ARIZONA AESTHETICS
COOLSCULPTING · STEM CELL THERAPY
HAIR RESTORATION

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MADE SCIENTIFIC

PRODUCT SPECIFICATION & CAPABILITY SUMMARY

MSC-Derived Secretome

Off-the-shelf, GMP-manufactured Wharton's-jelly MSC secretome for aesthetic and regenerative applications.

Prepared for Arizona Aesthetics (Erik Borchardt, Owner)

Prepared by Made Scientific · July 8, 2026

DRAFT — Secretome CoA is tentative, to be confirmed by Arizona. MSC drug-product release specifications shown are Made's GMP criteria per the Nov 2025 Scientific & Regulatory Opinion.

ABOUT

About Made Scientific

Made Scientific (formerly BioCentriq) is a cell & gene therapy CDMO providing process and analytical development through GMP manufacturing — from bench to late-phase and commercial supply — from its Princeton, NJ facility. Made Scientific is owned by GC Cell of South Korea, one of Korea's largest healthcare and life-science companies, with operations dating to the 1960s. Secretome for the Arizona program is produced within this established GMP infrastructure and quality system.

CAPABILITIES

Clinical, BLA & Commercial Cell Therapy Support

Beyond the MSC secretome program, Made Scientific supports a broad portfolio of advanced cell and gene therapies across development stages, including:

- Autologous CAR-T and TCR-T cell therapies
- iPSC-derived therapeutics
- Tumor-infiltrating lymphocytes (TIL)
- NK and NK-like cell therapies
- Cell-encapsulated technologies
- Mesenchymal stromal cell (MSC) therapies
- Extracellular vesicle (EV) products: secretome and exosome
- Cell-device combination products
- Custom product development and bespoke manufacturing programs

This capability breadth allows the same quality system, program management, and clinical-to-commercial manufacturing infrastructure used for Arizona's secretome supply to scale into later-phase and commercial regenerative programs.

INFRASTRUCTURE

Facility & FDA Registration

- FDA-registered establishment (FEI 3039488058); GMP facility network across Princeton and Newark, NJ — clinical-to-commercial cell therapy manufacturing.
- 60,000 sq ft; BSL-2 compliant. Six (6) ISO 7 GMP cleanrooms with open operations in ISO 5 biosafety cabinets; dedicated air handling; single-use technology and automated cell processing.
- Full process & analytical development and pilot labs; qualified GMP-compliant gamma irradiator.
- 12,000 sq ft expansion (with Orchestra Life Sciences) adding 9,000+ sq ft of GMP cleanrooms — full late-phase/commercial capacity Q3 2026.

QUALITY

Quality & Compliance Posture

- Quality Management System compliant with US FDA 21 CFR 1271 and 210/211, and ICH Q7, Q9 & Q10; aligned to EudraLex Vol. 4, Annex 1.
- Independent Quality Unit holds final batch-disposition authority; ALCOA+ data integrity; formal change control, CAPA, and supplier qualification.
- Controlled-rate freeze with end-to-end cold-chain logistics (LN_2 vapor phase, −150 °C to −196 °C, full chain-of-custody) suitable for international shipment.

PRODUCTS

Product Family

Product	Format	Status / development
Off-the-Shelf Secretome	4–5 mL vial (2 mL–5 mL CIP polymeric or borosilicate glass)	Current — available now
Secretome for nebulizer / intranasal	2 mL vial	Future — no process change; fill volume + vial swap only
Concentrated Secretome	<4 mL, higher viscosity (TFF concentration step)	Future — ~3-mo development; late 2026
MSC Drug Product — 10M / 20M / 50M cells	Vials (custom fill volume)	Available — custom release options
MSC Drug Product — 100M–150M cells	Cryobags	Available — custom release options
Purified WJ-derived Exosome	Custom vial / bag per program	Custom development
Bone-Marrow-derived Exosome	Custom vial / bag per program	Custom development

CUSTOMIZATION

Custom Vial, Formulation & Packaging Options

Made Scientific is a custom cell-therapy manufacturing business. Beyond the standard secretome formats, Arizona Aesthetics can specify vial, formulation, and packaging to fit its clinic workflow.

- **Vial options:** 2 mL–5 mL CIP polymeric vial (validated to cryopreserved / LN_2 temperatures) or borosilicate glass (validated to –80 °C). Any vial format can be requested, including 2R / 6R / 10R and 2 mL–5 mL CIP options.
- **Lyophilization:** Lyophilized secretome offering for stable shelf life — planned, coming soon.
- **Stability program:** Active stability program running to establish long-term stability, with a 36-month target.
- **Custom potency assays:** Custom potency assay development for the CoA, tailored to applicable indications.
- **Custom formulations:** Formulation development adjusted to product and application requirements.
- **Branding & packaging:** Arizona Aesthetics logo on vial label; vials placed in secondary carton / packaging. Custom labels and custom packaging available upon request.

LOGISTICS

Drop-shipping & Scalable Supply

- **Drop-shipping service:** Orders placed via distributor; Made drop-ships directly to the clinic with overnight supply options, including dry-ice shipment and bulk shipment in LN_2 dewars.
- **Scalable platforms:** Manufacturing platforms designed to meet the largest market demand, from small clinic lots through commercial-scale regenerative supply.

