

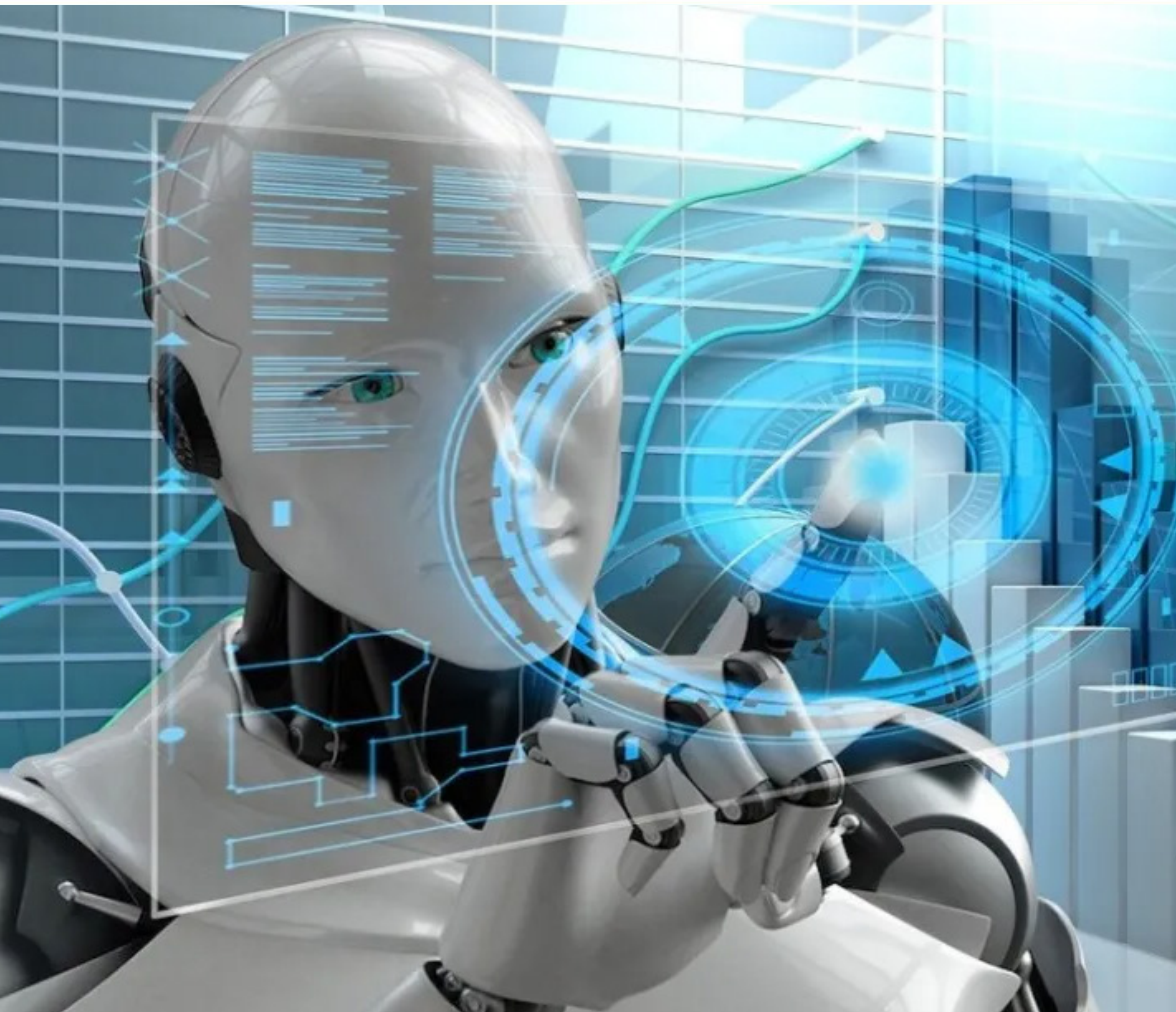
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CONTACTS

Phone: **97-748-70-03**

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OPTIMIZATION OF MANUFACTURING EFFICIENCY USING SIMULATION MODELING: PHARMACEUTICAL PRODUCTS DATAMATRIX LABELLING COST MINIMISATION

