



Abstract

This study focuses on the development of a Sampling Plan to implement an improved inspection process in machining. The goal is to optimize the efficiency of the inspection process without compromising quality standards, reducing inspection time and associated costs. Using the implementation of DMAVD (Define, Measure, Analyze, Design and Verify) in which a performance qualification is conducted to assess the capability of the existing inspection process and determine an optimal sampling plan to improve efficiency. The results indicate that the current process is stable and capable, allowing the implementation of a sampling plan to reduce inspection time. A plan based on the Ppk of the critical characteristics of the EDO is proposed, ensuring the quality of the product while optimizing the efficiency of the inspection process. This strategy contributes significantly to the optimization of the production process and compliance with quality standards

Key Terms — EDO, Inspection Method, Ppk Sampling Plan; Quality

Problem Statement

The current methods in the inspection process for a product in medical devices presents a challenge at the time of inspection, because this product in its validation as a transfer product, as it is, is inspected at 100%, for such reason that creates that the batches in production are not delivered on time or the weekly goal is not met due to the time it takes to inspect a complete batch. This product is currently in production. This data will be collected to generate a Performance Qualification to examine the process capability of the current process and the sampling plan needed to implement an improved inspection process in the machining process. With the data obtained, we will look for the first three production batches that reach 100 samples, enough to be able to perform statistical analyses and verify if they meet the requirements to perform an optimization in the inspection in the machining area.

Methodology

The DMADV methodology will be carried out to Design and Implementation Process to Optimize the Inspection Method at Machining Process to product of 100 % Inspection. This is a methodology that Six Sigma contemplates as it helps us evaluate the problem. In phases, they were worked on as follows shown in Figure 1

