

# ***Design and Implementation Process to Optimize the Inspection Method at Machining Process to product of 100 % Inspection***

*Omar Reyes Rivera  
Manufacturing Engineering  
Rafael Nieves, Pharm D.  
Industrial and Systems Engineering  
Polytechnic University of Puerto Rico*

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**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.

## **RESEARCH DESCRIPTION**

Optimizing the inspection process is critical to on-time production and ensuring timely delivery of medical device batches to meet market demand. This optimization reduces inspection time and optimizes overall production lead time. Cost-effectiveness is paramount, as 100% inspection incurs significant time and resource costs, so implementing an improved process with an optimized sampling plan can result in savings while maintaining quality standards. Conducting a performance qualification provides valuable information on current process capability, making it easier to identify areas for improvement and implement measures to increase efficiency. Quality assurance remains paramount, and the proposed changes ensure that product quality and safety are not compromised.

## **RESEARCH OBJECTIVES**

The objective of this study using DMAVD is to develop a Performance Qualification (PQ) to assess the process capability of the existing inspection process for the actual product in the medical device industry. Additionally, the study aims to determine an optimal sampling plan that can be implemented to improve the efficiency of the inspection process within the machining process. All this will be done considering quality control and that all the

parameters established in the product are satisfactory to carry out and carry out the objectives of this study.

## RESEARCH CONTRIBUTIONS

The optimization and application of sampling in the inspection process makes significant contributions. First, it focuses on improving the efficiency of the product inspection process with the objective of reducing inspection time without compromising quality. Secondly, it involves the generation of savings in financial terms and reduction of operational costs in resources. Overall, the research aims to overcome the challenges posed by current inspection methods by optimizing processes to ensure the timely delivery of high-quality medical devices.

## LITERATURE REVIEW

A Performance Qualification is an activity performed to validate manufacturing processes and their performance. Therefore, this phase of Performance Qualification seeks to verify the stability of the process over time under normal operating conditions to challenge functionality and safety to prove the product process is compliant. The process that needs a monitoring inspection needs to go through the validation process in the different phases. A medical device is intended to be deployed in human beings and for that reason must comply with the regulated requirements. If it does not go through a validation process those that are performed by monitoring these products can lead to costly product recalls, human lessons and make the product non-compliant to the company. [1]

A process capability is a measure taken in manufacturing processes to determine if the process is produced to the required specifications. According to the regulation by FDA in 21 CFR section 820.250 states that “where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability

and product characteristics.”. Therefore, this process tells us how well it is manufactured in compliance with the accepted criteria of long-term specifications such as Ppk. A Ppk greater than 1 means that the system is producing 95% of the specifications, demonstrating that the higher the result, the fewer variations there are in the manufacturing process. [2]

If these Ppk values are lower, the process being executed is not capable and is not meeting the critical requirements or acceptances of the process. Therefore, when a Ppk is executed, it is sought that the processes are more denominated in the value of the target or nominal value of the specification. [2]

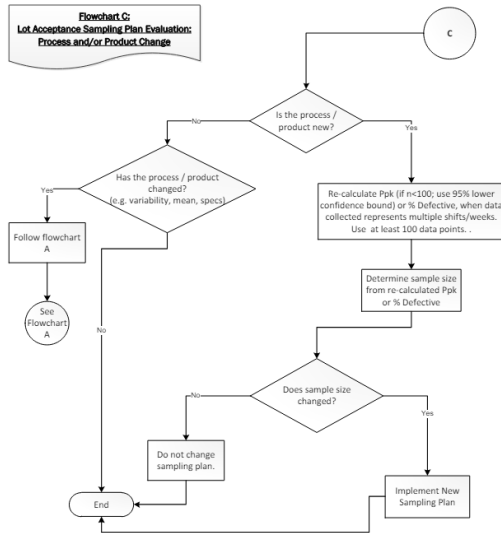
Inspection by sampling involves taking samples from a batch of products to determine their acceptability according to quality standards. This saves time and costs compared to 100% inspection, although it does not guarantee total lot quality. To ensure consistent quality, a system is needed that balances costs, benefits manufacturers, and consumers, and reduces the risk of non-conforming products. The design of the inspection scheme and the determination of the sample size are crucial aspects to achieve this balance. [3]

## 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. We started with Define, in which we defined the problem in which the inspection process on a product is 100% in the machining process.

