BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Allied to soon get CE mark approval from EU

February 15, 2013 | News | By BioSpectrum Bureau



Singapore: Australia's Allied Healthcare is progressing in the regulatory process for obtaining European CE Mark approval for CardioCel, its lead regenerative tissue product for the repair and treatment of congenital heart defects (CHD).

Allied has progressed with the process-to-date, including receiving its ISO 13485 certification, a key part of the CE approval process. Allied has now successfully completed stage I and II audits, resulting in the company receiving its ISO certification and expects to receive European marketing approval for CardioCel by mid-2013.

"Obtaining ISO 13485 is a critical step along the path to obtaining a CE Mark, which opens up the European Union market as well as many other markets around the world to grow significant revenue from our lead regenerative tissue product starting in 2013. This will also assist in Allied obtaining its Health Canada Medical Device License for CardioCel", said Mr Lee Rodne, Allied Healthcare's MD.

Certification against ISO 13485 indicates that Allied has successfully implemented a quality management system that conforms to the International Organization for Standardization (ISO) standards for medical devices. ISO 13485 is an internationally recognised standard defining requirements for the design, development and manufacturing of safe medical devices.

Allied has also recently successfully undergone a quality management system audit by the Therapeutic Goods Administration (TGA) as part of the Conformity Assessment Review of CardioCel.

Ã?Â