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The Role of Process Capability, Gage R&R, and TMV in Enhancing Medical Device Development

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Abstract: ***Process capability, a statistical measure of a process's inherent ability to produce output within specified limits, offers substantial benefits throughout the product lifecycle. This paper explores the critical role of process capability analysis in enhancing medical device product development while ensuring robust Test Method Validation (TMV) and Gage R&R. Rigorous inspection methods are essential for assessing both internally manufactured and externally sourced components within the medical device development process. During product development, understanding process capability enables proactive identification of potential manufacturing challenges, facilitating Design for Manufacturability (DFM) and promoting robust process design. This paper delves into the implementation of Test Method Validation (TMV) within this context, examining the types of studies conducted and the effective analysis of their outcomes. Leveraging process capability analysis leads to improved product quality, reduced manufacturing timelines and costs, strengthened regulatory compliance, and ultimately, enhanced patient safety.***

Keywords: Process capability analysis; Test method validation (TMV); Gage R&R studies, Medical Device product development; Medical device manufacturing

1. Introduction

Process capability studies are critical for evaluating the effectiveness of manufacturing processes in meeting specified requirements [1]. In the context of test method validation, these studies assess the inherent variability of the measurement system itself. This is crucial because an inaccurate or imprecise measurement system can lead to erroneous conclusions about product quality and performance. Gage Repeatability and Reproducibility (R&R) studies are a specific type of process capability analysis designed to quantify the variability associated with measurement systems [2]. These studies evaluate the extent to which variations in measurements are due to the measurement system itself (repeatability and reproducibility) versus true variations in the product being measured. By understanding the contribution of measurement system variability, manufacturers can implement corrective actions to enhance the accuracy and precision of measurement processes. This includes identifying and addressing sources of variability such as operator technique, equipment calibration, and environmental factors. Ultimately, implementing process capability studies and conducting gage R&R analyses ensures that measurement systems are fit for their intended use, leading to more reliable and accurate product data, improved process control, and ultimately, enhanced patient safety and product quality [1].

Test Method Validation (TMV) is a critical process in ensuring the reliability and accuracy of testing procedure. It involves a systematic evaluation of a specific inspection method to demonstrate that it consistently produces valid and reliable results [3]. This validation process aims to confirm that the chosen test method is suitable for its intended purpose and can accurately measure the characteristics of interest. Section 7.3 in ISO 13485:2016 lays out requirements of the medical device design and development [4]. The organizations shall provide all documents of below stages of product development process during audit,

1) Design and Development Planning
2) Design and development inputs
3) Design and development outputs
4) Design and development review
5) Design and development verification
6) Design and development validation
7) Design and development transfer
8) Control of design and development changes
9) Design and development files

TMV and Gage R&R play integral roles at various stages of product development. They can be used in Design and Development verification and validation stages, where manufacturing, mechanical, and quality engineers develop new inspection methods for the new parts. Test method validation and Gage R&R studies are also used to revalidate the inspection methods during production when any discrepancies are observed or there are any changes to the part [5]. TMV is crucial part of Production Part Approval Process (PPAP) as well.

General Steps in Test Method Validation

- A team of engineers (Mechanical, Manufacturing, Quality, and Metrology) reviews the drawing and identifies the critical dimensions that need to be inspected. Based on critical dimensions, the team develops an inspection method where they define criteria for which steps the inspector will follow while inspecting parts, tolerances, tools, CMM codes (if inspection will be on an automated machine), etc.
- After the creation of the inspection method, the team develops a test method validation protocol using company procedures and templates to validate the inspection method. It is very important to use criteria defined in company procedures regarding sample size and test runs. The TMV protocol shall provide information on how many samples will be used, the steps the inspector will follow to execute the protocol, the data collection sheet, and how many inspectors will perform the inspection and in which order.
- The sample size selection is one of the crucial areas to focus in this process. Sample size should be able to give

great level of confidence to trust the process. A small sample size might pass the test initially but could fail in long run. A very large sample size could increase time in the process. Thus, sample size matters a lot.

