

Breaking Boundaries. Transforming Lives.

Helping a Transformative Company Navigate
Its Own Digital Transformation



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CELL AND GENE THERAPY

Data-Driven Lab and Production Operations

We help Orca Bio deliver on its promises more safely and effectively, using a data-driven approach and digital technologies.

Since its inception in 2016, Orca Bio — built on research conducted by its founders at Stanford University — has been on a mission to redefine the traditional transplant process, by developing high-precision cell therapies for the treatment of cancer, autoimmune diseases and genetic blood disorders.

Orca Bio is helping to deliver on the promise of cell therapy without compromise. Utilizing its purified, high-precision investigational cell therapies, Orca Bio endeavors not merely to replace patients' blood and immune systems with healthy ones but also to truly restore their lives.

Growing Pains

Facing continuous growth, the team at Orca Bio realized that, to fulfill their mission, operations would need to optimize and scale. This company, focused on transforming people's lives, knew it needed to undertake a (digital) transformation of its own.

Integrating the Right Partner

To help ensure a smooth and successful journey, they reached out to Inflexion Point, systems integrators with 40 years of experience serving the world's leading life-sciences companies, and Parsec, maker of the award-winning TrakSYS® operations management software.

Setting Clear Goals

InflexionPoint worked closely with Orca Bio in a series of workshops to establish clear goals for the business and the digital transformation project.

Orca Bio's personalized cell therapy products are designed to treat blood cancers and other diseases. Rapid processing time for each customized cell therapy batch is vital, and the critical steps include:

1. Collecting raw materials
2. Shipping to manufacturing facility
3. Manufacturing final products
4. Sending products to clinical sites
5. Administering them to patients

Challenges

- Geographically dispersed network of clinical outlets
- Reliance on home-grown applications and spreadsheets
- Information silos that stifled collaboration

Solution

- Expand Orca Bio's digital support for operations involving asset and materials management, maintenance, and operations event management
- Implement digital interfaces specifically tailored to Orca Bio's use cases

Results

- Optimized inventory-related production activities by more than 50%
- Accurately forecast equipment availability
- Integrate maintenance activities that reduce or eliminate unplanned downtime
- Streamlined systems validation process, improving internal compliance

An Agile Approach

With both parties having established clarity of vision, the team at Orca Bio had the confidence to tackle several manufacturing operations use cases simultaneously. The teams adopted an agile approach, dividing the work into the following parallel workstreams:

- Asset Management
- Inventory Management
- Manufacturing Operations Management
- Labeling
- Capacity Planning

For each workstream, a team of Subject Matter Experts (SMEs) developed their requirements that were then distilled into features. Bodies of work were defined, and a backlog was established to manage the development of the various software solutions.



The new system is not only helping Orca Bio to continue meeting quality standards but also to optimize resource usage and, over time, learn from our own data.

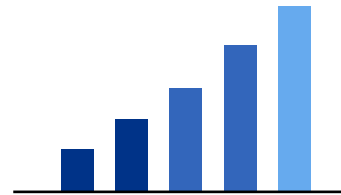
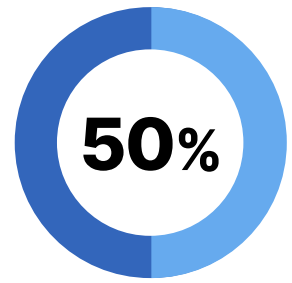
Veronica Gacitua, Head of Software Systems

End-to-End Visibility and Control

Working alongside the team at Orca Bio, InflexionPoint implemented a solution to support Orca Bio in scaling its operations while maintaining regulatory compliance. TrakSYS was implemented at Orca Bio's Sacramento location, initially targeting production for the clinical stage and designed to continue supporting commercial operations during the software lifecycle.

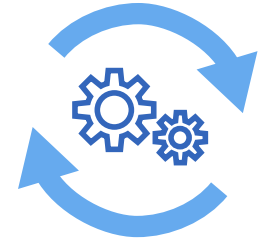
Capitalizing on the platform's native extensibility, InflexionPoint architected Orca Bio's deployment such that TrakSYS became an integral part of manufacturing operations, managing equipment onboarding and maintenance, resource allocation for planned jobs, material kitting and consumption, in-processing labeling, and more.

Optimized inventory-related production activities by 50%



Streamlined inventory management and accuracy

Increased throughput with accurate forecasts of equipment availability



Scaling Confidently

The operations management systems implemented by InflexionPoint have enabled Orca Bio to scale confidently by ensuring its processes are clearly defined, validated, and ready for expansion. When an organization experiences the rapid growth Orca Bio has, training personnel and ensuring that processes are being followed rigorously is critical. Having TrakSYS orchestrate and enforce processes ranging from inventory and asset management to operations and scheduling has enabled Orca Bio to thrive alongside its fast-paced expansion and shift from clinical to full-scale volume production.

Measurable Results

The system has also enabled Orca Bio to start managing capacity in a more automated way, with improved traceability and visibility for assets and materials used in each manufacturing batch, algorithmic production scheduling, and material and quality management.