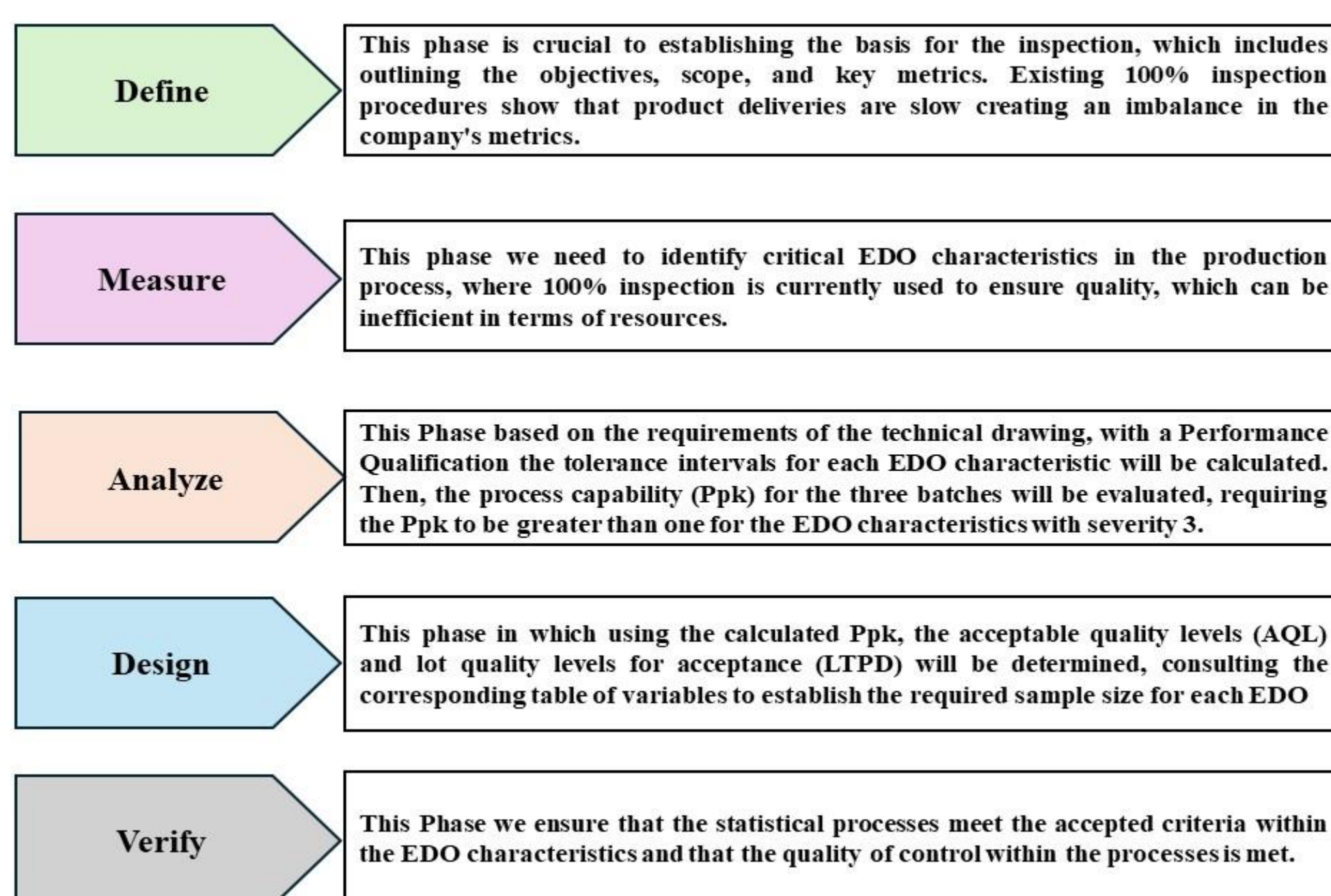


Figure 1: DMADV Methodology

Results and Discussion

DEFINE PHASE

The inspection process is currently 100% on the product in the machining area. This process causes the deliveries of the batches to customers to be delayed, therefore it is desired to design a sampling plan within a Performance Qualification to achieve that ideal sampling plan without the need to leave the quality of the product control.

MEASURE PHASE

The product contemplates 6 in-process measures but within the drawing there are 3 critical characteristics or EDO.

