

CytoNiche Takes 3D RecomTrix™ Microcarriers Global with FDA and NMPA Regulatory Filings

SINGAPORE, August 25, 2026 /EINPresswire.com/ -- CytoNiche Biotech, a developer of advanced 3D cell manufacturing technologies, has expanded the global regulatory portfolio of its proprietary [3D RecomTrix™](#) recombinant collagen microcarriers (CW01), with multiple Drug Master File (DMF) and Master File (MF) submissions to the U.S. Food and Drug Administration (FDA), complementing its existing excipient registration with China's National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE).

The U.S. regulatory portfolio for 3D RecomTrix™ CW01 comprises a Type II DMF (DMF043937) and Type IV DMF (DMF043963) with the FDA Center for Drug Evaluation and Research (CDER), together with a Type II Master File (MF32742) with the FDA Center for Biologics Evaluation and Research (CBER). CW01 also holds an NMPA CDE Excipient Registration (F20250000786).

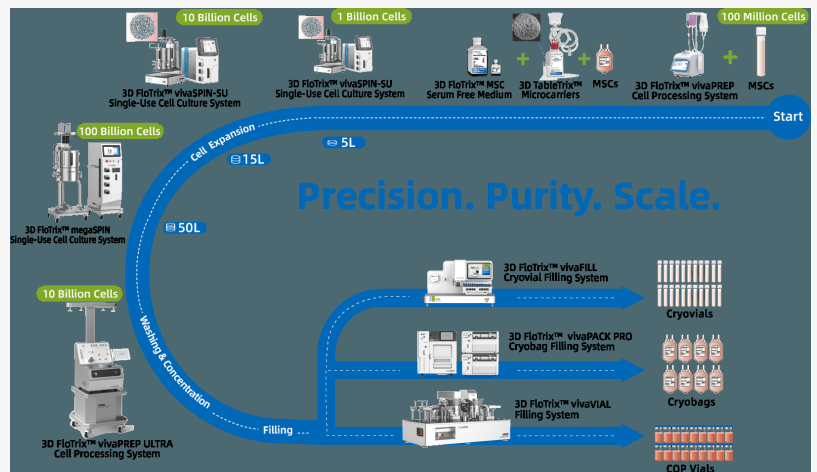
These filings further establish the regulatory foundation for CW01 as a defined, animal-free microcarrier designed for scalable cell manufacturing and support CytoNiche's continued expansion across global biopharmaceutical markets.

Advancing Raw Material Standards for Cell Manufacturing

As cell and gene therapy manufacturing progresses towards clinical and commercial scale,



CytoNiche's Microcarrier Portfolio



End-to-End Solution for Scalable MSC Manufacturing

greater emphasis is being placed on raw material definition, traceability and process consistency.

3D RecomTrix™ CW01 is manufactured from GMP-grade recombinant collagen, providing a defined, animal-free substrate for 3D cell expansion. Its material composition is designed to address the increasing need for controlled and standardised inputs in cell manufacturing workflows.

The microcarriers feature an elastic, highly porous three-dimensional architecture with more than 90% porosity and a high specific surface area, providing an expansive substrate for cell attachment while supporting efficient utilisation of bioreactor volume.



3D RecomTrix™ Recombinant Collagen Microcarrier CW01 (Powder/Tablet)

Engineered for Scalable, Closed-System Manufacturing

Beyond material composition, CW01 incorporates CytoNiche's proprietary dissolvable microcarrier technology to facilitate cell expansion and downstream harvesting within an integrated manufacturing workflow.

Its elastic 3D architecture is designed to provide hydrodynamic protection for cells during dynamic cultivation. Following expansion, the dissolvable microcarrier structure enables gentle, enzyme-free cell harvesting, supporting streamlined downstream processing.

CW01 is also pre-sterilised by radiation and disperses upon hydration, enabling direct integration into automated and closed-system manufacturing processes.

Together, these attributes position 3D RecomTrix™ as a microcarrier platform designed to align cell expansion performance with the requirements of increasingly sophisticated manufacturing environments.

Extending CytoNiche's Global Regulatory Footprint

The latest FDA and NMPA filings build upon CytoNiche's established regulatory experience with its flagship [3D TableTrix™](#) Microcarrier Series. The 3D TableTrix™ Microcarriers has completed a

Type II FDA DMF (DMF037798), Type IV FDA DMF (DMF035481) and Type II FDA Master File (MF29721), alongside two NMPA CDE excipient registrations (F20200000496; F20210000003).

By extending this regulatory framework to its recombinant collagen microcarrier portfolio, CytoNiche is strengthening its ability to support biopharmaceutical developers seeking defined and scalable manufacturing solutions for cell and gene therapy applications.

As the industry moves towards increasingly standardised and commercially scalable production, the integration of advanced materials, controlled manufacturing processes and regulatory documentation will become increasingly important.

CytoNiche continues to advance its 3D cell manufacturing platform through disruptive and scalable manufacturing innovations, driven by its mission to advance global access to cell technologies and enable more efficient, reliable and accessible pathways to cell-based therapies worldwide.

[About CytoNiche](#)

Founded in 2018, CytoNiche Biotech is a provider of 3D cell mass production systems for therapeutic applications. Built on its proprietary dissolvable microcarrier technology, CytoNiche's 3D Cell Intelligent Manufacturing system has supported the regulatory approval of China's first stem cell drug, Amimestrocel Injection.

Its 3D FloTrix™ platform integrates GMP-compliant dissolvable microcarriers, serum-free media, automated bioreactors, cell processing systems and single-use closed-loop consumables to support cell manufacturing from expansion through harvesting, processing and final filling.

For more information, please visit: <https://en.cytoniche.com>

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