



## Empowering Healthcare Equity: Synergy Biologics' Commitment to Inclusive Care

At Synergy Biologics, we believe that quality healthcare should be accessible to all, regardless of background, location, or socioeconomic status. Our mission is to bridge healthcare gaps by providing advanced, affordable, and innovative solutions that drive equitable outcomes for all patients.

### Our Approach to Healthcare Equity:



#### Accessible Innovation:

We offer cutting-edge amniotic tissue solutions that are cost-effective, allowing healthcare providers to deliver high-quality care to underserved populations without compromising on standards.



#### Driving Cost Savings:

Through strategic pricing and our vertically integrated model, we help healthcare systems reduce off-contract spending by up to 60%, ensuring that resources can be redirected to areas in need.



#### Commitment to Inclusion:

Synergy Biologics is dedicated to supporting diverse patient communities by collaborating with healthcare organizations to reduce disparities and promote better health outcomes for all.



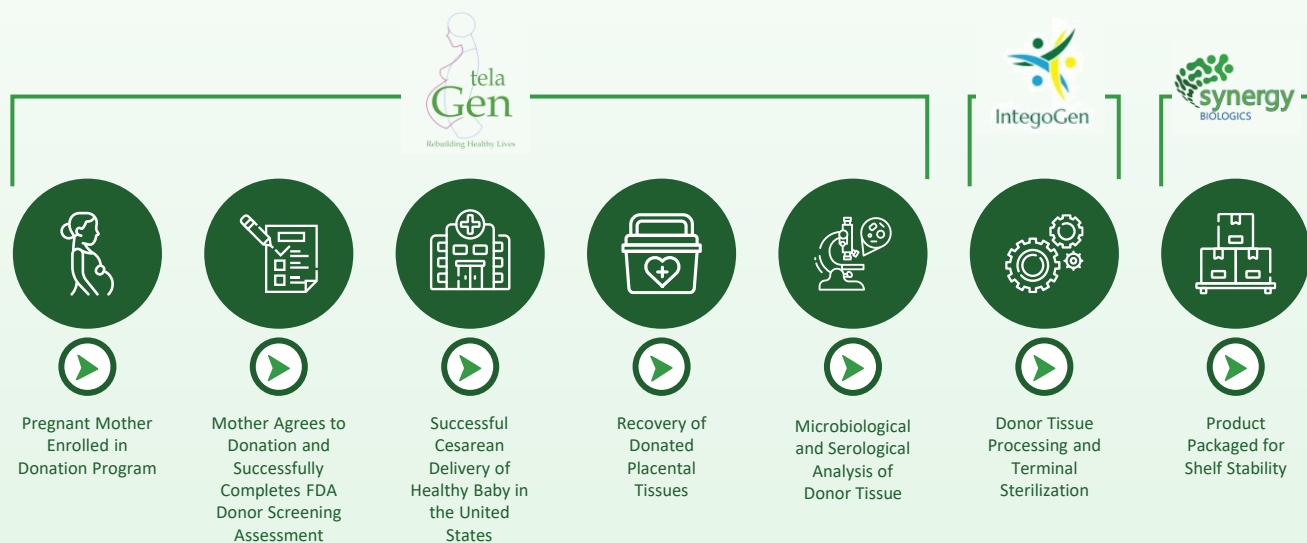
#### Together for Better Health:

Partner with Synergy Biologics and join us in our journey to create a more equitable healthcare landscape—where every patient has access to the treatment they deserve.



**For more information on how Synergy Biologics can support your Healthcare Equity initiatives, contact us today!**

# REDUCING COSTS THROUGH VERTICAL INTEGRATION



## AMNION IS AMNION

### FDA Regulations:

surgiGRAFT™ products, along with all other amnion tissues on the market, are regulated by the FDA under 21 CFR part 1271 and section 361 of the public health service act.

In 21 CFR 1271.10, the regulations identify the criteria for regulation solely under section 361 of the PHS Act and 21 CFR Part 1271. An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria (21 CFR 1271.10(a)):

1. The HCT/P **is minimally manipulated**;
2. The HCT/P is **intended for homologous use only**, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent;
3. The manufacture of the HCT/P **does not involve the combination of the cells or tissues with another article**, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
  - i. The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
  - ii. The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
    - a. Is for autologous use;
    - b. Is for allogeneic use in a first-degree or second-degree blood relative; or
    - c. Is for reproductive use.

If an HCT/P does not meet the criteria set out in 21 CFR1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions in 21 CFR 1271.156 , the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including 21 CFR Part 1271, and premarket review will be required.

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