Design and Implementation Process to Optimize Raw Material Inspection Methods

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Abstract

VitalTech Innovation, LLC is a medical device company targeted to patients diagnosticated with scoliosis or other medical conditions that affects the spinal/cervical system by significantly improving the management and quality of life for patients. Innovative instrumentation, such as pedicle screws and rods, allows for more effective stabilization of the spine during surgical operations. These medical innovations collectively contribute to enhanced patient care, enabling earlier detection, personalized treatment plans, and improved surgical outcomes for individuals living with spinal/cervical conditions.

The implementation of the DMADV which stands for (Define, Measure, Analyze, Design and Verify) methodology is suitable for this research which aim to optimize inspection methods during the process of Incoming in the VitalTech Innovation, LLC. The area of Incoming hold a significant importance for receiving and inspecting raw materials, chemical agents, and other components. By applying the methodology of DMADV, our objective is to diligently define the precise goals and optimization requirements. This involves a comprehensive measurement of the existing inspection processes, followed by a thorough analysis to identify potential areas for improvement.

Key Terms — DMADV method, sampling plan, inspection method, raw material and stainless-steel rods.

Problem Statement

The current inspection methods for raw materials, specifically titanium and stainless steel, present a challenge in terms of optimization, with a notable discrepancy in the sample sizes between the two materials, particularly evident in the inspection of stainless-steel rods. The existing protocols lack uniformity, as the larger sample size for stainless-steel rods introduces inefficiencies and potentially disproportionate resource allocation in the inspection process. This discrepancy raises concerns about the precision and effectiveness of the quality control measures for stainless-steel, a critical material in various industrial applications. Therefore, addressing the disparity in sample sizes and optimizing the inspection methods for both titanium and stainless-steel rods becomes imperative to ensure consistent and reliable quality standards across all raw materials utilized in manufacturing processes.

Methodology

In the Define phase, project goals and objectives are clearly outlining the project objective with a defined scope. The Measure phase involves quantifying current processes, involving quantifying key aspects, and establishing measurable metrics, providing a baseline for performance evaluation. As the methodology progresses, the Analyze phase is a comprehensive examination of existing processes is conducted, identifying inefficiencies and areas for improvement. The Design phase leverages insights from the analysis to create an improved and optimized solution, incorporating best practices and innovative approaches. The final Verify phase, ensures that the implemented changes meet the defined objectives and conform to quality standards. The benefits of DMADV are various – it enhances efficiency by eliminating redundancies and streamlining processes, ensures consistency in outcomes through standardized practices, reduces errors and defects through rigorous analysis, and ultimately leads to improved product quality. Additionally, DMADV encourage a culture of continuous improvement within an organization, as it encourages ongoing refinement and optimization. Its structured nature enables organizations to identify challenges, adapt to evolving circumstances, and stay ahead in a dynamic business industry.

