Strategic Optimization of Sampling Points in API Tablet Coating

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Abstract *— This project evaluates a strategic adjustment in the tablet coating process by modifying in-process sampling points to monitor coating progression in pharmaceutical manufacturing. The current method, relying on late-stage sampling (60%, 70%, 80%), contributes to extended equipment downtime due to laboratory (HPLC) analysis delays. This study explores the feasibility of shifting sampling to earlier stages (40%, 50%, 60%) to reduce hold times without compromising product quality or regulatory compliance. Using real production data and rigorous statistical methods, including paired t-tests, Pearson correlation analysis, Fisher's Z-tests, and variance comparisons (F-tests), this study statistically validated the accuracy and robustness of endpoint predictions. Results demonstrated that earlier sampling points provide statistically equivalent predictive accuracy with significantly improved operational efficiency, including reduced downtime (up to 2.64 hours per batch), increased production capacity (~13 million additional tablets annually), and substantial economic savings related to reduced overtime and deviation investigations. This optimized approach aligns strongly with lean manufacturing principles, offering a practical, scalable, and regulatory-compliant solution for maximizing throughput and efficiency in pharmaceutical contract manufacturing environments.*

Keywords *— API Coating Process, Downtime Reduction, Endpoint Prediction, Operational Efficiency.*

PROBLEM STATEMENT

The current coating process for API tablets requires collecting three in-process samples at 60%, 70%, and 80% of the calculated endpoint in liters. These samples are analyzed through High-Performance Liquid Chromatography (HPLC), resulting in a production hold of approximately three hours while waiting for test results. This waiting period delays the coating process and limits equipment availability, ultimately affecting overall production efficiency.

This project aims to evaluate the feasibility of modifying the sampling points to 40%, 50%, and 60% of the process endpoint. Based on preliminary data, this adjustment could significantly reduce waiting time across all three API presentations. Additionally, to fully assess the robustness of early sampling strategies, the study also evaluated alternative combinations, such as using all five sampling points (Scenario C) and sets excluding the 60% point (Scenarios D and E), to explore their impact on model accuracy and precision. This initiative aims to improve process flow, reduce equipment downtime, and enhance operational efficiency while preserving product quality and regulatory compliance.

The proposed improvement supports lean manufacturing principles and cost-efficiency metrics, contributing to better equipment absorption and increased production capacity.

RESEARCH DESCRIPTION

This project focuses on optimizing the tablet coating process by adjusting the in-process sampling strategy currently set at 60%, 70%, and 80% of the theoretical endpoint in liters. It explores the feasibility of shifting these sampling points earlier in the process (to 40%, 50%, and 60%) to reduce or eliminate production downtime without compromising quality.

This initiative is especially relevant in the context of a Contract Manufacturing Organization (CMO), where maximizing equipment utilization and minimizing cycle time directly affect cost

efficiency and client satisfaction. By reducing the waiting time for HPLC results, coating equipment (coaters) can become available sooner for subsequent batches, increasing throughput and resource efficiency.

Conducting this study is important to identify practical adjustments aligned with lean manufacturing principles. The expected outcome is an improvement in cost-efficiency through better equipment absorption—a key performance indicator—and a reinforcement of the company's competitive position in the pharmaceutical manufacturing market.

RESEARCH OBJECTIVES

This section defines the general and specific objectives of the study.

General Objective

Evaluate the impact of adjusting in-process sampling points on the efficiency and throughput of the tablet coating process, ensuring product quality and regulatory compliance.

Specific Objectives

- Assess the reduction in waiting time and equipment downtime by shifting the sampling points to 40%, 50%, and 60% of the coating process.
- Ensure that product quality remains within specification under the proposed sampling approach.
- Quantify the potential increase in coating capacity as a result of reduced process interruptions.
- Analyze improvements in cost-efficiency through enhanced equipment absorption and reduced idle time.
- Compare various sampling scenarios—including three-point, five-point, and reduced-point strategies—to evaluate their predictive performance and variability.

