Skyland PIMS™
Skyland
A product of Analytics

Understanding Why Skyland PIMS®
Was Selected – Novavax

Headquartered in Gaithersburg, Maryland, Novavax is a late-stage biotechnology company that promotes improved global health through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. The company's vaccine candidates are genetically engineered using three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis.

Operational Needs

Novavax has more than a decade of experience contending with some of the world's most devastating diseases, including seasonal influenza, RSV, Ebola, MERS, and SARS. It is preparing to enter phase III clinical trials with NVX-CoV2373, a leading COVID-19 vaccine candidate. As part of the US government's Warp Speed initiative, large scale manufacturing capacity is already being established for NVX-CoV2373 leveraging a global network of CMOs and partnerships.

Driven by its COVID-19 vaccine development and manufacturing data management complexities, Novavax wanted to harden its data infrastructure, discontinue wide scale use of Excel for batch/process/product data management, and accelerate data sharing among a large external network.

Evaluation Process

With accelerated production timelines a key focal point, selecting a system that would meet these timing requirements was a key factor. Staff involved in selecting a process information management system had extensive knowledge of the available solutions, including Discoverant, Statistica, and ProcessPad. Given these solutions involve lengthy deployment time, require added resources/overhead to manage, and have limited scalability, Novavax quickly identified PIMS as the right solution for their needs.

Customer Quotes

Director of Data
and Analytics, Novavax

° PIMS meets our needs perfectly and Skyland service has been phenomenal.

° The reasons why we selected PIMS are definitely the CMO data sharing and speed of deployment, which are an imperative given the urgency of manufacturing our vaccine on a global scale.

° We needed to move fast on our COVID-19 vaccine, replace Excel data management, and scale/accelerate CMO data sharing, PIMS was the perfect product.

Why Skyland PIMS?

The following were reported as top value props:

- Deployment Speed – Deployed in less than a week, PIMS™ enabled Novavax to fast track their COVID-19 data infrastructure ahead of scaling up global manufacturing operations
- CMO Collaboration – PIMS enables Novavax to monitor its supply chain and gain real time operational oversight of multiple CMO manufacturing sites worldwide
- Completeness - PIMS provides batch data and specifications and control limits management, analytics and integration capabilities with CMO historians

Keys to Success

The following were reported as important to closing the sale:

- Prioritization – Skyland's sales team fast tracked presentations and prioritized requests from Novavax, enabling PIMS implementation to be started in less than a week
- User Acceptance – Novavax provided end user groups (dev, tech transfer, ops, etc.) the opportunity to evaluate PIMS via online demo and Q&A sessions resulting in early user acceptance

Expected Benefits

Novavax expects PIMS will provide the following:

- Accelerated Tech Transfer – Following the successful completion of its phase III COVID-19 vaccine trials, Novavax will rely heavily on PIMS to accelerate tech transfer into commercialization and drive tight collaboration with a vast network of global CMOs
- Continued Process Verification – Given the urgency, large batch sizes involved, and stringent quality controls for its COVID-19 vaccine, Novavax is already preparing for 21 CFR Part 11 compliance and elevated FDA data integrity scrutiny

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.
Email: engage@skylandanalytics.net

Skyland **PIMS**™
Skyland
A product of **Analytics**