

TrakSYS: The Key to Modern Manufacturing

A Life Sciences Manufacturer Boosts Quality, Efficiency, Compliance, and Traceability in Bulk Batch Production



Highlights

- **Successfully transitioned paper-based, manual workflows to centralized data management system**
- **Automated tracking of raw materials and finished products**
- **Enhanced control over signatures and signoffs to ensure compliance with CFR21 Part 11**

Customer

A global manufacturer of lubricants and soaps used in the medical industry, with operations at a Midwest USA site.

Challenge

The client faced significant challenges in managing their bulk batch production processes. They were using paper batches in Excel, printing them off, writing by hand, and then going through a sign-off process before saving them in a binder. This manual workflow made it difficult to access records easily.

Another major issue was the risk of accidentally dispensing the wrong product, which happened a couple of times a year, resulting in increased costs due to the loss of raw materials, product, and time.

Additionally, the company needed to comply with CFR 21 Part 11 regulations for electronic records and signatures, which their existing framework could not support.



Solution

The client chose TrakSYS, a best-in-class manufacturing operations management system, to address their challenges. Software engineers at Adatafy™, a Novaspect trademark, configured the TrakSYS system to manage bulk batch production, recipe management, and material traceability.

System features included:

- **Electronic Records and Signatures:** Ensuring compliance with CFR 21 Part 11.
- **Audit Control:** Enhanced control over the development of system solutions around signatures and signoffs.
- **Material Traceability:** Automated tracking of raw materials and finished products.
- **Standardized Processes:** Formalized and standardized operating procedures, replacing informal and paper-based methods.
- **Data Repository:** Centralized data management system for recording and future reference.
- **Workflow Management:** Customizable workflows to match the company's unique processes.
- **Integration Capabilities:** Seamless integration with Warehouse Management Systems (WMS), Computerized Maintenance Management Systems (CMMS), and Enterprise Resource Planning (ERP) Systems.

Outcome

The successful implementation of TrakSYS transformed the client's manufacturing operations and led to significant improvements:

- **Reduced Errors and Improved Efficiency:** The implementation of TrakSYS minimized the risk of using incorrect raw materials, significantly reducing costly production errors and streamlining operations through standardized processes and electronic records.
- **Enhanced Compliance and Traceability:** The system ensured compliance with CFR 21 Part 11 regulations and improved material traceability, allowing for easier tracking and auditing of production batches.
- **Scalability and Future Expansion:** TrakSYS's flexibility and scalability supported future expansions and additional functionalities, setting the stage for continued improvements.

The project demonstrated the system's ability to enhance efficiency, compliance, and traceability, setting the stage for future expansions and continued improvements.

The client is now better equipped to meet industry standards and regulatory requirements, ensuring high-quality production and operational excellence.



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