RESEARCH CONTRIBUTIONS

This project will contribute to optimizing the tablet coating process by proposing a data-driven modification to the current sampling strategy. The key contributions include:

- A reduction in production downtime by adjusting sampling points, resulting in greater availability of coating equipment.
- Improved equipment absorption, which directly supports cost-efficiency, is a critical metric for CMOs.
- Demonstrated assurance that the modified sampling points maintain product quality and comply with regulatory standards, reinforcing process robustness.
- A practical model that can be replicated or adapted to other products or coating processes, supporting the company's culture of continuous improvement.
- A comprehensive evaluation of various sampling configurations, including both complete and reduced models, to ensure a robust and replicable strategy.

These contributions are expected to enhance manufacturing performance, align operations with lean principles, and improve the organization's value proposition for both existing and potential clients.

LITERATURE REVIEW

The tablet coating process is a critical step in the manufacturing of oral solid dosage forms, especially for products containing Active Pharmaceutical Ingredients (APIs). This process contributes not only to the visual appearance and stability of the final product but also to dose uniformity and protection of the API. To ensure product quality and process control, in-process controls (IPCs), such as sampling and testing, are performed throughout the coating stage.

Sampling Strategies in Coating Processes

Sampling in pharmaceutical manufacturing is essential for quality assurance throughout all stages of production. Regulatory authorities emphasize the importance of well-defined sampling procedures for raw materials, intermediates, and final products. However, the selection of in-process sampling points during coating is often driven by operational convenience rather than a formal statistical or capability analysis [1].

Scientific literature reinforces the importance of representative sampling to ensure consistent product quality. For instance, modern research demonstrates how strategic sampling points and monitoring tools can improve endpoint prediction in coating processes, reducing variability and enhancing control [2]. Several studies suggest that increasing the number of sampling points across the coating process improves the ability to predict the endpoint and final product quality [3]. Yet, excessive sampling can disrupt the coating process, increase workload, and lead to longer cycle times. Therefore, it is important to strike a balance between data sufficiency and process efficiency.

Role of Analytical Tools: HPLC vs. NIR

High-Performance Liquid Chromatography (HPLC) remains the gold standard for quantitative analysis of APIs in coated tablets, due to its precision and regulatory acceptance [4]. However, HPLC is time-consuming, requires laboratory resources, and often results in process hold times while results are pending.

Near Infrared Spectroscopy (NIR), while a rapid and non-destructive method, demands rigorous model development and validation, both for the method and the equipment. Recent publications have highlighted the value of NIR and Raman spectroscopy for real-time monitoring but also acknowledged that its implementation remains product- and process-specific and may not be feasible in all manufacturing environments [5]. In the case of this project, the 50/500 mg presentation does not have a validated NIR model and must rely on HPLC as the standard analytical method.

Predictive Tools and Statistical Modeling

Recent advancements in data analytics and the application of Quality by Design (QbD) principles have enabled the development of predictive models to anticipate coating endpoints based on process data. These models leverage historical results, such as API percent at specific coating volumes, to forecast the optimal stopping point for the process [3].

Studies on multivariate modeling, aligned with Process Analytical Technology (PAT) principles, show that coating endpoints can be effectively predicted using real-time data [6]. Such predictive tools reduce reliance on extensive sampling and improve the efficiency of decision-making during the coating process. Statistical comparison of different sampling schemes—such as early (40%, 50%, 60%) versus late (60%, 70%, 80%)—can help determine whether fewer or earlier samples can still yield accurate endpoint predictions, reducing interruptions without sacrificing control.

Relevance to This Project

Literature supports a data-driven approach to sampling strategy design. This project applies a validated prediction tool to evaluate whether early sampling points can offer comparable reliability to the current method in predicting the coating endpoint. The endpoint prediction is essential for determining coating completion; thus, alignment between simplified and complete models is critical.

By analyzing real batch data, this study aims to demonstrate that a modified sampling scheme may reduce production downtime and improve operational efficiency, without compromising product quality or regulatory compliance.

These findings align with the principles of lean manufacturing and continuous improvement and may serve as a foundation for broader application across products or processes in similar manufacturing contexts.

METHODOLOGY

This project will follow the DMAIC methodology (Define, Measure, Analyze, Improve, Control), a structured approach widely used in process improvement projects. Each phase is adapted to the specific goals of this initiative: optimizing the in-process sampling strategy during the tablet coating process.

