



Experts in cGMP Cell Bank Manufacturing

MAXIMIZE THE POTENTIAL OF EACH TISSUE DONATION.

RoosterBio has developed a highly productive cell banking platform, leading to the manufacture and release of over 300 Master and Working Cell Bank Lots with established release criteria, to target quality specifications, and under Quality Management Systems. This manufacturing expertise enables the efficient, consistent production of enough cellular material from a single tissue donation to seed 1000s of 50L bioreactor manufacturing runs, turning a single tissue donation into a nearly inexhaustible source of cellular starting material.

Leveraging this expertise, RoosterBio supports advanced therapy developers with three options for cGMP cell bank access, including low passage Master Cell Banks for engineering applications, Working Cell Banks for immediate clinical manufacturing, and custom cell banks built to program specifications. These options allow developers to bypass the monetary investment, time, and risks associated with manufacturing cGMP cell banks suitable for all stages of clinical development with the ability to support commercial scale manufacturing.

In addition to cell bank access, RoosterBio provides the media, analytics, manufacturing processes, quality and regulatory support, and technical support required to further manufacture cell banks into advanced therapies.

OFF-THE-SHELF, cGMP MASTER CELL BANKS FOR CELL ENGINEERING & CUSTOM CELL BANKING **AVAILABLE NOW**

- Low population doubling level cGMP Master Cell Banks optimal for gene editing, cell engineering, or custom cell bank manufacturing applications.
- Derived from GTP sourced bone marrow (hMSCs), umbilical cord (hMSCs), or neonatal foreskin (hDFs)
- Multiple donors available
- Tissue donations sourced in accordance with 21 CFR Part 1271 Subparts A-C and applicable sections of Subpart D under Section 1271.150 and manufactured with methods and controls in compliance with current US FDA Good Manufacturing Practices (cGMP) and under ISO certified Quality Management Systems.
- FDA Type II Master File in place to streamline regulatory submissions

OFF-THE-SHELF cGMP WORKING CELL BANKS FOR CLINICAL MANUFACTURING **AVAILABLE NOW**

- cGMP Working Cell Banks manufactured from established and fully released Master Cell Banks for the quickest path to clinical manufacturing
- One Working Cell Bank vial can manufacture billions of MSCs or trillions of EVs when paired with RoosterBio cGMP media and established scalable 2D and 3D processes
- Available from bone marrow (hMSCs), umbilical cord (hMSCs), and neonatal foreskin (hDFs) cGMP Master Cell Banks
- Multiple donors available
- Lot specific release and characterization testing conforms to ISCT guidelines and includes identity, expansion performance, differentiation capacity, and functional immunomodulatory and cytokine secretion profiles.
- Manufactured from cGMP Master Cell Banks with methods and controls in compliance with current US FDA Good Manufacturing Practices (cGMP) and under ISO certified Quality Management Systems.
- FDA Type II Master File in place to streamline regulatory submissions

CUSTOM CELL BANKS FOR PROGRAM SPECIFIC NEEDS **BUILT FOR YOUR PROGRAM**

- Leverage RoosterBio's extensive cell manufacturing expertise to establish cGMP cell banks specific to a program's needs
- Derive cell banks from newly sourced donor tissue or from available cGMP Master Cell Banks or Working Cell Banks
- Evaluate multiple donors prior to full cell bank manufacturing and testing
- Build a tiered cell bank structure that maximizes each tissue's potential yield to meet current clinical and future commercial lot size needs
- Customize final vial parameters, PDL expansion ranges, and release and stability testing programs.
- Available with supporting cGMP Analytical Development and Testing Services



RoosterBio®

EVERY PROGRAM'S CELL BANK NEEDS ARE DIFFERENT. ROOSTERBIO HELPS THERAPEUTIC DEVELOPERS FIND THE RIGHT SOLUTIONS TO MEET THOSE NEEDS.

cGMP PRODUCTS FOR CLINICAL MANUFACTURING

RoosterBio's cGMP CliniControl™ portfolio, paired with established processes, provides a complete manufacturing workflow supported by U.S. FDA Type II Master Files. Introduced in 2019, adoption of these products has enabled advanced therapy candidates to rapidly reach the clinic.

cGMP WORKING CELL BANKS

cGMP RoosterVial™ off-the-shelf, xeno-free WCBs derived from GTP sourced bone marrow (hMSCs), umbilical cord (hMSCs), or neonatal foreskin (hDFs).

PRODUCT	DESCRIPTION & UNIT SIZE	CATALOG NO.
RoosterVial™-hBM-20M-CC	20 million xeno-free cryopreserved bone marrow-derived hMSCs	MSC-CC040
RoosterVial™-hUC-20M-CC	20 million xeno-free cryopreserved umbilical cord-derived hMSCs	C04020UC
RoosterVial™-hDF-20M-CC	20 million xeno-free cryopreserved neonatal foreskin-derived hDFs	C06020DF

cGMP BIOPROCESS EXPANSION MEDIA & BIOREACTOR FEED

cGMP prcRoosterNourish™ expansion media and prcRoosterReplenish™ bioreactor feed are serum-free, xeno-free media that support scalable clinical manufacturing of hMSCs, iPSC-MSCs, immortalized MSCs, and fibroblasts without requiring media exchange.

PRODUCT	DESCRIPTION & UNIT SIZE	CATALOG NO.
prcRoosterNourish™-MSC-CC	500 mL bottle of RoosterBasal2.0-CC (Part No. M22520) + 10 mL bottle of prcRoosterBooster-MSC-CC (Part No. S03004)	K82304
prcRoosterNourish™-MSC-CC	10 L bag of RoosterBasal2.0-CC (Part No. M22120) + 2 x 100 mL bags of prcRoosterBooster-MSC-CC (Part No. S03003)	K82203
prcRoosterReplenish™-MSC-CC	100 mL bag of 50X bioreactor feed	S02001

cGMP EV / EXOSOME PRODUCTION MEDIA

CliniControl cGMP RoosterCollect™-EV is a chemically defined, protein-free extracellular vesicle collection media.

PRODUCT	DESCRIPTION & UNIT SIZE	CATALOG NO.
RoosterCollect™-EV-CC	1 L bottle of EV/exosome collection media	M02002
RoosterCollect™-EV-CC	10 L bag of EV/exosome collection media	M02004

cGMP GENETIC ENGINEERING MEDIA

CliniControl cGMP RoosterGEM™ is a complete, chemically defined media for both viral and non-viral primary cell engineering.

PRODUCT	DESCRIPTION & UNIT SIZE	CATALOG NO.
RoosterGEM™-CC	200 ml bottle of genetic engineering media	M03001

QUALITY BUILT IN

RoosterBio's CliniControl product line of cells, bioprocess expansion media, and EV production media are manufactured with methods and controls in compliance with current US FDA Good Manufacturing Practices (cGMP) and manufactured under ISO certified Quality Management Systems. At a minimum, our CliniControl bone marrow, umbilical cord birth tissue, and neonatal foreskin donations comply with 21 CFR Part 1271 Subparts A-C and applicable sections of Subpart D under Section 1271.150. Donors of human blood-derived raw material in CliniControl media are tested in compliance with federal regulations set out in 21 CFR 610.40. Additionally, CliniControl prcRoosterNourish™-MSC-CC, prcRoosterReplenish™-MSC-CC, and RoosterCollect™-EV products are supported for use as ancillary materials and CliniControl RoosterVial™ products as starting materials by US FDA Master Files to streamline regulatory submissions. Contact us for region-specific regulatory support.

