HepQuant Names Pharma and Medical Device Veteran Ally Xu Director of Regulatory and Quality Affairs

DENVER (Feb. 1, 2021) -- HepQuant, LLC, a Denver, Colorado-based company with a unique, patented and patent-pending technology for evaluating the liver in patients with chronic liver disease, today announced that pharmaceutical and medical device industry veteran Ally Xu has joined the company as Director of Regulatory and Quality Affairs.

Backed by more than three decades of progressive regulatory and business management experience, Ms. Xu will be responsible for executing all regulatory strategies and tactics in HepQuant's pursuit of FDA and international approvals for its innovative liver health tests. She is also charged with managing all product and clinical quality strategies.

"We are extremely pleased to bring someone of Ally's pedigree and talents to support our mission of bringing an alternative, less-invasive liver health measurement instrument to future patients and medical communities around the globe," said Dr. Gregory T. Everson, CEO & Chief Medical Officer at HepQuant. "Ally will play a critical role as HepQuant seeks to capitalize on our past year's momentum and bring advanced diagnostics solutions to stakeholders."

"I share the same passion with Dr. Everson and the HepQuant team in bringing a comprehensive approach and innovative technology to the hepatic diagnostic and therapeutic area," said Ms. Xu. "I am excited by the opportunity to be a part of a team that is addressing a critical, unmet need in this vital medical space."

With broad range of experiences and academic credentials in regulatory, quality operations and clinical evaluations, including pre-market submission, post-market surveillance and reporting, Ms. Xu most recently served as Regulatory Lead at CONMED, a global medical technology company specializing in the development and sale of surgical and patient monitoring products and services that allow physician customers to deliver high quality care and enhanced clinical outcomes for their patients.

Prior to CONMED, Ms. Xu served as Manager, Regulatory Affairs at Terumo BCT, a global leader in medical device and combinational product development and manufacturing, where she led a team of regulatory professionals, supporting EU Technical Files and APAC registrations for Class IIb and Class III sterilized disposable sets, software-supported medical equipment, stand-alone software (SaMD), combination products and solutions (considered drug or device depending on countries).

She started her career at the Guangdong Institute for Drug Control, GDFDA , the Chinese regulatory authority similar to the FDA in the US. Before her Terumo BCT tenure, Ms. Xu served in different regulatory affairs roles at different sizes of medical device and pharmaceutical companies including BD Pharmaceutical Systems, Ferguson Biotechnologies, Baxter Healthcare and Glaxo-SmithKline.

Ms. Xu graduated from Shanghai Medical College of Fudan University in Shanghai, China, where she earned a Bachelor of Science degree in Pharmacology (equivalent to the Pharm.D in the US). She completed a Master of Business Administration from Marshall School of Business in the University of Southern California (USC). She was the Distance Educational Program Manager for the Regulatory Science Program in the School of Pharmacy in USC and was also accepted as a master.

About HepQuant

Headquartered in Denver, Colorado, HepQuant, LLC, is a privately-held diagnostics company. HepQuant's products are investigational combination drug and in-vitro diagnostic devices and have not yet been evaluated or reviewed by the US Food and Drug Administration (FDA) for commercial sale. They are currently available for investigational use via the FDA guidelines for investigational device exemptions (IDEs). For additional information, visit www.hepquant.com.

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