

RMS - Regrow gets GMP, GLP & GCP certification

Mumbai, Sep 19, 2011: Regenerative Medical Services, 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.