Define

The current coating process uses three sampling points (60%, 70%, and 80% of the coating endpoint in liters), selected in the past when the process was simplified from five samples. Initially, using NIR minimized the impact of HPLC-related delays; however, its limited availability today has reintroduced significant hold times.

The objective is to evaluate whether a revised sampling strategy, based on earlier sampling points, could reduce downtime while maintaining product quality and predictive control over the coating endpoint.

Measure

Data was collected from ten commercial batches per API presentation using a special protocol that reintroduced sampling at five points: 40%, 50%, 60%, 70%, and 80%. All samples were analyzed via HPLC, and results were entered into a validated prediction tool that estimates the coating endpoint by correlating volume and %API assay. This dataset provides a reliable basis for comparing different sampling scenarios.

Analyze

Five sampling scenarios were analyzed and compared to the prediction generated using all five points:

- Scenario A: Using early sampling points (40%, 50%, and 60%).
- Scenario B: Using the current sampling approach (60%, 70%, and 80%).
- Scenario C: Using all five sampling points (40% to 80%) – used as reference.
- Scenario D: Early points only (40% and 50%), excluding 60%.
- Scenario E: Late points only (70% and 80%), excluding 60%.

For each batch, the endpoint predicted by Scenarios A, B, D, and E was compared to Scenario C. The analysis included:

- The mean difference in endpoint prediction
- Standard deviation and variability
- Confidence intervals
- Statistical significance

The endpoint prediction is essential for determining coating completion; thus, alignment between simplified and complete models is critical. The goal was to determine whether Scenario A provides a level of endpoint prediction comparable to (or better than) the current method and to assess the role of the 60% point in prediction stability.

Improve

If Scenario A demonstrates sufficient accuracy and consistency, a proposal will be developed to implement this revised sampling strategy. Benefits include:

- Reduction in process hold time
- Increased availability of coating equipment
- Improved absorption (cost-efficiency)

Recommendations will be supported by quantitative results and aligned with regulatory expectations and internal quality policies.

Control

To sustain the improvement, updates to procedures (SOPs), batch record templates, and quality agreements will be proposed if the new sampling approach is adopted. A monitoring plan will also be considered to ensure predictive performance is maintained over time and across products. These controls are intended to formalize the improvements and maintain their effectiveness over the long term.

RESULTS AND DISCUSSION

A comprehensive statistical and visual analysis was conducted using endpoint prediction from five distinct sampling strategies across fourteen commercial batches of API tablets. Each batch was sampled at 40%, 50%, 60%, 70%, and 80% of the theoretical endpoint, and all samples were analyzed via HPLC. Endpoint predictions were generated using a validated model, and five sampling scenarios were constructed:

- Scenario A: 40%, 50%, and 60%
- Scenario B: 60%, 70%, and 80% (current strategy)
- Scenario C: 40% through 80% (full five-point model, reference)
- Scenario D: 40% and 50%
- Scenario E: 70% and 80%

Graphical Analysis

This section presents a graphical evaluation of the endpoint prediction results obtained from the different sampling strategies. Visual tools such as boxplots, bar charts, scatterplots, and time series plots were utilized to assess prediction accuracy, variability, and overall model reliability, providing a clear visual interpretation of statistical findings.

Boxplot of Prediction Differences

A boxplot was generated to visually compare the prediction errors of each scenario against the reference model (Scenario C). The following observations were noted:

- Scenario A displayed a narrow interquartile range with a median near zero, indicating high consistency and minimal bias. It had no visible outliers.
- Scenario B, currently in use, also showed a tight spread but exhibited a slight positive bias, which aligns with the statistically significant mean difference previously observed.
- Scenario D had the widest spread and two extreme outliers, suggesting high variability and instability in endpoint predictions.
- Scenario E showed broader dispersion with a median below zero, pointing to a tendency toward underprediction.

These graphical insights confirm the robustness of Scenario A, both in statistical and practical terms, and highlight the limitations of Scenario D and E as alternative strategies.

