

CASE STUDY



Precision BioSciences Deploys Skyland PIMS® Life Science Process Data Management Software in Support of Its Manufacturing Operations

Precision BioSciences (NASDAQ: DTIL) is a clinical stage biotechnology company developing allogeneic CAR T and in vivo gene correction therapies. With an eye towards therapeutic applications, the company's ARCUS® genome editing platform has the potential to deliver safer, more specific genetic edits. ARCUS has a naturally occurring gene editing property that shuts itself off after making a highly specific DNA edit. This built-in safety switch is a key differentiator compared to other gene editing technologies. The company has about 225 employees.

Operational Needs

Precision BioSciences produces multiple allogeneic CAR T products via in-house and contract manufacturing groups. Without automated data acquisition capabilities, batch data is manually recorded and transcribed into an Excel file, which is then e-mailed or shared on a network folder. Data is then verified and a PDF entered into the ELN for QA. All of this requires manual workflows.

Why Skyland PIMS?

The following were reported as top value propositions:

- Repository – PIMS™ will be a single source of verified and trusted data.
- Transparency – Batch data verification stakeholders see where data is and who has the next action.
- Price – PIMS pricing was attractive vs. higher cost solutions.
- Partnership – Precision sees Skyland as a partner, willing to listen and be flexible.

Keys to Success

The following were reported as important to closing the sale:

- Demo – Product demonstration was reported as key to stakeholder buy-in.
- IT – Important to involve IT as early as possible in sales process.



Customer Quotes

Process Engineer at
Precision BioSciences

- Top benefits of PIMS will be that we no longer have to rely on e-mail and Excel, and we will have one source of verified data and nearly real-time access.
- Data verification has been streamlined with Skyland. We will see where the data is in the pipeline and who is up next so that QA no longer has to scramble before sending data to the FDA.
- PIMS' value is the data repository, streamlined batch review and verification, and knowing what data can be trusted.
- Regarding Continued Process Verification, we plan to validate the software, and then there will be no more need to put batch data into our ELN. PIMS 21 CFR Part 11 does matter. PIMS will be part of our GMP (Good Manufacturing Practice). CPV is the goal.
- Our experience with Skyland has been very positive. They have been very helpful in understanding our needs and timeline and our unique situation. They've been great to work with across the board, especially on pricing and to understand the optimal licensing arrangement across our product portfolio.

Expected Benefits

Precision expects PIMS will provide the following:

- Excel – Eliminate manual batch data organization and analysis processes in Excel with use of PIMS' import template for streamlined data collection and import.
- ELN – Once validated, PIMS will eliminate the need to store manufacturing batch data in the electronic lab notebook.
- CPV – PIMS will play a role in the company's GMP and CPV strategy.

Additional Quotes:

Skyland subject matter experts showed off the technical side of PIMS and were patient, not pushy. The demo had significant value; it helped us to present the vision to stakeholders and demonstrate how it could change our ability to organize batch data.

*PIMS fits in our IT framework and security policies.
PIMS checked all the IT policy boxes.*

ABOUT SKYLAND PIMS

Skyland PIMS was designed for the life science industry by the developers of the very first drug manufacturing informatics tool. Enhanced and cloud-based, PIMS is the industry leading data management tool which orchestrates the aggregation, analysis and sharing of product and process data across your manufacturing network in a Part 11-compliant, validatable workspace. With Skyland PIMS, your team will improve data integrity, remain compliant and make better, more rapid product and process decisions with confidence.

Contact us today to explore how Skyland PIMS can support your data management needs.

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