Aziz Saipov

Head of sales and marketing, JV Jurabek Laboratories Ltd
(MSc Business Intelligence and Analytics, Westminster International University in Tashkent)
ORCID: 0009-0002-3835-5969
aziz_saipov@yahoo.com

Abdumalik Djumanov

Rector of Pharmaceutical Technical University, PhD
ORCID: 0009-0006-5904-3816
a.djumanov@pharmatechuni.uz

Abstract: Sudden regulatory changes leading to modifications in manufacturing processes may lead to increased cost due to inefficient decisions. Current study evaluated the use of simulation and optimization tools to support strategic decision making in pharmaceutical manufacturing sector of Uzbekistan on the example of optimization of the datamatrix labeling process at Jurabek Laboratories. Outcomes of the simulation model was verified for consistency with real life data through expert reviews and distribution-fit tests, whereas optimization models validity was tested through sensitivity analysis. The result of research led to a set of recommendations on optimized labor quantity, that suggests a reduction in the number of operators from 8 to 4 for sticking and 4 to 3 for scanning, which can help to keep production at the same rate while cutting down labor cost by 70 million UZS monthly or by 42%. The findings provide practical insights that can contribute to more effective manufacturing practices in the pharmaceutical industry in Uzbekistan through the use of simulation modeling and optimization techniques.

Key words: discrete event simulation, optimization, pharmaceutical manufacturing, labor optimization, management science.

INTRODUCTION

Sudden changes in regulatory requirements create challenges for manufacturers affected by such changes, especially if such changes lead to rearrangements of manufacturing processes. Moreover, the desire to improve manufacturing efficiency while ensuring cost-effectiveness and quality has raised the need of adoption of advanced simulation techniques and optimization algorithms across industries.

Recent introduction of medicines "track & trace" system in Uzbekistan through digital labeling of medicines with datamatrix (DM) codes [1] required from pharmaceutical manufacturers producing or selling medicines in Uzbekistan to apply labels with datamatrix codes on each package of drug starting from 1st of September 2022. Sudden change in regulation that forced pharmaceutical manufacturers to establish datamatrix labelling process within a short period of time may have resulted in implementation of inefficient manufacturing processes.

The research question was set as how advanced simulation techniques together with optimization algorithms can improve Jurabek laboratories datamatrix labelling process to reduce operational labor cost and improve overall efficiency. This research question led to shaping the following research objectives:

1. Review existing literature on introduction of track and trace system in Uzbekistan, as well as simulation techniques and optimization algorithms applicable to manufacturing,
2. Investigate current manufacturing processes of datamatrix label sticking process to develop and verify simulation model,

3. Design and implement a simulation model,
4. Evaluate the impact of optimization strategies on key performance indicators such as production time, resource utilization, and cost-effectiveness,
5. Investigate the adaptability of the proposed optimization for real-world process,
6. Provide recommendations for the practical implementation of findings in real-world manufacturing settings,
7. Contribute to the academic and practical understanding of how simulation techniques and optimization algorithms can be used for enhanced manufacturing process.

This research studied discrete event simulation and optimization tools and techniques that can help pharma manufacturers in Uzbekistan to simulate datamatrix labeling process and come up with cost-effective decisions resulting in reduced operational costs, enhanced production efficiency, by identifying bottlenecks or extra resources and streamlining the datamatrix labelling process. The significance of this research lies in its focus on applying these advanced methodologies to a specific manufacturing company, providing practical recommendations that could lead to substantial improvements in operational effectiveness.

LITERATURE REVIEW

The redesign of any manufacturing process for new production steps requires identification of the steps of the process and resources needed for it on various stages. Identification of optimal number of resources can be through trials of various combinations in real life, but in most cases, it may be too expensive and risky. However, with the development of simulation techniques and software, complex manufacturing processes can be modeled, analyzed, and optimized virtually [2]. Simulation modeling process is the process of transferring of the real system concept into a form that can be easily changed and analyzed [3]. Such simulation tools are also used by pharmaceutical companies to develop production processes and optimize manufacturing [4].

As many researchers suggest, simulation can bring significant improvements in manufacturing efficiency, however, most of the research debate about what is the most effective type of simulation model. Several studies reveal that Agent-based modeling (ABM) and Discrete event simulation (DES) is considered to be more efficient simulation approaches [3, 5].