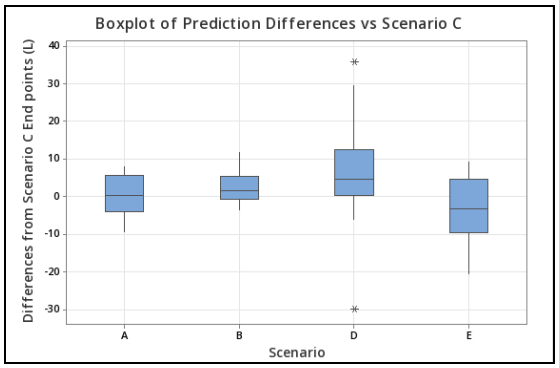

Figure 1
Boxplot of Prediction Differences from Scenario C for All Sampling Strategies

This figure illustrates each scenario's variability and central tendency relative to the reference model.

Bar Chart of Means and Standard Deviations

A clustered bar chart was created to compare each sampling scenario's mean prediction differences and standard deviations relative to the five-point reference model (Scenario C).

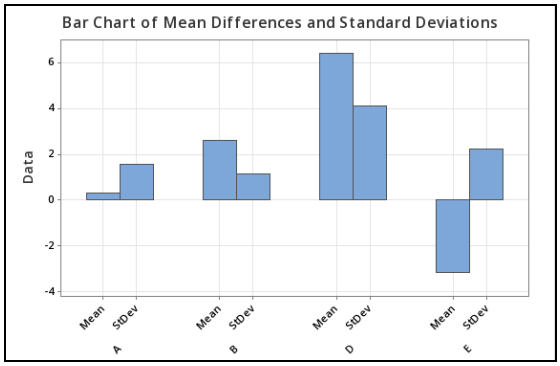

Figure 2
Clustered Bar Chart Comparing Each Sampling Scenario's Mean Differences and Standard Deviations

The visualization confirms key performance trends:

- Scenario A had the smallest mean error (~0.30 L) and low variability, reinforcing its statistical alignment.
- Scenario B displayed a slightly higher mean error (+2.60 L) but the lowest variability, suggesting stable yet biased endpoint predictions.
- Scenario D showed the highest mean error and variability.
- Scenario E had moderate variability but showed an underestimation of the endpoint.

Lower values are associated with better endpoint prediction accuracy and consistency.

Scatterplots

Two scatterplots were developed to evaluate the relationship and predictive alignment between the scenarios and the reference model (Scenario C).

- Scenario A vs. Scenario C: The data points aligned closely along the identity line (y = x), indicating a strong linear relationship and high endpoint prediction accuracy.
- Scenario B vs. Scenario C: Although a linear trend was observed, the points consistently appeared above the line of identity, suggesting a systematic overprediction compared to the reference model. This aligns with the statistically significant bias detected in the paired t-test.

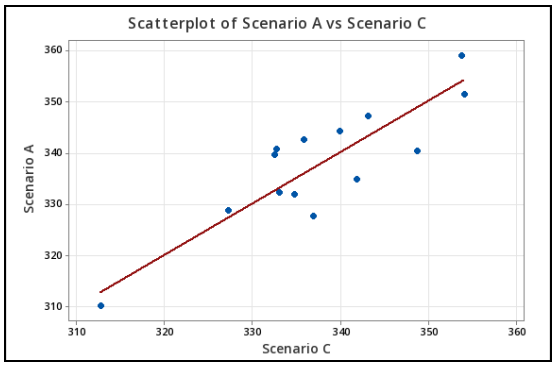

Figure 3
Scatterplot of Scenario A vs. Scenario C

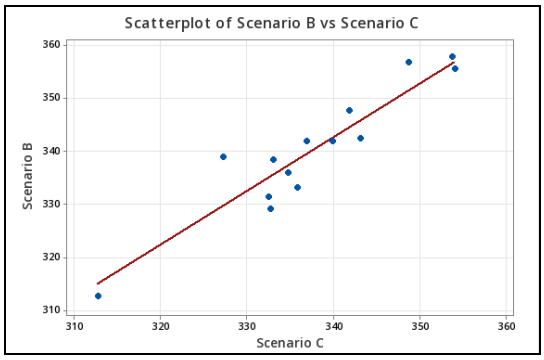

Figure 4
Scatterplot of Scenario B vs. Scenario C

These figures visually compare the scenarios' endpoint predictions to the reference, using regression lines to illustrate correlation and predictive bias.

Time Series Plot by Batch

A time series plot was generated to visualize the endpoint prediction values for each scenario across 14 commercial batches. The chart includes Scenario A, Scenario B, and the actual reference model (Scenario C).

