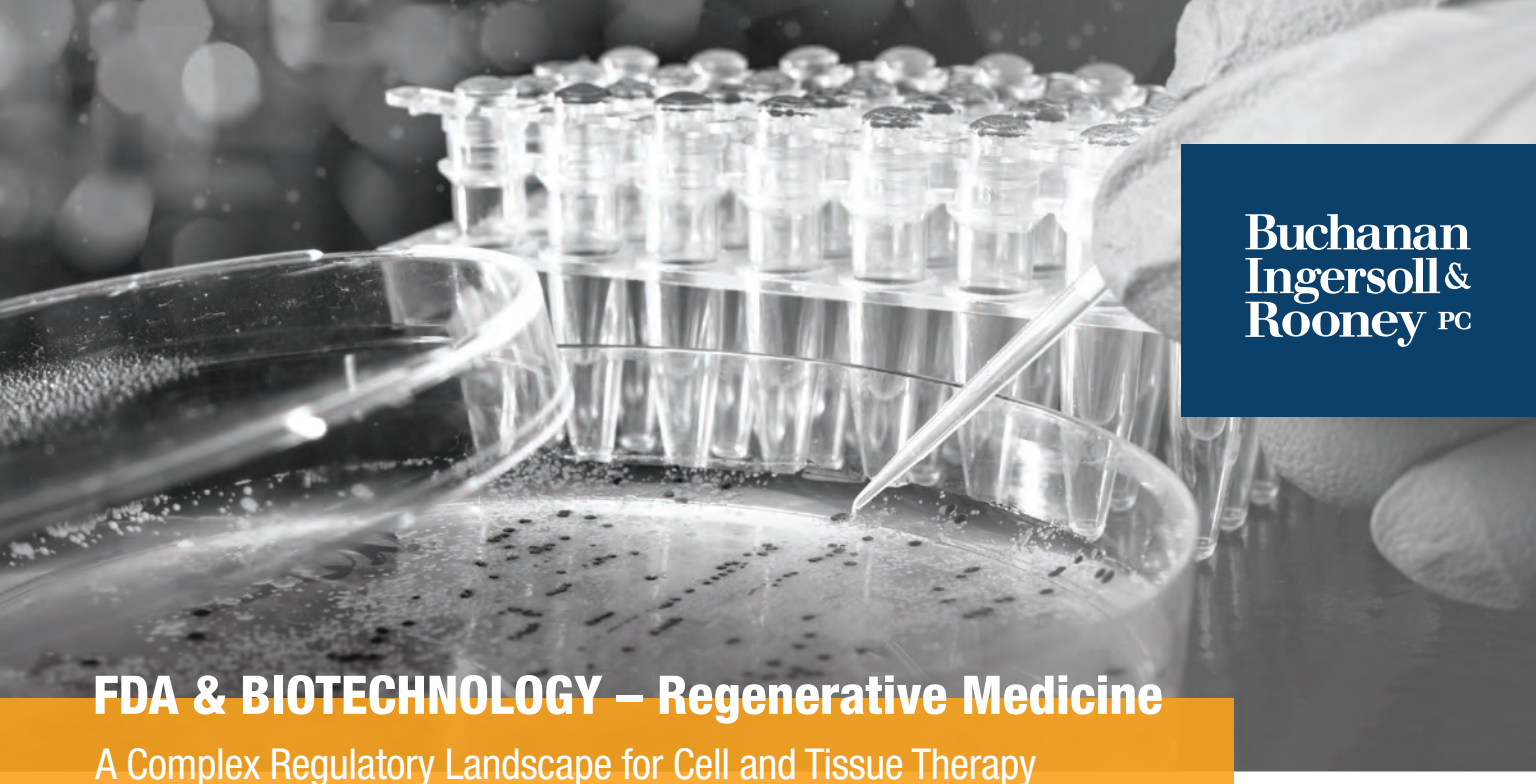

Buchanan Ingersoll & Rooney PC

FDA & BIOTECHNOLOGY – Regenerative Medicine

A Complex Regulatory Landscape for Cell and Tissue Therapy

The Food and Drug Administration (FDA) has issued a complex series of regulations and guidance documents for regenerative medicine technologies. This framework presents a myriad of unique issues which you must consider early in the research and development phase of your regenerative medicine product.

How We Can Help You

Researchers, physicians, pharmaceutical companies, and the FDA face a growing array of complex product development and approval considerations. What does this mean to you? It means you need counsel who knows this landscape well.

Your Regulatory Challenge

The FDA has implemented a comprehensive "risk-based" regulatory framework for human cells, tissues, and cellular and tissue-based products (HCT/Ps). Depending upon the level of risk posed to a recipient receiving an HCT/P, the sponsor (or physician) may have few, some, or many FDA-imposed regulatory requirements to meet. On occasion, HCT/Ps can also be combined with another FDA-regulated product, such as a medical device, to become a single FDA-approved product. Such combination products raise additional important questions about which FDA Center will regulate the product, and how.

FDA's regulations and guidance documents provide information about product development and FDA's enforcement approach. However, understanding how these apply to you requires special knowledge of and experience with these products.

Experienced HCT/P Counsel

Our team has deep training and experience in molecular biology, pharmacology, bioethics, and clinical trial considerations. We can assist you with all aspects of FDA's regulations and guidance, including product jurisdiction issues, possible FDA regulatory pathways to market, legal challenges, and more. We've worked with clients ranging from large and mid-sized pharmaceutical and biotech companies to small innovators and even investors, and our knowledge in this market sector positions us well to review and consult on your regulatory issues from all angles.

We have worked with our regenerative medicine clients in the following ways:

- Determining whether their HCT/P is "minimally manipulated"
- Developing a business strategy for autologous stem cell products that successfully takes into account the regulatory requirements for these products
- Requesting internal review of an FDA decision regarding the regulation of a client's product
- Providing guidance regarding the regulation of bone marrow transplants and hematopoietic stem cells
- Analyzing whether a tissue product used by a physician is a minimally manipulated HCT/P
- Assisting with licensing disputes involving cell and tissue products
- Preparing for and attending client meetings with the FDA regarding cell and tissue product regulatory requirements
- Providing legal and regulatory guidance for preparation of Phase 1 investigational new drug applications (INDs)
- Responding to Form FDA 483 inspection observations for cell and tissue facilities
- Identifying importation and exportation requirements for stem cells
- Addressing cell and tissue labeling requirements
- Addressing issues related to tissue collection for clinical research and clinical trials
- Advising on informed consent issues for a Phase 1 clinical trial
- Conducting website reviews for cell and tissue products and services
- Assessing patient registry and data ownership issues for stem cell products
- Assisting with an investor's due diligence of a company offering an autologous HCT/P

ADVANCING OUR CLIENTS' GOALS

Helping a University Researcher Obtain a Phase 1 IND for an HCT/P

We have worked with a researcher at a prominent university to help him receive an IND for early human testing of an autologous HCT/P product. We helped him identify the required pre-clinical studies, prepare a pre-IND meeting package, and attend a pre-IND meeting. We also worked together to prepare an IND that addressed all of FDA's questions, helping him obtain FDA concurrence that he could use his HCT/P in a human study.

Assisting Investor with Due Diligence of a Company Offering an HCT/P

We have helped an investor conduct due diligence of a company with an autologous HCT/P, offering regulatory counsel on product status and compliance with FDA requirements. We advised on HCT/P establishment registration and product listing, whether the company's standard operating procedures complied with current good tissue practices (cGTPs), and assessed whether the cells were minimally manipulated and intended for homologous use.