

Gene Therapy, Chain of Custody Innovation for Oncology-Immunology Startup

A biotech startup focused on personalized medication sought to change the way cancer is treated. Through gene therapy, they planned to empower patient's own immune systems to combat cancer by re-engineering patient's T-Cells. With solutions created for such specialized needs and highly sensitive genetic materials, this client knew they needed to take the utmost precautions to meet compliance and security measures and FDA chain of custody standards. They wanted to ensure, given the sensitivity of their line of business, that technology did not get in the way of curing cancer.

The technical challenges of gene therapy

The FDA has very stringent rules and regulations surrounding chain of custody. These rules become even more strict when genetic material is involved. In gene therapy, a patient's own DNA is their treatment, so following chain of custody by knowing the location of their genetic material at all times is imperative. This is key not only in completing successful clinical trials in a very specific timeframe (the typical door-to-door transport time is 40–50 hours or less), but in adhering to strict FDA and HIPAA guidelines around personally identifiable information and genetic materials.

“Errors along any point of the process or supply chain can be potentially devastating for patients... Innovative therapies that may not only treat but potentially cure cancer and genetic diseases are promising, but if those therapies cannot be distributed to patients (or the patients cannot be brought to the therapies) they have no value,” said Sascha Sonnenberg, Vice President of Cell & Gene and CTS Services at Marken.

Tracking chain of custody can be accomplished in many ways — shipping orders, package tracking numbers, or even smart packaging that monitors and reports on location, temperature, shock, and orientation. With so many variables involved, a tailored CRM solution like Salesforce makes tracking the end-to-end journey of each patient seamless.



Building a platform for curing cancer

The client knew that Salesforce capabilities could provide drug manufacturers an integrated view of all patient and provider interactions. But in order to meet tight deadlines with accurate results, they needed a partner they could trust to build the application in a way that met their specific business processes, activities, and requirements.

The biotech client partnered with Silverline to create a portal that allowed doctors and nurses to register their cancer patients for therapy treatment and follow the chain of custody along as the genetic materials were re-engineered. Silverline configured Service Cloud and Communities to accommodate the front end of the process, which includes:

- Patient registration process
- Cell Order process
- Integrations to and from other client-owned systems, such as Oracle and Veeva
- Integrations to and from the client's wholesaler and ATAS (Arm-to-Arm System) web application as applicable
- Integration with phone system for call center needs

Silverline worked collaboratively across client teams to ensure no stone was left unturned. Consulted teams included, but were not limited to: Product Management at both Corporate and Region level; Marketing, which provided a Promotional Review Committee and relevant Portal materials (or equivalent) for regulatory review; the core Oracle ERP team; Veeva team (physician master); Cell Transplant Account Managers and support staff; environmental training teams for new facilities and providers; logistics teams for labeling and tracking shipments' chain of custody; clinical research staff for US trials; global product managers in charge of country-specific issues; and a validation team for FDA (and equivalent) validation testing.



Portal creation and integrations

Process automation was key to ensure all steps were accounted for and occurred without hiccups. Once their patient is approved, the HCP will schedule an apheresis date, which will dictate the schedule of all other milestones within the treatment plan. Once accepted, the scheduling, transportation, and procedural information can be monitored and tracked from the time the cellular material leaves a patient's body to the time it is put back in.

Detailed reporting functionality and in-depth dashboards were created to aid in monitoring and managing assets throughout each patient's journey. Lastly, robust integrations between systems were implemented to allow for seamless communication between environments.

Reporting and analytics

In order to provide accurate and timely reports surrounding chain of custody, Silverline customized the platform to help them accomplish the following process:

- Client handles the awareness, acquisition, and approval of the patients as facilitated by the Health Care Professionals (HCP)/Physician
- Client handles the re-engineering (i.e., manufacturing) phase of the process
- HCP/Hospitals handle testing, apheresis, and infusion

Using built-in analytics, Silverline tailored the Org to provide insights into precise whereabouts of individual treatments, along with pertinent patient, provider, and payer information. The solution also includes the automation of multiple processes, such as retrieving a PO, initiation of sales order, patient consent using DocuSign, and monitoring process statuses.

With proper precautions taken and chain of custody maintained, the client was ready to go global.



About Silverline

Silverline has real-world expertise in the Healthcare industry, including industry sub-segments such as Provider, Payer, Medical Device, and Life Sciences. We combine strategic planning, implementation, and ongoing support to help clients realize continuous value with the Salesforce platform. To find out more, contact us at healthcare@silverlinecrm.com.

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Global rollout meets managed services

With the initial system complete, Silverline extended its core implementation team with its managed services offering to continue improving, implementing, and innovating — but more importantly, iterating.

Through the utilization of this scaled delivery approach, Silverline helped bring the portal to more than 16 countries with functionality in more than 20 languages — all managing the cutting-edge cell therapy cancer treatment. “It was a mighty success in an exacting environment,” said Silverline Delivery Director Ken Jacobson.

“Essentially we built the whole system so that you can put in any number of languages, and we built customizations to the process in order to accommodate slight differences based on regulatory agency requirements in particular countries,” Jacobson said.

With all versions of the Lightning Communities up and running along with Service Cloud, the managed services team provided ongoing tactical and strategic support with a focus on:

- Patient enrollment process and hospital community
- Operational and institutional setup support
- Branded portal configuration support
- Integration troubleshooting

The client now plans to continue its global expansion and extension of the platform as their therapy matures and patient/provider needs evolve.

