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The use of improved traditional GMP manufacturing techniques contributes to the success of large scale state-of-the-art production of EMA-approved cartilage substitute

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Recent progresses in several different fields of advanced therapies manufacturing showed an increasing demand for new, enhanced, effective processing and expansion methods. Main goals of this renewed effort aim at reducing the impact of the COGS in the development, adoption and finally commercialization of ATMPs. Moreover, discovery and clinical proof of different, improved treating methods for certain diseases, opens demand for having available high quantities of a given product, impacting on and challenging the production capacity for suitable and successful scale-up. The approach described here, while not changing the process as initially developed and approved by the regulatory authorities for low-scale production, addresses the issues above, boosting the production capabilities in a brand-new full GMP-compliant designed plant. Key points are the use of isolation technology, together with a new modular and flexible approach for safe incubation of a large number of individual batches. This approach has been coupled with an accurate matching between the low- and large-scale process steps, a significant level of process automation (both in worklist and patient material management) and finally, a complete top-class track&trace software control and management system. Under these premises, the plant will be able to deliver the required doses of the ATMP drug (several thousand patients per year), under full respect of all the quality issues and in total compliance with all the regulatory rules.

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