

QUALITY IMPROVEMENT ANALYSIS USING JMP FOR A PHARMACEUTICAL MANUFACTURING FACILITY

Client Objective

A pharmaceutical manufacturer wanted to reduce the rate of batch rejections in their tablet production line. With regulatory pressure and financial implications mounting, they needed a statistical analysis to identify critical process parameters contributing to product failures.

They had collected extensive production data over 18 months but lacked the internal capability to statistically model the relationships between machine settings, environmental conditions, and batch outcomes. The goal was to use JMP to uncover root causes and guide process improvements.

My Role and Responsibilities

As an external statistical analyst, I led the full statistical investigation using JMP. My responsibility was to provide a detailed statistical workflow and interpret the findings for the production and quality assurance teams.

Tasks included:

- Preparing the manufacturing data for analysis
- Running process capability studies
- Conducting regression and correlation analysis to find variable associations
- Using control charts and Pareto analysis to track defect trends
- Reporting findings and improvement recommendations to technical and non-technical stakeholders

Data Overview

- **Source:** Machine logs, environmental sensors, QA batch test results
- **Size:** 5,800 production records
- **Variables:**
 - Process variables: Mixing time, granulation temperature, compression force, coating time
 - Environmental factors: Room temperature, humidity

- Output measures: Tablet hardness, disintegration time, pass/fail outcome

Techniques Used in JMP

- **Exploratory Analysis:**
 - Distribution analysis and correlation matrices
 - Outlier detection using box plots and scatterplot brushing
- **Process Capability Analysis:**
 - Cp, Cpk analysis for hardness and disintegration
 - Comparison across shifts using shift-wise subgrouping
- **Statistical Modeling:**
 - Multiple linear regression with backward elimination
 - Stepwise logistic regression to predict binary pass/fail outcomes
 - Interaction effects between machine and environment parameters
- **Quality Tools in JMP:**
 - Control Charts (X-bar and R) to monitor ongoing stability
 - Pareto Chart to identify the top causes of batch failure
 - Partition Trees to visualize variable splits contributing to rejection

Key Findings

- Batches processed during the **second production shift** had 2.4x higher failure rates
- **Granulation temperature** above 47.5°C significantly increased tablet rejection probability ($p < 0.01$)
- High **room humidity** combined with prolonged coating time created a critical failure interaction
- Coating failures alone accounted for 41% of rejections (from Pareto analysis)

Deliverables

- A structured analysis report including regression tables, control charts, and prediction probabilities

- Interactive JMP Journal with embedded visuals and interpretation
- A simplified dashboard for internal QA team to track ongoing performance metrics
- Final presentation slides shared with the QA Director and Plant Head

Impact & Outcome

The client adopted several process changes:

- Installed an environmental control alert system for humidity regulation
- Rescheduled high-sensitivity batches to morning shifts
- Optimized coating parameters based on the regression model's recommendations

As a result, batch rejection rates dropped from 6.8% to 2.3% over the next two production cycles.