Empowering Innovation in MedTech: How the GMP Uplift Essentials Program Supports VitalTrace's Mission

Perth, Australia – VitalTrace, a pioneering company in the medtech industry, is advancing maternal and neonatal health through groundbreaking innovation. Currently in the research and development phase, VitalTrace is developing a novel medical device, a biomarker aimed at improving the monitoring of a baby's well-being during childbirth real-time. With plans for its first clinical trial and FDA breakthrough designation already secured, the company is committed to addressing significant gaps in current obstetric technology.

To bring its vision to fruition, VitalTrace has faced many of the typical challenges of medtech startups, including building in Good Manufacturing Practice (GMP) throughout the R&D process, ensuring compliance GMP standards, sourcing skilled GMP-trained staff, and navigating the complexities of regulatory requirements.

One of the tools in overcoming these challenges, includes Vital Trace signing up a number of staff to participate in CBE's GMP Uplift Essentials Program. Supported by MTPConnect and WA's Department of Jobs, Tourism, Science and Innovation (JITSI), the Essentials Program equips teams with Hands-On experience and knowledge essential for understanding the GMP rules.

Centre for Biopharmaceutical Excellence

Since attending the program's Case Study and Hands-On Workshops in September, 2024, the impact has been transformative for VitalTrace. Through adopting principles and practices learned during the program, the company has:

- Implemented proper cleanroom and gowning protocols.
- Enhanced their documentation practices, reinforcing the mantra: "If it wasn't documented, it didn't happen."
- Improved cross-department collaboration and communication with a shared language.
- Improved risk management and environmental monitoring.

The training has also heightened awareness of the amount of validation and calibration required to maintain GMP standards, documentation for regulatory preparedness and the risks management enabling VitalTrace to address risks more effectively and ensure operational efficiency.

CBE Director, Steve Williams said "This WA program was very interactive and engaging for the participants with extensive Q&A during the Case Study Workshop.

"In particular, the Vital Trace team had the opportunity to experience hands-on activities, giving a baseline of GMP competency for them to build on."

Speaking about the program, Vital Trace's Head of Regulatory and Quality, Dr Celine Royet highlighted the program's importance in creating a unified understanding of GMP standards across the teams and everyone's role in quality.

"This training is providing the foundation for the development of a high-value industry and innovation for patients," Dr Royet said.

"We highly recommend this training to all start-ups. We would like to thank REDI, JITSI and their partners for this initiative and hope it will continue and diversify in the future."

Programs like GMP Uplift Essentials, supported by REDI and its partners, play a crucial role in enabling startups like VitalTrace to navigate complex regulatory landscapes. By fostering a skilled medtech workforce, such initiatives are paving the way for innovation, supporting companies endeavouring to translate, leading to economic growth, and improved health outcomes.

For more information about Vital Trace visit
www.vitaltrace.com.au

For more information about the GMP Uplift Essentials Program visit https://uplift.learnworlds.com/home