- Scenario A closely followed Scenario C in most batches, demonstrating strong alignment and minimal deviation.
- Scenario B consistently appeared slightly elevated, reinforcing the overprediction trend observed in the statistical and scatterplot analyses.
- Scenarios A and C showed parallel movement across all batches, indicating that early sampling provides reliable endpoint prediction.
- Batches A30520 and A30521 showed slight overprediction under Scenario A. Upon review of batch and equipment logs, both run experienced Main Air Flow alarms during the early coating process. While these events did not result in extreme deviations, they suggest that minor process disturbances can affect endpoint dynamics and introduce mild prediction shifts, further emphasizing the model's responsiveness to real-time process variability.

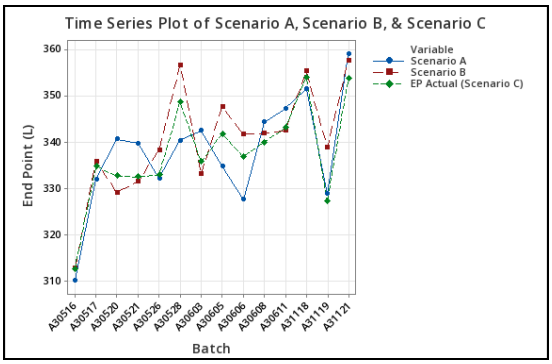

Figure 5
Time Series Plot Comparing Endpoint Prediction Across Batches for Scenarios A and B Against the Reference (Scenario C)

Statistical Comparison of Sampling Scenarios

Following the graphical assessment, the study proceeded with a statistical comparison of sampling scenarios using robust inferential methods. Paired t-tests, Pearson correlation, Fisher's Z-tests, and F-tests were conducted to quantitatively validate the graphical insights and confirm the statistical significance and reliability of the sampling strategies.

Paired T-Test Comparison

A paired t-test was conducted to compare each sampling scenario statistically against the full five-point model (Scenario C). The results are summarized in the following table:

Table 1
Paired t-Test Results Comparing Each Sampling Scenario Against The Reference Model (Scenario C)

Scenario	*Mean Difference (L)*	*Standard Deviation*	*p-value*	*Significance*
A	0.30	5.91	0.854	Not significant
B	2.60	4.26	0.040	Significant
D	6.41	17.98	0.205	Not significant
E	3.17	17.59	0.512	Not significant

The table summarizes each comparison's mean difference in endpoint prediction (in liters), standard deviation, 95% confidence interval, and p-value. Statistical significance is indicated for p-values < 0.05.

Scenario A showed the smallest mean difference (0.30 L) with no statistically significant deviation from the reference, demonstrating strong alignment with the full model. In contrast, Scenario B, which reflects the current strategy, presented a statistically significant difference ($p = 0.040$), suggesting a consistent overprediction bias.

Scenarios D and E exhibited higher variability and broader confidence intervals, confirming they are less reliable for accurate endpoint prediction.

Scenario B (60%, 70%, 80%) is currently implemented in place of the original five-point model (Scenario C).

The results presented in this study reveal that Scenario B produces a statistically significant deviation from the reference model ($p = 0.040$), suggesting a consistent overprediction bias that may have gone unnoticed.

In contrast, Scenario A (40%, 50%, 60%) shows strong statistical alignment with the five-point model ($p = 0.854$) and offers operational improvements. These results support a data-driven transition to early sampling, reinforcing process robustness and operational efficiency.

Pearson Correlation Analysis

Pearson correlation coefficients were calculated between the endpoint predictions of each scenario and those of the reference model (Scenario C) to evaluate the predictive strength of each sampling strategy.

Table 2
Pearson Correlation Coefficients Between Scenarios and Reference Model

Scenario Comparison	*Pearson r*
Scenario A vs Scenario C	0.868
Scenario B vs Scenario C	0.937

These correlation values were used to compare the alignment of each scenario with the reference model and served as input for the subsequent Fisher's Z-test.