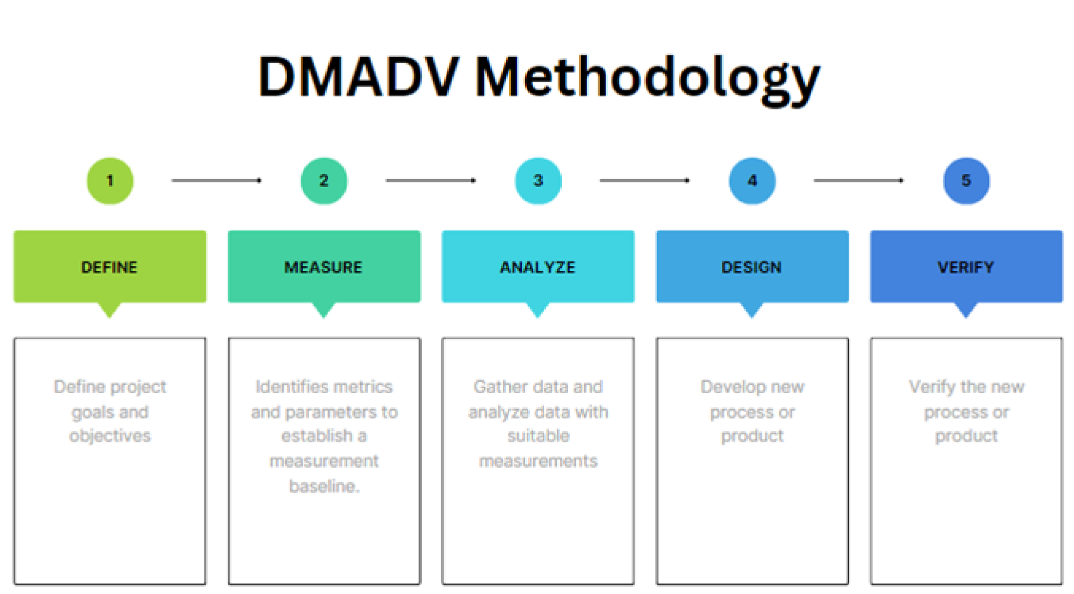

Figure 1: DMADV Methodology

Results and Discussion

Define Phase

The definition phase is crucial for establishing the foundation of the inspection project, including outlining objectives, scope, and key metrics. One crucial aspect of this process involves the meticulous measurement of rods at three distinct points: each end and the center, to guarantee precision in their dimensions. This inspection method of three points ensures a thorough assessment of the rod's dimensions.

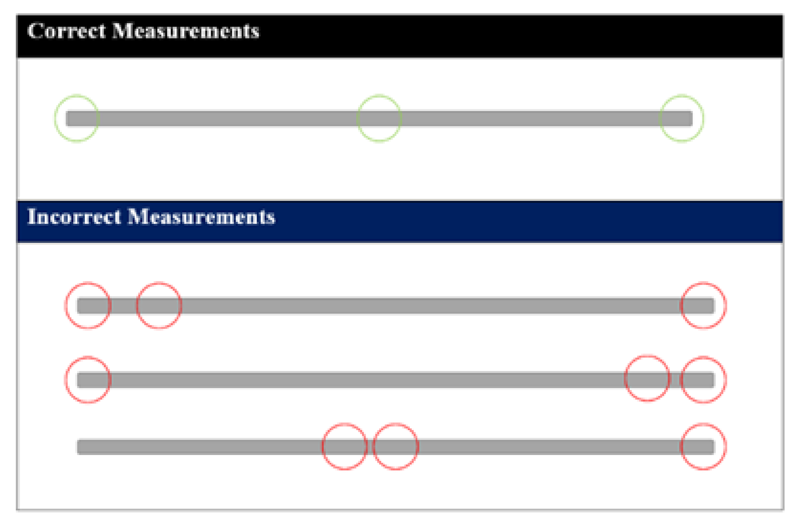

Figure 2: Inspection Method Illustration

Measure Phase

A sample size (n) of 30, including 10 stainless-steel rods, is measured to confirm compliance with rigorous quality control standards. Each stainless-steel rod undergoes measurements at three (3) key points, reflecting a strict evaluation process aligned by following acceptance criteria requirements.

Figure 3: Process Flow for Purchasing Components

Analyze Phase

In the Analyze phase of inspection methods, a performing gather of data to identify root causes of inefficiencies or defects during the process of inspection methods at Incoming Inspection Area. Statistical analysis is a crucial role in this phase to identify the process performance.

