

ACF Bioservices completes cGMP-compliant testing facility for gene and cell therapy products

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Singapore- ACF Bioservices (an Absorption Systems company) announces the completion of construction on its dedicated cGMP-compliant 3400 square foot facility for gene and cell therapy product testing.

The quantitative cell-based in vitro potency assays support FDA-mandated product release requirements. These potency assays range from relatively simple protocols to more complex and elaborate designs that determine the mechanism of action of a gene therapy product.

According to Patrick Dentinger, President and CEO, "The dedicated cGMP facility is a natural extension of Absorption Systems' GLP Biology services. With the emergence of gene and cell-based therapies, in vitro models that predict relative potency in humans is a preferred approach for product release testing and stability testing."

Before the initiation of Phase 3 clinical studies, the U.S. Food and Drug Administration (FDA) mandates a validated potency assay, which is a prerequisite for commercial approval. Once an assay is validated, it is transferred into the dedicated and access-limited ACF Core Facility. All instrumentation and equipment is fully validated and staffed with trained operators who follow established Standard Operating Procedures (SOPs), all in compliance with cGMP guidelines. At this point, the assay becomes a standard protocol that is routinely repeated to support release and/or stability testing of the gene or cell therapy product, which ensures consistency and conformance to pre-determined specifications for each production batch.