- Organization shall develop criteria for sample size selection based on their medical device class and criticality of the individual parts. If particular part is a critical componence of the assembly, TMV shall be performed with more samples to get at least 95% of confidence. Team can consider severity and probability matrix from Failure Mode and Effect Analysis (FMEA) and other risk management files.

A risk-based approach for determining statistical sample size in design verification testing connects Confidence and Reliability requirements to the Severity of harm associated with potential product failure [**6**]. For attribute tests (pass/fail) results, below formula can be used to calculate sample size based on confidence and reliability,

$$N = \ln (1 - C) \div \ln (R)$$

Where: N = sample size
C = Confidence (%)
R = Reliability (%)

Below Table 1 provides sample size information for attribute tests based on the question, and Table 2 provide more information regarding severity ranking based on patient, business and quality system impact for the reference [6]. Table 2 can be used to identify severity level to find confidence and reliability levels associated with them in order to calculate sample size.

Table 1: Confidence and Reliability Levels based on Severity

Severity of Harm	Confidence Level ®	Reliability level ®	Sample Size (N)
Catastrophic	95%	99%	299
Critical	95%	97%	99
Serious	95%	95%	59
Minor	95%	90%	29
Negligible	95%	80%	14

Table 2: Severity Levels based on Patient, Business, and Quality System Impact

Severity Ranking	Patient/User	Business	Quality System
S5: Catastrophic	Results in death	N/A	A serious and/or widespread failure in a process or system that could likely result in a significant action by a notified body or regulatory authority following an audit/inspection.
S4: Critical	Results in permanent impairment or life-threatening injury	N/A	A failure in a process or system that would be potentially cited by a notified body, regulatory authority, or customer as a significant non-compliance.
S3: Serious	Results in injury or impairment requiring professional medical intervention	High impact to business; (results in scrap, rework, or downtime or customer dissatisfaction). Impact to customer as a result of the nonconformity.	An issue potentially having a significant impact on Quality System or compliance to standards or regulations.
S2: Minor	Results in temporary injury or impairment not requiring professional medical intervention	Moderate impact to business (results in scrap, rework, or downtime). May impact customer as a result of potential delays.	An issue having little impact on Quality System or compliance to standards or regulations, yet if not addressed could become a problem.
S1: Negligible	Inconvenience or temporary discomfort	No or little impact to business (results in no scrap, rework, or downtime). No impact to Customer.	No impact on the Quality System or compliance to standards or regulations. Possible Opportunity for Improvement.

Gage Repeatability and Reproducibility (R&R)

Gage R&R studies provide confidence in measurement system performance, it is important to collect data from more than one inspector in random samples [7]. Gage R&R studies are used to assess the variability within a measurement system. This helps determine if the measurement system itself is accurate and precise enough for its intended use [8]. Organization shall develop their own criteria to accept gage R&R results.

Key components of measurement error:

- Repeatability: Variation within an operator using the same equipment.
- Reproducibility: Variation between different operators using the same equipment.
- Part-to-part variation: Actual differences between the parts being measured.

Below acceptance criteria are widely used in companies,

Total Gage R&R contribution in the % tolerance is:

- <= 10%; The measurement system performance is **Acceptable**
- Between 10% to 30%; performance is **Acceptable to Marginal**. Improvements can be made.
- >=30%; the measurement system performance is **Unacceptable**

2. Summary

Process capability studies are crucial for evaluating manufacturing processes, while Gage R&R studies assess measurement system variability. Inaccurate measurement systems can lead to erroneous conclusions about product quality. Test Method Validation (TMV) ensures the reliability and accuracy of testing procedures. Process capability, TMV, and Gage R&R are indispensable tools in medical device development. They ensure accuracy in measurements, reliability in testing methods, and adherence to regulatory standards. By integrating these processes effectively,

organizations can achieve higher product quality, reduced costs, and improved patient safety.

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Author Profile

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