Optimization techniques, when integrated with DES, serve to search for the best configuration of system parameters that improve predefined performance metrics. Carson and Maria claim that optimization offers a methodical approach to decision-making by utilizing simulation models' predictive power to assess the effectiveness of various system configurations [6].

Right optimization techniques is the key to improve the efficiency and effectiveness of the simulation study. Problem complexity represented by the number of variables, constraints and the nature of objective function (linear, nonlinear, discrete, or continuous) plays a key role in optimization techniques selection. While simple linear objective functions and constraints may be solved by classical optimization methods, more complex, nonlinear and multi objective problems will require more sophisticated approaches [7].

Winston has recommended the following seven steps that will guide organizations through optimization process [8]:

1. Problem formulation (specifying the objectives and area of study).
2. System observation (identification of parameters and constraints).
3. Mathematical problem formulation (mathematical model).
4. Model verification (validation).
5. Suitable alternative selection (best match for objective, sensitivity analysis).
6. Results presentation (model and recommendation to decision-makers or organization).
7. Implementation and constant further evaluation.

Application of the use of machine learning and artificial intelligence to the simulation and optimization technologies discover new opportunities for further improvements of manufacturing processes by offering the potential to automate the optimization process, reducing time and expertise needed to identify and implement effective solutions [9].

Despite the acknowledged benefits of simulation and optimization in manufacturing, the literature reveals a gap in their application to the specific challenges of the pharmaceutical manufacturers in Uzbekistan. This study aims to bridge this gap by developing and validating a simulation model, optimized through linear programming algorithms to enhance the efficiency and cost-effectiveness of the datamatrix labelling process on the example of one pharmaceutical manufacturing company in Uzbekistan. By focusing on the specific application of simulation and optimization technique to the process of data matrix labelling in pharmaceutical industry in Uzbekistan, current study seeks to make its contribution with valuable insights to both academic literature and industry practices, addressing a critical gap in the current research background.

RESEARCH METHODOLOGY

This study used mixed-methods research approach with interviews and observations to collect both quantitative and qualitative data that was further used as a basis in the development and validation of the simulation model of the process and optimization algorithms.

Observations of manufacturing process and unstructured interviews of personnel performing datamatrix sticking and scanning were conducted to understand the current process, identify inefficiencies, gather detailed insights into the workflow, identify machinery used, human interaction, and collect needed data. This primary data collection method was chosen for its ability to provide context-specific insights, crucial for developing a realistic and relevant simulation model.

Since the manufacturing facility works 24 hours with four 12-hour shifts, observations were performed during 6 different days of a week, covering day and night shifts and whole working day, to ensure coverage with observations in the start and end of shifts, as well as before, during and after breaks. Observational checklist was used to systematically record the observation time, vials arrival count, count of labeled items and scanned items per minute during the datamatrix labeling process. In total 86 records of vial arrival, label sticking time and label scanning time were recorded. The historical operational data on production volume was gathered from the company representatives to carry out a more detailed model verification through comparison of simulated results with actual.

Initial simulation concept model in form of the process flow was developed during interview with the head of production unit, who also later reviewed and verified the correctness of concept model, process flow and basic assumptions. Observations were conducted after the development of concept model, and collected data was analyzed through XLSTAT tool that allowed to test and identify the distribution of values of the parameters needed for each process in simulation.

Once key parameters and their distribution were identified, SIMUL8 discrete event simulation tool was used to develop virtual simulation of the process. Developed model was verified through test runs for one day and one shift duration, to see if no errors occur. The slowing of simulation speed allowed to see the reduction of number of personnel during the breaks as in real life. In addition, expert review through cross check with concept model for consistency was performed together with department head. Simulation model was verified with 30 shifts trial runs that were compared with historical values based on its mean value as well as lower and upper limits. In addition, the results of 15 shift trial runs were mixed with 15 historic values and out of mix of 30 values 5 cards containing 6 mixed values were created for expert review. The cards were shown to the shift manager who was asked to point on 2 simulated outcomes on each card.

Solver MS Excell tool was used to develop linear programming model of the optimization task, with the objective to identify minimum monthly cost of labor for the process of sticking and scanning datamatrix labels by adjusting the number of employees performing the sticking and scanning. Further, sensitivity analyses were performed using solver table to identify how the monthly labor cost depends on speed of performance of sticking and scanning processes.

