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Capability by Design: A novel paradigm for selecting raw material suppliers aligned with Quality by Design

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Capability indexes can be used to estimate how likely a given supplier of raw materials is to meet customer's requirements for these raw materials. It is therefore usually used by a customer operating a process as a criterion for selecting raw material suppliers. However, both univariate and multivariate capability indexes provided so far in the literature assume that the specifications are regions defined in the original space of raw material properties without considering their relationships with the Critical Quality Attributes (CQAs) of the manufactured product. For that reason, these specifications may become meaningless, increasing the costs in the acquisition of raw material lots. Alternatively, calculating capability indexes directly within the CQA space would require manufacturing products from raw material lots, without knowing in advance if the product manufactured is going to be good or bad, with the subsequent potential associated costs. Therefore, the supplier assessment could be considered as a Capability by Testing approach.

We present a novel Latent Space-based Multivariate Capability Index (LSb-MCpk) that resolves these two challenges [1]. The most remarkable advantage of the proposed LSb-MCpk is that it is not exclusively defined either in the multivariate raw material space or in the CQA space of the product manufactured, but in the latent space connecting both. This advantage is key to establishing the so-called Capability by Design aligned with the Quality by Design initiative. Indeed, the LSb-MCpk quantifies the ability of each supplier of a particular raw material to produce a certain percentage of the final product with assurance of quality which could be used for real-time release. This information can be obtained at the reception of the supplier´s raw materials, before producing a single unit of the product. In addition, diagnosing assignable causes can be carried out when the lots of the supplier raw materials do not respect the correlation structure from the past (by using the Squared Prediction Error contribution plots), or when the supplier cannot consistently operate within the design space (by using the score contribution plots). The proposed LSb-MCpk is based on Partial Least Squares (PLS) regression, and it is illustrated using data from an industrial study.

[1] J. Borràs-Ferrís, C. Duchesne, and A. Ferrer, Chemom. Intell. Lab. Syst., 258, 2025.

Type of presentation

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