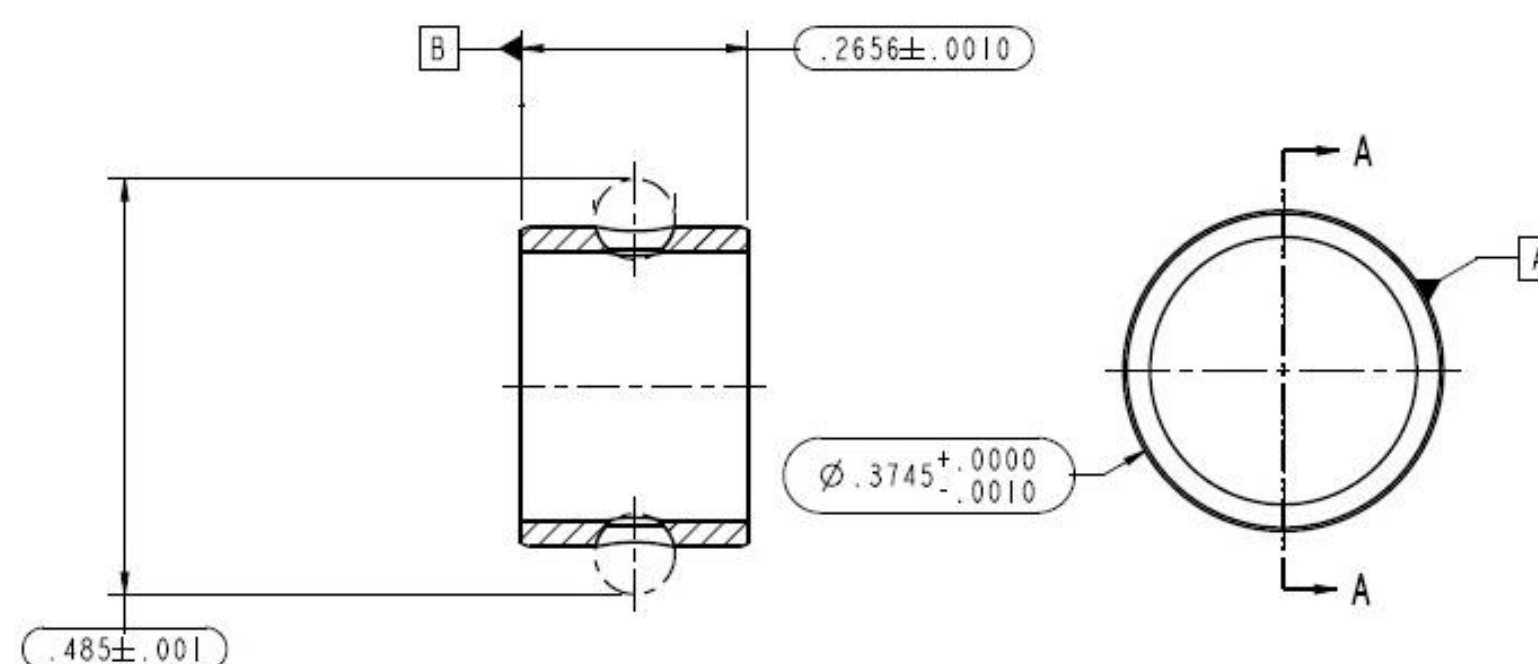


Figure 2: EDO Characteristic

ANALYZE PHASE

A performance qualification was carried out, where SPCs of Tolerance Interval and Process Capability were made. During the execution of the batches, the tolerance intervals of each EDO characteristic are calculated.

Table 1

Result of Tolerance Interval for EDO .2656 in

Lots	Acceptance Criteria	Result
1	.2646 in / .2666 in	.2650 in / .2658 in
2		.2650 in / .2659 in
3		.2651 in / .2659 in

Table 2

Result of Tolerance Interval for EDO .485 in

Lots	Acceptance Criteria	Result
1	.484 in / .486 in	.4848 in / .4858 in
2		.4847 in / .4857 in
3		.4849 in / .4852 in

Table 3

Result of Tolerance Interval for EDO .3740 in

Lots	Acceptance Criteria	Result
1	.3735 in / .3745 in	.3738 in / .3744 in
2		.3738 in / .3744 in
3		.3739 in / .3743 in

Results and Discussion

We continue with the Process Capability, looking for the Ppk in the batches for each EDO