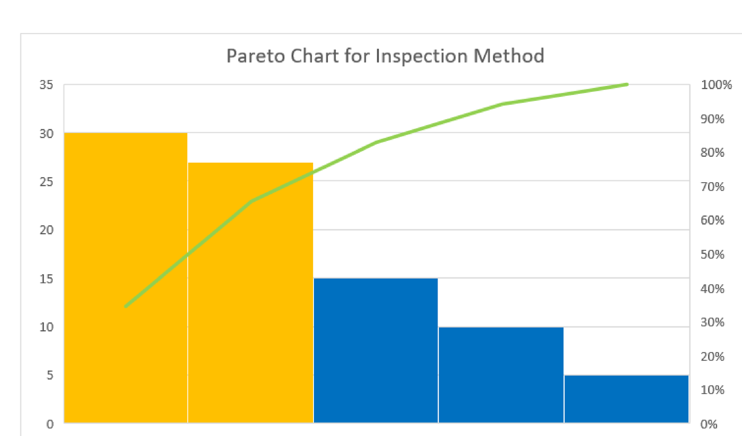

Figure 4: Pareto Chart Results

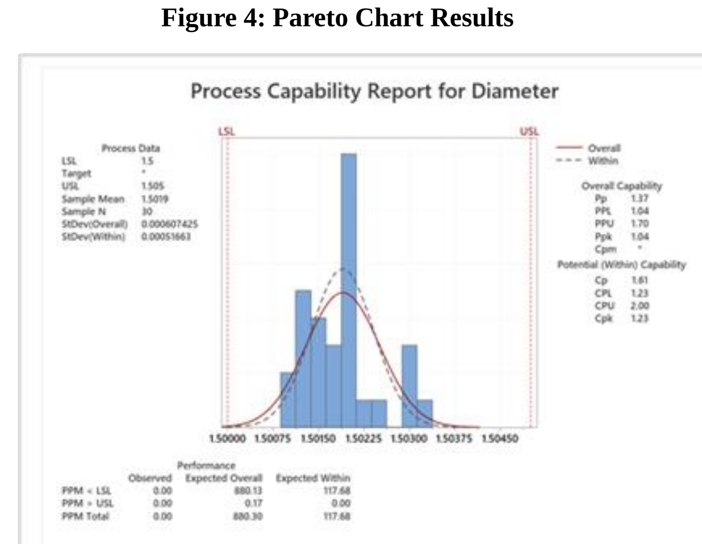

Figure 5: Process Capability for Diameter

Results and Discussion

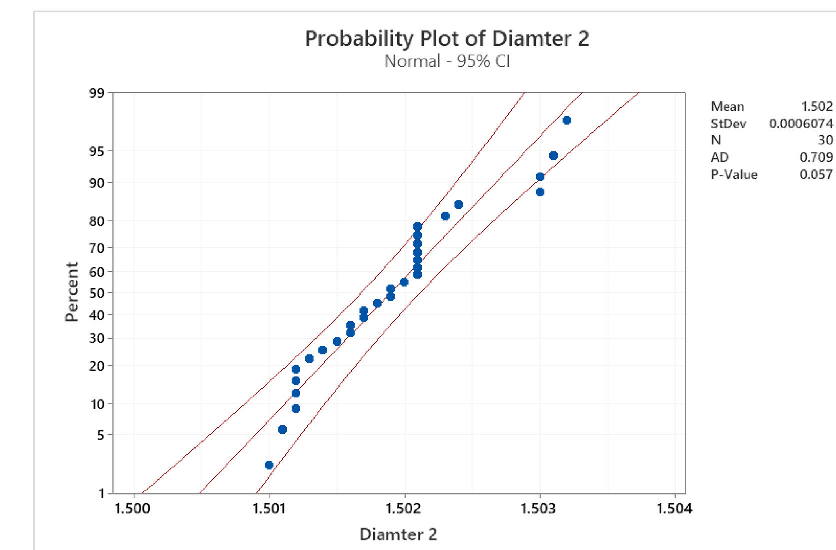

Figure 6: Probability Plot of Stainless-Steel Diameter

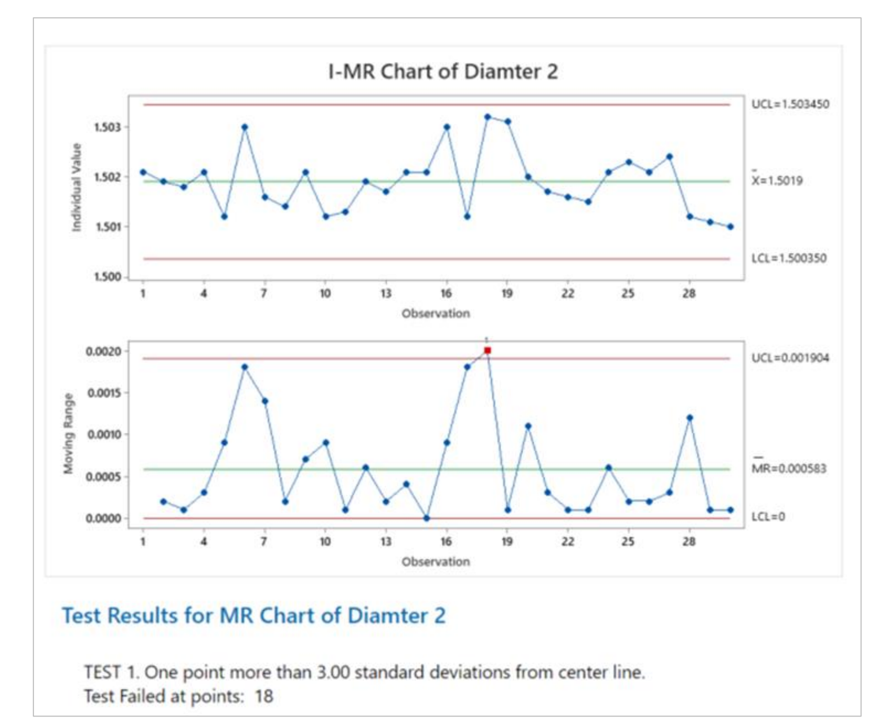

Figure 7: I-MR Chart of Stainless-Steel Diameter

Design Phase

The objective is to strategically reduce inspection points and lower the sampling plan for raw material specifically stainless-steel rods received at Incoming Inspection, particularly focusing on variable characteristics, by incorporating the Acceptable Quality Limit (AQL) principles. Designing a streamlined inspection plan involves careful consideration of AQL levels, which define the maximum acceptable defect rate. By strategically implementing AQL for variable characteristics, the Design phase ensures a balanced approach, reducing the number of inspection points while maintaining a stringent focus on critical quality attributes but also, it achieved consistent and high-quality outcomes in manufacturing processes.

