






## CASE STUDY:

# Leader in Restorative Cell Therapies Embeds Skyland PIMS® as Process Knowledge Base from Clinical to Commercial Manufacturing

### Overview

A leader in the development of restorative cell therapies has a pipeline of products that may offer rapid-onset pain relief and restored function for orthopedic use.

With more complex drug manufacturing processes, global supply chains and the explosion of personal data, the leader in restorative cell therapies understands the importance of data integrity and having precise control of their manufacturing processes. By implementing [Skyland PIMS](#) into their manufacturing plan, the drug developer is able to securely manage critical data in a collaborative, cloud-based, 21 CFR Part 11 compliant workspace.

 <b>Easily Manage Product, Process and Batch Data</b>	 <b>Accelerate Process Analysis and Reporting</b>	 <b>Improve Scale-up and Tech Transfer Performance</b>	 <b>Enhance Data Visibility and Integrity</b>	 <b>Realize Low Total Cost of Ownership (TCO)</b>
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### Business Challenge

Complex multi-step processes involving engineered tissue to create “batches of one” have caused an explosion of data and makes tracking of changes in limits and specifications difficult.

Like most life science organizations, the company had been using an Excel-based approach to manage specification, target control and batch data. They also relied heavily on paper batch data. As they started to outgrow Excel, they began evaluating their options for a robust tool to leverage their clinical data sets and process knowledge as a basis for commercial manufacturing.

Head of technical operations for the company reported, “Now that we are moving into commercial manufacturing, we needed a solution that allows for greater levels of data integrity and scale in terms of being able to generate and analyze even more batches as we go forward. We use Skyland PIMS to form the process knowledge base for the CMC section for our BLA.”

## Skyland PIMS Benefits:

Directly serves their process control strategy

Enables end-to-end data transparency and collaboration between sponsors and CMOs

Captures information in a way that can be updated as their process matures

Ensures data integrity and auditability versus using Excel for master data management

Supports traceable data entry verification

Speeds technology transfer and onboarding

Cost effective

Easily accommodates different types of manufacturing processes

The drug developer considered enterprise systems but with the alternatives costing far more and requiring large IT infrastructure, they ultimately chose the benefits of Skyland PIMS.

The drug developer's team was impressed by PIMS' intuitive workflows that required no training or coding. They also appreciated its simple integration, deployment and validation and Skyland's proven track record of delivering innovative and cost-effective cloud-based software to the life science industry.

### The Solution

PIMS provides the leading developer of restorative cell therapies with a system that can adapt, regardless of the manufacturing process, easily accommodating the process workflows of their tissue-engineered products. With the ability to define their own parameter classes and process definitions, customization and configuration by IT resources are not necessary, which is typical of enterprise systems.

The most valuable aspect of PIMS is its collaborative nature. With unlimited users or "seats", it can be utilized internally by sponsors or CDMOs/CMOs, or collectively as a shared database and the "single source of truth" for critical product data. PIMS displays information in a simple dashboard with the hierarchy data shown by Process Definitions, Specification Limits, Target Control Limits and Batch Management. Data can be further segmented by product or process formulations, unit operations, market of sale and site of production. PIMS was purpose built as a shared digital workspace, all while being secure with established role-based access throughout the suite.

PIMS interface is clean and intuitive, with the user in mind, while the backend is logically organized with the ability to connect with other systems, run reports and import and export data.

## ABOUT SKYLAND ANALYTICS

Skyland Analytics streamlines drug product and process data management by offering cloud-based software solutions that ensure Part 11-compliance, data transparency and data integrity throughout the product lifecycle and supply chain. With deep expertise in manufacturing, IT systems, data analytics and product quality, we are uniquely positioned to provide you innovative technology to enhance product quality and process analysis and manage data across your internal and external networks.

For more information, visit [www.skylandanalytics.net](http://www.skylandanalytics.net).