Simulation of the optimized result helped to evaluate the improvements against the current parameters that have been identified during the observations and allowed to assess the feasibility of implementing the optimized process in the actual manufacturing environment, considering physical, technical, and human factors.

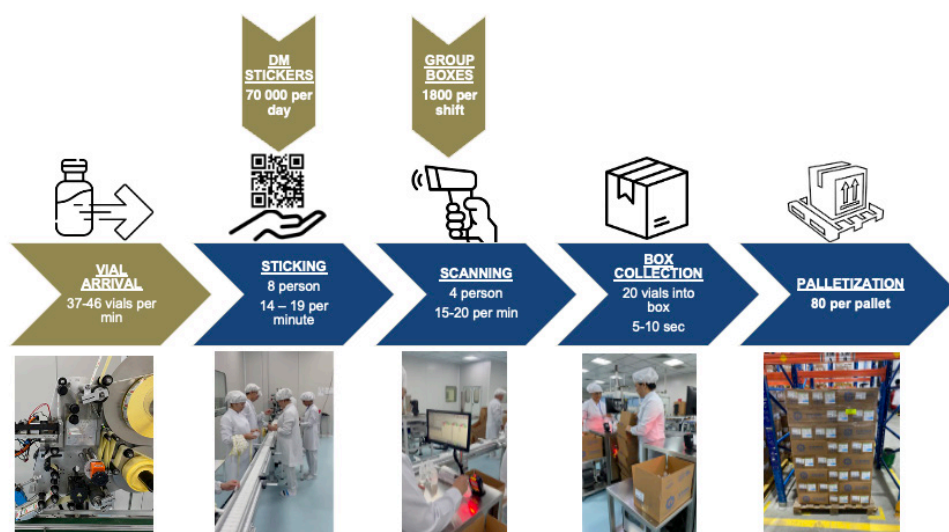


Figure 1. Simulation concept model (developed by authors).

The simulation system elements of DM labelling process were determined as given in the following Table 1.

Table 1. Datamatrix labelling process simulation system elements definition.

Name	Description
System	DM label sticking on vials and scanning DM labels for aggregation on box level
System state	number of vial waiting for DM sticking, 0 or 1 to indicate sticking point is idle or busy at time t; 0 or 1 to indicate scanning point is idle or busy at time t.
Entity	Vials, Stickers, Group boxes
Attributes	First-in First-out
Event	Vial arrival, DM sticking, DM scanning, Box palletization
Activity	Vial interarrival time, Sticking time, Scanning time, Palletization time (see Appendix 1 for observation results)
Delay	After scanning for aggregation, vials wait untill 20 vials are collected in one box and than send for palletisation. Boxes waits until 80 boxes are collected for one pallet and then exit to warehouse. Each person may have unscheduled breaks, not exceeding 30 minutes (which counts for 96% efficient time (30 min / 720min))
Clock	Manufacturing process runs 24 hours 7 days. Working shifts <ul style="list-style-type: none"> Dayshift - 8:00 – 20:00, Nightshift - 20:00 – 8:00 Shift changeover 60 min (30 min for start + 30 min for end) Sticking process meal break (2 groups, 60 min each) <ul style="list-style-type: none"> Dayshift - 11:30-13:30; nightshift - 23:00-01:00 Scanning break <ul style="list-style-type: none"> no break for meal (operator change)

A conceptual model of DM labelling process was converted to a computer model using SIMUL8 application software as reflected in Figure 2 given below.