Fisher's Z-Test Comparison of Correlation Coefficient

A Fisher's Z-transformation was conducted to assess whether the observed difference in correlation between Scenario A (r = 0.868) and Scenario B (r = 0.937) was statistically significant, using n = 14 batches per scenario. The test yields the following table:

Table 3
Correlation Strength for Scenarios A and B Using Fisher's Z-Transformation

Scenario A (r)	*Scenario B (r)*	*n*	*z-value*	*p-value*	**Significance**
0.868	0.937	14	-0.91	0.365	Not significant

P-value > 0.05 indicates no statistically significant difference in correlation. Since the p-value exceeds 0.05, the result indicates that the difference in correlation strength is not statistically significant, suggesting that Scenario A and Scenario B have comparable predictive alignment with the reference model.

F-Test for Equality of Variances

An F-test was performed to evaluate whether the standard deviations of Scenarios A and B differ significantly. The test results were as follows:

Table 4
F-Test Comparing the Variability of Endpoint Predictions for Scenarios A and B

Scenario A	*Scenario B*	*F-value*	*DF1*	*DF2*	*p-value*	*Significance*
140.78	146.22	0.96	13	13	0.947	Not significant

The result supports that both scenarios have comparable consistency.

Given the high p-value, there is no statistically significant difference in variance between the two scenarios. This finding supports the assertion that Scenario A performs on par with Scenario B regarding endpoint prediction consistency.

Operational Impact: Capacity and Absorption

In addition to statistical robustness, Scenario A demonstrated tangible operational advantages when applied to commercial-scale batches of 100/1000 mg and 50/1000 mg tablets.

Table 5
Coating Time and Downtime Savings by Presentation (in hours)

Presentation	*Current DT*	*Time 60–80%*	*Sampling Time*	*Expected DT*	*DT Saving*
100/1000 mg	3.2	3.3	0.66	0.66	2.64
50/1000 mg	3.2	2.4	0.66	1.46	1.74

Based on an estimated annual production volume of 175 million coated tablets:

- 100/1000 mg: 40 lots/month → 44 additional lots/year (~6.15 million tablets)
- 50/1000 mg: 50 lots/month → 51 additional lots/year (~7.28 million tablets)

Total Capacity Increase: ~13.43 million tablets/year.

These operational absorption improvements translate into approximately $2.2 million annual financial gains.

Calculation Formulas

The following section provides the calculation formulas used to quantify the operational benefits of the proposed sampling strategy.

Additional Capacity

$$\text{Additional Capacity (tablets/year)} = \text{Additional Lots/year} \times \text{Tablets per Lot} \quad (1)$$

Example for (1) 100/1000 mg: 44 lots/year × 140,000 tablets/lot = 6,160,000 tablets/year.

Absorption Improvement

Operational absorption improved by an estimated $2.2 million per year, distributed as follows:

- $1.02 million: 50/1000 mg
- $1.20 million: 100/1000 mg

These values were calculated based on the estimated additional production capacity gained (approximately 13.43 million tablets/year) and the standard cost-absorption rates per tablet.

These gains enhance scheduling flexibility, reduce bottlenecks, and significantly improve cost-efficiency, key metrics in contract manufacturing settings.

Additional Cost Impact Analysis

The operational delays associated with the current sampling strategy (Scenario B) contribute to recurring overtime and quality deviation costs.

- Estimated Overtime: ~190 hours/month
- Overtime Rate: $27/hour (base rate $18 × 1.5 OT multiplier)
- Monthly OT Cost: ≈ $5,130
- Annual OT Cost: ≈ $61,560

In addition, the use of later sampling points (Scenarios B and C) increases reliance on automation prompts that have occasionally failed. So far, two deviations have been recorded due to the system failing to trigger sampling notifications on time. These deviations were not caused by process failure, but by automation inconsistencies.

Each incident required:

- Generation of special instructions to take delayed samples
- Technical justification and analysis to define revised sampling points
- Delays for HPLC tests under non-routine procedures
- Deviation investigation, including interviews, documentation, and QA review

The deviation management process, interviews, root cause analysis, documentation, and QA review, required approximately 3 full working days per case.

- Estimated cost per deviation:
  $40–$50/hour × ~24 hours = $960–$1,200 per case
- Estimated total cost of the two known deviations:
  $1,920–$2,400, excluding lab materials and productivity losses.

Implementing Scenario A would eliminate late-stage sampling dependency, reducing the risk of automation-related failures and improving control over sampling events. This shift enhances throughput, minimizes downtime, and prevents unnecessary investigations, conservatively saving over $60,000 in overtime annually and avoiding thousands in quality-related costs.

