

# GENITOPE



## Streamlined Batch Record Process, Faster Delivery of the Right Therapy.

Based in Fremont, California, Genitope Corporation was founded in 1996 by Dr. Dan W. Denney, Jr. Genitope Corporation is a biotechnology company focused on the research and development of novel immunotherapies for the treatment of cancer.

Genitope Corporation's lead product candidate, MyVax® Personalized Immunotherapy, is a patient-specific active immunotherapy based on the unique genetic makeup of a patient's tumor and is designed to activate the patient's immune system to identify and attack cancer cells. As of the time this is written, Genitope Corporation just completed the pivotal Phase III for MyVax® Personalized Immunotherapy and is in the process for preparing the license application to the FDA for go forward with commercialization of MyVax®.

## The Challenge

MyVax® Personalized Immunotherapy is a patient-specific active immunotherapy that is based on the unique genetic makeup of a patient's tumor and is designed to activate a patient's immune system to identify and attack cancer cells. Genitope's manufacturing process relies on the production of multiple small individualized batches specific to each patient's DNA instead of large process-based batches.

Genitope manufactures many small batches and requires clear traceability from patient biopsy to patient therapy. Record-wise, this translates into thousands of batches in parallel and thus the equivalent volume of information to review and approve to release a batch. Process-wise, many functions such as Molecular Biology and Cell Line selection, which are R&D activities in many companies, are in fact manufacturing processes at Genitope. These functions are non-linear, have many loops and repetitions and require considerable configuration. To serve patients effectively, Genitope needed a solution to streamline their manufacturing processes and optimize the batch review cycle.

*"When Elan Software System's eBR solution is deployed in production, it will allow us to scale from clinical to commercial production levels with minimal resource increase, while expediting batch record review."*

*Bob Dvorak, Director Business systems (IT)*