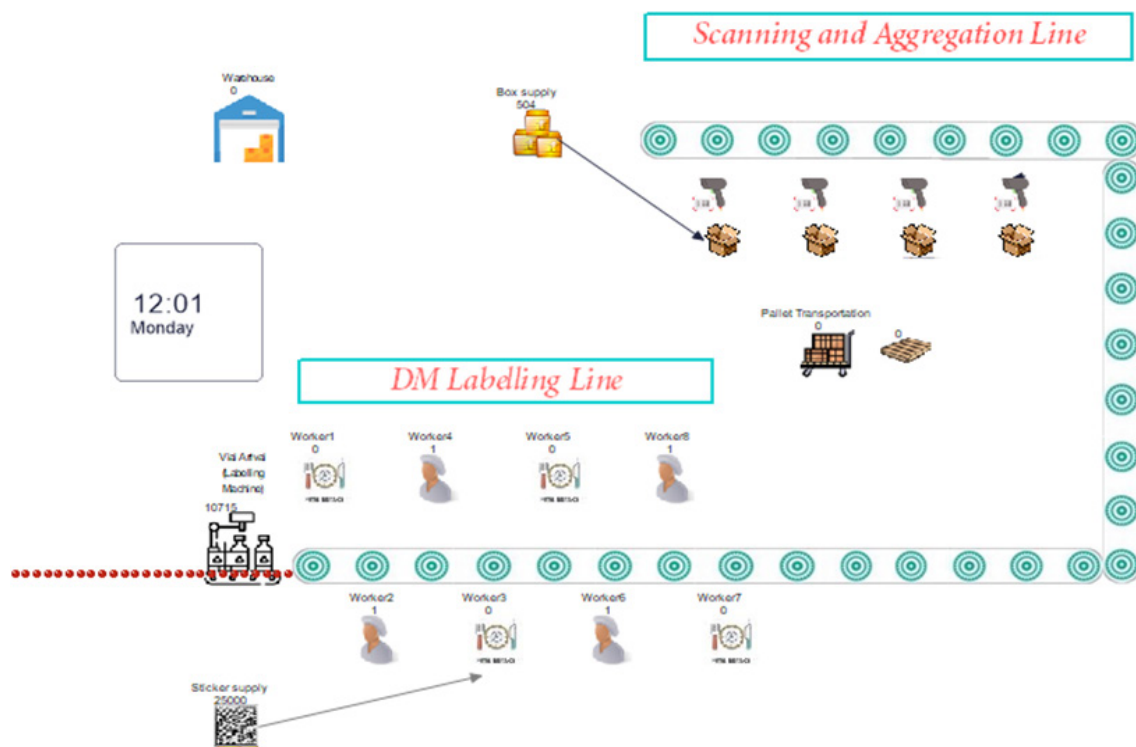


Figure 2. SIMUL8 model for current sticking and scanning process (developed by authors using SIMUL8 software application).

Input modeling. The input to the simulation model was a dataset recorded as inter-arrival time of vials. As observed, the frequency distribution diagram of vials inter-arrival time was assumed as similar to Erlang distribution (Figure 3). To prove this, using the arithmetic mean and standard deviation of the input data we delivered a goodness-of-fit test based on χ^2 -test method that proved an alternative hypothesis stating that inter-arrival time was not Erlang distribution. Consequently, a custom empirical distribution was used in the simulation model.

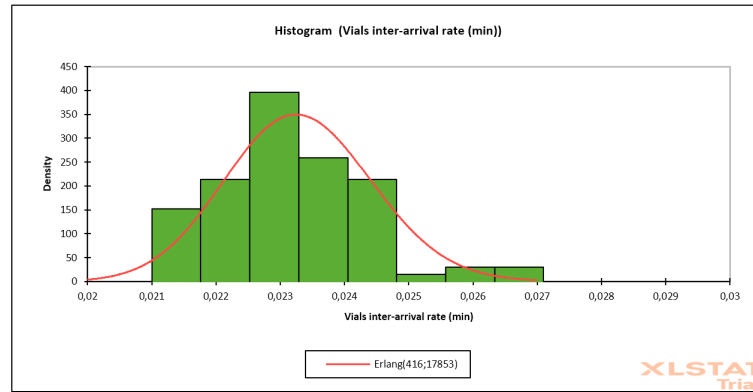


Figure 3. Input data – vials’ inter-arrival time distribution (developed by authors using XLSTAT software).

Following the same methods, a goodness-of-fit of the observed data on services time – sticking time and scanning time were tested against specific time distributions (Figure 4). Using χ^2 -test method, the sticking time distribution was tested for a goodness-of-fit with Erlang distribution whilst the scanning time distribution was tested for a goodness-of-fit with Fisher-Tippett distribution. Both hypothesis tests proved alternatives hypotheses, i.e. these distributions were not similar to assumed distribution types. As a result of these goodness-of-fit tests, we used observed empirical distributions in the simulation model.