Quality and Predictive Control

Earlier availability of HPLC results provides the opportunity to predict potential deviations earlier in the coating process, increasing the chances of timely interventions. This supports Quality by Design (QbD) principles, reduces batch risk, and strengthens control strategies.

Results and Discussion Summary

The collective statistical, graphical, and operational findings strongly support Scenario A as a reliable, efficient, and robust in-process sampling strategy. It preserves endpoint prediction accuracy while significantly improving manufacturing performance.

Table 6
Comparative Summary of Scenario A and Scenario B Across Key Performance and Operational Metrics

Category	*Scenario A (40–60%)*	*Scenario B (60–80%)*
Prediction Bias	Minimal (0.30 L)	Significant overprediction (2.60 L)
Correlation (to Ref.)	Strong (r = 0.868) – statistically equivalent	Slightly stronger (r = 0.937)
Variability	Comparable – Not significantly different	Slightly lower – Not significantly different
Equipment Downtime	Reduced by up to 2.64 hrs/lot	Longer retention time
Capacity Impact	~13.4M additional tablets/year	None
Absorption Gains	~$2.2M M/year	None
Overtime Impact	Potential reduction of $60,000/year	Current average: 190 hrs/month
Deviation Risk	Reduced – earlier detection possible due to earlier sampling	Actual risk - late sampling delayed detection and response |

CONCLUSIONS

This study successfully optimized in-process sampling during the tablet coating process through a data-driven, statistically rigorous, and operationally validated approach. Scenario A, utilizing early sampling points at 40%, 50%, and 60% of the theoretical endpoint, consistently delivered endpoint predictions statistically and visually comparable to the current method (Scenario B) and the complete reference model (Scenario C).

Key Findings

- **Endpoint Prediction Accuracy:** Scenario A exhibited the lowest prediction bias (mean difference = 0.30 L), significantly outperforming Scenario B, which consistently showed a statistically significant overprediction bias (mean difference = 2.60 L, $p = 0.040$).
- **Statistical Robustness:** Inferential statistical methods, including paired t-tests, Pearson correlation (Scenario A vs. Scenario C: $r = 0.868$), Fisher's Z-test ($p = 0.365$), and F-test for variances ($p = 0.947$)—demonstrated that Scenario A provides predictive performance comparable to the current sampling strategy, with no statistically significant differences in correlation strength or variability.
- **Operational Efficiency:** Scenario A significantly reduced equipment downtime, achieving savings of up to 2.64 hours per coating lot. This reduction translates directly into substantial productivity gains, enabling an estimated increase in annual production capacity of approximately 13.4 million additional tablets and operational absorption improvements of approximately $2.2 million annually.
- **Economic Impact:** Adopting Scenario A results in substantial financial benefits beyond capacity improvements. Reducing sampling-related delays can save over $60,000 per year on overtime costs. Additionally, by minimizing reliance on automation triggers, Scenario A significantly reduces the risk of deviations that have previously incurred investigation costs ranging from $960 to $1,200 per incident, thus reinforcing its financial and compliance advantages.
- **Enhanced Quality and Predictive Control:** The earlier availability of HPLC results under Scenario A enables proactive detection and timely intervention when process deviations occur. This aligns strongly with Quality by Design (QbD) principles and regulatory expectations, fostering a robust, predictive, and proactive quality control environment.

Strategic and Practical Advantages:

The adoption of Scenario A offers clear and measurable benefits:

- Minimal prediction bias and high predictive accuracy.
- Significant reduction in equipment downtime and increased manufacturing throughput.
- Direct and substantial economic savings from reduced overtime and decreased deviation investigation efforts.
- Improved process control, proactive risk management, and regulatory compliance.

In conclusion, Scenario A is recommended as the optimal sampling strategy for the tablet coating process. Its robust statistical validity, significant operational and financial advantages, and alignment with regulatory and quality standards position it as a strategic improvement for pharmaceutical manufacturing processes. The demonstrated success of Scenario A establishes a scalable framework that can be confidently replicated across various product strengths and similar manufacturing processes, further enhancing the organization's efficiency, reliability, and competitive edge.

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