

GMP cell CDMO I Peace obtains accreditation as ISO 17025: 2017 compliant

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Starts undertaking quality evaluation and characterisation of iPSCs in accordance with ISO standards



Leading GMP cell CDMO I Peace, Inc., specialising in induced pluripotent stem cells (iPSCs) and iPSC-derived cell therapies, has announced that its Palo Alto quality control testing facility has been accredited as ISO 17025: 2017 compliant.

The accreditation was certified by ANSI National Accreditation Board, one of the leading accreditation bodies in the world. The tests in the scope of accreditation center on the characterization of iPSCs and include cell count and viability per USP <1046>, detection of pluripotency marker expression by flow cytometry per USP <1027>, and also by immunofluorescence assay.

I Peace has also been accredited for a quantitative real-time PCR method to detect residual Sendai virus vectors in the reprogrammed cells. The current ISO accreditation at the I Peace Palo Alto facility shows that its quality control testing is carried out at a high standard.

I Peace cell manufacturing facility in Kyoto, Japan has been certified as compliant with US FDA cGMP 21 CFR 211 and 1271, and ICH Q7, and licensed by the Japanese government to manufacture specific cell products, suggesting that its quality management system meets the industry's highest standards both in manufacturing and quality control testing of the manufactured cell products.

With this ISO accreditation, I Peace has started undertaking quality evaluation and characterisation of iPSCs for its existing customers as well as other companies and research institutions in the cell therapy industry.