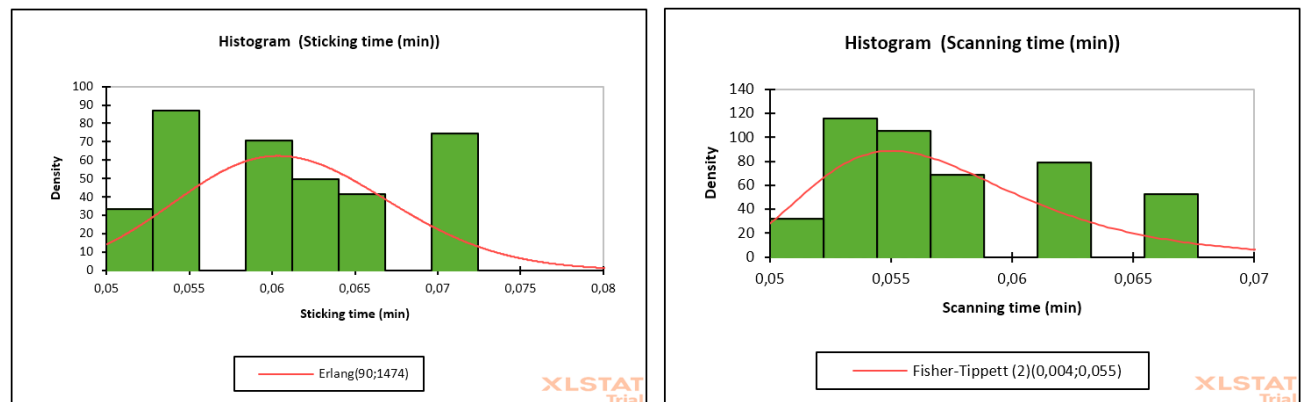


Figure 4. Frequency distributions of sticking time and scanning time (developed by authors using XLSTATS software).

Optimization model. Since the company was not clearly sure how many datamatrix sticking and scanning employees are needed per each shift to perform the process without reducing the production output, it was not able to minimize the monthly labor cost for the employees performing these processes. Therefore, the linear programming (LP) model with the objective function to minimize monthly labor cost was developed with the following parameters taken from observations and simulation runs as given in Table 2:

Table 2. Input parameters and their values for LP model.

Parameter	Sticking process	Scanning process
Speed of processing per minute	16.00	18.00
Monthly salary (UZS) per employee	3,500,000.00	3,500,000.00
Number of shift teams per month	4.00	4.00
Shift duration (min)	720.00	720.00
Scheduled and unscheduled breaks (min)	150.00	90.00
Operation minutes per shift	570.00	630.00

LP model was defined as follows:

Decision variables: Having x_1 – sticking personal quantity, and x_2 – scanning personal quantity, the following optimization function was developed.

Objective function: $\text{Min } Z = 3\,500\,000 x_1 + 3\,500\,000 x_2 \rightarrow \text{min}$
 (minimize monthly labor cost for sticking and aggregation scanning process)

Constraints:

Average vial arrival quantity of 30 simulation runs was used to define capacity of arriving vials:

Sticking capacity constraint: $9120 x_1 \Rightarrow 32\,029$ (labor capacity for sticking shall be enough to process arrived vials)

Scanning capacity constraint: $11340 x_2 \Rightarrow 32\,029$ (labor capacity for scanning shall be enough to process arrived vials)

x_1 - integer

$x_1 \geq 0$.

Optimization model verification. LP optimization model's accuracy and reliability was verified by consistency check that was conducted to confirm that the model's equations, constraints, and objective functions were properly defined and in line with the problem statement. This process involved verifying that all equations had the correct units and dimensions to avoid scaling problems or misinterpretations. The data's relevance was guaranteed through primary source data collection, ensuring it accurately represented the company's current practices. It was not possible to compare optimal outcomes with historic values for same configuration since production data with suggested number of labor was not available.

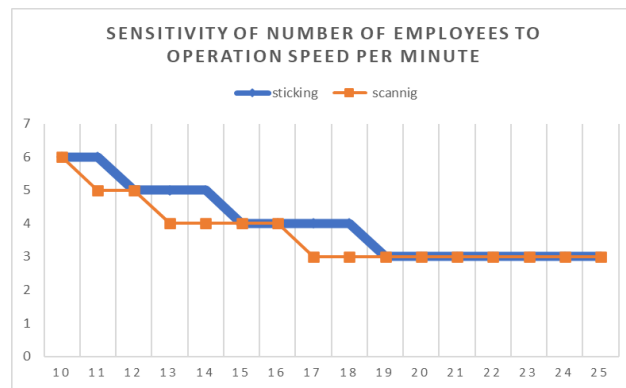


Figure 5. Sensitivity analysis outcome - employee number impact on operation speed

