A PROCEDURE BASED ON OBSERVATIONAL DATA TO DETERMINE THE SAMPLE SIZE AND THE CRITICAL CAUSES FOR THE FAILURE RISK EVALUATION

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Abstract

The pre-series is a small study that can qualify and validate a manufacturing process of a new product, allowing the researches and the workers to refine, improve, and modify the procedures, materials, measurements systems for the full-scale production. This study presents a method for identifying failure sources and determining the optimal sample size using production data that are recorded for the traceability documentation. Applied to ultrasound (US) probes manufacturing, the analysis evaluates multiple process variables to detect critical factors and interactions affecting failure risk. Based on these findings, the required sample size is defined to effectively monitor and control the production process. The approach is adaptable to different manufacturing environments and is ultimately integrated into a framework following a Design of Experiments (DoE) guideline, by obtaining the specific design matrix, and trials, for an efficient testing.

Keywords*: Sample size, Failure risk evaluation, Observational data, New Product Development*

1. INTRODUCTION

Pre-series study is performed to consider potential pitfalls in product design and to assess the proposed project's and process's feasibility. The aim is to determine the strengths, weaknesses, and potential areas of improvement [1] that leads to the failure risk evaluation by considering the vast number of parameter variations [2]. In this study, we analysed observational data collected during the production process to determine the sample size and the sources of variability that may directly affect the failure risk. The approach is applied to a specific case study, related to ultrasound probes for medical imaging [3]. Unlike traditional pilot-study

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sample-size approaches, the proposed methodology derives the experimental plan directly from observational traceability data, linking failure-risk modelling to the subsequent DoE (Design of Experiments).

At the end, the sample size is arranged with a specific design in this context.

2. METHODOLOGY

The study procedure consisted of four main steps:

1. Analysis of the existing dataset, considering the specific data and variables;
2. Statistical modelling step, in which several response variables (if available) can be studied as measures of the failure risk;
3. Once the best statistical models are estimated, fix the number of observations useful for tracking the production process;
4. Simultaneously with step#3: create the specific array, based on a design of experiment matrix, to fix the specific tracking unit.

3. RESULTS AND DISCUSSION

The study confirms the importance of collaboration between engineers and statisticians in critically re-examining each stage of ultrasound transducer manufacturing. More than 20 process variables and 10 response variables were analyzed, selected through expert discussion and previous research experience [3][4]. The statistical analysis revealed that three factors significantly contributed to the observed failure risk by considering significant effects (pvalues lower than 0.05) and the effect size:

- Factor A: backing;
- Factor B: piezoelectric element;
- Factor C: machine.

For a new product pre-series the factors can have two levels, therefore the sample size is 8 and it is arranged with a specific orthogonal array in a DoE (Design of Experiments) context as shown in Table 1.

Table 1: DoE matrix for the efficient testing

Randomized	St. order	Factor A	Factor B	Factor C
4	1	-1	-1	-1
7	2	-1	+1	+1
3	3	-1	-1	+1
1	4	-1	+1	-1
6	5	+1	-1	-1
5	6	+1	+1	+1
2	7	+1	-1	+1
8	8	+1	+1	-1

4. CONCLUSIONS

The results allowed us to find the critical points, and the specific variables responsible for them; moreover, the sample size was fixed, also considering the potential interactions (1st order) which may occur. This procedure can be generalised to any process data, provided the statistical modelling can be adjusted based on the type of response variable (continuous or binary) and the nature of the independent variable. The study provides a practical framework for pre-series planning and product-change validation, applicable to low-volume/high-mix manufacturing processes beyond ultrasound probes.

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