

Life Sciences Review

LIFESCIENCESREVIEW.COM

REGULATORY
SERVICES
EDITION



WAYS PHARMACEUTICAL SERVICES

Driving Regulatory Submission Success

Life sciences teams are looking for better operating models and improved performance in the highly competitive business of drug, biotech, and device development. Outsourcing regulatory submission management has evolved as an effective strategy for companies who want to focus on their core competencies. These teams need consistent access to resources that maintain proficiency on current and evolving requirements and have full submission capabilities. WAYS Pharmaceutical Services positions itself as a regulatory submission management partner (RSMP) that provides expert services to life sciences teams. WAYS invests in the technology, processes, and skillsets required to maintain submission capabilities. Sponsors trust WAYS to organize, assemble, publish, and submit their regulatory submissions to health authorities. The company's team members have experience submitting to US FDA CDER, CBER and CDRH, Health Canada, European, and other regional health authorities.



Matt Stroschein

As collaborators who seek solutions, the WAYS team has developed a collection of strategic partnerships with various specialist vendors. The company's team members are introduced to the company's close-knit network of partners to offer added value to clients. These practiced partnerships enable WAYS to offer optional regulatory affairs, biostatistics, clinical programming, and medical writing services to their clients.

Matt Stroschein, CEO at WAYS Pharmaceutical Services, believes that the company's success has everything to do with the type of talent they have been able to attract and retain. He notes, "Our team members approach each client project with creativity, confidence, and empathy. That unique mix of skills makes their submission experience even more valuable to clients."

The WAYS team believes that clients can experience the results of these talents and attributes in every interaction. Creativity, confidence, empathy, collaboration, solution seeking, and partnering are part of every client engagement that the company fosters.

WAYS Pharmaceutical Services' Head of Operations, Vanessa Phillips, says, "We look for submission expertise, but we are also interested in a particular mindset. We want collaborators and people who will excel in our very collaborative culture. We want people with whom we and our clients are able to connect—we are one team, working together toward a shared goal, and it's important that our clients feel that."

The two executives describe the attributes they consider when recruiting new employees. They prioritize the importance of understanding the critical nature of drug development. This view of the bigger picture reminds team members of the impact their actions have on patients in need of new therapies. Whether completing crucial tasks such as proactively reaching out to health authorities to confirm their approach to a submission, liaising with submission authors, or working against a tight deadline, the WAYS team constantly seeks new solutions that support their clients' goals.

"That's also where empathy is important," notes Vanessa. "Our clients have a lot riding on their regulatory submissions. If they have a bad day, our team does too! It's the nature of the close relationships we develop with our clients and the shared experience of working toward a common goal."

Regardless of the scenario, WAYS takes a consistent approach to client projects. "We are privileged to have a team of regulatory operations professionals who are well-known for their quality of work and their ability to establish strong working relationships with their clients. We are very protective of that reputation and work hard to maintain it," says Stroschein. "The industry has seen a great deal of change in recent years. New technologies and evolving submission standards are changing what we do but not how we do it. Our approach to attracting great talent, engaging them in interesting projects, and working toward client goals will remain the foundation of our success." **LS**