Sensitivity analysis. Since sticking and scanning processes are performed manually by personnel, the quantity processed highly depends on the skills of the operator performing the process. The speed of sticking or scanning per minute highly influences the number of employees required to perform the process, and if speed will drop from average of 16 or 18 to 10 per minute, the company will have to attract 6 people for each process instead of 4 or 3 as proposed by the simulation and optimization techniques. (Figure 5).

The sensitivity analysis also helps to conclude that with mastering the speed of sticking the number of personnel may be reduced, but it will not make significant difference once the speed reaches 19 for sticking and 17 for scanning. (Figure 5).



Figure 6. Outcomes of the sensitivity analysis of labour costs on sticking speed and scanning speed (developed by authors).

Analyses of speed sensitivity on processing capacity and total labor cost shows that with the increase of sticking speed in the range from 10 to 15 per minute, each incremental change significantly influences the labor cost, whereas after reaching the speed of 19 per minute, the improvement in capacity of sticking does not have any reflection on reduction of labor cost. Similar situation can be observed with scanning, whereby after reaching the speed of 17 per min, labor cost stays unchanged.

Research outcomes

The analyses of performance measure in form of working % for initial run (8 sticking and 4 scanning person) showed that:

- 5 out of 8 sticking operators are working with a very low workload.
- 1 out of 4 scanning operator was working with only 41% workload, while other 3 operators working between 58% - 68% (Table 3).

This allowed to make a conclusion that there is a room for optimization on the number of operators both for sticking and scanning processes, which will help to reduce the labor costs and keep the production at the same output level. It also indicates that there is no bottleneck currently at these two processes.

To identify further implications in the change of number of sticking and scanning operators, additional runs with several scenarios were applied to simulation:

- scenario 1 – 6 sticking and 3 scanning operators,
- scenario 2 – 4 sticking and 3 scanning operators,
- scenario 3 – 4 sticking and 2 scanning operators.

The results of working percentage as a performance measure is given in the Figure 4 shows that by reducing the number of employees, it is possible to increase the workload still keeping it below 90%.

Table 3. Performance evaluation – service busy time ratio vs number of operators (developed by authors).

									№ of scanning operators			
	1	2	3	4	5	6	7	8	1	2	3	4
Initial (8x4)	62%	59%	53%	33%	11%	10%	7%	7%	68%	64%	58%	41%
Scenario 1 (6x3)	63%	60%	55%	36%	16%	14%			78%	77%	76%	
Scenario 2 (4x3)	67%	65%	62%	49%					79%	78%	75%	
Scenario 3 (4x2)	67%	65%	62%	49%					88%	88%		

The validation of the outcomes from different scenarios showed that scenario 1 and 2 has almost the same number of processed vials within the shift as initial simulation model, which are within the range of historical data, however, the outputs of scenario 3 are below the historical values, indicating that the output volume in model with 4 sticking and 2 scanning operators drops and seems to be not feasible in real life (Figure 8).

