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Standardized GMP-compliant human umbilical cord-derived mesenchymal stem cells for cellular therapy

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Human mesenchymal stem or stromal cells (MSCs) represent a potential resource not only for regenerative medicine but also for immunomodulatory cell therapies. The application of different MSC culture protocols has significantly hampered the comparability of experimental and clinical data from different laboratories and has posed a major obstacle for multicentre clinical trials. Human umbilical tissue, as biological waste, provides an easy accessible source of mesenchymal stem cells with some considerable advantages. Consequently, various preclinical and clinical investigations have demonstrated enormous potential of umbilical cord derived stem cells in regenerative medicine. Therefore, increasing clinical applications of these cells has elucidated the importance of safety concerns regarding clinical transplantation. Consequently, clinical-level preparation of umbilical cord derived stem cells in accordance with current good manufacturing practice guidelines is an essential component of their clinical application to guarantee the safety, quality, characteristics, and identity of cell products. Additionally, GMP-compliant cell manufacturing involves several events to offer a quality assurance system during translation from the basic stem cell sciences into clinical investigations and applications. On the other hand, advanced cellular therapy requires extensive validation, standardization, process control, and certification. It also evidently elucidates the critical importance of production methods and probable risks. Therefore, implementation of a quality management and assurance system in accordance with GMP guidelines can greatly reduce these risks, particularly in the high-risk category or "more than minimally manipulated" products.

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