

GMP Manufacturing of Human Cell and Tissue Therapy Products

INCELL has been a San Antonio-based products manufacturer and contract services provider since 1993. INCELL is registered with FDA for Good Manufacturing Practices (GMP), storage and distribution of autologous and allogeneic human cell and tissue products (HCT/P) and medical devices. GMP Quality Systems not only assure that facilities, equipment, and materials meet standards, but that staff members have the appropriate training to perform the work. Batch records are made for each manufactured product to define individual steps and review before a product can be provided a Certificate of Analysis and released for sale. GMP manufacturing of human cells and tissues for clinical use has many challenges, including extensive national and international regulatory guidelines. “Quality by Design” (QbD) is integrated into new product development, with elements ranging from tissue procurement to Chain-of-Custody to raw materials to high grade packaging materials, logistics and detailed documentation. Choices and risk assessment (e.g., safety, testing, efficacy, time to market, costs, shelf life, and quality) are considered in the context of GMP requirements and QbD, as well as the intended use. Case Study examples will describe how INCELL’s robust platform technologies and multiple Master Files at FDA, combined with its unique GMP products and contract manufacturing services are facilitating and accelerating development of many new products that are expected to impact regenerative medicine applications that target numerous unmet medical needs.