In the **Define** phase, the inspection process of inspecting a product in the machining process. The definition phase is crucial to establishing the basis for the inspection, which includes outlining the objectives, scope, and key metrics. Existing 100% inspection procedures show that product deliveries are slow creating an imbalance in the company's metrics.

Then we go to the **Measure** phase where we need to identify critical EDO characteristics in the production process, where 100% inspection is currently used to ensure quality, which can be inefficient in terms of resources. To address this, data collection will proceed by selecting three production batches, each consisting of 100 units, where the relevant EDO characteristics will be recorded. [4]



**Figure 1**  
**Flow Chart for Sampling Plan**

After having the features, we enter the **Analyze** phase in which based on the requirements of the technical drawing, with a Performance Qualification the tolerance intervals for each EDO characteristic will be calculated. Then, the process capability (Ppk) for the three batches will be evaluated, requiring the Ppk to be greater than one for the EDO characteristics with severity 3.

After completing the Performance Qualification, we enter the **Design** phase in which using the calculated Ppk, the acceptable quality levels (AQL) and lot quality levels for acceptance (LTPD) will be determined, consulting the corresponding table of variables to establish the required sample size for each EDO characteristic and the flowchart required shown in Figure 1. Finally, the largest sample size obtained will be selected as the worst case for each EDO

characteristic, thus completing the worst-case selection process. [5]

In the **Verify** phase, we ensure that the statistical processes meet the accepted criteria within the EDO characteristics and that the quality of control within the processes is met. [5]

## RESULTS AND DISCUSSION

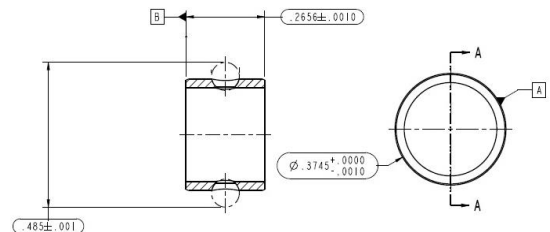
This section presents the analysis of results and discussion of the problem established and how the design and implementation of Optimize the Inspection Method at Machining Process.

### Design 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

Three production lots were chosen, each of which has a total of 100 samples. The product contemplates 6 in-process measures but within the drawing there are 3 critical characteristics or EDO, in which they are:  $.2656 \text{ in} \pm .0010 \text{ in}$ ,  $.485 \text{ in} \pm .001 \text{ in}$  and  $.3745 \text{ in} +.0000 / -.0010 \text{ in}$ . Figure 2 shows in detail the EDO characteristics that are presented in the product drawing.



**Figure 2**  
**EDO Characteristic**

### Analyze Phase

During this 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. The tolerance intervals with the specifications are shown in the following Table 1, Table 2 and Table 3:

**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

Based on the results obtained, the tolerance intervals of each batch are accepted according to the criteria found in the EDO, ensuring 95% confidence of leveraging the 95% of this population.

We have the results of the tolerance Intervals, we continue with the Process Capability, looking for the Ppk in the batches for each EDO, to be a Ppk greater than or equal to 1, This is since the severity of EDOs is 3. For better visibility of the results of the Ppk refer to Table 4.

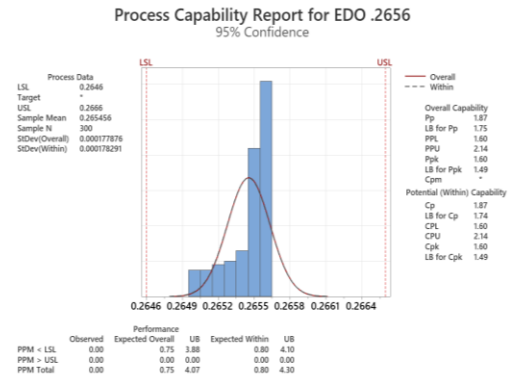
**Table 4**  
EDO Characteristic with Ppk Result