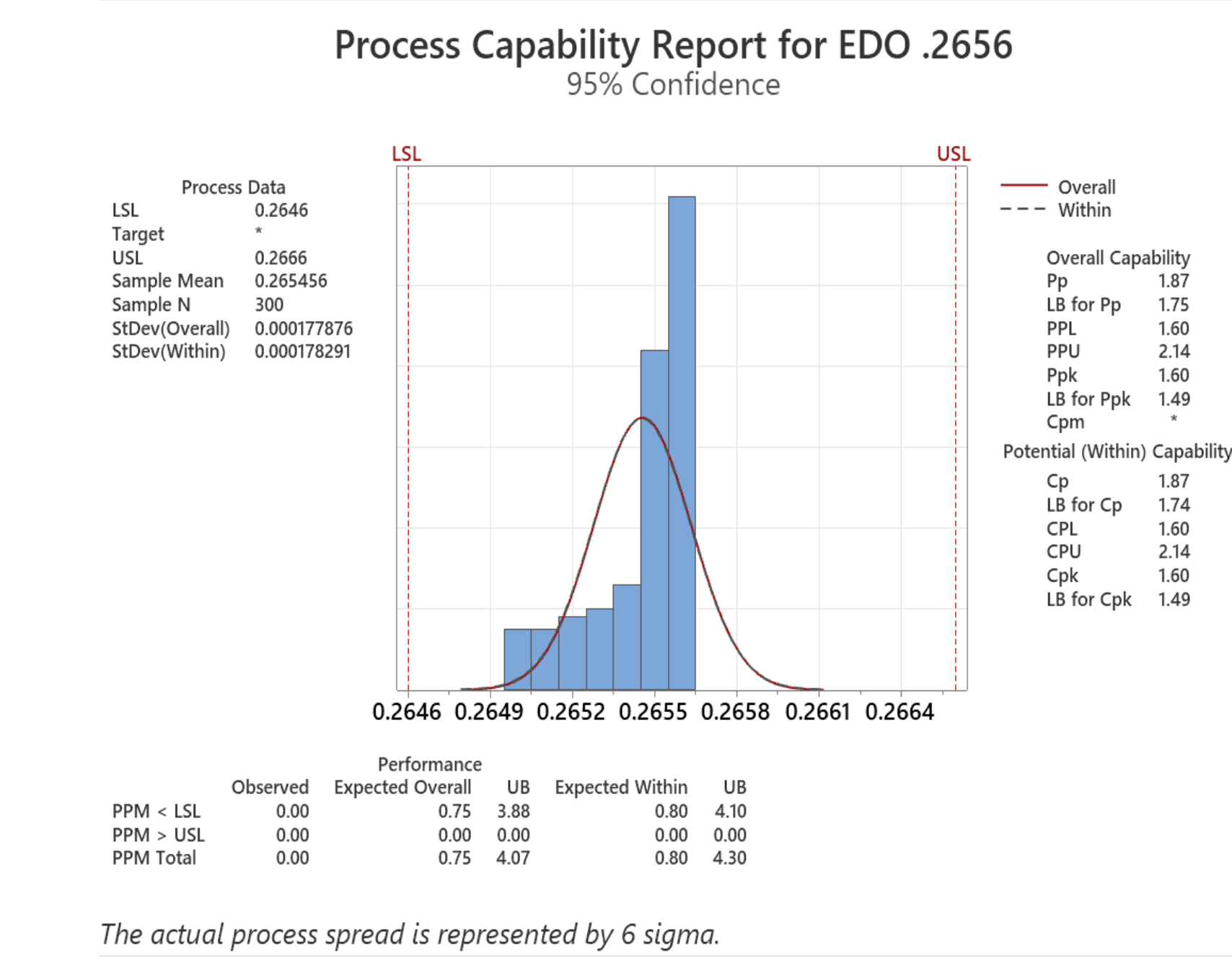


Figure 3: Result of Process Capability for EDO .2656 in

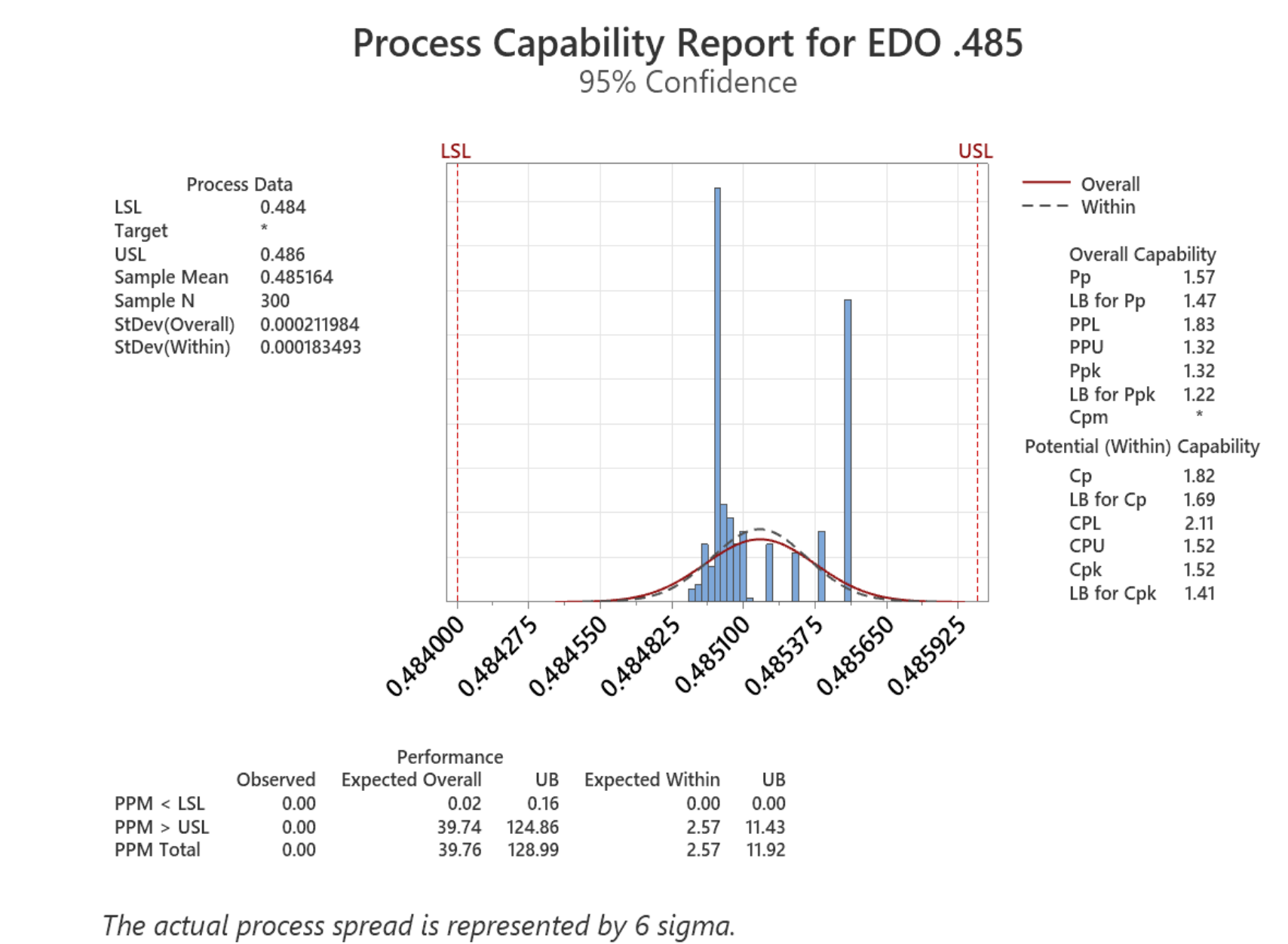


Figure 4: Result of Process Capability for EDO .485 in

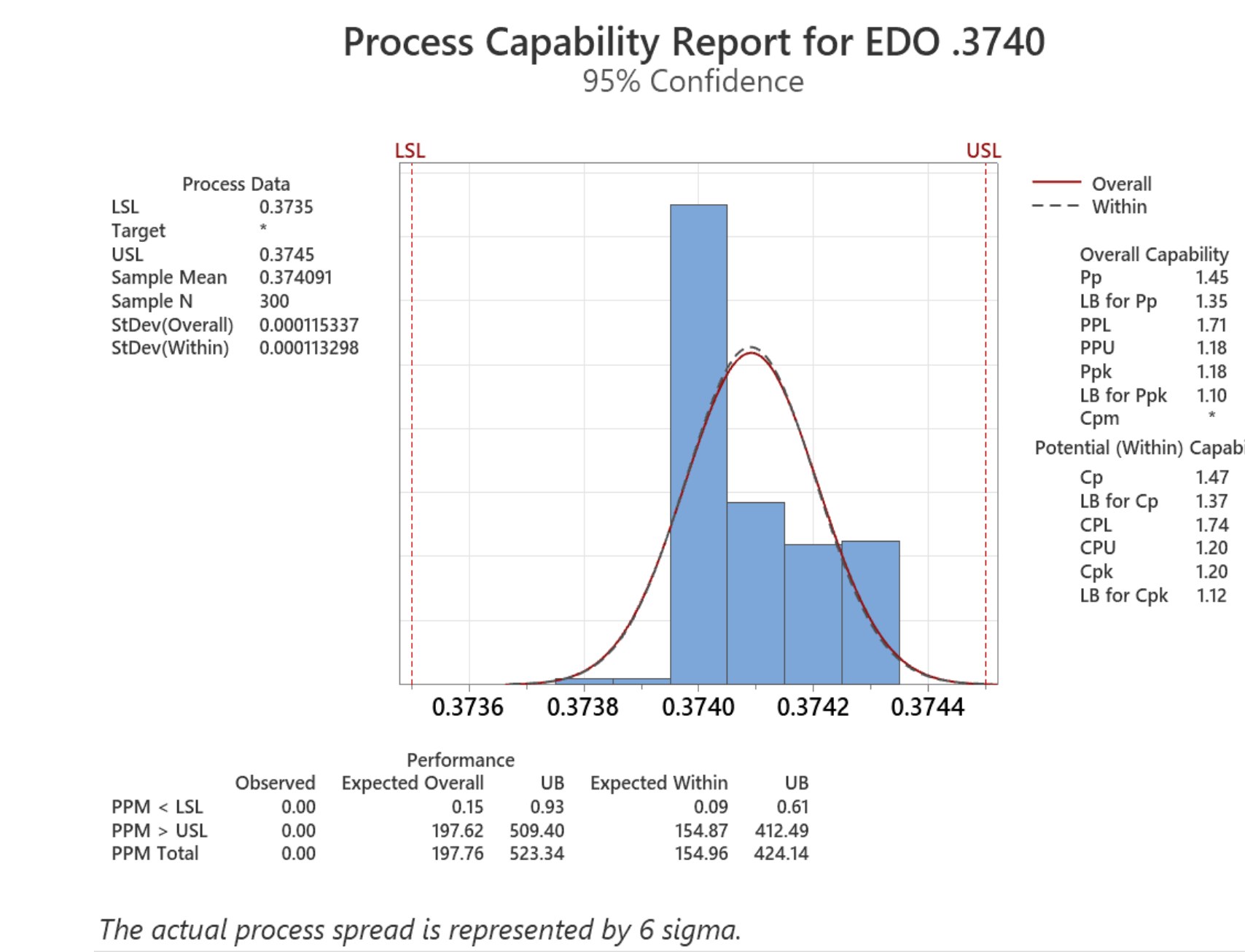


Figure 5: Result of Process Capability for EDO .3740 in

DESIGN PHASE

The results obtained from the Process Capability for each characteristic show that they are greater than 1. This shows that the process is currently a capable and stable process in production. For this reason, a sampling plan can be made to reduce the inspection time. Using an SPOD for Sampling Plan where we find the necessary tables to calculate which is the correct sampling plan

Results and Discussion

Table 4
 Sampling Plan for Variable Data

