as an opportunity to build a high-performing team that could reshape the way the industry viewed submission management. At that time, vendor interactions were complicated and demanded streamlining. With traditionally tight timelines, the last thing sponsor teams needed were complex processes to share their documents and data with their submission yendors.

As the industry gained experience with electronic submissions and the electronic Common Technical Document (eCTD) format, their technology and processes changed. In the early days of WAYS, the team spent time re-educating clients about the outdated need for large teams of publishers and hefty technologies that would create an unbearable burden for small, early-stage organizations.

Matt's first hires were the Head of Operations and Head of Regulatory Submissions that understood his vision. He knew who he wanted to hire, having worked with some

"We have attracted top talent to our low-key, no trauma, no drama environment. If we want to retain them, we must walk the walk and not just talk the talk. As a team, we have strategy sessions and operational reviews. We make decisions based on what is right for our customers and us. We know how lucky we are to have been able to maintain this type of environment, and I think, as a team, we are also very protective of it."

of the industry's best submission management resources in his previous role as Vice President of Operations at Octagon Research Solutions. As he built the team, it was essential to recruit high performers who understood what small organizations needed and who were focused on value creation.

The culture of WAYS began to emerge. The team spent time defining their service offerings and redefining how the services were delivered. As the team grew, the working principle of "no trauma, no drama submissions" seeped into every aspect of their work. They worked to simplify contracts, pricing, and every client interaction. Within this framework, the WAYS submission management experts could operate more freely and provide greater value by focusing on actual submission activities and keeping abreast of current regulations instead of worrying about low-value administrative tasks.

This strategy has been incredibly successful. The WAYS team concentrates on leading submission projects and helping clients align their product development teams toward their submission goals.

They develop and implement submission strategies unique to each client situation and still track emerging regulations and their impact on submission standards and processes.

As a virtual organization, the leadership team works to empower team members by building mutual trust. Matt carefully selected team members that he knew he could trust to support client goals. This level of trust typically develops over time, with experience. It is what fuels the culture and is the foundation of empowerment.

The level of trust is also reflected in Matt's management style. He takes on a coaching role and assumes mutual trust in all his interactions. "I recruit smart people who know how to do their jobs better than I do. I check in and let them know I am here, but I don't micro-manage. It's not my style, and it would drive away my most talented and creative people if I did."

The WAYS team consists of regulatory professionals with 15-20 years of experience consulting and managing submissions. This expertise helps clients manage submissions more efficiently, but it

also provides a valuable resource for other services. WAYS has developed a robust network of complementary service providers. Whether a client needs medical writing, statistical support, or a regulatory strategy, the WAYS team can introduce them to experienced partners. "Our collaborative network is an added value for our clients. Many are going down the development path for the first time and need specialist advisory services. We use our incredibly active network to give our clients options. If they need someone to do a commercial assessment, I have a resource. If they want help with a brand name, I have a resource. As we build our network, we make it available to clients so they can save time and resources."

The entire WAYS team has taken on the same approach to their work. The team focuses on developing and maintaining strong, trusted relationships with their clients and is always finding ways to add value. As a Regulatory Submission Management Partner (RSMP), the team felt it was necessary to develop training programs to support their client projects. These programs have become standard offerings. They help client teams understand the requirements for electronic

submissions and how the regulatory agency reviews their submission. They are a natural extension of the WAYS team's domain expertise.

As WAYS continues to grow, Matt is already looking to the next big challenge: maintaining service levels as the company scales. Since the company is self-funded, Matt does not feel pressured to report to the board or focus strictly on revenue. "We have attracted top talent to our low-key, no trauma, no drama environment. If we want to retain them, we must walk the walk and not just talk the talk. As a team, we have strategy sessions and operational reviews. We make decisions based on what is right for our customers and us. We know how lucky we are to have been able to maintain this type of environment, and I think, as a team, we are also very protective of it."

The team's focus on building relationships is part of the deal when you work with WAYS. As a result, when clients move to new companies, they often bring WAYS with them. About 40 percent of WAYS' current clients transitioned from other vendors. The team has taken time to plan for these interactions to ensure a smooth transition. "We can transition clients"

in a matter of days. We don't need a long, drawn-out process that doesn't add value. Getting clients up and running quickly – now that adds value."

Recently, the Chief Data Officer at a small, early-stage company that had worked with some of the WAYS team previously, reached out for regulatory submission support. The company was preparing for their first Investigational New Drug (IND) submission, with another expected within a couple of years. The client recently mentioned that they needed statistical support for some of their clinical trial data. WAYS was able to provide them with a skilled resource through one of their highly vetted partners. The client then introduced WAYS to their medical writing partner and document template partner. This introduction has since turned into vet another partnership for WAYS. It is a great example of the mutual respect between WAYS and their clients. As Matt notes, "Good people like to work with good people. We take our client's goals very seriously, and so they take us with them when they move to new companies."

In another example, the current Head of Regulatory Affairs at an oncology company has moved twice and brought the WAYS team with her on both occasions. WAYS has submitted and maintained six INDs and is now preparing for a New Drug Application (NDA). Along the way, the client implemented a new Regulatory Information Management system with WAYS providing the migration support and introducing reliable partners to make the legacy system migration a success. These activities and relationships are standard practices that offer greater value to clients.

The innovative approach to service enables the team to excel in a crowded field. Contract Research Organizations, large consulting companies, and technology vendors continue to compete for business. The WAYS team doesn't necessarily think that's a bad thing. Matt adds, "We provide expertise-driven submission capabilities. We aren't the commodity offshore publishing house with hundreds of publishers waiting for their next task. We are a Regulatory Submission Management Partner, and there is a big difference. Our team's experience is evident in the services we provide and the advice we give. It's a different approach, it's unique in the marketplace, and that's the WAYS wav."

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