

Advanced BioMedical Technologies Inc.'s Quality Management System Receives ISO 13485:2003 Certification

The Associated Press

Advanced BioMedical Technologies Inc. (OTCQB:ABMT), developer and manufacturer of orthopaedic internal fixation devices, is delighted to announce that the Company's Quality Management System (QMS) has been credited with ISO 13485:2003 certification.

The Company's Quality Management System (QMS) was certified by the Chinese SFDA (Guangdong) to meet YY/T 0287-2003 standard - the Chinese equivalent of ISO 13485:2003. According to the Chinese SFDA regulations, all mainland Chinese medical device manufacturers must establish document, implement and maintain a Quality Management System (QMS). Only the manufacturers with a SFDA certified QMS are allowed to apply for production permits and product registrations.

While the Company's facility and laboratory were under renovation in 2012, the Company had been identifying the processes needed for the Quality Management System and their application throughout the organization. The Company has established its quality objectives, the sequence and interaction of the quality management processes and determined the criteria and methods needed to ensure that both the operation and control of these processes are effective. The QMS was considered to have met its objectives and effectiveness after internal analysis and management reviews. The Company submitted its certification request to the SFDA (Guangdong). Having conducted several on-site examinations in late 2012, the SFDA (Guangdong) accredited our QMS with YY/T 0287-2003/ISO 13485:2003.

Wang Hui, CEO of the Company, said: "The SFDA certified QMS will enable the Company to manufacture and market its products once they are approved by the SFDA. Furthermore, Quality Management Systems around the world are generally based on ISO 13485; this certification will help the Company to be accredited in other countries in due course." About Advanced Biomedical Technologies Inc. (OTCQB: ABMT) Advanced Biomedical Technologies, Inc.'s primary product line includes internal fixation devices (bone screws, pins, wires etc..) consisting of proprietary high grade polymers (polyamide - "PA") which allow the body to degrade the products during the healing process. During the healing process, the products stimulate new bone growth which replaces the degrading device, leaving newer, stronger bone in the exact location of the injury; thus making the site of the injury stronger and more resistant to recurring damage. These products provide an alternative to metal implants and overcome the limitations of other re-absorbable fixation devices.

The products and materials that the Company has created differ from competing bio-degradable and metal based products being marketed today by: - The ability to

control the speed that the device degrades; therefore improving upon the healing time. - Eliminating the need for a second surgery to replace device due to infection or other post-operative complications. - The capability of being evenly absorbed from outer layer inwards, so that it gives enough restoration time for bone healing and re-growth.

About ISO 13285:2003 ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems.

As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with ISO 13485:2003 reflect exclusion of design and development controls.

If any requirement(s) in Clause 7 of ISO 13485:2003 is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.

The processes required by ISO 13485:2003, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.

Forward-Looking Statements This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking

statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development or marketing of our products, government regulatory agencies may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our continuing efforts to develop bone fixation devices may be unsuccessful, our common stock could be delisted from the over-the-counter market, and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

Contact: Chiming Yu TEL: 718-766-7898 Kai Gui TEL: 718-766-7898 EMAIL: info@abtbiomedical.com SOURCE Advanced BioMedical Technologies Inc.

-0- 01/15/2013 (OTC-PINK:ABMT) / CO: Advanced BioMedical Technologies Inc.

ST: New York China IN: OTC HEA MTC MEQ BIO PRN -- NE42676 -- 0000 01/15/2013 14:36:20 EDT <http://www.prnewswire.c>

Source URL (retrieved on 12/21/2014 - 9:06pm):

http://www.mdtmag.com/news/2013/01/advanced-biomedical-technologies-incs-quality-management-system-receives-iso-134852003-certification?qt-recent_content=0&qt-most_popular=0