MARKET & COMPLIANCE

- **OUR PRODUCTS ARE DERIVED ONLY FROM HEALTHY, PRE-SCREENED LIVE C-SECTION BIRTHS.**
- **TO ENSURE PATIENT SAFETY, OUR DONOR SELECTION, AMNION RECOVERY AND PROCESSING PROCEDURES MEET OR EXCEED ALL APPLICABLE INDUSTRY STANDARDS.**
- **ALL PRODUCTS UNDERGO INDEPENDENT STERILITY TESTING AND ARE MANUFACTURED IN A GTP FACILITY.**
- **SIGNATURE BIOLOGICS HCT/P PRODUCTS ARE COMPLIANT UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT ACCORDING TO 21 CFR PART 1271.10. THEY ARE REGULATED AS A HUMAN CELL AND TISSUE PRODUCT – FOR HOMOLOGOUS USE ONLY.**
- **PRESCRIPTION USE ONLY FOR SALE TO LICENSED HEALTHCARE PROFESSIONALS.**

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MISSION & VISION

Signature Biologics uses its innovative techniques to manufacture human placental derived products to support and improve the natural healing processes of the body. We strive to produce best-in-class products that better the quality of life of patients.

Our vision is to maintain the premier status as the trusted source of innovative placental derived therapeutic solutions in the nation, characterized by the highest quality products and improved functional patient outcomes.

VALUES

QUALITY: To meet or exceed the highest regulatory standards to ensure products consistently meet established specifications.

INTEGRITY: To conduct all business operations with the utmost commitment to transparency, trustworthiness, and golden rule ethics.

INNOVATION: To utilize a constant focus on research to develop novel and unique processes and best-in-class products.

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Beyond Stem Cells

Placental Allograft Product Education

www.signaturebiologics.com

Healthcare Provider Educational Information

BEYOND STEM CELLS

TISSUE VERSUS CELLULAR ISOLATES

Signature Biologics products are structural tissues. They are minimally manipulated to not alter the original relevant characteristics of the tissue's utility for reconstruction, repair, or replacement.

Cellular isolates may require advanced manipulation and do not serve a structural purpose.

MINIMAL MANIPULATION

Minimal manipulation is the processing of the tissue so that it does not alter the structure and purpose of the HCT/P.

FDA 21 CFR Part 1271 guidelines permit the use of crystalloids (sterile saline), a storage agent (DMSO) or a sterilizing, preserving agent.

Additionally, Signature Biologics does not combine cells or other tissues with the product in order to retain the original structure and purpose of the tissue for homologous use.

HOMOLOGOUS USE

Homologous use means performing the same basic function or functions in the recipient as in the donor, examples include:
barrier, conduit, cover, or cushion.

ONE TISSUE – MANY COMPONENTS

UNIT OF MEASURE

In order to quantify the number of cells in tissue, one must alter the tissue resulting in unreliable characterization. Signature Biologics identifies tissue products by weight as the unit of measure (mg per mL). This unit of measure can be tested during production to ensure accuracy in measurement so you can expect the same quantity of tissue in each vial produced.

- Reliability and consistency in manufacturing from vial to vial
- Assurance that each vial will contain the proper amount of tissue

MOLECULAR COMPONENTS

The cellular layers of placental derived tissue contain additional molecules:

- Naturally occurring cytokines, chemokines, mRNA, and prostanoids, including PGE2
- Hyaluronic acid (HA), an important, natural anti-inflammatory lubricant

IMMUNE PRIVILEGED

The placental tissue does not contain human leukocyte antigens (HLA) which makes it immune privileged.

SETTING THE STANDARD

cGMP AND cGTP

Signature Biologics production and quality standards are built to current good manufacturing practices (cGMP) and current good tissue practices (cGTP), which focus on the safety and cleanliness of the laboratory environment.

ISO 9001 CERTIFIED

Signature Biologics is ISO 9001 certified, which ensures transparency in quality across the organization. Everything we do is driven by standard operating procedures, process controls and validations.

ENVIRONMENTAL CONTROLS

At Signature Biologics, we utilize custom designed production facilities to control the safety of the processing environment, including:

- 24/7 Environmental monitoring of labs
- Tissue processed in a certified ISO 5 clean room at the center of the certified ISO 7 lab
- Tissue packaged in dual sterility packaging