Verification Phase

The current sampling plan for stainless-steel rods perform 100% inspection. However, the recommendation considering the implementation of the Acceptable Quality Level (AQL) standard to optimize the sampling plan. This strategic adjustment aligns with the goal of enhancing operational efficiency, ensuring high-quality standards, and minimizing resource utilization. Therefore, promoting a more sustainable and effective quality control process for stainless-steel rods.

Lot size (Number of ordered products)		General Inspection Levels			Special Inspection Levels			
		I	II	III	S-1	S-2	S-3	S-4
2	8	A	A	B	A	A	A	A
9	15	A	B	C	A	A	A	A
16	25	B	C	D	A	A	B	B
26	50	C	D	E	A	B	B	C
51	90	C	E	F	B	B	C	C
91	150	D	F	G	B	B	C	D
151	280	E	G	H	B	C	D	E
281	500	F	H	J	B	C	D	E
501	1 200	G	J	K	C	C	E	F
1 201	3 200	H	K	L	C	D	E	G
3 201	10 000	J	L	M	C	D	F	G
10 001	35 000	K	M	N	C	D	F	H
35 001	150 000	L	N	P	D	E	G	J
150 001	500 000	M	P	Q	D	E	G	J
500 001	10000000	N	Q	R	D	E	H	K

ISO 2859-1, ANSI/ASQ Z1.4, MIL-STD 105E, Single Sampling Plan

Figure 8: Sample Size Code Letter

Results and Discussion

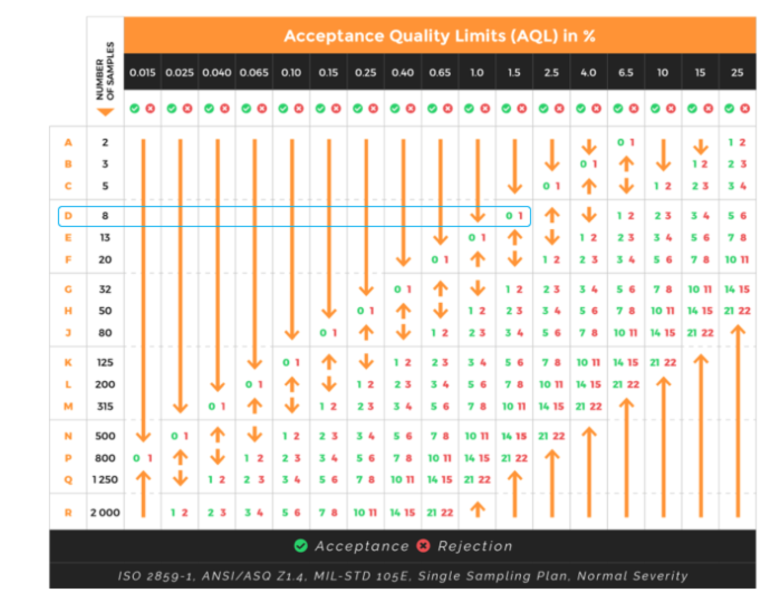

Figure 9: Sampling and Acceptance Limits

Conclusions

The inspection method process for rods at Incoming area, particularly focusing on titanium and stainless-steel rods, reveals a notable discrepancy in the sampling plan for both materials. However, the evaluation of rod inspection method, there is a discrepancy in the sampling plans applied to titanium and stainless-steel rods. The existing protocols lack consistency, introducing challenges in ensuring a standardized process evaluation for both materials. Addressing these discrepancies has becomes crucial for effective inspection methodology, ensuring that the sampling plan aligns with the specific characteristics and acceptance criteria requirements of titanium and stainless-steel rods.

In conclusion, the application of code letter D in quality control suggests a recommended sampling size of n = 9, marking a departure from the performing a 100% inspection approach for stainless-steel rods. This adjustment introduces a more efficient and statistically significant sampling method, enabling a thorough assessment of product quality while reducing the inspection sampling size. Embracing this approach aligns with industry standards, striking a balance between quality control standards and operational efficiency.

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