

CpK Distribution: The Fact Underlying Process Capability Indices – Part II: Application

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Introduction

Part I of this article (1) introduces the theory of sampling distribution of process capability index (CpK) – one of the most commonly used process performance metrics in pharmaceutical and other industries. The theory is successfully proven by a simulation test. Such a CpK distribution – similar in shape to that of chi square is a function of sample size (n) and lot CpK. Normally population or lot parameters are estimated using sample statistics, lot and sample CpK statistics are the same. CpK is based on specifications and process standard deviation. If the specifications are very wide, CpK value is going to be above 1.33 and this can be natural process as well. The key informative characteristics of the distributions will provide the approach to estimation of lot CpK and the high confidence that CpK results less than 1.33 are scientifically acceptable. From various CpK distributions with the same sample size but different true CpKs, the corresponding standard CpK distributions, as described below, derived from those distributions will be identical to each other where their beneficial characteristics are advantageously applied.

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