

Pharma

AMAN KHERA The rebel in the room, doesn't stay in her lane

s one who embraces the nickname Rebel Regulator, Aman Khera doesn't stay in any predefined regulatory lanes. Her leadership style transfers easily across boundaries to create strong bridges among internal groups, sponsors, regulatory agencies, and advocacy organizations.

Her work ethic and expertise make her a unique and irreplaceable asset to Worldwide Clinical Trials, where she serves as VP, global head of regulatory strategy, providing strategic guidance, developing, and translating regulatory strategies into solutions for sponsor companies.

Aman has always enjoyed being taken out of her comfort zone, such as when she took on a leadership role with a large CRO to oversee a transformational drug development partnership with a top biopharmaceutical company. Her role encompassed driving the nitty gritty regulatory aspects for projects, growing and developing a high-performing team, leading the business through change, and ensuring business continuity with the utmost quality.

"This was a great opportunity to show my relentless commitment to delivering results, where I was able to look for ways to improve processes, drive efficiencies and optimization, and create a sustainable vision that had, and continues to have, a positive impact," she says. Aman is proud of the company's successful navigation of the pandemic's impact on the business and industry.

"Not only did we have to think about doing all we could to ensure clinical research did not halt in diseases and indications that we were already working in, we had to think about companies also pivoting to COVID-19 research," she says. "Each company required the same care, attention, and consideration. There were multiple meetings with multiple sponsor companies. After all — patients cannot wait, nor should they."

Going forward, Aman is looking into how strategy and innovation are intersecting within the industry, and how she can help make change for the better. "Of course, regulatory is my background, but my interest spans many intersections in industry, even thinking about diversity, equity, and inclusion," she says. "Not only am I taking a deep interest in how technological innovations will continue to disrupt the industry, but also how regulations, ethics, and compliance will continue to have a loud voice at this industry table."

Across her career, Aman has been passionate about patient safety, new treatments, communicating with people, developing people, and seeing advancements in new therapies for humanity.



EQUITY IN HEALTHCARE

A passion for Aman is to help patients and caregivers, particularly in the rare disease fields where families are usually raising funds themselves for treatment or travel.

"Anything I can do to help, whether it be reaching out to the family to provide some guidance in searching for clinical trials, being some sort of support or directing them to groups that may be able to help or sharing the stories helps reinforce why we are in the industry we are in," she says. "It is always very humbling to hear about people, beyond the data."

Leadership for Aman is about role modeling and behaving how she would expect others to behave.

"If you want to inspire others then you have to inspire yourself first and be the best person you can be," she says.

She strives to be selfless and check her ego at the door. "Humans are not machines and to fit people into functions, roles and processes also means considering the disrupters — the biggest one being people's lives — be it mental or physical health, or family demands," Aman says. "If I am to be an effective leader, I need to ask the questions about what people need to be able to do their job well."

Aman gives back beyond the doors of her company. She joined Amnesty International at 11 as an active young member, which has shaped her lifelong passion for human rights and justice.

PASSION. INTEGRITY.

Amanjot Kaur Khera

TITLE: VP, Global Head of Regulatory Strategy COMPANY: Worldwide Clinical Trials EDUCATION: Executive MBA in progress (graduate May 2022); Medical Biochemistry B.Sc., Hons, Brunel University, London, UK INDUSTRY AWARDS: Shortlisted for the Regulatory Excellence Awards, 2017 in the Inspiration category

ASSOCIATIONS: DIA, RAPS (Regulatory Affairs Professional Society), TOPRA (The Organization for Professionals in Regulatory Affairs)

GIVING BACK: Amnesty International HOBBIES: Home renovator, landscaping, hiking, traveling TWITTER: @rebel_regulator

Pharma Voice

SHANNON HEACOCK Why not?

Shannon Heacock

TITLE: Head of Regulatory Submissions COMPANY: WAYS Pharmaceutical Services LLC

EDUCATION: BA, Cabrini College

PERSONAL AWARDS: PharmaVOICE 100 COMPANY AWARDS: "GEM" awards (Going the Extra Mile)

ASSOCIATIONS: CurePSP; TOPRA

GIVING BACK: CurePSP, Wounded Warriors

Fund, St. Jude's Hospital

HOBBIES: Book/wine club, working out

linging tight to the advice of her sister, that being a good person goes a long way, Shannon Heacock helped her colleagues and clients get through the COVID-19 pandemic with an attitude of contagious optimism.

It's this attitude and an innate ability to listen that permeates everything she does. Throughout her career, Shannon has built a reputation as a compassionate and empathetic leader.

"I have empathy not only for my clients, but also the patients and caregivers that are anxiously waiting for a drug to hit each milestone in the development/marketing process," she says. "I want my clients to know I am always trying to find creative ways to turn projects around as quickly as I can while maintaining high quality."

As a leader in the regulatory services arena, Shannon has invested her time and energy in developing and maintaining strong relationships with clients and partners. She understands that people do business with people who care.

Many of her clients start working with Shannon as they prepare for their first IND submission to the FDA. This can be a challenging time for a small team. It is often fraught with uncertainty, constant questions, and fear of the unknown. Shannon understands this and generously shares her expertise to reduce uncertainty and to help her clients position themselves to achieve their development goals. Having worked on approximately 150 INDs, she is able to draw on her vast experience to steer clients away from potential pitfalls. She sees her role as a customer advocate and, as a result, she is constantly looking for ways to improve their experience and clear the path to success.

The decision to break away from a comfortable career in typical corporate America and join WAYS Pharmaceutical Services to help build a successful company from the ground up has been her best professional decision to date.

"Professionally, I am excited to see WAYS grow, and see how my career grows with it," Shannon says.

She strikes the delicate balance of making progress toward a goal while encouraging team members to apply their time and talents, broaden their skill sets, and achieve their goals.

She seeks to inspire by showing her enthusiasm and love for what she does and leads by example.

"If I'm not willing to do something, then why would someone else?" she

asks. "I also like to ensure those I work with have a safe space and feel they can come to me with anything."

During the height of the pandemic, for example, she and her team kept one another motivated by taking turns to remind one another that COVID would pass and soon they would be able to get back to "normal."

"When conversations became heavy, we reminded ourselves to keep a light heart and tried our best to laugh our way through, while embracing the sadness around us — not always an easy feat," she says.

Shannon recognizes that personal life is as important as career, saying it's okay to work to live and not live to work. Indeed, her biggest challenge was being a caregiver for her mother when she was diagnosed with progressive supranuclear palsy (PSP) and balancing her career at the same time.

"Trying to balance my time, from a physical and mental standpoint, was something I

EMPATHETIC. CREATIVE.

worked on from beginning to end," she says. After her mother's passing, Shannon organized a benefit in her memory that raised close to \$12,000 for Cure PSP.

Through everything, Shannon is a dedicated mentor, both professionally and as a peer mentor for those with PSP or those caring for patients with PSP. "I have found regardless of the type of mentor relationship, there is always a lot I can learn from my mentee and put that information toward those I work with in the future," she says.

She also participates in conducting mock interviews with 8th graders where she gets to chat and discuss personal and professional goals.

"The best way I have found to really engage and get some type of feedback is to never speak down to anyone, or act as if the way I did things is the way it should be done," she says. "Rather, I try to find topics that interest the individual and build from there."

Sparking innovation by...

CHAMPIONING THOSE AROUND ME AND PROVIDING THE RIGHT TOOLS