Business Standard

RMS - Regrow gets GMP, GLP & GCP certification

Announcement / Corporate September 14, 2011, 20:01 IST

Regenerative Medical Services Pvt. Ltd. a leading Biotechnology company in India focused on the delivery of the most advanced Stem Cell therapy treatment, received the 3 major certifications, Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) from the International Accredited Body - BSI (British Standard Institution).

The GMP, GLP and GCP certifications received by RMS-Regrow® are recognition from an approved international body which validate the procedures adopted and followed at RMS-Regrow®. These certifications place RMS Regrow® in the select league of companies that have been awarded such a global honor. It is a matter of National pride for the company not only to be involved in the commercial delivery of Cellular Therapies & Stem Cell Banking, but also to be internationally recognized for the same.

"This is a landmark achievement for us as this certification has come within the first two years of the company's operations since September 2009 after receiving its ISO 13485:2003. This significant milestone enables the company to advance the global commercialization of cellular therapies, live up to the commitment of exceeding customer expectations and maintaining manufacturing excellence" said Dr. Satyen Sanghavi, Chief Scientific Officer at RMS.

Good Manufacturing Practice [GMP] is a regulatory requirement that is recognized worldwide for sound quality principles. Under GMP guidelines, all critical processes are validated to ensure consistency and compliance with specifications. GMP are the systems required to be adapted in development, quality control, quality system covering the manufacture and testing of medical therapies & drugs including active pharmaceutical ingredients, diagnostics, pharmaceutical products, and medical devices.

Good Laboratory Practice (GLP) is a system, which has been evolved by Organization for Economic Co-operation and Development (OECD) used for establishing non-hazardous nature of company products wherein the laboratory studies are planned, performed, monitored, recorded and reported. GLP practices are intended to promote the quality and validity of test data. National GLP Compliance Monitoring Authority was established by the Department of Science & Technology, Government of India, with the approval of the Union Cabinet on April 24, 2002.

Good Clinical Practice (GCP) is an international quality standard that is provided by International Conference on Harmonization (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. It also provides assurance of the safety and efficacy of the newly developed compounds. Good Clinical Practice Guidelines include standards on how clinical trials should be conducted; define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors.

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RMS Regrow bags 3 major certifications from international accredited body, BSI

Our Bureau,
Hyderabad Thursday, September 15, 2011, 08:00 Hrs [IST]

Regenerative Medical Services (RMS) Pvt. Ltd. a leading Biotechnology company in India has bagged 3 major certifications, Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) from the International Accredited Body - BSI (British Standard Institution).

RMS Regrow's main focus is delivering Stem Cell therapy treatment. It is the only company in India which is conducting research on advanced cell therapy treatments and Cord Blood Banking (Babycell). Through its Stem Cell Processing Centre, the firm offers autologous cartilage and bone cell therapeutics to patients. It also aims at applying regenerative medicines to bring effective patient specific therapeutics to bed side.

With the GMP, GLP and GCP certifications, RMS Regrow is placed in the select league of companies in the world complying with standard procedures that are approved international body. There are very few companies in India that have acquired such standards in quality especially in the commercial delivery of Cellular Therapies & Stem Cell Banking.

"This is a landmark achievement for us. It will enable us to advance the global commercialization of cellular therapies, live up to the commitment of customer expectations and maintaining manufacturing excellence" said Dr Satyen Sanghavi, chief scientific officer at RMS.

In the present context of global business, Good Manufacturing Practice [GMP] is an important regulatory requirement for the medicine manufacturing firms. It gives them worldwide recognition for their quality products. Under GMP guidelines, all critical processes are validated to ensure consistency and compliance with specifications. GMP are the systems required to be adapted in development, quality control, quality system covering the manufacture and testing of medical therapies & drugs including active pharmaceutical ingredients, diagnostics, pharmaceutical products, and medical devices.
For Economic Co-operation and Development (OECD) used for establishing non-hazardous nature of company products GLP has become an important criterion to be followed by the organizations. GLP system has been evolved to perform planned laboratory studies, check performance, monitor records and reports. GLP practices are intended to promote the quality and validity of test data.

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About RMS - Regrow®

RMS Regrow® is a leading biotechnology company in India, focused on advanced cell therapy treatments and Cord Blood Banking (Babycell). Through their SCPC (Stem Cell Processing Centre) – the only one in India, RMS Regrow® offers autologous cartilage and bone cell therapeutics to patients. RMS Regrow® aims at applying regenerative medicines to bring effective patient specific therapeutics to bed side. The treatments are now available at various hospitals across India. A synergy between the hospitals, clinicians and RMS - Regrow® is anticipated to bring a health boom in India. Patented and successfully practiced, these therapies are destined to change the outlook of health industry. Currently focusing on its expertise, RMS - Regrow® is involved in the following services:

Autologous Cartilage Regeneration Therapy (ACI)- Chondron™
· Autologous Bone Regeneration Therapy (ABI)- Ossron™
· Umbilical Cord Blood Banking – Babycell™
· Wound & Pain Management