EDO Characteristic	Ppk
.2656	1.60
.485	1.32
.3740	1.18

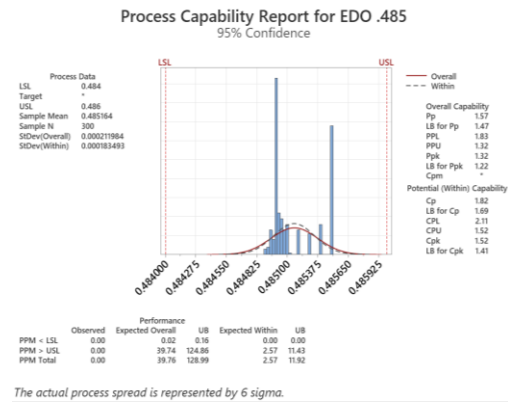
### Design Phase

Once the Process Capability has been carried out. 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

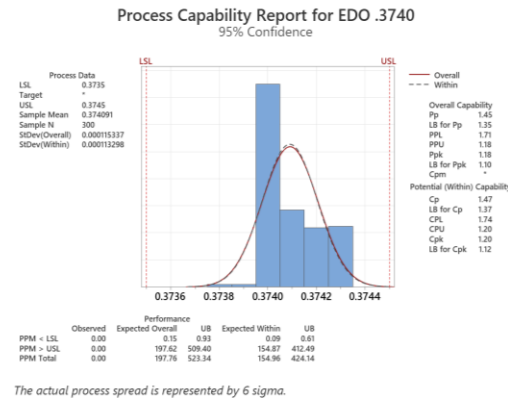
that is currently at 100% inspection. For this reason, a sampling plan can be made to reduce the inspection time that is currently encountered. Below are the results obtained from the Process Capability of each EDO feature in Figure 3, Figure 4 and Figure 5.



**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

Using an SPOD for Sampling Plan where we find the necessary tables to calculate which is the correct sampling plan, as shown in Table 5. In which it tells us that to obtain a sampling plan our EDO characteristics of severity 3 its Ppk must be equal to or greater than 1.

**Table 5**  
**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	No Inspection Required	No Inspection Required	n=5; p(k)=9.45% (AQL = 1.0%) LTPD = 30	n=8; p(k)=5.93% (AQL = 0.65%) LTPD = 20	n=9; p(k)=4.06% (AQL = 0.4%) LTPD = 15
	No Inspection Required	n=5; p(k)=9.45% (AQL = 1.0%) LTPD = 30	n=8; p(k)=5.93% (AQL = 0.65%) LTPD = 20	n=9; p(k)=4.06% (AQL = 0.4%) LTPD = 15	n=11; p(k)=2.56% (AQL = 0.25%) LTPD = 10
2	n=8; p(k)=5.93% (AQL = 0.65%) LTPD = 20	n=5; p(k)=4.06% (AQL = 0.4%) LTPD = 15	n=11; p(k)=2.56% (AQL = 0.25%) LTPD = 10	100 % Inspection Required	100 % Inspection Required
	n=9; p(k)=4.06% (AQL = 0.4%) LTPD = 15	n=11; p(k)=2.56% (AQL = 0.25%) LTPD = 10	100 % Inspection Required	100 % Inspection Required	100 % Inspection Required
3	n=11; p(k)=2.56% (AQL = 0.25%) LTPD = 10	n=17; p(k)=1.31% (AQL = 0.15%) LTPD = 5	100 % Inspection Required	100 % Inspection Required	100 % Inspection Required
	n=11; p(k)=2.56% (AQL = 0.25%) LTPD = 10	n=17; p(k)=1.31% (AQL = 0.15%) LTPD = 5	100 % Inspection Required	100 % Inspection Required	100 % Inspection Required

### 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.

**Table 6**  
**Result of Sampling Size in the Characteristics**

EDO	Ppk	AQL	LTPD	N
.2656	1.60	0.4	15	9
.485	1.32	0.4	15	9
.3740	1.18	0.25	10	11

### CONCLUSION

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.

To determine the sampling plan for this product we are currently at 100% inspection. A performance qualification was carried out to search for a normal tolerance interval of each critical characteristic in the three batches in order to

identify that the process is within the limits of its specification. The results on them were successes demonstrating that they are within the acceptable criteria of the specifications brought by the EDO.

However, Ppk (Process performance index) was also calculated, in which the value of each of the EDOs presented were the following, 1.60, 1.32 and 1.18, demonstrating that the process is capable of producing adequately and that it is complying with the specifications of accepted criteria. Therefore, this assessment is important as it allows me to search for and optimize the inspection process in the machining area. Enhancing the quality of the process.

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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