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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.

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Izvirni znanstveni članek

Ovrednotenje robustnosti zasnove proizvodnje s procesnim pristopom – študija primera medicinskih izdelkov

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POVZETEK

Robustnost izdelka je definirana kot zanesljivost delovanja vseh proizvedenih enot. Pogosto se zgodi, da izdelki, izdelani s procesnim pristopom, niso načrtovani hkrati s proizvodnim procesom, zato je do zaključka oblikovanja izdelka treba večkrat prilagoditi proizvodni proces. Zato tudi določitev procesno pogojenih odstopanj med izdelki v fazi zasnove ni mogoča. Robustnost proizvodnega procesa (kako sposoben je ta doseči specifikacijo izdelka), postane jasna šele v poznejših fazah ali po testiranju in ponovitvah. V tem članku je predlagana metoda za izračun robustnosti tipa *izdelek-do-izdelek* v zgodnji fazi zasnove proizvodnje s procesnim pristopom. Metoda uporablja podatke o spremenljivosti in prilagodljivosti zasnove proizvodnega procesa v kombinaciji s podatki o občutljivosti iz faze zasnove izdelka, da predvidi variabilnost v uporabnosti izdelkov. Uporabljen je faktor zrelosti tehnologije za določitev stopnje zaupanja v proces. Za izračun robustnosti zasnove proizvodnje s procesnim pristopom je predlagan štiristopenjski postopek Definiraj, Poveži, Preslikaj in Ovrednoti. Postopek je preizkušen na izdelku za oskrbo ran. Rezultati kažejo, da je metoda uporabna in uspešna. Študija primera je pokazala, da je z ustreznimi meritvami in prilagodljivostjo, večja robustnost dosegljiva tudi pri večji variabilnosti parametrov.

PODATKI O ČLANKU

Ključne besede:
Robustnost izdelka
Zasnova proizvodnje s procesnim pristopom
Inteligentna proizvodnja s procesno tehniko
Kompenzacija variacij
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