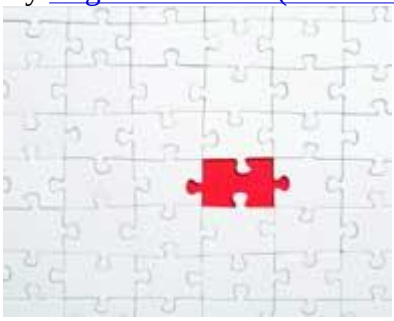
Statistics/Variation

By Eugenie Webster (Khlebnikova) Jan 6, 2013 4:48 pm PST



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I. Introduction

Analysis and control of variation play an important role in pharmaceutical manufacturing. Since each product has some degree of variation, the variation must be controlled to ensure quality, safety, and efficacy. Statistical tools to analyze and control variation can be used from drug development to routine manufacturing. The guidance documents listed in this chapter outline the general requirements for variation analysis and control through the use of statistics. These documents cover the following topics: state of control, process capability, sampling, sampling size and sampling plans, variability, and general requirements for applying statistics to analyze data.

Tags:
GMP - Variation & Statistics, Regulatory & Industry Guidance

Eugenie Webster (Khlebnikova)
Eugenie Webster (Khlebnikova) is a Senior Process Engineer at McNeil Consumer Healthcare, division of Johnson and Johnson, located in Guelph, Ontario, and has over 16 years of validation experience in the pharmaceutical...
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