Quantifying the robustness of process manufacturing concept – A medical product case study

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ABSTRACT

Product robustness refers to the consistency of performance of all of the units produced. It is often the case that process manufactured products are not designed concurrently, so by the end of the product design phase the Process Manufacturing Concept (PMC) has yet to be decided. Allocating process capable tolerances to the product during the design phase is therefore not possible. The robustness of the concept (how capable it is to achieve the product specification), only becomes clear at this late stage and thus after testing and iteration. In this article, a method for calculating the unit-to-unit robustness of an early-stage for a PMC is proposed. The method uses variability and adjustability information from the manufacturing concept in combination with sensitivity information from products’ design to predict its functional performance variation. A Technology maturation factor for addressing varied process capability confidence was applied. A four-step process of Define, Connect, Map and Quantify was proposed for calculating PMC robustness and was tested for a wound-care product. The results show that the method was applicable and enabled PMC selection based on quantified robustness. The case also demonstrates that higher robustness is possible even at higher parameter variability with suitable measurements and adjustability.

Keywords: Product robustness, Process manufacturing concept, Smart process manufacturing, Variation compensation, Industry 4.0

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