Journal of Process Control 21 (2011) 137–150

Contents lists available at ScienceDirect

Journal of Process Control

journal homepage: www.elsevier.com/locate/jprocont

Multivariate regression modeling for monitoring quality of injection moulding components using cavity sensor technology: Application to the manufacturing of pharmaceutical device components☆

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ARTICLE INFO

Article history:
Received 29 May 2010
Received in revised form 27 October 2010
Accepted 27 October 2010

Keywords:
Cavity sensor technology (CST)
Moulding process control
Online dimensions control
Pharmaceutical device
Multivariate data analysis
Design of experiment

ABSTRACT

There is an increased demand within the moulding industry to improve the quality of moulded parts by maintaining consistent tolerances and overall dimensions. This interest is more important in areas of the moulding industry that are dedicated to pharmaceutical devices, where a quality by design approach is now expected to be adopted. A pharmaceutical device is an assembly of different plastic components which are manufactured by injection moulding; many have critical quality parameters which affect not only the device appearance but also more importantly its performance for drug delivery. Hence, the need of better understanding and control of injection moulding processes. This study presents the use of multivariate regression modeling approach to monitor the quality of the final product using cavity sensor technology (CST). The influence of the injection moulding process parameters on the quality of the final parts have been investigated using a design of experiment approach. The results demonstrate that the Partial Least Squares (PLS) regression model based on cavity pressure sensor data could be successfully used to monitor the quality (weight, dimensions) of the final product in plastic injection moulding.

1. Introduction

The injection moulding technique is widely used in the manufacturing of precision plastics parts such as medical devices, optical lenses, etc. This process maybe complex depending on the complexity of the manufactured components, with very tight tolerances and complex shapes as described in Zhai et al. [1]. The current expectations from mould industry are shorter time in designing the tools, shorter manufacturing cycle times, accurate dimensions and weight with consistent tolerances and overall good visual quality, as well as rapid tool design changes. The latter have led to some bottlenecks in the mould industry, such as the ones specialized in moulding pharmaceutical devices components, where quality by design approach implies the full understanding and control of the components quality critical parameters.

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Monitoring injection moulding processes are usually established by empirical methods, namely:

(i) Produce a component drawing and carry out a tooling flow analysis.
(ii) Manufacture the mould or tooling.
(iii) *Optimization*: establish injection moulding parameters using a structured approach to identify the most stable moulding process. This is based on a sequential univariate approach – melt temperature, injection speed, holding and cooling times.
(iv) The parts are then measured and inspected. The tool is modified, if required, to bring the dimensions and visual quality into specification.
(v) Following tool correction section "iv" is repeated using the original optimized process.

During routine manufacture the components are inspected and assessed for quality at regular time intervals based on batch size during manufacture, and a number of components from a given shot are taken and measured. If they are out of tolerance or have defects the batch is either wholly or partially rejected. If the

Abbreviations: CST, cavity sensor technology; ABS, acrylonitrile butadiene styrene; DOE, design of experiments; PLS, partial least squares; OOS, out of specifications; ICH, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; Dim, dimension.

☆ This paper was presented as an oral presentation at the IFPAC 2010 conference in Baltimore in February 2010.

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0959-1524/$ – see front matter.
doi:10.1016/j.jprocont.2010.10.018