



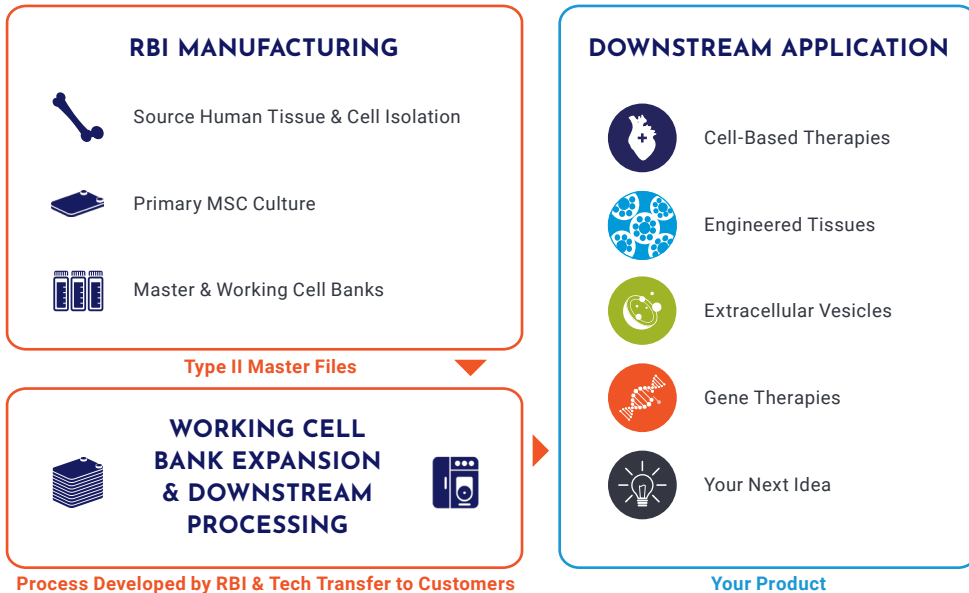
# Process Development Services

YOUR PROCESS, YOUR KNOWLEDGE

**Leverage our unparalleled expertise in hMSC manufacturing to streamline your path towards a clinically and commercially viable cGMP manufacturing process.**

The path from early product idea to clinical implementation for cell-based therapies can be challenging and time consuming with the strict regulatory reviews and requirements. That is why RoosterBio has streamlined the path to clinical manufacturing, leveraging the productivity of our **industry leading hMSC bioprocess systems with Process Development Services** to help our customers build cGMP manufacturing processes right sized for your specific product and clinical stage. Our solutions will enable your custom manufacturing process to align with regulatory guidance, be scalable to fit future needs, and rapidly turn your product concept into a clinically tested therapeutic.

RoosterBio's multi-year focus on hMSCs has resulted in innovative core technologies and process expertise as a strong foundation to support customers in their cell manufacturing programs, letting them focus on their novel IP with great success in radically shortening their development timeline into cGMP manufacturing.

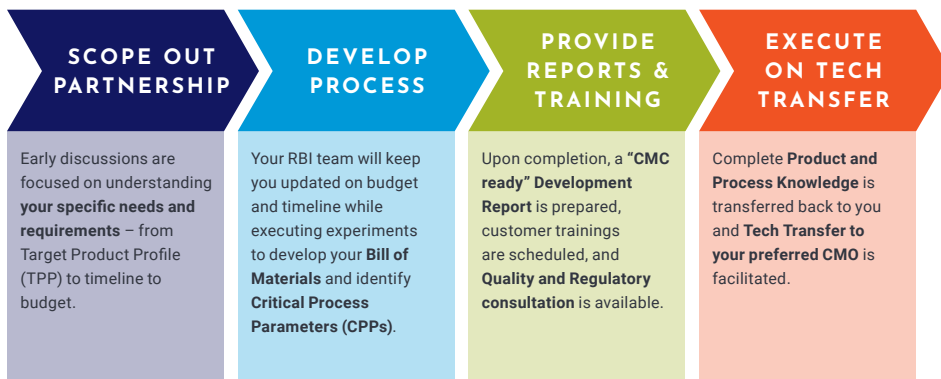


## SERVICE FEATURES

- Process Customization & Optimization
- Upstream & Downstream Development
- Analytical Services
- Transparent & Timely Communication

## SERVICE BENEFITS

- Streamline Process Development
- Allocate Resources Efficiently
- Reduce Costs & Risks
- Accelerate Path to Clinical



**WE PROVIDE TAILORED PROCESS DEVELOPMENT SERVICES TO YOUR PRODUCT NEEDS.**



# RADICALLY SHORTENING TIMELINES FOR hMSC-BASED PROCESS DEVELOPMENT

## Applications for Process Development Services

CELL THERAPY | EXTRACELLULAR VESICLE PRODUCTION | GENE-MODIFIED CELL THERAPY

### Process Design & Program Development

- Process modeling and streamlining for scalable cell production
- Cost of Goods (COGs) analyses with proposed changes to minimize COGs
- Technology Transfer

### Upstream Process Development

- Process design and monitoring
- Donor selection criteria based on final product Critical Quality Attributes (CQAs)
- 2D and 3D Process development in various technology platforms and scales
  - Flasks for early upstream optimization studies
  - CellStacks for rapid scale-up and feasibility studies
  - 3D Bioreactor process development for optimum scale up
- Process Optimization
  - Media exchange and feed strategies to increase productivity
  - 2D and 3D process optimization focused on yield, productivity, process economics, and ease of implementation
  - DOE for parameter screening & optimization.
  - Microcarrier selection for optimized 3D cell culture process
- Closed system engineering for streamlined manufacturing process

### Downstream Process Development

- Harvest procedure development and scale-up
- Microcarrier separation from bioreactor culture
- Scalable volume reduction and washing (TFF/kSep)
- Formulation, aseptic fill & finish, and cryopreservation of final cell product
- Extracellular vesicle (EV) collection

### Analytical Services

- MSC characterization / potency assays
- MSC Release Criteria
  - Identity: Cell surface marker profile
  - Purity: Cell surface marker profile associated with unwanted or contaminating cells
  - Potency: Immunomodulatory activity, cytokine secretion, trilineage differentiation
  - Sterility: Compendial tests are used, surrogate assays can be implemented for products that are infused fresh
- Cell counting based on NIST best practices
- In-process sampling and testing
  - BioProfile analyses of nutrient utilization and metabolite production
- EV particle characterization (Nanoparticle Tracking Analysis)



*“RoosterBio provided great communication both ways with timely and productive meetings, as well as great teamwork and scientific expertise synergy. They offer great flexibility, excellent quality of data presentation and reporting, and optimal quality for scientific results while facilitating the optimization and implementation in process development projects.”*

- Anonymous RoosterBio Customer

[CONTACT US](#) TO LEARN MORE AND LET US WORK TOGETHER TO  
ACCELERATE YOUR PRODUCT AND PROCESS DEVELOPMENT EFFORT!



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RoosterBio, Inc is a privately held manufacturing platform technology company based in Frederick, MD focused on accelerating the development of a sustainable regenerative medicine industry, one customer at a time.