



■ Business impact

A top-20 pharmaceutical company's early warning system from SAS has:

- Saved millions of dollars by reducing the batch failure rate.
- Increased the pass-through rate to 99 percent from 95 percent in less than a year.
- Reduced product recalls and eased FDA reporting and compliance.

■ Challenges

- **Difficulty isolating problems.** Problems are difficult to solve if they occur inconsistently or manifest as multiple problems over time.
- **Inefficient use of valuable resources.** Production problems often require support of the preclinical team.
- **Costly rework.** Assigning people to find and fix problems is expensive.
- **Recurring problems.** There's no formal process for building knowledge of "solved" problems back into the system to help prevent recurrence.



**THE
POWER
TO KNOW®**

How can we improve product quality and reduce our regulatory compliance risks?

YOUR GOAL: Reduce batch failures by making quality a part of process design

Pharmas operate in a world where product recalls can dismantle a company's reputation, and rejected drug batches can cost hundreds of thousands of dollars. While manufacturing in any industry is an exact process, it is especially true in drug manufacturing, where precise tracking of components with highly controlled dosage formulas is required.

Unfortunately, such precision also means there are many potential points for data corruption. If all data isn't captured and consolidated correctly, a company may be forced to scrap an entire production batch and start the run again.

Determining the root cause of a pharmaceutical manufacturing problem is extremely time consuming. Problems often aren't identified until the product comes off the manufacturing line and fails to meet specifications. If problems can't be pinpointed and corrected early in the process, the company is at risk of interrupting the total supply chain. This is especially costly when the drug is at peak demand.

OUR APPROACH

The key to reducing batch failures is to fully understand batch genealogy—knowing the source batch for each lot—and to make sure the problem isn't repeated in the future. This means validating your data sources and analyzing the metadata for traceability and impact analysis.

We approach the problem by delivering software and services that help you:

- **Integrate quality control** into your data management processes.
- **Incorporate advanced analytics** to find the root cause of production problems and give you the ability to predict what will happen.
- **Build past "learning" into future processes** to avoid repeating problems.

SAS believes that manufacturing quality should not be a by-product of inspections—it should be part of process design. Traceability is essential to accomplishing this, but that's possible only when your data systems are part of your analytics and reporting system.

SAS organizes all legacy and standard systems into a single information environment, so you can see your manufacturing process and quality in one view rather than as a series of handoffs between separate processes.

THE SAS® DIFFERENCE: An early warning system to avert production interruption

In a cGMP environment, you need to fully understand your metadata, particularly when some data sources are not validated and additional validation is required. SAS helps you build an early warning system that:

- **Reduces the time it takes to find and isolate a problem** and analyze its root cause.
- **Alerts you to potential problems** before they occur.
- **Helps you avoid diverting resources, consuming extra time and scrapping batches** each time a problem arises. By building learning into the process, the problem is caught earlier each time a batch is run.

SAS' integrated platform provides an innovative way to analyze manufacturing processes and data that was previously impossible. It also can improve other critical business metrics—such as inventory optimization, supply chain optimization and resource optimization—helping you gain additional benefits from the information in your ERP systems.

CASE STUDY: A top-20 pharmaceutical research company

Situation

A blockbuster drug had a series of batch failures, which stalled sales and resulted in lost market share at the peak of demand. The manufacturing team spent weeks of 24/7 work to find the batch failure source and take corrective action. At more than \$1 billion in projected revenue per year, each week of no shipments was costing millions of dollars. The CEO declared, "This can never happen again."

Solution

The company chose SAS to:

- **Implement an end-to-end platform** that combines integrated data management, predictive modeling, quality control, reporting and analysis to reduce the risk of production interruption.
- **Gather manufacturing process data and perform sophisticated root cause analysis** of potential batch failures before they happen. An integrated reporting system surfaces information and makes alerts immediately visible to everyone.
- **Establish a hub for all data outside of SAP.** Pulling data outside and putting it back would have cost twice as much (for custom integration, manual error intervention and data reconciliation) as the SAS solution.

Results

The company's early warning system from SAS has resulted in:

- Reduced batch failure rate, which will save millions of dollars.
- Pass-through rate increased to 99 percent from 95 percent in less than a year.
- Fewer product recalls.
- Easier FDA reporting and compliance.

The vision

Advanced analytics for early warning alerts

What if your manufacturing environment was completely integrated so you could see issues early enough to make an optimal decision about how to fix a problem before it happens?

Quality control

What if you could see all factors that affect product quality – including metrics on your supply chain vendors – and determine whether the combination of those inputs is in or out of control, rather than having to look at them one at a time?

Data integration to create a single view

What if you could organize all legacy and standard systems in one environment, and have a single, consolidated view of all your manufacturing process data?

Metadata tracing as part of an integrated platform

What if you could input alternate values for a specific data point and analyze the impact of the change across your manufacturing process?

SAS FACTS

- SAS® is the de facto industry standard for clinical data transformation, analysis, reporting and submission.
- 100 percent of the top 20 life sciences companies worldwide are SAS customers.
- SAS has been a CDISC member and a leader in the definition and implementation of CDISC standards since 2000.

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