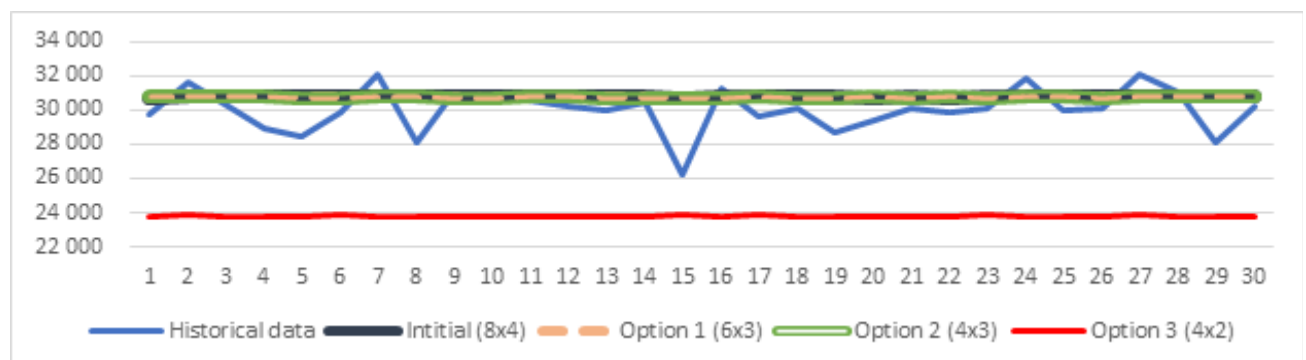


Figure 8. Comparison of historical data and simulated scenarios

Moreover, analyses of job completion showed that with initial option, as well as scenario 1 and 2 - 96% arrived vials were packed (jobs completed), whereas with scenario 3 - only 74% of arrived vials were packed during the shift.

Possible improvements through optimization. Optimization solution by MS Excel’s SOLVER also supports the finding of simulation trials with scenario 2 being the most optimal combination of employee number (Appendix 5). Solver result indicates that to be able to process all arrived vials, with the average processing speed of 16 per minute for sticking and 18 per minute for scanning, the number of labor can be reduced to 4 sticking and 3 scanning operators per shift (Figure 6). By reducing the labor to suggested optimal amount in all

four shifts, company will reduce and minimize the monthly labor cost for the processes related to sticking and scanning from 168 mln UZS to 98 mln UZS.

Conclusion and recommendation. Deep analysis of current datamatrix labeling and scanning process with simulation and optimization tools have identified major inefficiencies, particularly 128% unused capacity in sticking and 42% in scanning processes (Table 4). Through the application of advanced simulation and optimization tools, the study have identified a strategic reduction in labor as a viable solution to address these inefficiencies.

Table 4. Summary comparison of current and optimal solution

Comparison of current situation with optimal solution			
	Sticking process	Scanning process	Salary expense
Current number of employees per shift	8	4	168 000 000
Current capacity	72 960	45 360	
Resource utilisation	228%	142%	
Unused capacity	128%	42%	
Optimization suggested number of employees	4	3	98 000 000
Current capacity	36 480	34 020	
Resource utilisation	114%	106%	
Unused capacity	14%	6%	
Saving per month (UZS)			70 000 000
% of saving from current expense			42%

The results of the study confirm that by reducing the number of sticking operators from 8 to 4 and scanning operators from 4 to 3 the company will be able to optimize resource utilization, as a result, reducing unused capacity to 14% for sticking and 6% for scanning. Such optimized configuration will ensure efficient processing of the current workload with extra capacity to cover some increases in vial arrival rates.

Such workforce adjustment will lead to a significant reduction in monthly labor costs from UZS 168 million to UZS 98 million which is 42% cost savings, resulting in monthly savings of UZS 70 million. These findings highlight the effectiveness of simulation and optimization tools in making data-driven decisions that substantially enhance operational efficiency (Figure 9).

However, considering the sensitivity results of these outcomes to variations in speed of employee performance - especially, observed minimum speed of 14 vials per minute for sticking and 15 vials per minute for scanning – step by step implementation of proposed changes is advised. Therefore, it is recommended to reduce the number of employees from 8 to 5 for sticking and keep 4 for scanning. This step by step approach will allow the company to evaluate the impact of labor reductions on the process in a controlled manner, and minimize the risks of unpredictable outcomes.

Implementing such strategy will provide possibility to assess and adapt to real-world variations and complexities that simulation might not fully reflect. It also ensures step by step transition and real-time operational feedback.

Limitations of the study and recommendations for future research

Observations under current study were limited with the observation of production of infusion solutions with the bottle dosage of 250 ml. Although employees during the interview confirmed that there is almost no difference in the speed for processing of 100 ml and 250 ml bottles, further studies may verify and adjust the results to fit both dosages.

Observations showed that actual performance for sticking speed varies from 14 to 19 per minute and for scanning speed from 15 to 20 per minute, therefore more detailed study on the following aspects maybe studied additionally:

factors affecting the speed of sticking and scanning process with identifying inefficient actions of employees while performing the tasks,

correlation of processing speed with the work experience as the speed improves with practice to perform repeated operations,

influence of tiredness over the shift to the performance that may be studied with possible introduction of short breaks to increase efficiency.

Historic data was limited with 30 records, that may have outliers for shift performances, thus further deeper study covering wider period can be performed to improve simulation outputs verification.

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