Severity Rating	Occurrence Rating				
	Ppk ≥ 1.67	1.67-Ppk < 1.20	1.20-Ppk < 1.00	1.00-Ppk < 0.78	0.78-Ppk
1	100%	100%	100%	100%	100%
2	100%	100%	100%	100%	100%
3	100%	100%	100%	100%	100%
4	100%	100%	100%	100%	100%
5	100%	100%	100%	100%	100%

VERIFY PHASE

We have the calculation of the sampling plan where the results on the Table 6 demonstrated in the sampling size will be chosen as the worst case, the lowest Ppk among the three characteristics as the minimum sampling size required for the inspection process to be used in production. Next, the EDO .3740 in feature has a Ppk of 1.18, being the lowest among the other features, resulting in a sampling size of 11.

Conclusions

Based on the results mentioned above. Evaluating the essential requirements to carry out an inspection sampling is important as it guarantees the quality of the product that you will have in the end when it reaches the customer. On the other hand, it helps to reduce delivery time and cost.

In conclusion, after having Ppk and the tolerance intervals within the required specifications, we passed the sampling plan within SPOD managed by the medical device company, choosing the characteristic with the lowest Ppk as the worst case for the inspection process, we arrived at the result of a sampling size of n = 11.

The results obtained lead us to an effective sampling method that statistically complies with the product. It also reduces inspection time by complying with operational standards and quality control standards.

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