

Chrono Therapeutics Receives ISO 13485 certification

Hayward, California, July 20, 2016 -- Chrono Therapeutics, a pioneer in digital drug therapy, announced today that its Hayward, California location has received ISO 13485 certification from accredited certification body DEKRA Certification B.V. This certification demonstrates Chrono's commitment to establishing and following policies, practices and procedures to meet the customer, safety and regulatory requirements applicable to medical devices.

ISO 13485 is an International Organization for Standardization (ISO) standard that describes the requirements for a comprehensive quality management system for the design, development, production, installation, and delivery of medical devices. The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. To become certified as ISO 13485 compliant, Chrono underwent a thorough evaluation of its quality management system via a Stage 1 pre-certification audit in February 2016 and a Stage 2 certification audit in May 2016. There were zero nonconformities noted in the Stage 2 certification audit.

"Receiving ISO 13485 certification is a significant milestone for Chrono that underscores our high quality approach to regulatory and safety matters and prepares us for a successful product launch down the road," commented Dr. Alan Levy, the CEO and Chairman of Chrono Therapeutics.

About CHRONO

Effective care of the most hard-to-treat conditions requires approaches beyond simply taking medicine. Chrono's team is developing the first wearable transdermal drug delivery device that optimizes drug dosing, is embedded with sensor technology to track usage and is connected via Bluetooth to an evidence-based smartphone application that delivers real-time personalized behavioral support to keep users on track to achieving their goals. Chrono's first application is in smoking cessation, enabling smokers to overcome the world's deadliest addiction. For more information, visit www.chronothera.com