APPLICATIONS

Applications — Aesthetic & Regenerative

Aligned to Arizona Aesthetics' service lines — stem-cell / exosome hair restoration, exosome skin therapy, and regenerative wellness.

- **Hair restoration (androgenetic alopecia):** MSC-derived EVs/exosomes promote hair-follicle growth in preclinical models via Wnt/β-catenin signaling (miR-218-5p), increase VEGF expression in hair follicles, and enhance dermal-papilla cell proliferation; intradermal MSC-EV case series report improved hair density and caliber over 3–6 months.
- **Skin rejuvenation / anti-aging:** Secretome cargo — VEGF, HGF, bFGF plus matrix-remodeling factors — drives fibroblast migration and collagen deposition; MSC-EV studies target photoaging, wrinkles, skin elasticity, and hyperpigmentation (melanin-index endpoints).
- **Why the Wharton's jelly source matters:** neonatal WJ-MSCs deliver higher EV yield and higher angiogenic potency than adult (bone-marrow) sources, with no age-related donor senescence — the same angiogenic and matrix-remodeling mechanisms that underpin hair and skin outcomes.

Mechanistic and early-clinical findings summarized from Made Scientific's MSC-EV research report; provided for scientific context. RUO material — not FDA-approved for these indications; no disease claims. Aesthetic application and any claims are the responsibility of the treating practice.

SOURCE

Cell Source & Starting Material

- **Cell type:** Allogeneic human umbilical-cord Wharton's jelly MSC (hUC-WJ-MSC).
- **Starting material:** RoosterBio, Inc. (Ballenger Creek, MD) GMP Wharton's Jelly Umbilical Cord Working Cell Bank; expanded in GMP RoosterNourish-MSC-CC media (2D expansion).
- **Provenance:** Cell bank and media are made in FDA-registered facilities under 21 CFR 1271/211 and ICH Q7; cross-referenced in multiple FDA-cleared INDs (Phases I–III).
- **Donor:** Tissue collected and processed per 21 CFR 1271 and AATB standards — IRB oversight, informed consent, donor eligibility and infectious-disease testing.

PROCESS

Production Process — MSC Culture → Secretome

1. Thaw Wharton's jelly hMSC working cell bank.
2. Expand in culture (xeno-free media) to target density / passage.
3. Media exchange into conditioning phase (retained / conditioned media = secretome).
4. Harvest & clarify.
5. Sterile filtration.
6. Formulation (proprietary formulation, GMP-suitable).
7. Fill (5 mL vial, ~4cc).
8. QC release per CoA.

Product 3 (concentrated) adds a TFF (tangential-flow filtration) concentration step and adjusted CoA.

RELEASE TESTING

MSC Drug-Product Release CoA — Made's GMP Specifications

Release test	Method	Acceptance criteria
Identity — surface markers	Flow cytometry	CD73/CD90/CD105 ≥95%; CD34/CD45/CD19-CD79α/CD11b-CD14/HLA-DR ≤2%
Viability	Post-thaw viability	≥85% viable cells
Plastic adherence	Microscopy	Positive
Differentiation potential	Trilineage differentiation	Osteoblast, adipocyte & chondroblast confirmed
Sterility	USP <71>	Negative
Endotoxin	LAL	< 4 EU/vial
Mycoplasma	PCR	Negative
Adventitious agents	Per specification	Negative

RELEASE TESTING

Secretome CoA — Tentative, To Be Confirmed by Arizona

Secretome test	Method	Purpose / reporting
Sterility	USP <71>	Safety — no growth
Endotoxin	LAL	Safety — report EU/mL
Mycoplasma	PCR	Safety — negative
Total protein	BCA assay	Content / safety — report mg/mL
Protein content matrix	10-plex ELISA (Luminex / Procartaplex)	Cytokine & growth-factor content
Prostaglandin (PGE2)	ELISA	Immunomodulatory marker
Potency	Macrophage immunomodulation assay	Biological function
EV titer & particle size	NTA	Particle count; size ~120 nm
Particle charge	NTA / electrophoretic light scattering	Zeta potential
Intact-vesicle / exosome markers	3rd-party fluorescence	Vesicle integrity & exosome identity

REGULATORY

Regulatory Framework & Supply Model

- Made's hUC-WJ-MSC drug product is manufactured under full cGMP — 21 CFR 210/211 and 1271, ICH Q7/Q9/Q10, EudraLex Annex 1 — as attested in Made's signed Scientific & Regulatory Opinion (Nov 2025), issued to support partner IRB submissions and international clinical supply.
- Secretome drop-ship options span RUO through full-GMP release (see the drop-ship briefing). RUO material is supplied "not for administration to humans or animals" unless a GMP human-use release is elected.
- For Arizona: Made supplies the secretome at the elected release level; the distributor/clinic holds regulatory sponsorship for in-market administration and any claims. CoA scope and acceptance criteria finalize with Arizona and by product.