BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Singapore regulatory grants cGMP certificate to Lonza

April 21, 2014 | Regulatory | By BioSpectrum Bureau



Singapore: Biologics manufacturing global firm, Lonza Bioscience, has received cGMP certification from Singapore Health Sciences Authority (HSA).

The audit/conformity assessment, performed by the HSA, certifies that Lonza Singapore has maintained an overall acceptable level of compliance with the Pharmaceutical Inspection Convention/Co-Operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products (Part I) relating to finished products. This encompasses all the recommendations of the World Health Organization (WHO) in relation to GMP.

PIC/S guidelines to GMP for Medicinal Products (Part I) require that the company is compliant with the standards required for the following: quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacturing and analysis, complaints and product recall, and self-inspection.

"We are proud to be one of the first Cell Therapy contract manufacturers in Singapore to have received this certification," said Mr. Michael Cicio, Vice President of Operations. "This certification will allow Lonza to contract manufacture investigational medicinal products for aseptically prepared cell-therapy products and will facilitate the use of these products in both the United States and Europe."