



Biomaterials/Regenerative Medicine

Definition

The biomaterials/regenerative medicine industry, usually lumped under the title of “biofabrication,” involves two separate but overlapping areas of research.

Regenerative medicine is defined by therapies that are meant to regenerate or replace human cells to restore/establish typical function. This includes cell and gene therapies as well as scaffold placement and 3D-fabricated organs.

Biomaterials is a broader term, and encompasses any material, synthetic or biologic, that is used to reconstruct or replace tissues. This also includes tissue-like material that is derived from biology -- currently that's mainly fabrics and some plastics (more trendy, bio-art stuff). The definition is evolving, and some use it when describing biofuel/biochemical companies also.

Behaviors

- Non-therapeutic biomaterial companies are consumer-focused and act like tech startups
 - Often have strong marketing programs to appeal to consumer opinion, flashy websites to appeal to fashion brands
 - Most have not released mass-production methods but are working on batch-size clothing release
 - Participate in fashion industry, including showcases and art exhibitions
- Regenerative medicine companies exist in complex, highly-regulatory environments and number in the 10's with respect to FDA approvals
 - Space is mixed with both large pharmaceutical companies and startups as well as medium-sized companies working in the space
 - Successful startups are bought in phase 1-2 of clinical trials if results are good; are then incorporated into themed product suites under label of “biologics”; tough to get preclinical approval to move into phase 1
 - Heavily connected to academia, vast majority of startups are associated with universities; rely on academic laboratories to perform preclinical testing, etc
 - *Cell therapy* is the transplantation of viable cells into the body to replace diseased tissue; currently only a couple of dermatological cell therapies approved and 1-2 immune cell therapies for cancer
 - A natural progression of cell therapy is to assemble organs/tissues using

these cells and place them in the body ⇒ biomaterials

- *Gene therapy* is the use of viral vectors or gene delivery mechanisms to edit cell DNA directly in the body, correcting genetic disorders, cancer, etc.
- Biomaterials companies include organ and tissue fabrication companies, 3D bioprinting companies, and companies that make synthetic biomaterials to aid in tissue regeneration
 - Vast majority of pharmaceutical and medtech companies looking to make investments in this field
 - *Organ fabrication*: involves tissue engineering, typically done with bioreactors OR 3D bioprinters; no full, functioning organ has ever been fabricated yet, and none have been approved
 - *Tissue fabrication*: can involve edited or non-edited cells (non-edited cells do not have to go through FDA approval process and are instead given a certification as a tissue bank); only two tissue fabrication therapies are approved, and these are for the skin (overlap with cell therapies). Edited cells go through tough regulatory process; some strides have been made in kidney, heart and lung tissue
 - *Synthetic biomaterials/scaffolds*: do not involve cells; rather, have webs of material that are implanted into the body and encourage cells to grow into it. Highly materials-science based vs. biology; companies have more regulatory flexibility. Had not been successful until the advent of 3D printers + new materials. (ex. Spider silk, types of plastic, collagen, hydrogel matrix)
 - *Combination Products*: involve both scaffolding and cells (engineered or non-engineered)
 - Most of the market currently taken by orthopedics (bone) because this is what products exist and are easiest to get approval for

Types of Roles Available

- *Tissue Engineer/Materials Scientist/Research Associate*: Research positions more specific than pharma/biotech -- tissue or human-focused genetic engineering for non-synthetic therapeutics; materials science for synthetic therapeutics
- *Clinical or Regulatory Affairs*: Finds research laboratories to perform preclinical testing with; writes NIH, DARPA grants for preclinical testing; analyzes preclinical results and determines whether enough for FDA; keeps track of clinical trials within the company and of competitors
- *Manufacturing and Quality Affairs*: Mixture of mechanical, chemical and biological: how to scale up production processes to get a lot of product efficiently with low error
- *Management*: Working with investors, setting up collaborations/meetings with large pharmaceutical companies, establishing business plan

Valued Skills

- Strong laboratory or technical background: for regenerative medicine and tissue/organ fabrication, human cells and lentiviral modification as well as cellular biomechanics; for synthetic biomaterials, materials science
- For non-therapeutic biofabrication: creativity, design aptitude, chemical synthesis knowledge
- Organizational skills, efficiency, precision: good documentation is important

Relevant Companies

Therapies

Allergan	Aesculap Biologics
Vericel	Allevi
Organogenesis	Integra
Orthocell	Bluebird Bio
Organovo	Cellink
Tissue Regeneration Systems	EpiBone
Novartis (Some Products)	Amgen (Some Products)

Non-Therapies (i.e. Consumer Products)

Ecovative	Modern Meadow
Mycoworks	Spiber
Algiknit	Algenesis

To Follow/Join:

- A16z Bio: Andreessen Horowitz has a large regenerative medicine portfolio and often writes about it in their biological fund newsletter.
- Alliance for Regenerative Medicine (ARM): Industry group for regenerative medicine companies, has member companies working in the field (good place for searching for companies)
- Advanced Regenerative Manufacturing Institute (armi): Similar to ARM but hosts more consumer-focused events; conferences on biofabrication, see summary of recent conference here: [a16z](#)
- Biofabricate: Collaborative to promote sustainable bio-based materials in fashion and

consumer industry, releases reports and publications

Relevant Majors: Chemistry, BME, MCDB, MechE (with heavy biological focus), ChemE

- *BENG 435*: Biomaterial-Tissue Interactions: cover the aspects of integrating regenerative medicine products into the body
- *BENG 434*: Biomaterials: base concepts around biomaterials + regenerative medicine products, what exists today
- *BENG 353*: Intro to Biomechanics: essential concepts in cell interactions that are required for tissue engineering